

MAY 03 2013

NOTICE OF NONCOMPLIANCE

Elise LeGoff and Aude Poiret Bonnet
Ecocert S.A.
BP 47
32600 L'Isle Jourdain
FRANCE

Dear Ms. LeGoff and Mrs. Bonnet,

On May 15, 2012 the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) sent Ecocert S.A. (ECO) a Notice of Noncompliance as a result of the Renewal Assessment conducted in October 2011. ECO submitted a response to the noncompliances cited on June 22, 2012. Our review of that response indicates that additional response, supporting documentation, and/or objective evidence is necessary before the NOP can move forward on these specific issues. The outstanding noncompliances are as follows:

NP7246EEA.NC8 – Outstanding – Additional Information Required: NOP §205.642 Fees and other charges for certification states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator.” Additionally, the clause states “...the fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable, and the certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.” *ECOCERT adopted a new series of fee schedules on January 1, 2007, and is currently using this international fee matrix for charging clients during the 2007 certification year. The company has not filed the updated fee schedule with the Administrator. Additionally, there is no reference to nonrefundable portions of the certification fees in the structure of the fee schedule, and policy dictates that only those requesting a fee schedule are actually provided with one.*

- **2008 Corrective Action:** Ecocert submitted the 2007 fees and the new fees for 2008 were sent to the USDA on January 7, 2008. Ecocert has also stated that when new fees are developed, they will be sent to USDA prior to their use. The information about the non-refundable portions of the fees is given in Article 4 of the inspection contract. Ecocert has also stated that their policy is that every applicant gets a cost estimate following the application which informs them about the estimated annual costs for inspection and certification of the operation concerned.
- **2009 Mid-Term Assessment Verification of Corrective Action:** The current 2009 Fee Schedule was submitted to the USDA as required. However, the information on the non-refundable portions of the fees in Article 4 of the inspection contract was not submitted to the USDA.
- **2009 Corrective Action:** A revised fee schedule (2009 Ecocert Group Tariff Base) was submitted that included information on the non-refundable portions of the fees.
- **2011 Renewal Assessment Finding:** The fee schedule submitted was for all offices, except the one used in the France office. In the Germany office, the fees charged to clients

were not consistent with the submitted fee schedule. Clients were charged 91 EU per hour and the highest rate on the fee schedule was 90.75 EU per hour. In the Columbia office, a fee charged to a crop operation identified as “Gastos de Control Interno” did not correspond to any of the fees included on the submitted fee schedule. The Columbia office stated this was a special fee for a review of the internal control system. Additionally, no fee schedule is provided to applicants for certification just the estimate (quote).

- **NOP Assessment of ECO Corrective Action Response:** There were four issues identified with fee schedules during the 2011 Renewal Assessment: 1) Ecocert did not submit a fee schedule for the France office; 2) The Germany office was charging 91€/hour when the fee schedule allowed for 90,75€/hour; 3) The Colombia office charged a fee for review of an internal control system (for grower group clients) that was not on the fee schedule; and 4) Ecocert policy was such that clients did not receive a copy of the fee schedule when an estimate was provided. In the response received from Ecocert in response to this finding, Ecocert responded only to issue #4 regarding not supplying the fee schedule to clients. To address this issue, Ecocert revised their “template letter for applicants,” document L05, to include the fee schedule in documents sent to new applicants. Ecocert also revised instruction document I09 for all subsidiary offices to follow when formulating quotes for new clients; the instruction now indicates the fee schedule must be sent to clients. There are a few other adjustments made to I09; however, none of these changes addresses the three outstanding issues from the 2011 finding.

NP1283MMA.NC2 – Response Not Accepted: NOP §205.501 (a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to comply with the requirements for accreditation set forth in this subpart.” *The procedure for performance evaluations of Certification Officers (CO) requires the review of one file. This is not an adequate annual performance evaluation as required by §205.501 (a)(6) concerning the review of job duties and responsibilities; instead it is a specific file review evaluation. When COs are identified on the list of “supervised COs,” (either because the CO is new to the position or receives a poor performance evaluation) then oversight by the Certification Manager increases. This requires an in-depth review of 5 files throughout the year. The files are reviewed both for compliance with the Ecocert process as well as NOP production requirements. The final “resolution” or “decision” of these reviews is either “OK,” which means the file may have some or extensive issues with following the Ecocert process but none that would require Ecocert SA to stop the file from moving forward in the certification process; or “stop file,” where the file must discontinue the certification process until the CO provides Ecocert SA required information. In addition a review of the “supervised CO review spreadsheet” verified that Ecocert SA does not review a complete file before making a determination. Under a number of categories on the spreadsheet that include but not limited to “label compliance” and “OSP completeness”, the Ecocert SA reviewer might note, “not attached” or “not included on Extranet file.” However, the review continues without this information. As such, the procedure of the review is incomprehensive and, ultimately, insufficient to demonstrate increased oversight/supervision of COs, since files can contain incomplete information and/or can demonstrate clear non-compliance with the Ecocert certification process and still move forward as “OK.” With this process in place, the supervision program of the COs is inadequate to determine satellite offices’ ability to comply with NOP regulations.* **NOP Assessment of ECO Corrective Action:** Ecocert’s corrective action includes revising the evaluation form for Certification Officers (COs) and supervised COs, and revising the evaluation procedure to increase the number of files to review for the annual evaluation. The response addresses some issues above re: quantity and quality of file reviews and evaluating COs

for all job duties and responsibilities; however, does not address the issue noted above: “as such, the procedure of the review is incomprehensive and, ultimately, insufficient to demonstrate increased oversight/supervision of COs, since files can contain incomplete information and/or can demonstrate clear non-compliance with the Ecocert certification process.... With this process in place, the supervision program of the COs is inadequate to determine satellite offices’ ability to comply with NOP regulations.”

NP1283MMA.NC3 – Additional Information Required (specifically point d): NOP

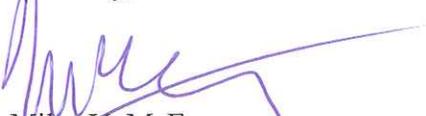
§205.501 (a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

- d. *For the livestock and handling grower group visited during the witness audit in Brazil, Ecocert certified the grower group without any certified organic feed (flowers, nectar) for the bees. NOP Assessment of ECO Corrective Action:* Ecocert indicated OSP forms and inspection checklists would be revised to describe the feeding requirements and verification of feed compliance. Ecocert also stated qualified parties (inspectors, client managers, certification officers, concerned operators) would be notified of program updates via letter format. A copy of the letter was provided; however, objective evidence showing the changes to the OSP and inspection checklists was not provided. Also, Ecocert’s response did not *explicitly* state they would require certified organic feed for all livestock operations, including bees. This is implied in the response, but not stated.

In order to clear these noncompliances, ECO must propose and implement measures that will correct this action **and** prevent future reoccurrences. The proposed corrective actions must also indicate how the ECO management system will be modified to prevent a future noncompliance. Please submit proposed corrective actions to the NOP **within 30 days** from the date of receipt of this letter, indicating how this noncompliance will be corrected. Please refer to **NOP 2608**, Responding to Noncompliances, for further instruction. Failure to promptly resolve this noncompliance may result in proposed adverse actions against ECO as an accredited certifying agent for the USDA.

If you have questions regarding this notice, please contact your Accreditation Manager, Meg Kuhn, at meg.kuhn@ams.usda.gov or (202) 260-8635.

Sincerely,



Miles V. McEvoy
Deputy Administrator
National Organic Program

cc: NOP Appeals
USDA Grading and Verification Division

Audit Resolution Chronology Log

Audit Identifier (if any): NP4258EEA
Audit Type: Midterm Assessment
Accredited Certifying Agent Name: Ecocert SA
Accreditation Manager (who is working on the project): Janna Howley

Date	Activity
11/10/14	MLC assigned to RY.
01/06/15	RM reassigned to JH. JH added to WTL and saved docs to file folder.
01/08/15	JH begins document review
01/27/15	JH drafted NC report.
01/30/15	<p>Mtg w LC because there were multiple questions about what the auditor documented in the audit report:</p> <ol style="list-style-type: none"> 1. Should (b) (5) <div style="background-color: black; width: 100%; height: 80px; margin-top: 5px;"></div> 2. NP7246EEA.NC8: (b) (5) <div style="background-color: black; width: 100%; height: 100px; margin-top: 5px;"></div> 3. NP1283MMA.NC2: (b) (5) <div style="background-color: black; width: 100%; height: 80px; margin-top: 5px;"></div> 4. NP1283MMA.NC3: (b) (5) <div style="background-color: black; width: 100%; height: 80px; margin-top: 5px;"></div> <p>JH proposed to LC that an AIA Desk Verification be conducted on the above issues, versus rolling them over until the next assessment (likely in 2016). It appears that Ecocert was attempting to provide documentation, and auditor was actually able to confirm that corrections were implemented. LC suggested following up with auditor to get additional clarification and then contact Ecocert to conduct a desk verification.</p>
02/04/15	<ul style="list-style-type: none"> • Deleted "2012 On-Site Observations" in the four NCs identified in item 1, 01/30/15 chrono log notes. • Emailed Rick Skinner (9:49am) to determine whether he was able to verify the four items

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	<p>listed in NP7246EEA.NC8. It appears that Ecocert did not respond directly to NOP regarding three of the four issues in the NC, but simply updated their documents, which corrected the NCs, and which auditor appeared to verify.</p> <ul style="list-style-type: none"> JH reviewed previous Ecocert files related to the NCs. (b) (5) (2:43pm reply from Rick Skinner): "I had to review their response that they provided NOP in 2013 and verify that their corrective actions had been initiated as described. The reason this is outstanding is that when I did the assessment – NOP had not responded to Ecocert with any decisions regarding their 2013 submission. I found that it would be against protocol to clear something that had not been approved by NOP." JH copied Ecocert documents and emails related to the three outstanding NCs into 2014 Audit folder to better be able to conduct desk verification.
02/10/15	<p>JH met with Rick Skinner at ACA Training to determine if he was able to verify the three outstanding NCs referenced above. Rick was able to verify two of the three items; however, he did not verify Item D of NP1283MMA.NC3, which related to a livestock/handler grower group witness audit visit in Brazil and Ecocert certifying the operation, despite the lack of certified organic feed for the bees. Rick's notes also indicated that "there was not further response on findings A, B, C, E, F. Ecocert figured that the balance were resolved and have not responded further." This status of this NC is still confusing.</p>
02/11/15	<p>JH met with Aude Bonnet of Ecocert at the ACA Training to review the three outstanding NCs, let her know JH was conducting a desk verification of these NCs, and get further clarification on NC3.</p> <ul style="list-style-type: none"> The NoNC that NOP issued on 05/03/13 indicates that Sections A, B, C, E and F were cleared after receiving Ecocert's corrective actions. JH reviewed this NoNC and CAs provided to the NOP. This varies from what the auditor's notes indicated in the 2014 audit checklist. As a result, JH will only review and verify Section D of the outstanding NC.
02/17/15	<p>Because Ecocert had no new noncompliances, updated the NC report to be a CA report, and a NoCont Accred letter.</p>
02/24/15	<p>JH emailed Aude at Ecocert to get additional information.</p>
02/25/15	<p>Rcvd response from Ecocert that they'd sent all of the information requested during their corrective action response.</p>
02/27/15	<p>Rcvd a call from Aude at Ecocert to try to better understand what JH was requesting. JH requested Ecocert's most recent versions of the OSP template and wild crop inspection checklist.</p>
03/02/15	<p>Aude emailed additional documents.</p>

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03/09/15	<ul style="list-style-type: none"> JH reviewed the most recent OSP template and inspection checklist. Both documents reflect updated requirements for wild crop harvest and beekeeping. JH updated the report and emailed to RM for review. Left comments in for RM reference.
03/10/15	RM forwarded to CC for review.
03/11/15	<ul style="list-style-type: none"> CC emailed JH with some comments in the document for further clarification. CC also stopped by JH's desk to ask about Ecocert's email return receipt system. Because audit report did not provide the details that would answer CC's question, JH emailed Rick Skinner to determine what email return receipt system Ecocert is using.
03/16/15	<ul style="list-style-type: none"> Rick had been out on audit until Friday, so responded back this AM. Email stated, "I can confirm that Ecocert is currently using the Outlook return-receipt system; however, the company is testing RPost, Legalpost, and some other newer applications. Until such time as the testing confirms the effectiveness of one of these newer applications that could prove to be more effective across their entire system, they will continue to use the Outlook Return-receipt system. I hope this helps – Rick." JH updated the report and emailed to CC for review.
03/16/15	<p>Discussion with Cheri about Ecocert report:</p> <ul style="list-style-type: none"> Remove language related to partial rebuttal and continued accreditation that came from audit report. Updated with NOP desk verification language. NP1283MMA.NC11 will not be cleared; reclassified as "Outstanding" because Outlook is not an acceptable return receipt system. Cited 205.661.
03/17/15 	<ul style="list-style-type: none"> Sent updated report to CC for review. Emailed Aude to determine if Ecocert had yet implemented a system like RPost or Legalpost.
04/02/15	Emailed Aude again (via RPost) to get response to 03/17/15 email. Rcvd out of office message (04/02-04/07). Requested response by 04/10/15. Flagged in Outlook to follow up.
04/07/15	<ul style="list-style-type: none"> Rcvd email from Aude. Ecocert is in the process of deciding on a new return receipt system: "Ecocert is still testing 3 final programs to determine the one that will suit the best for us. Indeed, we are facing different constraints that need to be evaluated first (as the fact that the software will be used in all countries, with different email system, that it should be legally acceptable for different regulations and countries, and so one...). Our schedule is to take final decision before end of April. I suggest to provide you name of the final software in our <u>annual report which is due for April 29</u>. Would that be acceptable for you?" Confirmed with CC that it would be ok to wait until end of April. Emailed Aude and let her know it would be ok. Asked her to make sure to cc: me on the annual report so I see that it came in and can finalize Ecocert's CA report. Also let Aude know that I would be on vacation until May 12th, but would process report as soon as back in office. Set Outlook reminder for May 13th to follow up on annual report arrival.

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04/16/15	JH updated the language in NP1283MMA.NC11 to reflect that Ecocert implemented RPost in late April 2015. Will wait until May 13 (when back in office) to confirm implementation with Ecocert and then submit the report and letter to RM for review.
05/13/15	JH emailed Aude to see if RPost system implemented.
05/18/15	<ul style="list-style-type: none">• JH rcvd confirmation from Aude that RPost is being implemented in all offices during the next 2-3 month period.• JH updated CA report and emailed docs to RM for review and approval.
05/20/15	Rcvd ok from RM to forward to CC for review.
05/21/15	Updated report to remove all track changes comments and forwarded report and letter to CC for review and hard copy approval.
05/22/15	Hard copies went to CC.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Ecocert S.A. An onsite audit was conducted, and the audit report reviewed to determine Ecocert’s capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Ecocert S.A (Ecocert)
Physical Address	BP 47, 32600, L’Isle Jourdain, France
Mailing Address	Same
Contact & Title	Aude Bonnet, NOP Certification Manager
E-mail Address	Aude.bonnet@ecocert.com
Phone Number	+335 62 07 65 72
Reviewer & Auditor	Janna Howley, NOP Reviewer Rick Skinner, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP Assessment Review & Desk Verification: January 26, 2015 Onsite audit: September 15-26, 2014
Audit Identifier	NP4258EEA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of Ecocert’s certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	Ecocert’s certification services in carrying out the audit criteria during the period: September 2012 through September 2014.

GENERAL INFORMATION

Ecocert S.A. (parent company) is a for-profit business, initially accredited as a USDA National Organic Program (NOP) certifying agent on April 29, 2002, for crops, wild crops, livestock, and handling operations. Ecocert has 969 clients certified to the NOP including 451 crop, 10 livestock (1 apiary), 137 wild crop, and 808 handling operations (673 processors, 79 distributors, and 55 trader/brokers). Ecocert also certifies 125 grower groups to NOP regulations.

Ecocert manages fourteen offices related to NOP world-wide, with key activities conducted in all of the offices. The Ecocert main office is located in L’Isle Jourdain, France. Ecocert has five offices in Africa (Burkina Faso, Madagascar, Morocco, South Africa, and Tunisia). Four of the five offices conduct key certification activities for NOP certification including: sending out application packets; sending out estimates; conducting the initial review for completeness and

compliance; assigning inspectors; and making the certification decision. South Africa currently does not perform activities of a satellite office. Activities in that region are conducted by the office in Madagascar.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether Ecocert's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to Ecocert.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP7246EEA.NC8 – Cleared – 7 CFR §205.642. Fees and other charges for certification states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator.” Additionally, the clause states “...the fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable, and the certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.”

2007 Comments: *ECOCERT adopted a new series of fee schedules on January 1, 2007, and is currently using this international fee matrix for charging clients during the 2007 certification year. The company has not filed the updated fee schedule with the Administrator. Additionally, there is no reference to nonrefundable portions of the certification fees in the structure of the fee schedule, and policy dictates that only those requesting a fee schedule are actually provided with one.*

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consistent with the submitted fee schedule. Clients were charged 91 EU per hour and the highest rate on the fee schedule was 90.75 EU per hour. In the Colombia office, a fee charged to a crop operation identified as “Gastos de Control Interno” did not correspond to any of the fees included on the submitted fee schedule. The Colombia office stated this was a special fee for a review of the internal control system. Additionally, no fee schedule is provided to applicants for certification, just the estimate (quote).

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2014 Verification of Corrective Action: Ecocert is providing each operation with a copy of the fee structure along with a quote for the entire cost of certification. The fee structure is based on unit cost of certification (daily) for specific types of certification. Because the operation is not aware of the number of units necessary to complete the certification, Ecocert provides the quote after the calculations for time and distance are determined. Fees for all countries were submitted with the annual report in April 2014. There have been three updates to the fee structure since that time: 1) Update on September 04, 2014 (Morocco only); 2) Update on July 07, 2014 (South Africa only; this office is managed from Madagascar); and 3) Update on June 13, 2014 (Tunisia). Tunisia stopped issuing quotations in the local currency and changed the fee quote to Euro. The updates from 2013 were included in the annual report in April 2014. Upon further review by the NOP it was confirmed that the 2013 fee schedules included all Ecocert offices, with specific payment conditions for each office. A reminder was sent to all subsidiaries that the fees have to be applied as per current fee schedule; in case of amendments, the designated subsidiary must first submit the new fee schedule to Ecocert for approval; Ecocert would then notify the USDA of the update.

NP1283MMA.NC1 – Cleared - 7 CFR §205.403 (a)(1) states, “A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter...”

2011 Comments: *For the grower group witness inspection, the internal control system (ICS) was set up to inspect all producers (bee keepers) but not to inspect all apiary locations. There is no minimum of locations required by Ecocert and no information in the organic system plan or grower group records concerning how many or which locations were inspected each year.*

2012 Corrective Action: Ecocert revised the Guideline for Grower Group, TS01 (EC-NOP) V03, to require “annual inspection by the ICS of all farms, production sites, grazing and apiary

areas....” Regarding the specific grower group from the witness inspection, Ecocert required the GG ICS to conduct an on-site inspection of all sites. This was achieved by issuance of a Notice of Non-Compliance to the operation (dated Nov 21, 2011) where a major non-compliance was issued, withholding issuance of updated organic certificate until the grower group demonstrated the ICS had visited each production site. If the corrective action submitted is effectively implemented, Ecocert has demonstrated the capability to comply with NOP accreditation requirements.

2012 On-site Observations: Ecocert revised their guidance document (*TS01 (EC-NOP) V3 – Guideline on Organic Certification of Grower Groups according to EC and NOP Regulations*) to require the ICS of all grower groups to inspect all sites within the operation. Notices sent out to all grower groups concerning the revisions and the grower group involved in the 2011 witness inspection was required to inspect all operations. However, the guidance document had not been fully implemented at the time of the Satellite office surveillance assessment and will have to be evaluated for implementation and effectiveness at a later date. During the grower group witness inspection, the inspector reminded the operation of the requirement that all sites are inspected by the ICS and ensured the requirement was met.

2014 Verification of Corrective Action: Ecocert’s *Guideline on Organic Certification of Grower Groups according to EOS and NOP Regulations, Grower Group Certification* was updated in 2012 and 2014. The checklist and guidance document have been implemented since 2012. The audit verified that since 2013, all grower groups are conducting annual inspections of all sites under the grower group organization, using this guidance document.

NP1283MMA.NC2 – Cleared – 7 CFR §205.501 (a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to comply with the requirements for accreditation set forth in this subpart.”

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and still move forward as “OK.” With this process in place, the supervision program of the COs is inadequate to determine satellite offices’ ability to comply with NOP regulations.

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2014 Verification of Corrective Action: Records showed that Ecocert submitted a clarification to their original corrective action following NOP determination that the original was inadequate. Ecocert updated its annual performance evaluation instruction (I07 EC-NOP) to have increased oversight by the Certification Manager, year-round file reviews to better monitor work performance, and immediate action in the case of file irregularities due to staff training issues. A second certification manager was also hired. The clarification demonstrated how Ecocert would review COs for all job duties and responsibilities. Ecocert did not receive a decision from the NOP after the additional information had been submitted. The corrective action was verified onsite, however, and the updated procedure was followed for all evaluations that were reviewed during the onsite assessment. The non-compliance remained outstanding after this updated corrective action was provided to NOP in 2013.

NP1283MMA.NC3 – Cleared – 7 CFR §205.501 (a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

2011 Comments:

- a. *For the wild crop operation visited during the witness audit in Brazil, to verify the land requirements of NOP §205.202 that no prohibited substances have been applied for a period of 3 years preceding harvest of the crop, Ecocert accepted a declaration from the Instituto Estadual de Florestas (IEF) which stated there had been no treatment with chemical pesticides or other non-conforming products in accordance with the regulations and standards (norms) that are the basis for organic production. The areas of wild harvesting and collecting are part of the Brazilian Atlantic Rainforest, which is owned by individuals but controlled under legal regulation by the IEF. As such, the verification of no use of prohibited materials document is from the IEF and covers the entire rainforest, rather than individual owners’ plots that are seeking certification. The IEF document was dated April 13, 2009 and because it covers the entire rainforest, Ecocert does not request verification of no prohibited materials for new plots added to the certified operation and in turn the inspector does not verify the information.*
- b. *The review of one exporter/handler file at the Ecocert Germany office verified that Ecocert allows certification of multiple distinct and separate operations under the*

- scope of one certification. The exporter/handler was the main certified entity with its own handling facility and with three processing subcontractors. There were organic system plans and individual inspection reports for the exporter/handler and subcontractors; however, only one certificate was issued which identified the exporter. In reference to the subcontractors, this does not meet the requirements of NOP §205.100 of what has to be certified and that they must be certified according to the provisions of Subpart E and §205.404 which requires a certificate to be issued that identifies the name and address of the certified operation.*
- c. For annual updates, Ecocert was sending certified operations a standard template letter (L04 (EC-NOP)v04en Notice Update OSP-Unit Description or the current version (v05en)). The letters did not address all requirements of NOP §205.406(a). Specifically, requirements that the updated organic system plan (OSP) include a summary statement with supporting documents which details revisions made to the OSP from the previous year; additions or deletions to the previously approved OSP intended to be undertaken in the coming year; additions or deletions to any information required pursuant to 205.401 (b); or provide an opportunity for Ecocert to request additional information to verify compliance based on the individual operations situation.*
 - d. For the livestock and handling grower group visited during the witness audit in Brazil, Ecocert certified the grower group without any certified organic feed (flowers, nectar) for the bees.*
 - e. A review of 16 approved retail labels in 3 handler operation files at the Brazil office revealed that the “Certified organic by...” statement was not below the information identifying the handler on all 16 labels.*
 - f. A review of 5 approved retail labels in 3 handler operation files at the Germany office revealed:
 - 1. In two of the files the “Certified organic by...” statement was not below the information identifying the handler on 4 of 4 retail labels;*
 - 2. In one file the “Certified organic by...” statement was missing on the one label in the file;*
 - 3. In one file, 2 of 2 retail labels using the USDA seal, both in color and black and white forms, did not replicate the figure in §205.311. Specifically, there was no defined outer ring of the USDA seal in either brown or black, respectively; and*
 - 4. In one file, 2 of 2 retail labels did not include an ingredient statement for the “organic” products and compliance with §205.303(b)(1) could not be verified.**

2013 NOP Assessment of ECO Corrective Action Response: Item D (above, in 2011 Comments): Ecocert indicated OSP forms and inspection checklists would be revised to describe the feeding requirements and verification of feed compliance. Ecocert also stated qualified parties (inspectors, client managers, certification officers, and concerned operators) would be notified of program updates via letter format. A copy of the letter was provided; however, objective evidence showing the changes to the OSP and inspection checklists was not provided. Also, Ecocert’s response did not explicitly state they would require certified organic feed for all livestock operations, including bees. This is implied in the response, but not stated.

2014 Verification of Corrective Action: The response to this noncompliance was first addressed in 2012. On May 5, 2013, NOP sent a Notice of Noncompliance with two noncompliances due to other issues and included Part “d” of this noncompliance. Ecocert responded on June 28, 2013. The NOP accepted corrective actions for Items “a, b, c, e, f” in 2013. The NOP accepted corrective actions for Item “d” in 2015.

Item “a”: Ecocert provided updated owner attestations of wild collection areas harvested. In addition Ecocert modified its inspection checklist to specify the type of operator who must provide an affidavit. A reminder was sent to all certification officers and inspectors regarding this report update. Ecocert provided the NOP with their most recent inspection checklist and OSP template; both documents confirmed that all wild crop plots must be listed so that inspections can verify practices at each site.

Item “b”: Ecocert issued certificates for the exporter/handler subcontractors. Copies were provided to the NOP. Additionally, Ecocert modified its instruction (*I13 EC-NOP*) to clarify that one certificate per operation will be issued. All certification officers were trained on this update in 2012. The requirement was also added as performance evaluation criteria. The updated instruction was provided to the NOP.

Item “c”: Ecocert revised its OSP template letter (*L04 EC-NOP v06en*) to include all NOP requirements related to 205.406(a). A copy of the template letter was provided to the NOP. A copy of *TS34 (EC-NOP) v02en*, which instructs operations how to complete and submit an OSP, was updated and provided to the NOP.

Item “d”, Ecocert submitted a revised inspection checklist and OSP to the NOP. The revised checklist included a new question to determine whether forage sources and feed were certified organic. Additionally, an internal memo on updated requirements for the inspection and certification of beekeeping operations was sent to all qualified parties in the organization in June 2012.

Items “e and f”: Ecocert contacted the operations with incorrect labels and copies of the modified, correct labels were provided to the NOP. Ecocert updated their instruction (*I24 EC-NOP v02*) on label verification and approval. Certification officers were trained on the revised instruction in April 2012. Additionally, Ecocert implemented a book of exercises on correct labels, as well as a checklist guide for label approval. Label verification was also added as a performance evaluation criterion for certification officers. Ecocert provided the NOP with the revised instruction and the training slides. Audit review of five files indicated that “certified organic by...” state was included, and in the right location on the label. A review of three files that use the USDA indicated that it is fully compliant with the regulations. A review of five files indicated that all products labeled as “Organic” identify each organic ingredient in the ingredient statement.

NP1283MMA.NC4 – Cleared – 7 CFR §205.501 (a)(11)(iv) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification.”

2011 Comments: *Notices of non-compliance issued by Ecocert include a prescribed corrective action.*

2012 Corrective Action: Ecocert submitted the following, “The column “Improvement actions AND date by which the operator must rebut or correct the noncompliance” was reserved to the client for its own answers. We propose to modify the title of this column to avoid any confusion and name it “Action set up by the operator and date of implementation.” The new template will be ready for use end of July. In addition, during the training of Certification officers held in L’Isle Jourdain in April 2012, certification officers have been reminded the type of information to be included in the notice of non-compliance and the importance of avoiding any consultancy.”

2012 On-site Observations: New templates were implemented by Ecocert at the end of July. At the Morocco office, a notification of non-compliance which was issued through their E-cert system on July 13, 2012, had prescribed corrective actions for 1 of the 5 non-compliances identified. At the Madagascar office, a notice of non-compliance which was issued using the new template had a column changed from “Improvement actions and date by which the operator must rebut or correct the noncompliance” to “Actions set up by the operator and date of Implementation.” All notifications of non-compliance issued by both offices prior to using the new template had the same issues with prescribed corrective actions.

2014 Verification of Corrective Action: Ecocert has implemented the new templates; they are in use at the locations reviewed. Records reviewed found there was evidence of prescribed corrective actions.

NP1283MMA.NC5 – Cleared - 7 CFR §205.501 (a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification...and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.”

2011 Comments: *There were no conflict of interest disclosure reports on file for 4 of the 5 Ecocert directors.*

2012 Corrective Action: Ecocert provided signed conflict of interest disclosure statements for all directors. The procedure *P05 (NOP)* has been revised to indicate COI statements are required for all responsibly connected parties, including directors, annually. If effectively implemented, Ecocert’s response demonstrates capability to comply with NOP accreditation requirements.

2012 On-site Observations: During the satellite office visits, all personnel required to have a conflict of interest disclosure report had a current report on file for both offices reviewed.

2014 Verification of Corrective Action: A review of files verified that conflicts of interest and confidentiality agreements are current for all staff.

NP1283MMA.NC6 – Cleared - 7 CFR §205.501 (a)(11)(vi) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.”

2011 Comments: *As verified by an interview with the NOP Certification Manager and the records reviewed, in some cases the Certification Officers conduct application reviews and make certification decisions for the same files. This occurred in 6 of the 10 files reviewed for this requirement. Ecocert’s procedures were revised to allow this process after the February 2010*

ACA training by the NOP in Nuremberg, Germany due to a misunderstanding by Ecocert. A copy of this training was not available by the end of the audit.

2012 Corrective Action: Ecocert updated documents related to application review and certification decision to require inspectors to conduct the application review and certification officers to conduct the inspection review/certification decision. Ecocert provided objective evidence (updated procedures, evidence of training of staff). If effectively implemented, Ecocert's response demonstrates capability to comply with NOP accreditation requirements.

2012 On-site Observations: Ecocert revised their *Procedure: Certification EC and NOP, Code: P01 (EC-NOP)V04* and *Procedure for Initial Application & Renewal (EC-NOP), Code: P14(EC-NOP)V06* to reflect that the person conducting the initial review and the one which reviews the inspection report and makes the final certification decision is a different individual. Training was held in April 2012 and certification officers were informed of the revisions to the procedure with implementation to be reviewed by Ecocert during file reviews. A review of six files at the satellite offices verified that the individual who conducted the initial review and inspection was different than the one making the certification decision.

2014 Verification of Corrective Action: A review of files during the mid-term assessment verified that the individual who conducted the initial review and inspection was different than the one making the certification decision.

NP1283MMA.NC7 – Cleared - 7 CFR §205.501 (a)(18) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and any requirements for the correction of minor non-compliances.”

2011 Comments: *Ecocert was providing the inspectors with the previous on-site inspection report prior to inspections. However, they do not notify the inspector of their decision regarding certification and any requirements for the correction of minor non-compliances after the inspection.*

2012 Corrective Action: Ecocert updated two instruction documents, *I04* and *I03*, that address how to “deal with non-compliances for certified operators/applicants.” These documents were updated to add the inspectors to the list of parties to whom a copy of the certification decision is sent. If effectively implemented, Ecocert's response demonstrates capability to comply with NOP accreditation requirements.

2012 On-site Observations: Ecocert revised their *Instruction Dealing with Non-compliances for Certified Operations under the NOP, Code: I04(NOP)V04* and *Instruction Dealing with Non-compliances for Applicants under the NOP, Code: I03(NOPe)V04* to include inspectors on the notification of non-compliances issued to operations following inspections. Training was held in April 2012 and certification officers were informed of the revisions to the procedure with implementation to be reviewed by Ecocert during review of reports and annual evaluations of certification officers. Verification that inspectors were notified was obtained by a review of two emails to operations concerning the inspection.

2014 Verification of Corrective Action: In each of the files reviewed, and during the review audit and witness inspection, it was indicated that inspectors are notified of the decision on

certification based on the results of the inspection. This is done when both the operator is notified and the certificate is issued.

NP1283MMA.NC8 – Cleared – 7 CFR §205.501 (a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary” and the *NOP Policy Memo 11-10* states, “The National Organic Program (NOP) is drafting guidance regarding certification of grower groups and will be requesting public comment before publishing final guidance and possible regulation change. In the interim, accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies.”

2011 Comments: *The Ecocert TS01(EC-NOP)VI – Guideline on Organic Certification of Grower Groups according to EC and NOP Regulations was reviewed against the NOSB Recommendation 2002 and NOSB Recommendation 2008 and verified they did not address the requirements for:*

1. *The GG identifying the designation of what is a specific member or subunit and then verification of these members and subunits by Ecocert during the application process (NOSB Recommendation 2008 section III.C);*
2. *Determining how many of the sub-units within a production unit must receive an annual inspection by the ACA’s inspector (NOSB Recommendation 2008 section III.D.1);*
3. *Determining which sub-units present the greatest risks of non-compliance (NOSB Recommendation 2008 section III.D.1);*
4. *The inspector selecting 25% of the remaining subunits at random (NOSB Recommendation 2008 section III.D.1); and*
5. *Mandatory inspection (by ACA inspector) of new entrants into the production unit (NOSB Recommendation 2008 section III.D.1).*

In addition the Guideline, Section I, Definitions states, “Sub-Group = Sub-Unit: Subdivision of the grower group in smaller units for example a village.” This definition is not in accordance with NOSB Recommendation 2008 section III which states, ““Sub-unit” means: A smaller discrete portion of a production unit, such as a field, plot, wild-crop harvest area, or distinct processing area.”

2012 Corrective Action: First, for items 1 – 5 above, Ecocert revised the GG Guidelines to address each point (see points above for GG guidelines page number update). Second, the GG Guidelines have also been updated to reflect the accurate definition of “sub-unit” (page 2). If effectively implemented, Ecocert’s response demonstrates capability to comply with NOP accreditation requirements.

2012 On-site Observations: Corrective actions submitted verified that the guidance document (*TS01(EC-NOP) V3 – Guideline on Organic Certification of Grower Groups according to EC and NOP Regulations*) was revised to address the requirements of items 1 – 5 above and the definition of a sub-unit was revised to reflect the one in NOSB Recommendation 2008. In addition training was held in April 2012 for certain certification officers who in turn trained other certification officers. The guidance document had not been fully implemented at the time of the satellite office surveillance assessment and will have to be evaluated for implementation and effectiveness at a later date.

2014 Verification of Corrective Action: A review of the updated procedures confirmed that the guidance has been implemented in the three grower group files that were reviewed during the assessment. The certifier developed a risk assessment program managed by a risk management staff person at Ecocert's main office. Grower groups' organizational structures, Internal Control Systems, and specific production details, are now assessed by this staff member.

NP1283MMA.NC9 – Cleared - 7 CFR §205.504 (c)(1) states, “A private or governmental entity seeking accreditation as a certifying agent must submit... (1) A copy of the procedures intended to be implemented to prevent the occurrence of conflicts of interest, as described in §205.501(a)(11).”

2011 Comments: *The Ecocert Prevention of Conflicts of Interest, Code: P05 (NOP), Version 01 procedure does not adequately address the requirement of 205.501 (a)(12)(ii) that if any person covered under 205.501 (a)(11)(i) (the ACA, a responsibly connected party of the ACA, etc...) had a conflict of interest with the certification of an applicant, the applicant will be referred to another ACA and Ecocert will bear the costs of certification. The procedure states if any person had a COI at the time of application for certification they will be referred to another ACA and Ecocert will bear the cost.*

2012 Corrective Action: Ecocert revised procedure *P05 (NOP)* to comply with §205.501(a)(12)(ii). A copy of the updated procedure was provided as objective evidence.

2012 On-site Observations: Ecocert revised and submitted their procedure *Prevention of Conflicts of Interest (Code: P05 (NOP), Version: 03)* to accurately reflect the requirements that if the ACA or a responsibly connected party of the ACA had a conflict of interest with the certification of an applicant the applicant will be referred to another ACA and Ecocert would bear the cost.

2014 Verification of Corrective Action: Ecocert's revised procedure (*P05*) was reviewed and reflects the requirements that if the ACA or a responsibly connected party of the ACA had a conflict of interest with the certification of an applicant the applicant will be referred to another ACA and Ecocert would bear the cost. Additionally, the 2013 and 2014 COI agreements were reviewed and those with declared conflicts were not involved in any certification activities with the applicant. This procedure is also evident in all training modules.

NP1283MMA.NC10 – Cleared - 7 CFR §205.510 (a)(1) states, “An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following report and fees: A complete and accurate update of information...”

2011 Comments: *Ecocert had not been sending in an annual report, as required by §205.510(a). Some information is sent to the NOP as it is updated, such as changes to the Certification Manager. However, there is no annual report completed and submitted as required. Because the Annual Report has not been submitted, the application for accreditation renewal did not contain all required components.*

2012 Corrective Action: Ecocert revised the Disclosure of Information procedures, which directs how Ecocert provides external reports and information and to whom. A copy of the revised procedures was provided as objective evidence. The procedure shows staff responsible

for reporting activities, dates by which reports are due, and management responsible for oversight. If effectively implemented, Ecocert's response demonstrates capability to comply with NOP accreditation requirements.

2014 Verification of Corrective Action: The submission of both the 2014 and 2013 annual reports was verified during the mid-term assessment

NP1283MMA.NC11 – Cleared - 7 CFR §205.660 (d) states, "Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts."

2011 Comments: *All notices of non-compliance, notices of proposed suspension, and notices of resolutions sent to clients via regular email only and not via a service which provides a dated return receipt.*

2012 Corrective Action: Ecocert's procedures indicate that all applicable notices will be sent via email with a delivery receipt; alternately, if no receipt is received for the email delivery, Ecocert will re-send the notice via certified mail. Instruction documents were updated to reflect the changes and copies were provided as objective evidence. If effectively implemented, Ecocert's response demonstrates capability to comply with NOP accreditation requirements.

2012 On-site Observations: Ecocert is still sending all notifications via regular email. However, they revised their instructions and a procedure to include that notifications have to be submitted via a delivery service which provides a dated return receipt and identified the acceptable methods as email, mail, or certified mail. Ecocert also had a training session in April 2012 for the contracting officers and put out an Internal Note which explained the process for obtaining a return receipt of delivery confirmation when sending the notifications via regular email. The Internal Note explained that some email addresses do not transfer a return receipt stating the email was received. In this case, the certification officer is to follow up with an email to the operator requesting confirmation they had received the notification and if no confirmation is received to send the notification via certified email with a dated return receipt. In two files reviewed at the Morocco Office where the email was not confirmed as delivered; Ecocert accepted it as delivered for one operation because they provided some corrective actions. There was no response from the second operation and no follow up from the office concerning sending the additional email or via certified mail to confirm receipt of the notification as required by the corrective actions. During the closing meeting, the Ecocert Technical Manager requested that the auditor of record include the statement that Ecocert had received confirmation that the email was sent. The two emails reviewed stated, "La remise à ces destinataires ou listes de distribution est achevée, mais la notification de remise n'a pas été envoyée par les adresses de destination." An internet translation of the statement into English provided the following: "The handing-over with these recipients or lists of distribution is completed, but the notification of handing-over was not sent by to addresses." Another translation returned the following: "The presentation has these recipients or listea distribution is completed, but the notification of the delivery has not been sent by the destination addresses." With either translation it is clear that the emails were sent but no verifiable proof that they were received by the recipients.

2014 Verification of Corrective Action: Ecocert procedures require all applicable notices to be sent via email with a delivery receipt; alternatively, if no receipt is received for the email delivery, Ecocert sends the notice via certified mail. These procedures were verified for implementation and effectiveness. Interviews indicated that return receipt is documented in the new data management system and; both methods of notification are used to ensure the ability to verify delivery. Ecocert previously used the Outlook return-receipt system; however, as of May 2015 they began the implementation of the RPost electronic return receipt system. The entire implementation, across all Ecocert offices, will take 2-3 months.

NP1283MMA.NC12 – Cleared - 7 CFR §205.662 (a)(1) – (3) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program’s governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: (1) A description of each noncompliance; (2) The facts upon which the notification of noncompliance is based; and (3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.”

2011 Comments: *In nine notifications of non-compliance files reviewed, one did not contain a description of the non-compliance and instead stated the labeling standards were sent to client; two did not include the facts upon which the non-compliance was based; and seven did not provide a date for the operation to provide corrective actions and/or to rebut the non-compliance.*

2012 Corrective Action: Ecocert addressed this issue by revising the Notice of Non-Compliance template, which was provided as objective evidence. Review of the updated template shows the form requires all points above (description of the NC, facts upon which it is based, and a date to rebut/correct). If implemented effectively, Ecocert’s response demonstrates capability to comply with NOP accreditation requirements.

2012 On-site Observations: Ecocert revised their template for the notifications of non-compliance to automatically input a date for the operation to rebut the non-compliance or submit corrective actions and stated the template would be used starting at the end of July 2012. Ecocert stated the importance of including the required information in the notices would be included as a reminder during the certification officer training for April 2012 and a communication to be sent to the certification officer’s by the end of June 30, 2012. At the Morocco office, 2 of 2 recent notifications of non-compliance reviewed, included the description of the non-compliances and the facts upon which the non-compliances were based. One of the 2 did not include a date to correct or rebut the non-compliance for 1 of the 3 non-compliances’ included on the notice. At the Madagascar office, a notice of non-compliance dated September 2012 included all requirements. Three of 3 notifications of non-compliances’ which were issued under the old procedure did not contain a date.

2014 Verification of Corrective Action: Each of the Notices of Noncompliance reviewed during the mid-term assessment confirmed that the submitted corrective action has been implemented and is effective in meeting the requirements of 205.662(a)(1)-(3). Each of the completed templates contained a description of each noncompliance, facts upon which it is based, and a date by which the operation must respond by rebutting or correcting.

NP1283MMA.NC13 – Cleared - 7 CFR §205.662 (c)(3) states, “The notification of proposed suspension or revocation of certification shall state: (3) the impact of a suspension or revocation on future eligibility for certification.”

2011 Comments: *One notice of proposed suspension did not include the impact of the suspension.*

2012 Corrective Action: Ecocert addressed this by providing an updated version of the Notice of Proposed Suspension template, which includes an impact/eligibility section. If effectively implemented, Ecocert’s response demonstrates capability to comply with the NOP regulations.

2012 On-site Observations: Ecocert revised their template for the notification of proposed suspension to include the impact of the suspension as stated in NOP §205.662(f)(1). A review of two notifications of proposed suspensions at the Morocco office verified they did not contain the correct impact of suspension as they stated, “Finally, we would also like to remind you that should your certification be totally suspended, you will not be able to sell, label or represent your product as organic for a period of 6 months.” One was dated October 2011 and the other August 14, 2012. A review of a notice of proposed suspension dated September 4, 2012 at the Madagascar office verified that the current template was used and had the correct impact of suspension.

2014 Verification of Corrective Action: The template for the notification of proposed suspension was documented as having been updated as described in the corrective action. A review of a notice of proposed suspension verified that the current template was used and had the correct impact of suspension.

NP2254MMA.NC1 – Cleared - 7 CFR §205.402(a)(1)(2) states, “Upon acceptance of an application for certification, a certifying agent must: (1) Review the application to ensure completeness pursuant to §205.401; (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part.”

2012 Comments: *Four of six files reviewed at the satellite offices (two files at each office) verified they did not include sufficient information to meet the requirements of an organic system plan (OSP) as described in NOP§205.201(a).*

- 1) *File #1 – handler and wild crop: The NOP portion of the Excel file requests “A description of the practices and procedures of production for each of” the organic products requested for certification “including the frequency at which production and handling occur”. The information provided by the operation was a general description of what activities are conducted and when (i.e. “Argan fruits – July, August, September – picking argan fruits – annually”; “Argan nuts – daily – crushing and sorting – daily”; and Argan oil – daily – pressing and filtrating oil – daily”). In the same file, the Excel file also requests, “Monitoring practices and associated recordkeeping documents used for correct and efficient implementation of the above described practices.” The information provided by the operation was, “by operations register”; and for what operations are monitored the file states, “crushing, transformation, storage” – register – daily.”*
- 2) *File #2 – handler: the OSP did not address the requirements of NOP §205.201(a)(1) and (a)(3) and there were no comments by the reviewer. It was not clear from the OSP what*

the company's activities were, as in one section it states they receive product already bottled and in another that they monitor bottling. If bottling was conducted there was no information on the bottling process.

- 3) *File #3 –coffee producer grower group: The operation was issued a notice of noncompliance which included non-compliances that should have been identified and addressed during the initial review prior to inspection. Items included:*
 - a. *The OSP indicated that the ICS was not yet implemented;*
 - b. *OSP indicated that maps or sketches of the fields and locations had not yet been implemented;*
 - c. *No adequate information in OSP on segregation (buffer zones) between organic fields and non-organic fields; and*
 - d. *OSP stated the internal inspection program for inspecting all producers every year was still being developed.*
- 4) *File #4 – crops and handling: This operation was also issued a notice of noncompliance that included non-compliances which should have been identified and addressed during the initial review prior to inspection. Items included:*
 - a. *Farming activity is not complete;*
 - b. *Planting and pruning are not described;*
 - c. *Monitoring at the milling factory and at the roasting level (exportation) are not described;*
 - d. *Frequency of monitoring at milling is not described;*
 - e. *Measures to avoid commingling at the roasting facility and during transportation are not described;*
 - f. *Measures to avoid contamination at the roasting facility and during transportation are not declared;*

For file #4, one of the Madagascar COs stated they were not aware of the milling operation prior to inspection. However, the OSP NOP worksheet, section 6 under Processing states, "Washing, milling factory used for organic and conventional products" as an identified risk. However, because there was an inadequate description of the management practices and physical barriers in the OSP it was not identified as a noncompliance until after the inspection.

2012 Corrective Action: Ecocert sent a 23-page training document on OSP review and an excerpt of a NOP training on review of OSPs to its Certification Officers at each satellite office, with instructions to provide the information to all staff working on OSP review. The training addressed the minimum requirements of what is to be included in OSPs, and how to review OSPs. It specified that in the review of an OSP during the first year, no inspection can be conducted until the OSP is complete and validated; a notice of noncompliance may be issued to applicants and an inspection cannot be conducted until the noncompliance is addressed. Ecocert corrected the files to which the noncompliance pertains. It collected updated OSP information for two of the operations and the remaining two operations surrendered certification. Ecocert provided additional training on OSP review to its staff in Madagascar in April 2013 for its inspectors, in July 2013 to all of the team, and again in January 2014 for the Certification Officers. In Morocco, the training was provided in October 2013 to a new staff member and in January 2014 to all of the team.

2014 Verification of Corrective Action: The NOP verified that the provided training documents and updated procedure (*P14 EC-NOP*) were currently in use. Ecocert's most updated OSP template was also provided to the NOP.

NP2254MMA.NC2 – Cleared - 7 CFR §205.405(a) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification.”

2012 Comments: *In 1 of 6 notices of denial reviewed, Ecocert issued a notice of denial to an applicant citing a correctable non-compliance and the process as a whole was not in accordance to the NOP requirements. The notice of denial stated, “Further to the review of the inspection report, the correction of the noncompliance is not possible because of the use of traps with ethanol and methanol”. The alcohol(s) is used as an attractant for the coffee berry borer and is contained in a bottle with no contact with the organic crop or land. The notice of denial was dated one day after a notice of non-compliance which was also issued. The notice of non-compliance did not include a date by which to respond to the non-compliances. The Ecocert Technical Director stated that the notice of non-compliance was issued first and then the denial so the operation had time to respond. However, as previously stated the notice of non-compliance was issued one day before the notice of denial and it did not include a date by which to respond. In addition, the notice of denial did not include the use of a prohibited substance on some plots which was included in the notice of non-compliance and the use of conventional seeds and seedlings without verification that they were untreated.*

2012 Corrective Action: Ecocert noted that this was an isolated case. Ecocert explained the mistake to the staff member responsible for the decision. Further, to prevent this mistake in the future, Ecocert issued a global communication to all staff to remind them of how to manage correctable and non-correctable noncompliances during initial inspection review. This training email gave an overview of the OSP review and inspection report review, and referred the reader to an attached instruction on file reviews.

Regarding the notice of denial and notice of noncompliance, Ecocert explained that its procedure for issuing a combined notice of noncompliance and denial of certification is to send two separate letters. Ecocert stated that for the specific incident noted in the noncompliance, both notices were actually sent on the same day via email, although the creation date of the documents was one day apart. Ecocert provided a copy of the email to the NOP. To prevent any future confusion regarding combined notices of noncompliance and denials of certification, Ecocert combined these notices into one template.

Regarding the notice of denial not including reference to two non-correctable noncompliances, Ecocert rebutted this part of the noncompliance. Ecocert noted that both noncompliances regarded the lack of documentation, not the use of prohibited inputs. Therefore, the noncompliance was correctable. In one file, the status of the seedlings had not been determined to be conventional, and additional information was needed. In the other, the nature and composition of lime was not determined to be synthetic, and additional information was needed. The NOP accepts the rebuttal of this part of the noncompliance.

2014 Verification of Corrective Action: The certifier submitted the new template that they are currently using which allows for the combined Notice of Noncompliance and Denial. This document was verified for implementation and effectiveness.

Non-compliances Identified during the Current Assessment

None.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a satellite office audit of EcoCert S.A - Ecuador. An audit was conducted, and the audit report reviewed to determine EcoCert Ecuador S.A.'s capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	EcoCert Ecuador S.A.
Physical Address	Córdova 518 y Mendiburo, Tercer Piso Oficina 11. Guayaquil, Ecuador
Mailing Address	Córdova 518 y Mendiburo, Tercer Piso Oficina 11. Guayaquil, Ecuador
Contact & Title	Aude Bonnet, Certification Program Manager (Main Office, France) Ileana Cartagena, Quality Officer (Ecuador Office)
E-mail Address	aude.bonnet@ecocert.com; ileana.cartagena@ecocert.com
Phone Number	+33 0 5 62 07 52 06 (Main Office) +593 4 256 1253; +593 993 997 546 (Ecuador Office)
Reviewer & Auditor	Rebecca Claypool, NOP Reviewer; Robert Yang, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: May 3, 2016 Audit: December 31, 2014; January 29, 2015; March 11, 2015
Audit Identifier	NP4365RYA
Action Required	Yes
Audit & Review Type	Satellite Office Audit Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of EcoCert Ecuador S.A.'s certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	EcoCert Ecuador S.A.'s certification services in carrying out the audit criteria.

ORGANIZATIONAL STRUCTURE:

EcoCert Ecuador S.A is a subsidiary of EcoCert S.A., a for-profit business initially accredited as a USDA National Organic Program (NOP) certifying agent on April 29, 2002, for crops, wild crops, livestock, and handling operations. EcoCert S.A. provides operations located in Ecuador and Peru with USDA organic certification services through EcoCert Ecuador S.A.'s one office in Guayaquil, Ecuador. Certification activities carried out at this satellite office include contract

review; application review; conducting inspections; inspection report review; certification decision-making; materials and ingredient review/approval; and label review/approval. EcoCert S.A. currently certifies 17 operations to the USDA organic regulations in Ecuador and Peru, which includes 8 crops, 1 wild crop, 14 handling operations, and 7 grower groups. EcoCert Ecuador S.A. staff include one contracted inspector, one staff inspector, and one certification officer. EcoCert S.A. requires all EcoCert Ecuador S.A. staff to complete a conflict of interest disclosure and confidentiality statement forms annually.

CERTIFICATION PROCESS

EcoCert Ecuador S.A. staff typically provide applicants with electronic versions of an introductory letter that includes a link to the USDA organic regulations and a summary of the certification; a certification application form; and a fee schedule. Upon receiving a completed application form, staff issue the applicant a certification services quotation (i.e. cost estimate), a certification contract, and the applicable organic system plan questionnaires.

Upon receiving the signed quotation, completed organic system plan questionnaire(s), the staff or contracted inspector conducts an initial review for completeness and compliance. The certification officer then assigns the inspection to the appropriate inspector based on qualification and availability. Upon receiving the inspection report from the inspector, the certification officer reviews the report for compliance and makes the final certification decision. All notices resulting from the initial and final reviews are issued by the certification officer. The organic certificate is issued via EcoCert S.A.'s ECERT database system and signed by an EcoCert S.A. certification manager.

For continuation of certification, EcoCert Ecuador S.A. staff send its certified operations a letter at the beginning of each year as a reminder that an annual update must be submitted prior to the operation's anniversary date. The certification process, including the forms that must be completed, for continuation certification is the same as for initial application for certification.

EcoCert Ecuador S.A. conducts unannounced inspections and sampling according to EcoCert S.A.'s additional inspections and sampling policy. Operation selection is based on a risk assessment, which takes into consideration the operation's production type, scope, history of noncompliances, and any complaints received about the operation. An annual additional/sampling inspection plan is developed by the certification officer at the beginning of each year and submitted to the EcoCert S.A. office for approval.

Material evaluations are conducted by the certification officer with assistance from EcoCert S.A. staff, as needed. Materials are reviewed and approved according to EcoCert S.A.'s procedures and policies. Product labels are reviewed and approved by the certification officer, and the use of the approved labels is verified by the inspector during the on-site inspection. EcoCert Ecuador S.A. does not certify any operations in the United States, and therefore none of its operations export product under an equivalency or export arrangement.

ADMINISTRATIVE RECORDS AND PROCESSES

EcoCert Ecuador S.A. staff use the same documentation, including manuals and forms, as EcoCert S.A. EcoCert S.A. provides EcoCert Ecuador S.A. staff with initial and ongoing USDA

organic certification training. Topics include, but are not limited to, updates to National Organic Program requirements and certification procedures. EcoCert S.A. conducts performance evaluations of EcoCert Ecuador S.A. staff and inspectors annually. Annual program reviews of the certification activities carried out at the Ecuador office are conducted as part of EcoCert S.A.'s annual program review.

NOP DETERMINATION

The NOP reviewed the findings identified during the audit to determine whether noncompliances should be issued to EcoCert Ecuador S.A.

Noncompliances Identified during the Current Assessment

NP4365RYA.NC1 – 7 CFR §205.404(a) states, “Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report”

2014 Comments: *A review of five certification files revealed that in one instance the inspection report was submitted 3 months after the inspection, and in another instance the inspection report was submitted 4 months after the inspection. An interview with certification staff indicated that EcoCert Ecuador S.A.'s inspection report submission policy requires inspectors to submit completed inspection reports within 14 days after the inspection date.*

NP4365RYA.NC2 – 7 CFR §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use ... adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.”

2014 Comments: *A review of staff training records indicated that the most recent training the certification officer received was in April 2012. Additionally, the most recent training the two certification officers in EcoCert S.A.'s Colombia office received was in September 2013. The two certification officers are conducting certification reviews on behalf of the EcoCert Ecuador S.A.*

NP4365RYA.NC3 – 7 CFR §205.662(c)(1) – (4) states, “The notification of proposed suspension... of certification shall state: the reasons for the proposed suspension or revocation; the proposed effective date of such suspension or revocation; the impact of a suspension or revocation on future eligibility for certification; and the right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

2014 Comments: *A review of two combined notifications of noncompliance and proposed suspension EcoCert Ecuador S.A. issued revealed that in one instance EcoCert Ecuador S.A. accepted corrective actions and issued the operation a Notice of Noncompliance Resolution.*

NP4365RYA.NC4 – 7 CFR §205.671 states, “When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced.” Also, NOP 2613 Instruction Responding to Results from Pesticide Residue Testing, Section 5.3.3 No

EPA Tolerance or FDA Action Level states, "If testing detects a residue of prohibited pesticides above 0.01 parts per million (ppm), the certifying agent should: 1. Immediately notify the certified operation of the test results and indicate that the product may not be sold as organic."

2014 Comments: *A review of the EcoCert Ecuador S.A.'s responses to pesticide test results revealed 3 instances in which Mepanipyrim was detected on processed cocoa beans EcoCert sampled from 3 different operations. There is no EPA tolerance level or FDA action level established for Mepanipyrim in processed cocoa beans and the levels of detection exceeded 0.01 ppm. EcoCert Ecuador S.A. did not notify the operations that the product must not be sold, labeled, or represented as organically produced.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Aude Bonnet
EcoCert Ecuador S.A.
Córdova 518 y Mendiburo,
Tercer Piso Oficina 11.
Guayaquil, Ecuador

Dear Mr. Bonnet:

Between December 31, 2014 – March 11, 2015, a representative of the United States Department of Agriculture (USDA), National Organic Program (NOP), completed an audit of the EcoCert Ecuador S.A.'s organic certification program as part of its USDA Satellite Office Accreditation Assessment. On May 3, 2016, the NOP reviewed the results of the audit to determine EcoCert Ecuador S.A.'s compliance to the USDA organic regulations. A copy of the assessment report, NP4365RYA, is enclosed for your reference.

As the report indicates, four noncompliances, NP4365RYA.NC1 through 4, were identified during the audit as findings and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All proposed corrective actions must indicate how the noncompliances will be corrected and how the EcoCert Ecuador S.A.'s management system will be modified to prevent future noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608, Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 690-4540 or RobertH.Yang@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

MAY 16 2016

Aude Bonnet
EcoCert Ecuador S.A.
Córdova 518 y Mendiburo,
Tercer Piso Oficina 11.
Guayaquil, Ecuador

Dear Mr. Bonnet:

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As the report indicates, four noncompliances, NP4365RYA.NC1 through 4, were identified during the audit as findings and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All proposed corrective actions must indicate how the noncompliances will be corrected and how the EcoCert Ecuador S.A.'s management system will be modified to prevent future noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608, Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 690-4540 or RobertH.Yang@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney". The signature is written in a cursive, flowing style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

Applicant Name	EcoCert Ecuador S.A.
Physical Address	Córdova 518 y Mendiburo, Tercer Piso Oficina 11. Guayaquil, Ecuador
Mailing Address	Córdova 518 y Mendiburo, Tercer Piso Oficina 11. Guayaquil, Ecuador
Contact & Title	Aude Bonnet, Certification Program Manager (Main Office, France) Ileana Cartagena, Quality Officer (Ecuador Office)
E-mail Address	aude.bonnet@ecocert.com ; ileana.cartagena@ecocert.com
Phone Number	+33 0 5 62 07 52 06 (Main Office) +593 4 256 1253; +593 993 997 546 (Ecuador Office)
Reviewer & Auditor	Rebecca Claypool, NOP Reviewer; Robert Yang, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	Corrective Actions: June 17 – August 2, 2016 NOP assessment review: May 3, 2016 Audit: December 31, 2014; January 29, 2015; March 11, 2015
Audit Identifier	NP4365RYA
Action Required	None
Audit & Review Type	Satellite Office Audit Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of EcoCert Ecuador S.A.'s certification
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	EcoCert Ecuador S.A.'s certification services in carrying out the audit criteria.

EcoCert Ecuador S.A is a subsidiary of EcoCert S.A., a for-profit business initially accredited as a USDA National Organic Program (NOP) certifying agent on April 29, 2002, for crops, wild crops, livestock, and handling operations. EcoCert S.A. is closing the Ecuador office effective September 10, 2016. EcoCert S.A. provided operations located in Ecuador and Peru with USDA organic certification services through EcoCert Ecuador S.A.'s one office in Guayaquil, Ecuador. Certification activities carried out at this satellite office included contract review; application review; conducting inspections; inspection report review; certification decision-making; materials and ingredient review/approval; and label review/approval. EcoCert Ecuador S.A. certified 17 operations to the USDA organic regulations in Ecuador and Peru, which includes 8 crops, 1 wild crop, 14 handling operations, and 7 grower groups.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether EcoCert's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as “**Accepted**,” indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4365RYA.NC1 – Accepted. 7 CFR §205.404(a) states, “Within a reasonable time after completion of the initial on-site inspection, a certifying agent must review the on-site inspection report”

Comments: *A review of five certification files revealed that in one instance the inspection report was submitted 3 months after the inspection, and in another instance the inspection report was submitted 4 months after the inspection. An interview with certification staff indicated that EcoCert Ecuador S.A.'s inspection report submission policy requires inspectors to submit completed inspection reports within 14 days after the inspection date.*

2016 Corrective Action: EcoCert SA was aware that the Ecuador office was not complying with the 14 day submission policy, and attempted to correct the issue through personnel changes. The decision was made to close the Ecuador office. In addition, an IT tool, eCert, is being rolled out to all EcoCert subsidiaries in order to ensure a close monitoring and follow up of the time the inspectors take to submit their reports.

NP4365RYA.NC2 – Accepted. 7 CFR §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use ... adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.”

Comments: *A review of staff training records indicated that the most recent training the certification officer received was in April 2012. Additionally, the most recent training the two certification officers in EcoCert S.A.'s Colombia office received was in September 2013. The two certification officers are conducting certification reviews on behalf of the EcoCert Ecuador S.A.*

2016 Corrective Action: The skype trainings conducted all year long on regulation changes, new tools, and updates to instructions and procedures will be recorded in staff files through the F10 Evaluation – Qualification of Certification Officers (EC-NOP) document. The associated instruction I07 Evaluation and Qualification of Certification Officers (EC-NOP) and template F10 (EC-NOP) were updated accordingly.

NP4365RYA.NC3 – Accepted. 7 CFR §205.662(c)(1) – (4) states, “The notification of proposed suspension... of certification shall state: the reasons for the proposed suspension or revocation; the proposed effective date of such suspension or revocation; the impact of a suspension or revocation on future eligibility for certification; and the right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *A review of two combined notifications of noncompliance and proposed suspension EcoCert Ecuador S.A. issued revealed that in one instance EcoCert Ecuador S.A. accepted corrective actions and issued the operation a Notice of Noncompliance Resolution.*

2016 Corrective Action: EcoCert updated its Dealing with NOP Violations policy document I04 (NOP) v06. This instruction now clearly states that the only options for an operator receiving a “notice of proposed suspension” and/or a “combined notice of noncompliance and proposed suspension” is to request mediation and/or file an appeal to the USDA. The “notice of proposed suspension”, L05 (NOP) v06 template and the “combined notice of noncompliance and proposed suspension” L11 (NOP) v06 template were updated to include the option for mediation and appeals. Updated documents were submitted.

NP4365RYA.NC4 – Accepted. 7 CFR §205.671 states, “When residue testing detects prohibited substances at levels that are greater than 5 percent of the Environmental Protection Agency's tolerance for the specific residue detected or unavoidable residual environmental contamination, the agricultural product must not be sold, labeled, or represented as organically produced.” Also, NOP 2613 Instruction Responding to Results from Pesticide Residue Testing, Section 5.3.3 No EPA Tolerance or FDA Action Level states, “If testing detects a residue of prohibited pesticides above 0.01 parts per million (ppm), the certifying agent should: 1. Immediately notify the certified operation of the test results and indicate that the product may not be sold as organic.”

Comments: *A review of the EcoCert Ecuador S.A.'s responses to pesticide test results revealed 3 instances in which Mepanipyrim was detected on processed cocoa beans EcoCert sampled from 3 different operations. There is no EPA tolerance level or FDA action level established for Mepanipyrim in processed cocoa beans and the levels of detection exceeded 0.01 ppm. EcoCert Ecuador S.A. did not notify the operations that the product must not be sold, labeled, or represented as organically produced.*

2016 Corrective Action: EcoCert Ecuador received questionable lab results for the three operations noted by the auditor. The lab submitted the results on the same day, with the same positive test for Mepanipyrim, for three separate operations, inspected by different inspectors. When EcoCert tried to resample at the operations, the product was no longer available. EcoCert Ecuador did not follow its existing policy for residue sampling and did not respond to the results in a timely manner. EcoCert SA has closed the Ecuador office. EcoCert reiterated its residue sampling procedures to all of its offices and subsidiaries. EcoCert's policy states that inspectors take three samples when conducting residue tests. One will be analyzed right away by the lab, one sample will be kept with EcoCert (or the lab) and tested if there are doubts about the original test results. The third sample will be left with the operator. EcoCert will have the second sample tested in a reasonable amount of time, if the first test results appear questionable. Operators will be notified that products cannot be sold, labeled, or represented as organic when test results are over the prescribed limits for prohibited residues. Procedure documents were submitted.

Audit Chronology Log

Audit Identifier (if any): NP4365RYA

Audit Type: Satellite Office - Ecuador

Accredited Certifying Agent Name: Ecocert S.A.

Accreditation Manager (who is working on the project): Rebecca Claypool

Date	Activity
4/28	NC assigned to RC from RM.
5/3	RC reviewed the audit report and made minor formatting edits to create the NC Report and NoNC letter. Sent CC an email router doc for the review of the NC documents.
5/10/16	CC reviewed the noncompliance docs and RC printed docs for CC's signature.
5/11/16	RC removed references to "onsite" audit in the NC Report and NoNC letter. This was a desk audit. Reprinted docs for CC.
5/12/2016	GD processed and emailed NoNC report and letter to EcoCert.
6/16/16	CA Report assigned to RC
6/17/16	RC reviewed the CA and drafted the CA report. 3 NCs were accepted. The 4 th NC RC had question about and sent an email to CC for guidance.
6/23/16	RC Emailed for new CA to NC4. Due = 6/30/16
6/30/16	RC received an email response to NC4.
7/13/16	RC sent a draft email to CC to review for follow up on NC4.
7/14/16	RC sent Jeremie the email – Ecocert can rebut the NC, which it seems they are wanting to do, but they still have to follow the regulations. I also asked some questions about their residue sampling procedures.
7/26/16	Jeremie and I had a phone conversation about sampling and their NC4. They will submit CA for NC4 by 7/29/16.
7/29/16	RC received the corrective actions for NC4. Updated the CA Report and drafted and Notice of Continued Accreditation. Printed a hardcopy folder for CC to review.
8/2/16	MM returned the CA Report because NC4 was not sufficient. RC added more context to the CA response and reprinted the CA Report for CC to review.
8/3/16	RC revised the CA Report again to include the backstory in the CA comment. Submitted to CC for review. Printed hard copy for final approval.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

JUL 21 2017

NOTICE OF NONCOMPLIANCE

Camille Godard
Ecocert S.A.
BP 47, 32600, L'Isle Jourdain
France

Dear Ms. Godard:

On June 30, 2017, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) reviewed the information submitted by EcoCert S.A. to conduct a material review of the BioWash 100 product. EcoCert S.A. previously approved the use of BioWash 100, which was disputed by another accredited certifier on March 22, 2017. Upon review of the information provided, the NOP found that BioWash 100 contains synthetic ingredients which are not on the National List. Therefore, the use of this product does not comply with the USDA organic regulations. We have determined that EcoCert S.A. is noncompliant with the USDA organic regulations, 7 CFR Part 205, as follows:

AIA7201RC.NC1 – 7 CFR §205.105(a) states, “To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of: Synthetic substances and ingredients, except as provided in §205.601 or §205.603;”

Comments: *EcoCert S.A. approved the use of a material, BioWash 100 that contains synthetic glucoside not on the National List of Approved and Prohibited Substances.*

EcoCert S.A. must submit corrective actions to AIAInbox@ams.usda.gov within 30 days from the date of this Notice. The corrective actions should indicate how each noncompliance will be corrected and how the EcoCert S.A. management system will be modified to prevent a recurrence of the noncompliance. If you wish to rebut the noncompliance, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions. Failure to resolve the noncompliance may result in proposed suspension or revocation of EcoCert S.A.’s USDA accreditation.

Page 2

If you have questions regarding this notice, please contact Rebecca Claypool, Accreditation Manager, at Rebecca.E.Claypool@ams.usda.gov or (202) 350-5706.

Sincerely,



Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite Satellite Office Assessment - Turkey of the EcoCert S.A. (ECO) organic program was conducted on July 19, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess ECO's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	EcoCert SA (ECO) - ECOCERT IMO DENETIM VE BELGELENDIRME LTD. STI. (LLC.)
Physical Address	2132/2 Sokak. No:3 Daire :50, Bayrakli – Izmir TURKEY
Mailing Address	Main Office – L'Isle Jourdain, France
Contact & Title	Aude Bonnet, EcoCert S.A. Main Office; Mustafa Avci, General Manager ECO Turkey office
E-mail Address	aude.bonnet@ecocert.com and mustafa.avci@ecocert.com
Phone Number	+90 232-343 43 60 (Turkey)
Reviewer & Auditors	Rebecca Claypool, NOP Reviewer; Lars Crail and Mark Bradley, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: August 17, 2017 Onsite audit: July 19, 2017
Audit Identifier	NP7200LCA
Action Required	Yes
Audit & Review Type	Satellite Office Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of ECO's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	ECO's certification services in carrying out the audit criteria during the period: September 2014 through July 2017

The National Organic Program (NOP) conducted an onsite audit of the ECOCERT S.A.'s (ECO), satellite office in Izmir, Turkey (ECO Turkey). NOP Handbook NOP 2000, Accreditation Policies and Procedures, states that the NOP will assess all certifying agent satellite offices where key activities are conducted at least once during the five year

accreditation period. ECO Turkey office conducts all key activities with oversight from ECO's main office in France.

The audit occurred on July 19, 2017. The auditors reviewed the office's accreditation and certification activities through file review and personnel interviews. A two hour closing meeting at the ECO Turkey office was held on July 21, 2017. No witness or review audits were conducted by NOP during the satellite office audit.

ECO opened a branch office in Turkey during 1996 and the office became a legal entity in 2009. In May 2016, the Institute for Marketecology – Switzerland (IMO) Turkey closed its office and was merged with ECO Turkey. ECO Turkey manages certification activities in the following countries: Turkey, Kyrgyzstan, Kazakhstan, Tajikistan, Azerbaijan, Georgia, Russian Federation, Ukraine, Romania, Moldova, and the United Arab Emirates. There are 219 certified operation with the following scopes: Crops (104), Wild Crops (10), and Handlers (149). ECO Turkey certifies 59 grower groups.

Fourty-one individuals work at or from the ECO Turkey office. There is a general manager, six certification officers (i.e. reviewers/decision makers), six certificate of inspection/transaction certificate officers, and 24 (22 staff; 2 contractors) inspectors. ECO Turkey offers certification services for the European Union and Turkey organic regulations. Organic inspection services are separately offered for Japan, Korea, BioSuisse, and KRAV standards. The office offers a number of non-organic certification services including Good Agriculture Practices, textiles, and social standards.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether ECO corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to ECO.

Noncompliances Identified during the Current Assessment

NP7200LCA.NC1 – 7 C.F.R. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must....Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart:” §205.662(a)(3) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: the date by which the certified operation must rebut or correct each noncompliance....”

Comments: *The auditor reviewed two Notices of Noncompliance issued by ECO that did not indicate a deadline to rebut or correct the noncompliance.*

NP7200LCA.NC2 – 7 C.F.R. §205.662(b) states, “When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's

governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution.”

Comments: *During the review of a Notice of Proposed Suspension, the notification indicated that one noncompliance remained outstanding from an earlier issued Notice of Noncompliance that included five noncompliances. Four of the noncompliances were resolved according to certification personnel; however, a notice of resolution was not sent to the operation. During the review of a Denial of Certification, the operation was issued three noncompliances and two of the noncompliances were indicated as unresolved on the denial notification; however, there was no record of a notice of resolution issued for the third noncompliance that was resolved.*

NP7200LCA.NC3 – 7 C.F.R. §205.681(c) states, “...an appeal of a noncompliance decision must be filed within the time period provided in the letter of notification or within 30 days from receipt of the notification, whichever occurs later.”

Comments: *The auditor reviewed three Notices of Proposed Suspension that stated the suspension was effective the same date the notices were issued. ECO issued a Notice of Suspension on November 31, 2016 which did not allow the operation a minimum of 30 days to request mediation or file an appeal.*

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a compliance assessment of Ecological Farming Controlling Organization (ETKO) in accordance with the terms in a settlement agreement signed April 6, 2016. An onsite audit was conducted, and the audit report reviewed to determine ETKO's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Ecological Farming Control Organization (ETKO)
Physical Address	160 Sokak 13/3, Bornova – Izmir, 35100, Turkey
Mailing Address	160 Sokak 13/3, Bornova – Izmir, 35100, Turkey
Contact & Title	Dr. Mustafa Akyuz, General and QMS Manager
E-mail Address	ma@etko.com.tr
Phone Number	90 542 640 5944
Reviewer & Auditor	Rebecca Claypool, NOP Reviewer; Lars Crail, On-site Auditor(s).
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: July 19, 2017 Onsite audit: February 20 - 23, 2017
Audit Identifier	NP7051LCA
Action Required	Yes
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of ETKO's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	ETKO's certification services in carrying out the audit criteria during the period: April 6, 2016 through February 20, 2017

NOP conducted an onsite compliance audit of Ecological Farming Controlling Organization (ETKO) on February 22-23, 2017 at ETKO's main office in Izmir, Turkey. The purpose of the compliance audit was to assess ETKO's compliance with the terms of the settlement agreement signed with the NOP on April 6, 2016. ETKO agreed to submit corrective actions for the NOP's review, and if accepted ETKO would implement those corrective actions. ETKO also agreed to an additional onsite audit for NOP to assess the effective implementation of those accepted corrective actions, assess the status of corrective actions reviewed by IOAS for the European Union (EU) and Canadian Organic Regime (COR) accreditation. Lastly, the audit was to assess two additional corrective actions for noncompliances that were issued after the signing of the settlement agreement.

ETKO was accredited as a certifying agent on January 22, 2003 for crops, wild crops, and

handling. ETKO currently certifies 34 (18 crops, 1 wild crops, 14 handling) operations and one grower group to the USDA organic regulations in the following countries: Turkey, Korea, and Ukraine. ETKO is a for profit, limited liability company with two shareholders.

ETKO's staff consists of 24 individuals: 8 Administrative and 16 Certification personnel.

The prior onsite audit occurred May 12-16, 2014 for the purpose of renewing ETKO's accreditation.

One handler witness audit of a trader of frozen fruits and other assorted commodities was conducted on February 20, 2017 in Istanbul, Turkey. There were two one-day witness audits of handlers under a separate Audit Identification Number (NP6279LCA) in Kiev, Ukraine October 6-7, 2016.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether ETKO corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to ETKO.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP9222ZZA.NC21 – Cleared - 7 CFR §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.”

Comments: *Interviews conducted, records reviewed, and witness inspections observed, verified a general lack of understanding of the NOP standards. While personnel had sufficient experience and education in organic agricultural production and handling practices, there was insufficient understanding on the application of the NOP standards as evidenced by inadequate information in the approved organic compliance (system) plans with no issues of concern or non-compliances being identified over multiple years of certification. The primary Certification Committee (CC) member with expertise in crops was not familiar with basic requirements such as the 90/120 day rule for raw manure application, did not know where to reference in the NOP Rule to determine if an input is permitted, and did not know when commercially available seeds and planting stock could be used. Additionally, while it was stated that the Certification Committee (CC) had received training there were no training records for any of the CC members prior to 2009.*

Corrective Action: ETKO conducted training of inspectors, reviewers, and Certification Committee members on November 21, 2009 and March 12-14, 2010 which covered NOP standards, review, inspection, and certification procedures. ETKO has designed a 2010 training plan to ensure periodic training on the NOP is completed. ETKO submitted records of training for all inspectors, reviewers, and Certification Committee members.

2014 Verification of Corrective Action: The NOP auditor found the following issues of concern that demonstrated an insufficient understanding of the USDA organic regulations and NOP policies:

1. Label review – the label review checklist did not include USDA organic regulation label requirements to be verified.
2. Inspectors during the witness audits used incorrect regulation citations during exit interviews to identify findings.
3. OCP templates state the incorrect USDA organic regulations.
4. Inspectors are using outdated USDA organic regulations (2010).
5. Inspectors and reviewers not readily able to look up regulations.
6. ETKO personnel have an incomplete understanding of the noncompliance and adverse action notification procedures.
7. Several crop operation OCPs reviewed by the NOP auditor indicated “Not Applicable” for Crop Rotation practice standard (205.205).
8. ETKO personnel did not understand and document buffer zone requirements (205.202(c)).

2015 Corrective Action: ETKO submitted PowerPoint presentations, updated forms, training agenda, and training log of the training that was conducted for inspectors, staff, and advisory committee members. The documentation submitted also included copies of completed OCPs with documented buffer zones, and crop rotation practices.

ETKO has designated a responsible person to follow up on NOP updates to the Program Handbook and regulations. This person will translate all updates and provide them to staff members and inspectors by email and/or hardcopy. When necessary, related staff members will be trained for specific updates. The training will be recorded in the training register (new document) and the register will be provided to USDA with ETKO’s annual reporting. A copy of the training register form was submitted to NOP.

2017 Verification of Corrective Action: ETKO demonstrated during the witness audits conducted in Ukraine (2) and in Turkey (1) improved knowledge and understanding of the USDA organic regulations. Appropriate regulation citations were communicated to the operators during the inspections. Reviewed inspection report findings, noncompliances, and minor issues sent to the operations had the appropriate regulation citations for the evidence demonstrating noncompliance. Regarding the designated responsible person to follow up on NOP updates to the Program Handbook and regulations, this is the ETKO program manager and he showed the auditor email messages received from the NOP Organic Insider and then translated the information into Turkish before sending the materials to the appropriate certification staff. A training register is maintained and the auditor selected two NOP trainings to review the lesson plans, training materials, and the list of participants. The auditor found the records to be maintained in good order and no issues were noted. The auditor reviewed one noncompliance where the operator received a noncompliance for inadequate buffer

zones. This demonstrates that reviewers and inspectors are identifying and verifying buffer zone requirements.

NP4132LCA.NC1 – Cleared - 7 CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.” Furthermore, NOP 4009, Instruction – Who Needs to be Certified?, states “The OFPA requires that agricultural products sold or labeled as organically produced must be produced only on certified farms and handled only through certified handling operations (see 7 USC § 6506(a)(1)). The USDA organic regulations reiterate these requirements (see 7 CFR 205.100).”

Comments: *ETKO certifies projects that contain uncertified operations (i.e. contractors) that produce or handle organic products that are not certified entities.*

2014 Corrective Action: ETKO stated it will certify each subcontracted processing facility during the 2015 production period. ETKO sent a letter to all clients in August 2015 informing them of this requirement. ETKO issued a new instruction for staff, NOP Certification of Subcontracted Operators (TI 48), which describes the basic rules of subcontracted facilities under NOP certification requiring separate certification. ETKO updated the NOP procedure section 7.2.2.3 Processing and Handling Facilities, which requires subcontractors to be certified separately and refers to the instruction (TI 48) for details. ETKO staff was trained during the annual training in July 2015.

2017 Verification of Corrective Action: The auditor reviewed ETKO’s NOP Certification of Subcontracted Operators (TI 48) with the ETKO program manager and requested that the specific references be identified on the procedural document (i.e. NOP 4009, Who Needs to be Certified and NOP 5023, Substances Used in Post-Harvest Handling of Organic Products). One ETKO review personnel was interviewed to determine if he had been adequately trained on the topics and if ETKO continues to allow subcontracting of uncertified operations to produce or handle organic products. The reviewer was aware that this was not allowed and correctly identified the NOP guidance and instruction documents to support his answer.

NP4132LCA.NC2 – Cleared - 7 CFR §205.404(b)(3) states, “The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.”

Comments: *Certificates do not adequately indicate the certification scopes of Crop, Wild Crop, and Handling/Processing.*

2014 Corrective Action: ETKO submitted copies of corrected certificates identifying the scopes of certification. To prevent this from recurring, ETKO has updated the certificate template and the corrected form will now be used. ETKO submitted a copy of the revised template document with the correct NOP scopes of certification.

2017 Verification of Corrective Action: ETKO updated their certificate template. A review of the template shows that the elements align with NOP 2603, Organic Certificates. All operations will receive the new certificate as annual certification renewals occur and by January 1, 2018.

NP4132LCA.NC3 – Cleared - 7 CFR §205.662(c) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent... shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance...The notification of proposed suspension or revocation of certification shall state: (1) The reasons for the proposed suspension or revocation; (2) The proposed effective date of such suspension or revocation; (3) The impact of a suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *ETKO suspended an operation without issuing a Notice of Proposed Suspension. The same operation after receiving the Notice of Suspension effective for 30 days was issued a Notice of Proposed Revocation and subsequently a Notice of Revocation. The sequence of issued notices and contents of the notifications demonstrate that ETKO does not fully comprehend the process of issuing notifications for noncompliances and adverse actions.*

2014 Corrective Action: ETKO has updated their procedures and trained staff and inspectors on the following: NOP 4002 Instruction Enforcement of the USDA Organic Regulations: Penalty Matrix, NOP Penalty Matrix 2612 and NOP 4011 Adverse Action Appeal Process for the NOP. These documents were translated into Turkish in order to provide better understanding of the procedures by NOP involved ETKO staff members. The translated documents, training documents and agenda were submitted to NOP. Further, ETKO will check the NOP Handbook regularly and pertinent documents will be translated immediately. Translated documents will be studied with related staff and inspectors. ETKO submitted NOP Handbook documents to NOP as they were being translated.

2017 Verification of Corrective Action: A review of one suspended operation demonstrated that the proper process was followed from noncompliance to suspension.

NP4132LCA.NC4 – Outstanding - 7 CFR §205.403(c) states, “The on-site inspection of an operation must verify: (1) The operation’s compliance or capability to comply with the Act and the regulations of this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.”

Comments: *The following issues were identified by the NOP auditor during a review of the operation files and witness audits:*

- 1. Inspectors did not completely verify the information stated in the Organic Compliance Plans. If observations and interviews at the onsite inspection did not align with the Organic Compliance Plan, the inspector failed to state this finding as an issue of concern.*

2. *ETKO inspectors are responsible for collecting large amounts of information about the operations when the Organic Compliance Plan (OCP) is incomplete or in error. The inspector did not note the finding as an issue of concern, failing to indicate that the OCP is incomplete. The inspector did not record these findings in the inspection report. Minor updates or adjustments to the OCP during the onsite inspection is acceptable and can be noted in the inspector's report.*
3. *The inspection reports did not include a description and the outcome of the reconciliation activities (e.g. mass balance and audit trail audit) conducted by inspectors.*

2014 Corrective Action: ETKO submitted documentation from the training it conducted with inspectors on the following topics: “1) Using and evaluation of OCP during onsite inspection; 2) Review of organic compliance plans and identifying noncompliances before inspections, in order to avoid losing time to collect large amount of information and documents; and 3) How to make input-output balance and report it.” ETKO also submitted examples of completed inspection reports from inspectors showing input-output balance and updates to the inspection forms.

2017 Verification of Corrective Action: Witness audits observed in Istanbul and Ukraine demonstrated that inspectors are verifying the organic system plan adequately. Beginning in April 2017, the ETKO Inspection Report will be combined with the Annual Update and inspectors will be reporting verification on the same form. Mass-balance activities of the inspector are recorded on OP01 F24, Mass-Balance Traceability document; however, there is no section for the inspector to record traceability verification activities.

NP4132LCA.NC5 – Cleared - 7 CFR § 205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: *During a crop witness audit observation, the NOP auditor noted that the inspector was not equipped and possibly not adequately trained to conduct sampling for pesticide residues. Product samples were collected during the crop inspection; however, the inspector collected the samples with bare hands potential exposing the samples to contamination and jeopardizing sample integrity.*

2014 Corrective Action: ETKO submitted training slides and updated forms used to conduct training for NOP inspectors, staff, and advisory committee members on the following topics: OP 03 Testing, TI 05 Sampling Method, TI 40 NOP Guide Testing & Enforcement Action. Training took place July 6-9, 2015.

2017 Verification of Corrective Action: Witness audits conducted during this on-site audit were of certified handlers (i.e. traders) that do not physically handle product and therefore, no sampling was conducted or observed. A review of the current sampling forms used, photographs of sampling conducted, and the sampling procedures (TI 40, OP 03, TI 05) was conducted and determined to be adequate.

NP4132LCA.NC6 – Cleared - 7 CFR § 205.501(a)(21) states “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out

any other terms or conditions determined by the Administrator to be necessary.” NOP Policy Memo (PM) 11-10 (dated 01/21/11) states, “Grower group certification...accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies.”

Comments: *Grower Groups certified by ETKO do not have documented and functioning Internal Control Systems.*

2014 Corrective Action: ETKO created a form to be used for inspection of Internal Control Systems for grower groups and revised the OCP to include the grower group Internal Control System requirement. ETKO updated its NOP Certification Procedure Manual with the requirements to document and verify Internal Control Systems. These forms and procedures will be implemented this year for all grower groups. The forms and revised NOP Certification Procedure Manual were submitted to NOP. ETKO conducted training on this topic July 7, 2015. The training materials and an agenda were submitted to NOP.

2017 Verification of Corrective Action: ETKO currently certifies one grower group located in Turkey. A review of its records indicated that the grower group maintained an Internal Control System (ICS). A review of the ETKO 2016 inspection report showed that the ICS was verified by the inspector to be compliant.

AIA6155PZ.NC1– Cleared - 7 C.F.R §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2603 Instruction Organic Certificates section 3.1 states, “Organic certificates should be issued in English and include the following (* identifies elements required by 7 CFR § 205.404 of the USDA organic regulations): ...Labeling category for each product certified under the handling/processing certification category (not required for products in the crops, wild crops, or livestock certification categories). Labeling categories: 100% Organic, Organic, Made with Organic (specified ingredients or food groups), and Livestock Feed (Organic or 100% Organic);...”

Comments: *ETKO’s USDA-NOP organic certificates include the category title “100-95% organic” for products in the “organic” category of certification. “100-95% organic” is not a category of USDA organic certification. The categories are “100% organic”, “organic”, and “made with organic (specified ingredients or food group(s)).”*

2016 Corrective Actions: ETKO submitted copies of the corrected NOP certificate template with the product categories listed “100% organic”, “organic”, and “made with organic”; the revised NOP Certification Procedure section 7.5.2, which includes the certificate elements as listed in NOP 2603; Use of Logo and Licenses section 5.2 Labeling Requirements According to NOP indicating the USDA organic regulation product categories; and Assessment Label NOP section Subpart D labeling review checklist.

2017 Verification of Corrective Action: ETKO is currently issuing an updated certificate that is compliant.

NP6279LCA.NC1 – Cleared - 7 C.F.R. §205.501(a)(21) states, “Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2603, Organic Certificates, Section 3.1, indicates the elements of an organic certificate.

Comments: *The following organic certificate elements are incorrect or missing on the certificates issued to operations:*

1. *The certificate does not list an anniversary date.*
2. *There are two labeling categories (100% Organic, Organic, Made With Organic....) stated on the certificate when only one category should be listed.*
3. *The certificate states “Certification renewal must be done annually before the anniversary date;” however, there is no anniversary date on the certificate and “certification renewal” is not defined in the USDA organic regulations nor the NOP Handbook.*
4. *The certificate states, “NOP regulation Final Rule 7 CFR Part 205,” rather than “Certified to the USDA organic regulations, 7 CFR Part 205.”*

2016 Corrective Action: ETKO revised and submitted their certificate template. The certificate template lists an anniversary date, only one labelling category per product (i.e, 100% Organic, Organic, or Made with Organic), “Certified to the USDA organic regulations, 7 CFR Part 205”. ETKO revised and submitted their NOP Certification Procedure (Section 7.5.2). Their procedure requires their certificates to have an anniversary date, one labelling category for each product certified under the handling/processing scope, and state, “Certified to the USDA organic regulations, 7 CFR Part 205.”

2017 Verification of Corrective Actions: *The auditor reviewed the current certificate template and one issued certificate as an example. Both documents contain elements that align with instruction in NOP 2603, Organic Certificates. ETKO made one additional modification and removed the phrase: “The certificate should be updated at least annually.”*

Noncompliances Identified during the Current Assessment

NP7051LCA.NC1 – 7 C.F.R. §205.405(a) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification.

Comments: *The auditor reviewed two notice of certification denial cases. ETKO issued a notice of noncompliance and a notice of certification denial on the same day. The notice of noncompliance indicated that the operator had 30 days to respond to the noncompliance; however, since a notice of certification denial was also issued on the same day, the operation was not able to respond to the noncompliance. The result of issuing two notices at the same time resulted in conflicting information to the operation; instead a combined notification should have been issued. ETKO does not have a combined notice template in their quality system.*

NP7051LCA.NC2 – 7 C.F.R. §205.662(c)(4) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.... The notification of proposed

suspension or revocation of certification shall state: The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *A review of one issued proposed suspension notification allowed the operation an opportunity to submit corrective actions. Proposed suspension notifications allow operations to request mediation or file an appeal, but should not allow the operation to correct or address the noncompliance(s).*

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

On February 26-27, 2014, the USDA National Organic Program (NOP) conducted a compliance audit of the Georgia Crop Improvement Association, Inc. (GCIA). GCIA responded with corrective actions on May 1 and May 20, 2014.

GENERAL INFORMATION

Applicant Name:	Georgia Crop Improvement Association, Inc. (GCIA)
Est. Number:	N/A
Physical Address:	2325 South Milledge Avenue, Athens, Georgia 30605
Mailing Address:	2325 South Milledge Avenue, Athens, Georgia 30605
Contact & Title:	Terry Hollifield, Executive Director
E-mail Address:	gacrop@bellsouth.net
Phone Number:	(706) 542-2351
Auditor(s):	Betsy Rakola
Program:	USDA National Organic Program
Audit Date(s):	May 1-20, 2014
Audit Identifier:	NP4057JHA
Action Required:	No
Audit Type:	Corrective action review
Audit Objective:	To verify continuing compliance to the audit criteria; and to verify the implementation and effectiveness of corrective actions in addressing the previous noncompliances.
Audit Criteria:	7 CFR Part 205 National Organic Program, Final Rule, dated December 21, 2000; as amended
Audit Scope:	GCIA's corrective actions
Location(s) Audited:	GCIA office in Athens, Georgia

GENERAL INFORMATION: GCIA was accredited as a USDA organic certifying agent on April 29, 2002, for crops, livestock, and handling operations. The GCIA list of certified operations include 88 certified operations, consisting of 39 crop operations, 1 livestock

operation, and 48 handlers. There are no grower groups certified by GCIA. The certified operations are located in Alabama, Florida, Georgia, and North Carolina.

The GCIA office is located in Athens, Georgia, and all certification activities are finalized in this office. All staff are full-time employees based out of the Athens office, and they all conduct other duties for GCIA in addition to their work for the organic certification program.

A renewal assessment of the GCIA organic program was conducted in October 2012, and as part of the terms of accreditation. GCIA agreed to an additional audit to be conducted prior to the required mid-term assessment.

NOP DETERMINATION

NOP's assessment and accreditation decision of GCIA's compliance to the USDA organic regulations is based on a sample of its certification system records and activities.

This section describes the NOP's review and determination of the certifying agent's noncompliance response. The NOP has accepted the corrective actions. During the next on-site audit, the NOP will verify corrective actions for implementation and effectiveness.

Prior Non-compliance Corrective Actions

The NOP auditor reviewed information during the assessment to verify that the certifying agent effectively implemented the corrective actions from previous assessments. The auditor was able to verify all the items below which are labeled "cleared." One noncompliance was not cleared, NP2296MMA.NC4, and therefore certifying agent was required to address those issues by providing revised corrective actions to the NOP.

NP2296MMA.NC1 – cleared
NP2296MMA.NC2 – cleared
NP2296MMA.NC3 – cleared
NP2296MMA.NC5 – cleared
NP2296MMA.NC6 – cleared
NP2296MMA.NC7 – cleared
NP2296MMA.NC8 – cleared
NP2296MMA.NC9 – cleared
AIA030613BJR.NC10 – cleared
AIA13311RAM.NC1 – cleared

Non-Compliances – Certifier Response Accepted

Observations made, interviews conducted, and procedures and records reviewed verified that GCIA is currently operating in compliance to the requirements of the audit criteria, except as identified below. One new noncompliance was identified during the compliance assessment.

NP4057JHA.NC1 – Accepted. NOP §205.662(c)(2) states, “The notification of proposed suspension or revocation of certification shall state: The proposed effective date of such suspension or revocation.” *While the GCIA Notices of Proposed Suspension (NoPS) describe effective dates of a suspension, within 3 of 4 NoPS reviewed, the suspension effective date is in effect from the date of receipt of the NoPS. The notices state that the operation is suspended upon receipt of the NoPS for an identified time period. The NoPS also stated that after the suspension period is completed, the operation may be issued a Notice of Indefinite Suspension. The implication is that the NoPS had the same impact as a suspension, and that a possible result of a Notice of Proposed Suspension may be the issuance of an indefinite suspension where the suspension period is for an unidentified length of time.* **GCIA corrective action (May 2014):** GCIA stated that the indefinite suspension template is no longer in use. GCIA submitted a sample of a Notice of Proposed Suspension, which included the following improvements:

1. The proposed effective date was clearly listed as one month after the date of the letter.
2. The proposed timeframe was clearly stated as six months.
3. There was no reference to an indefinite suspension.

GCIA reviewed this procedure with the responsible staff during the exit interview with the NOP auditor.

NP2296MMA.NC4 – Accepted. NOP §205.405(a)(1) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant...The notification of noncompliance shall provide a description of each noncompliance.” *Three notifications of noncompliance issued to applicants for certification were reviewed. Of the three, one did not include a description of the noncompliances. Instead, the notification stated what the client had to submit in order to correct the noncompliance.* **Corrective action:** GCIA submitted a revised template, which contained a space to insert descriptions of the noncompliance. GCIA also submitted a Notice of Noncompliance issued in February 2013, showing references to the USDA organic regulations and descriptions of each noncompliance at issue. The GCIA Program Administrator will review all Notices of Noncompliance during the next six months to ensure correct implementation of the new procedures. **Verification of corrective action (February 2014):** GCIA is using its current Notice of Noncompliance template, providing a description of evidence why the regulation has been violated, and citing the USDA organic regulation number, but not a description of the regulation. For one file reviewed, the reasons described for the noncompliances were not clearly associated with regulation numbers cited. **GCIA corrective action (May 2014):** GCIA submitted a revised Notice of Noncompliance template, which included spaces for staff to type the relevant regulatory references. All noncompliance notices are issued by one staff member at GCIA. The GCIA Program Administrator will continue to review noncompliance letters for accuracy.

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

On February 26-27, 2014, the USDA National Organic Program (NOP) conducted a compliance audit of the Georgia Crop Improvement Association, Inc. (GCIA). GCIA responded with corrective actions on May 1 and May 20, 2014.

GENERAL INFORMATION

Applicant Name:	Georgia Crop Improvement Association, Inc. (GCIA)
Est. Number:	N/A
Physical Address:	2325 South Milledge Avenue, Athens, Georgia 30605
Mailing Address:	2325 South Milledge Avenue, Athens, Georgia 30605
Contact & Title:	Terry Hollifield, Executive Director
E-mail Address:	gacrop@bellsouth.net
Phone Number:	(706) 542-2351
Auditor(s):	Betsy Rakola
Program:	USDA National Organic Program
Audit Date(s):	May 1-20, 2014
Audit Identifier:	NP4057JHA
Action Required:	No
Audit Type:	Corrective action review
Audit Objective:	To verify continuing compliance to the audit criteria; and to verify the implementation and effectiveness of corrective actions in addressing the previous noncompliances.
Audit Criteria:	7 CFR Part 205 National Organic Program, Final Rule, dated December 21, 2000; as amended
Audit Scope:	GCIA's corrective actions
Location(s) Audited:	GCIA office in Athens, Georgia

GENERAL INFORMATION: GCIA was accredited as a USDA organic certifying agent on April 29, 2002, for crops, livestock, and handling operations. The GCIA list of certified operations include 88 certified operations, consisting of 39 crop operations, 1 livestock

operation, and 48 handlers. There are no grower groups certified by GCIA. The certified operations are located in Alabama, Florida, Georgia, and North Carolina.

The GCIA office is located in Athens, Georgia, and all certification activities are finalized in this office. All staff are full-time employees based out of the Athens office, and they all conduct other duties for GCIA in addition to their work for the organic certification program.

A renewal assessment of the GCIA organic program was conducted in October 2012, and as part of the terms of accreditation. GCIA agreed to an additional audit to be conducted prior to the required mid-term assessment.

NOP DETERMINATION

NOP's assessment and accreditation decision of GCIA's compliance to the USDA organic regulations is based on a sample of its certification system records and activities.

This section describes the NOP's review and determination of the certifying agent's noncompliance response. The NOP has accepted the corrective actions. During the next on-site audit, the NOP will verify corrective actions for implementation and effectiveness.

Prior Non-compliance Corrective Actions

The NOP auditor reviewed information during the assessment to verify that the certifying agent effectively implemented the corrective actions from previous assessments. The auditor was able to verify all the items below which are labeled "cleared." One noncompliance was not cleared, NP2296MMA.NC4, and therefore certifying agent was required to address those issues by providing revised corrective actions to the NOP.

NP2296MMA.NC1 – cleared
NP2296MMA.NC2 – cleared
NP2296MMA.NC3 – cleared
NP2296MMA.NC5 – cleared
NP2296MMA.NC6 – cleared
NP2296MMA.NC7 – cleared
NP2296MMA.NC8 – cleared
NP2296MMA.NC9 – cleared
AIA030613BJR.NC10 – cleared
AIA13311RAM.NC1 – cleared

Non-Compliances – Certifier Response Accepted

Observations made, interviews conducted, and procedures and records reviewed verified that GCIA is currently operating in compliance to the requirements of the audit criteria, except as identified below. One new noncompliance was identified during the compliance assessment.

NP4057JHA.NC1 – Accepted. NOP §205.662(c)(2) states, “The notification of proposed suspension or revocation of certification shall state: The proposed effective date of such suspension or revocation.” *While the GCIA Notices of Proposed Suspension (NoPS) describe effective dates of a suspension, within 3 of 4 NoPS reviewed, the suspension effective date is in effect from the date of receipt of the NoPS. The notices state that the operation is suspended upon receipt of the NoPS for an identified time period. The NoPS also stated that after the suspension period is completed, the operation may be issued a Notice of Indefinite Suspension. The implication is that the NoPS had the same impact as a suspension, and that a possible result of a Notice of Proposed Suspension may be the issuance of an indefinite suspension where the suspension period is for an unidentified length of time.* **GCIA corrective action (May 2014):** GCIA stated that the indefinite suspension template is no longer in use. GCIA submitted a sample of a Notice of Proposed Suspension, which included the following improvements:

1. The proposed effective date was clearly listed as one month after the date of the letter.
2. The proposed timeframe was clearly stated as six months.
3. There was no reference to an indefinite suspension.

GCIA reviewed this procedure with the responsible staff during the exit interview with the NOP auditor.

NP2296MMA.NC4 – Accepted. NOP §205.405(a)(1) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant...The notification of noncompliance shall provide a description of each noncompliance.” *Three notifications of noncompliance issued to applicants for certification were reviewed. Of the three, one did not include a description of the noncompliances. Instead, the notification stated what the client had to submit in order to correct the noncompliance.* **Corrective action:** GCIA submitted a revised template, which contained a space to insert descriptions of the noncompliance. GCIA also submitted a Notice of Noncompliance issued in February 2013, showing references to the USDA organic regulations and descriptions of each noncompliance at issue. The GCIA Program Administrator will review all Notices of Noncompliance during the next six months to ensure correct implementation of the new procedures. **Verification of corrective action (February 2014):** GCIA is using its current Notice of Noncompliance template, providing a description of evidence why the regulation has been violated, and citing the USDA organic regulation number, but not a description of the regulation. For one file reviewed, the reasons described for the noncompliances were not clearly associated with regulation numbers cited. **GCIA corrective action (May 2014):** GCIA submitted a revised Notice of Noncompliance template, which included spaces for staff to type the relevant regulatory references. All noncompliance notices are issued by one staff member at GCIA. The GCIA Program Administrator will continue to review noncompliance letters for accuracy.

Audit Resolution Chronology Log

Audit Identifier (if any): NP4057JHA
Audit Type: Compliance Assessment
ACA Name: Georgia Crop Improvement Association (GCIA)
Accreditation Manager: Renee Mann; NC report assigned to Meg Kuhn; Betsy Rakola reviewed corrective actions

Date	Activity
2/26-27/14	Julie Hartley conducted a compliance assessment of GCIA.
3/11/14	QAD submitted the final report to NOP.
3/24/14	NC report was assigned to Meg Kuhn for processing. MK reviewed NC report, no issues were identified. NC letter was drafted and final folder for mgt signature was prepared.
4/1/14	Betsy sent the approved NoNC and NC report to GCIA via RPost email.
4/16/14	GCIA requested an extension of the due date for corrective actions until the first week of May. Betsy approved the extension.
5/1/14	GCIA submitted corrective actions.
5/16/14	<p>Betsy reviewed the corrective actions. The response was good but lacked specificity and evidence. Betsy requested additional information within two weeks, as shown below.</p> <p>NP2296MMA.NC4</p> <ol style="list-style-type: none"> 1. Could you tell me a little more about how staff were trained about how to select the correct regulation and how to describe the regulation on a Notice of Noncompliance? For example, did you look at NOP training to review the regulations? Did you all write any new procedures/instructions? Were there any meeting notes or memos to staff? 2. How will GCIA check up on the noncompliance letters to make sure that they include the correct regulation and a description? <p>NP4057JHA.NC1</p> <ol style="list-style-type: none"> 1. This response looks good overall. Are the instructions for the new Notice of Proposed suspension written in any policies or procedures? 2. Could you also tell me a little more about how and when staff were trained on the updated template?
5/20/14	GCIA provided additional corrective actions. Due to their small staff, GCIA does not



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Mr. Terry Hollifield
2325 South Milledge Avenue
Athens, GA 30605

Dear Mr. Hollifield:

On February 26 – 27, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a Compliance Assessment of the Georgia Crop Improvement Association (GCIA) organic certification program. The objective of the assessment was to determine GCIA's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4057JHA, is enclosed for your reference.

As the report indicates:

- Ten noncompliances from various reports were cleared; specifically: NP2296MMA.NC1-3, NC5-9; AIA030613BJR.NC10; and AIA13311RAM.NC1.
- One noncompliance, NP4057JHA.NC1, was identified during the assessment.
- One noncompliance, NP2296MMA.NC4, remains outstanding from your previous audit.

Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the GCIA's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Renee Mann, at (202) 260-8635 or Renee.Mann@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

APR 1 2014

Mr. Terry Hollifield
2325 South Milledge Avenue
Athens, GA 30605

Dear Mr. Hollifield:

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- One noncompliance, NP2296MMA.NC4, remains outstanding from your previous audit.

Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the GCIA's management system will be modified to prevent future noncompliances.

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Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division



**Livestock, Poultry and Seed Program
Quality Assessment Division
Quality System Audit Report**

AUDIT INFORMATION

Applicant Name:	Georgia Crop Improvement Association, Inc. (GCIA)
Est. Number:	N/A
Physical Address:	2325 South Milledge Avenue, Athens, Georgia 30605
Mailing Address:	2325 South Milledge Avenue, Athens, Georgia 30605
Contact & Title:	Terry Hollifield, Executive Director
E-mail Address:	gacrop@bellsouth.net
Phone Number:	(706) 542-2351
Auditor(s):	Julie Hartley
Program:	USDA National Organic Program
Audit Date(s):	February 26-27, 2014
Audit Identifier:	NP4057JHA
Action Required:	Yes
Audit Type:	Compliance Assessment
Audit Objective:	To verify continuing compliance to the audit criteria; and to verify the implementation and effectiveness of corrective actions in addressing the previous noncompliances.
Audit Criteria:	7 CFR Part 205 National Organic Program, Final Rule, dated December 21, 2000; as amended
Audit Scope:	The company's corrective actions including personnel, processes, procedures, facilities, and records related to the corrective actions.
Location(s) Audited:	GCIA office in Athens, Georgia

GENERAL INFORMATION: The Georgia Crop Improvement Association, Inc. (GCIA) was accredited as a USDA National Organic Program (NOP) certifying agent on April 29, 2002, for crops, livestock, and handling operations. The GCIA list of certified operations include 88 certified operations, consisting of 39 crop operations, 1 livestock operation, and 48 handlers. There are no grower groups certified by GCIA. The certified operations are located in Alabama, Florida, Georgia, and North Carolina.

The GCIA office is located in Athens, Georgia, and all certification activities are finalized in this office. All staff are full-time employees based out of the Athens office, and they all conduct other duties for GCIA in addition to their work for the organic certification program.

A renewal assessment of the GCIA organic program was conducted in October 2012, and as part of the terms of accreditation. GCIA agreed to an additional audit to be conducted prior to the required mid-term assessment.



Livestock, Poultry and Seed Program Quality Assessment Division Quality System Audit Report

FINDINGS

Observations made, interviews conducted, and procedures and records reviewed verified that GCIA is currently operating in compliance to the requirements of the audit criteria, except as identified below. The corrective actions for nine noncompliances identified during the 2012 Renewal Assessment and a previous noncompliance issued in November 2013 were verified and nine out of the ten corrective actions for the non-compliances were found to be implemented and effective, so the noncompliances were cleared. One noncompliance identified during the 2012 Renewal Assessment remains outstanding and one new noncompliance was identified during the compliance assessment.

NP2296MMA.NC1 – Cleared – NOP §205.402(a)(1) and (2) state, “Upon acceptance of an application for certification, a certifying agent must review the application to ensure completeness pursuant to §205.401 [and] determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part.” *Two of the 6 files reviewed were missing information for a complete organic system plan (OSP). The livestock OSP listed the substances used, but the description of use was in general terms (i.e. insect control, mite control) and did not indicate where they would be used and how as required by §205.201(a)(2). The OSP listed boric acid but did not include where and how it would be used, information necessary to verify whether it was in compliance by prohibiting contact with pullets and hens. The OSP also listed sulfur but did not state whether it was used on the poultry or in the laying houses. The OSP for the handling operation visited for the witness inspection did not clarify what activities were being conducted or what products were produced by each of the three facilities included in the OSP. The materials list and products produced were submitted for all 3 facilities without defining which activities were conducted at each processing facility.* **Corrective action:** GCIA obtained additional information from the livestock operation on their use and planned use of materials, including a description of where and when the materials would be used. GCIA emailed its review staff to state that they must pay attention to the use of approved materials for livestock OSPs, and that usage must be in compliance with the NOP, verified and documented during the onsite inspection. During the upcoming renewal of accreditation cycle, GCIA plans to require each processing facility to have an individual Organic Product Summary Plan. GCIA’s organic system plan forms require applicants to list all materials used and, if the materials are approved with restrictions, to explain how the planned use complies with the USDA organic regulations. GCIA plans to provide staff training on this issue during the second quarter of 2013, after which it will send confirmation of the training to the NOP. The Program Administrator will monitor the implementation of these procedures by reviewing all applications, inspection reports, and training materials. If the implementation is not successful, then GCIA will conduct additional training. **Verification of corrective action (February 2014):** Handling facilities have individual Organic Product Summary Plans. Files reviewed showed adequate information described for materials used. For the livestock operation, GCIA issued a review of materials letter to the operation identifying which products were approved or denied and reasoning. Training concerning this issue was held May 2013. Additional training was determined to not be necessary.



Livestock, Poultry and Seed Program Quality Assessment Division Quality System Audit Report

NP2296MMA.NC2 – Cleared – NOP §205.403(c)(1)(2) states, “The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part [and] that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.” *The inspector did not conduct an adequate in/out balance and audit trail during the witness inspection of the handling operation.* **Corrective action:** The GCIA program manager sent an email to staff in January 2013 emphasizing the importance of in/out balances and added a question to the inspectors’ checklist asking whether the inspector was able to complete a reasonable in/out balance. GCIA modified its program manual, which now requires the inspector to inform the Program Administrator immediately if a facility markets more organic product than it produces or purchases. GCIA will report such discrepancies to the NOP within two business days. GCIA will conduct training on the issue during a certification committee meeting in the second quarter of 2013. **Verification of corrective action (February 2014):** Review of six inspection reports noted the in/out question on the inspector checklist is documented by the inspector. The inspector has also included documentation of in/out balance or audit trail within the files reviewed. No instance of a facility marketing more organic product than it produces or purchases has been identified. Training concerning this issue was held May 2013.

NP2296MMA.NC3 – Cleared– NOP §205.510(b)(2) states, “Certifying agents must maintain records according to the following schedule: records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation.” *The labels of the witness audit handler were not reviewed and could not be verified as those approved by GCIA. The USDA auditor obtained copies of the 6 labels used by the handler and compared them against those approved in the client’s file. All 6 were different. In addition, GCIA did not have a label control procedure or a process in place to keep track of approved labels. However, the 6 labels reviewed complied with the USDA organic regulations.* **Corrective action:** GCIA sent an email instructing administrative staff to provide the inspector with copies of previously approved labels prior to the annual onsite inspection and to place all approved labels in the client’s file for future reference. GCIA also added this requirement to its organic certification manual, added questions about label reviews to the inspectors’ checklist, and discussed the new requirements at a staff meeting. GCIA administrative staff will keep a copy of sample labels in each certification file. The Program Administrator will monitor the implementation of the new label review procedures. **Verification of corrective action (February 2014):** Of five files reviewed, copies of current labels were in the files, and new labels for one operation were currently being requested and reviewed prior to an onsite inspection. Labels are stamped approved, if applicable, and initialed as reviewed; and use of the additional questions on the inspection checklist has been implemented.

NP2296MMA.NC5 – Cleared – NOP §205.503(c) states, “A private or governmental entity seeking accreditation as a certifying agent must submit the following information: each area of operation (crops, wild crops, livestock, or handling) for which accreditation is requested and the estimated number of each type of operation anticipated to be certified annually by the applicant along with a copy of the applicant's schedule of fees for all services to be provided under these regulations by the applicant.” *The Application*



Livestock, Poultry and Seed Program Quality Assessment Division Quality System Audit Report

for Accreditation (TM-10CG) submitted by GCIA did not include an estimate for each type of operation anticipated to be certified by GCIA. The section of the form was left blank and did not indicate which scopes of certification were being requested. At the time GCIA was accredited for crops, livestock, and handling operations. **Corrective action:** GCIA amended its timeline book, which lists critical reporting times and records their completion, to instruct staff to complete this information on future Applications for Accreditation. GCIA also submitted an estimate of the number of operations certified as of May 2012 and an updated fee schedule. **Verification of corrective action (February 2014):** The timeline book is segmented by month and outlines duties to be completed. GCIA's accreditation anniversary is on April 29; the timeline book page for September (at least 6 months prior to the GCIA accreditation anniversary) outlines the elements due to be submitted every 5 years for the accreditation application, including, for example, an estimate of the number of operations certified. An administrative assistant is responsible for the timeline book and accreditation application submission, and reviews the responsibilities outlined in the timeline book each month.

NP2296MMA.NC6 – Cleared – NOP §205.504(a)(2), (b)(3), (c)(2), and (d)(2) state, “A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques; its ability to fully comply with and implement the organic certification program...and its ability to comply with the requirements for accreditation set forth in §205.501:

- 1) The name and position description of all personnel to be used in the certification operation, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent...
- 2) A copy of the procedures to be used for complying with the recordkeeping requirements set forth in §205.501(a)(9)...
- 3) For all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent, a conflict of interest disclosure report, identifying any food- or agriculture-related business interests, including business interests of immediate family members, that cause a conflict of interest...
- 4) Copies of at least 3 different inspection reports and certification evaluation documents for production or handling operations certified by the applicant during the previous year for each area of operation for which accreditation is requested.”

*1) GCIA submitted a list of personnel with their renewal of accreditation application. However, they did not submit a list of the members of the GCIA Board of Directors. The list of responsibly connected parties was obtained and reviewed during the renewal assessment. 2) GCIA did not submit a recordkeeping procedure with their application for renewal of accreditation and the on-site assessment verified there was no procedure in place. However, all records were maintained for the required period of 5 and 10 years as applicable. 3) GCIA did not submit all required conflict of interest (COI) disclosure reports; GCIA only submitted a COI disclosure report for the GCIA staff and the two active certification committee members but did not submit these reports for members of the GCIA Board of Directors. 4) GCIA did not submit any reports or certification evaluation documents. **Corrective action:** GCIA keeps*



Livestock, Poultry and Seed Program Quality Assessment Division Quality System Audit Report

a Timeline Book to serve as a recordkeeping procedure. GCIA edited this book to ensure that a list of members of the Board of Directors, a recordkeeping procedure, conflict of interest disclosure reports, and reports/certification evaluation documents will be submitted with future Applications for Accreditation. GCIA submitted a program manual, which showed compliant records retention procedures. GCIA submitted 3 copies of inspection reports and a list of members of its Board of Directors as supporting documentation, as well as copies of Conflict of Interest statements for all members. **Verification of corrective action (February 2014):** The timeline book is segmented by month and outlines duties to be completed. GCIA's accreditation anniversary is on April 29; the timeline book page for September (at least 6 months prior to the GCIA accreditation anniversary) outlines the elements due to be submitted every 5 years for the accreditation application, including, for example, a list of GCIA Board Directors. An administrative assistant is responsible for the timeline book and accreditation application submission, and reviews the responsibilities outlined in the timeline book each month.

NP2296MMA.NC7 – Cleared – NOP §205.662(c) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification.” *GCIA sent Notices of Proposed Revocation to two operations for failure to submit updated organic system plans and certification fees. A correctable violation should not result in a proposed revocation, but rather a proposed suspension.* **Corrective action:** GCIA updated its program manual to state that it will now issue proposed suspensions instead of proposed revocations for correctable violations, such as the failure to submit annual updates and fees. GCIA will provide training on this issue at a certification committee meeting during the second quarter of 2013. The Program Administrator will monitor successful implementation for a period of six months. **Verification of corrective action (February 2014):** No proposed revocations have been issued since the corrective actions were implemented. Proposed suspensions issued are applicable to the violation. The Program Manager continues to review all notices issued. Training concerning this issue was held May 2013.

NP2296MMA.NC8 – Cleared – NOP §205.663 states, “Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent...” *GCIA's Administration and Policy Manual states that GCIA will not offer mediation.* **Corrective action:** GCIA modified its program manual to state that it will utilize mediation as a means for dispute resolution, utilizing the USDA organic regulations as a guide. **Verification of corrective action (February 2014):** The GCIA Administration and Policy Manual remains updated to reflect amendments made; and the GCIA Notices of Proposed Suspension include statements concerning the right to request mediation. Mediation has not been requested by any operation. Training concerning this issue was held May 2013.

NP2296MMA.NC9 – Cleared – NOP §§205.510(a)(1) and (4) state, “An accredited certifying agent



Livestock, Poultry and Seed Program Quality Assessment Division Quality System Audit Report

must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following ... : a complete and accurate update of information submitted pursuant to §§205.503 and 205.504 [and] the results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review.” *There was no evidence that the annual report was submitted to the Administrator for 2010. The NOP confirmed that GCIA did not submit an annual report in 2010. **Corrective action:** Due to major staffing changes, GCIA erred in not submitting the annual report. GCIA updated its timeline book to note the date on which annual reports must be submitted each year. GCIA also discussed the issue at a staff meeting to make sure that all personnel are aware of the reporting requirements. **Verification of corrective action (February 2014):** The timeline book is segmented by month and outlines duties to be completed. GCIA’s annual report is due each year on April 29; the timeline book page for April outlines the elements due to be submitted. An administrative assistant is responsible for the timeline book, and the annual report submission is delegated to another administrative assistant for completion. Although there is no procedure dedicated to the use of the timeline book, either administrative assistant is able to train another staff member or new staff member if staffing changes occur in the future.*

AIA030613BJR.NC10 – Cleared – NOP § 205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.” *GCIA is accredited for livestock; however, its inspection reports and Organic System Plans (OSP) did not include any questions regarding the pasture rule. The forms did not capture information on pasture management, grazing periods, or dry matter intake. **Corrective action:** GCIA submitted revised livestock OSPs and inspection reports. The OSP incorporated questions regarding the months during which cattle grazed, as well as dry matter worksheets. The OSP also requested information on pasture management. The inspection report included questions on pasture, grazing methods, and the verification of grazing records. **Verification of corrective action (February 2014):** GCIA has implemented the use of additional questions within the inspection report template to address the pasture rule. The revised Livestock OSP template has not been used as GCIA uses a Poultry OSP template for its only livestock operation.*

AIA13311RAM.NC1 – Cleared – NOP §205.662, states, “Noncompliance procedure for certified operations (e) Suspension or revocation. (1) If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation. (2) A certifying agent or State organic program's governing State official must not send a notification of suspension or revocation to a certified operation that has requested mediation pursuant to §205.663 or filed an appeal pursuant to §205.681, while final resolution of either is pending. *GCIA included a requirement from § 205.662(c)(4) to a letter issued according to §205.662(e). Specifically, the Notice of Indefinite Suspension, issued by GCIA on October 14, 2013, allows a certified operation to submit an appeal after being issued a notice of proposed suspension. Suspensions, which are issued according to §205.662(e), must not contain instructions permitting an appeal of a suspension decision. **Corrective Action:** GCIA revised its Notice*



Livestock, Poultry and Seed Program Quality Assessment Division Quality System Audit Report

of Suspension and Notice of Indefinite Suspension by deleting the right to appeal statement and issued a corrected notice to the operation. GCIA reviewed the change with staff. **Verification of corrective action (February 2014):** Notices were issued to multiple operations in December 2013 to reflect the amendment to the notice concerning the operations' right to appeal. None of the operations issued amended notices have contacted GCIA, requested reinstatement, or complained about the amendment made.

NP2296MMA.NC4 – Outstanding – NOP §205.405(a)(1) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant...The notification of noncompliance shall provide a description of each noncompliance.” *Three notifications of noncompliance issued to applicants for certification were reviewed. Of the three, one did not include a description of the noncompliances. Instead, the notification stated what the client had to submit in order to correct the noncompliance.* **Corrective action:** GCIA submitted a revised template, which contained a space to insert descriptions of the noncompliance. GCIA also submitted a Notice of Noncompliance issued in February 2013, showing references to the USDA organic regulations and descriptions of each noncompliance at issue. The GCIA Program Administrator will review all Notices of Noncompliance during the next six months to ensure correct implementation of the new procedures. **Verification of corrective action (February 2014):** GCIA is using its current Notice of Noncompliance template, providing a description of evidence why the regulation has been violated, and citing the USDA organic regulation number, but not a description of the regulation. For one file reviewed, the reasons described for the noncompliances were not clearly associated with regulation numbers cited.

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1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

JUL 21 2017

NOTICE OF NONCOMPLIANCE

Linda Van Hook
Global Culture
P.O. Box 1640315 Meigs Rd, Ste A 404
Santa Barbara, CA 93109

Dear Ms. Van Hook:

On April 14, 2017, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) notified Global Culture its 2017 annual report was due. The NOP granted Global Culture an extension on April 18, 2017 and accepted an extended submission date chosen by Global Culture on May 9, 2017. As of the date of this letter the NOP has not received a 2017 annual report from Global Culture. We have determined that Global Culture is noncompliant with the USDA organic regulations, 7 CFR Part 205, as follows:

AIA17191JL.NC1 – 7 CFR §205.510(a) states, “(a) Annual report and fees. An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) A complete and accurate update of information submitted pursuant to §§205.503 and 205.504; (2) Information supporting any changes being requested in the areas of accreditation described in §205.500; (3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and (5) The fees required in §205.640(a).”

Comments: *Global Culture has not submitted to the NOP the annual report due April 14, 2017. The NOP granted an extension of one week on April 18, 2017. On May 9, 2017, Global Culture informed the NOP it would submit its annual report on May 15, 2017. The NOP has not received the Global Culture annual report due April 14, 2017.*

Global Culture must submit corrective actions to AIAInbox@ams.usda.gov within 30 days from the date of this Notice. The corrective actions should indicate how each noncompliance will be corrected and how the Global Culture management system will be modified to prevent a recurrence of the noncompliance. If you wish to rebut the noncompliance, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Page 2

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions. Failure to resolve the noncompliance may result in proposed suspension or revocation of Global Culture's USDA accreditation.

If you have questions regarding this notice, please contact Jason Lopez, Accreditation Manager, at JasonJ.Lopez@ams.usda.gov or (202) 260-9445.

Sincerely,



Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Linda Van Hook
Global Culture
P.O. Box 1640315 Meigs Rd, Ste A 404
Santa Barbara, CA 93109

Dear Ms. Van Hook:

On April 14, 2017, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) notified Global Culture its 2017 annual report was due. The NOP granted Global Culture an extension on April 18, 2017 and accepted an extended submission date chosen by Global Culture on May 9, 2017. As of the date of this letter the NOP has not received a 2017 annual report from Global Culture. We have determined that Global Culture is noncompliant with the USDA organic regulations, 7 CFR Part 205, as follows:

AIA17191JL.NC1 – 7 CFR §205.510(a) states, “(a) Annual report and fees. An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) A complete and accurate update of information submitted pursuant to §§205.503 and 205.504; (2) Information supporting any changes being requested in the areas of accreditation described in §205.500; (3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review; and (5) The fees required in §205.640(a).”

Comments: *Global Culture has not submitted to the NOP the annual report due April 14, 2017. The NOP granted an extension of one week on April 18, 2017. On May 9, 2017, Global Culture informed the NOP it would submit its annual report on May15, 2017. The NOP has not received the Global Culture annual report due April 14, 2017.*

Global Culture must submit corrective actions to AIAInbox@ams.usda.gov within 30 days from the date of this Notice. The corrective actions should indicate how each noncompliance will be corrected and how the Global Culture management system will be modified to prevent a recurrence of the noncompliance. If you wish to rebut the noncompliance, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

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Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions. Failure to resolve the noncompliance may result in proposed suspension or revocation of Global Culture's USDA accreditation.

If you have questions regarding this notice, please contact Jason Lopez, Accreditation Manager, at JasonJ.Lopez@ams.usda.gov or (202) 260-9445.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: AIA Inbox

Audit Resolution Chronology Log

Audit Identifier (if any): NP4168OOA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: Global Organic Alliance, Inc. (GOA)
Accreditation Manager (working on report): Janna Howley

Date	Activity
09/04/14	JH received Audit Report from CC.
09/22/14	JH reviewed report and drafted NC report and letter.
09/23/14	JH updated inspection report (after talking with LC to confirm process) to reflect that F2 in the report didn't line up with the actual NC in the Findings in the report. JH also decided (with LC approval) to not include NC8 in the NoNC report because the certifier provided updated information while inspectors were on-site that showed they were in compliance. So NC9 from audit report will now become the new NC8.
09/23/14	Submitted to RM for review and approval.
09/25/14	JH received comments back from RM re the broadness of the regs (NOP 205.501a3) applied to the two bullet points in the one noncompliance (NC2). If the specific regs are applied to each of the points noted in the audit report, then NC2 is actually two separate noncompliances, so will turn bullet point one (now NOP 205.405a) into NC2, and then add the second bullet point (205.403c1) into NC9.
09/30/14	LC issued the NoNC and NC Report to GOA via registered email. LC entered the assignment into the database and closed it.
01/15/15	LC requested CAs from GOA and received them. Betty showed that the CAs had been sent to the AIAInBox on Sep 28 th .
03/31/15	JH emailed RM to let her know CAs had been received, but not assigned out to AM.
04/01/15	RM assigned CA report to JH. JH added to WTL.
04/06/15	<ul style="list-style-type: none"> • JH began document review. • Emailed Betty with clarification questions about NC1-NC7. CAs did not address process updates at all. Requested training documents and/or policy manual to verify that processes are being updated and implemented, not just individual documents or templates. Due date of 04/17/15. Flagged in Outlook to follow up. • GOA rebutted NC9. Listed in the CA section of the NC.
04/14/15	Revd additional information from GOA.
04/15/15	JH revised report based upon updated information.
05/15/15	<ul style="list-style-type: none"> • JH had been holding off on contacting GOA, or completing CA report, because GOA was being issued a NoPS from the NOP. NoPS was sent to them on 05/05/15; they have 30 days to respond. JH talked to CC; CC confirmed that JH should continue processing the report and contact GOA for any needed information. • Emailed (RPost) Betty regarding additional information on NP4168OOA.NC2 - NC4. Deadline of Friday, June 4th (JH is out on audit from 05/25-06/04).
05/19/15	Revd additional information from GOA.
05/20/15	Updated report to reflect received information. Sent to RM for review.
05/22/15	Revd comments back from CC regarding four NCs: NP4168OOA.NC2, NP4168OOA.NC4, NP4168OOA.NC7, NP4168OOA.NC9

Audit Resolution Chronology Log

Audit Identifier (if any): NP4168OOA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: Global Organic Alliance, Inc. (GOA)
Accreditation Manager (working on report): Janna Howley

06/17/15	<ul style="list-style-type: none"> • Emailed LC (he was witness audit auditor) regarding NP4168OOA.NC9. JH also reviewed the witness audit report. LC responded back that he would accept their rebuttal. • Provided two comments in CA report regarding NP4168OOA.NC2, NP4168OOA.NC4. • Emailed RM regarding onsite inspector evaluation NC in light of the proposed IOIA pilot program.
06/22/15	<ul style="list-style-type: none"> • Emailed GOA to determine how they have updated their internal documents to reflect participating in the IOIA onsite inspector evaluation pilot project, and to see how they will get into compliance if the pilot project does not continue. Response requested by 06/29/15. • Rcvd response. GOA is not going to use IOIA program; they will do the inspector onsite evaluations themselves. They are increasing their onsite evaluation rate to 20% in 2015, with a goal of evaluating 100% of their inspectors basically every five years. • Updated the report and sent to RM for review.
07/15/15	Conference call w Betty and AIA staff to review NCs related to private label certification and inspector evaluations. CC gave Betty one week to provide additional information to the related NCs, because the existing corrective actions are not adequate. JH emailed Betty regarding three NCs, with a deadline of 07/22/15.
07/24/15	JH emailed GOA to see if corrective action information had been sent in. Betty confirmed that it had, but was sent to AIAInbox, via Dropbox, which USDA computers can't open. JH requested they upload files to CloudVault, which they did.
07/28/15	<p>Following documents were submitted by GOA:</p> <ul style="list-style-type: none"> • Inspector Evaluation Annual F026F • Inspector Evaluation Certification F026B • Inspector Evaluation Operation F026C • Inspector Evaluation Procedure P006D (revised 20 July 2015) • Policy Manual (revised 20 July 2015) • Witness Audit Evaluation F026E • Ahold USA letter • California Farms letter • Giant Eagle letter • Good Food Made Simple letter <p>Reviewed docs, updated letter and sent to CC. OK to print.</p>
07/29/15	Emailed signed letter and report to GOA.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Global Organic Alliance, Inc.'s (GOA) organic program was conducted on June 17 & 19, July 9 and August 4-6, 2014. The National Organic Program (NOP) reviewed the auditor's report to assess GOA's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Global Organic Alliance, Inc. (GOA)
Physical Address	3185 Township Road 179, Bellefontaine, OH 43311-0530
Mailing Address	Same
Contact & Title	Betty Kananen, President/Chief Executive Officer
E-mail Address	goaorg@centurylink.net
Phone Number	937-593-1232
Reviewer & Auditors	Janna Howley, NOP Reviewer Darrell Wilson & Lars Crail, On-site Auditors
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: May 20, 2015 Onsite audits: June 17 & 19, July 9 and August 4-6, 2014
Audit Identifier	NP416800A
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of GOA's certification.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	GOA's certification services in carrying out the audit criteria during the period: September 2012 - August 2014.

Global Organic Alliance (GOA) is a for-profit, privately owned organization incorporated by the state of Ohio in 1997. GOA offers organic certification to organic producers and processors/handlers. GOA has been accredited to the National Organic Program (NOP) as a certifying agent since April 2002, for the scopes of crop, wild crop, livestock and handling. GOA has 828 clients certified to the NOP, including 288 crop, 451 livestock, 3 wild crop, and 64 handling operations. Clients are located throughout the US, and the Philippines. All certification activities are conducted at the Bellefontaine office.

Nine administrative and technical staff members operate the GOA certification program. The staff consists of the Chief Executive Officer/President, a Certification Director/Quality Manager,

three Certification Coordinators, a Certification Review Specialist and three Administrative Assistants. GOA has a four-member Advisory Board; it functions strictly as a source of advice and information and has no certification duties. GOA currently has 51 subcontracted inspectors for inspection activity.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether GOA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

AIA13339BJR.NC1 – Cleared

AIA13339BJR.NC2 – Cleared

NP2219NNA.NC1 – Cleared

NP2219NNA.NC2 – Cleared

NP2219NNA.NC3 – Cleared

NP2219NNA.NC4 - Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4168OOA.NC1 – 7 CFR §205.662 (c)(3) states, "When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state: The impact of a suspension or revocation on future eligibility for certification."

Comments: *One Notice of Proposed Suspension issued indicated a proposed suspension of 6 months. However, when the suspension was issued the suspension was for one year.*

Corrective Action: GOA has changed its procedure so that all Notices of Proposed Suspension will be proofread, and initialed, by the Office Manager before mailing. A copy of the Notice of Noncompliance will now be attached to the Notices of Proposed Suspension. An example of the new letter, updated procedure, and Office Manager position description were provided to the

NOP.

NP416800A.NC2 – 7 CFR §205.405 (a) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant.”

Comments: *In one of the reviewed files, fruit that originated from Chile, certified to the EU regulations, was being included in product being produced as NOP organic. There was no supporting documentation provided that indicated that the fruit was certified to NOP regulations. The certifier failed to identify the noncompliance and issue a Notice of Noncompliance.*

Corrective Action: GOA updated its *Certification and Attestation of Compliance Procedure* document to include the requirement that all documentation needed to verify compliance to the product or process requested for certification must be submitted to GOA. GOA also requested, and received, the correct supporting documentation for the product originating from Chile. GOA conducted trainings on this updated requirement at its annual staff training on March 3, 2015, and its inspector training on March 4, 2015. Copies of the new procedure were provided at both trainings. A copy of the *Certification and Attestation of Compliance Procedure* document was provided to the NOP for review.

NP416800A.NC3 – 7 CFR §205.403 (a)(1) states, “A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.”

Comments: *One of the six files reviewed was granted certification as “Private Label” without conducting an on-site inspection. Discussions with the CEO and the Certification Director indicated that certificates are being issued for all Private Label reviews without inspections.*

Corrective Action: GOA revised all document templates related to its Private Label review and approvals, including the *Work Instructions, Private Label Application, GOA Approval Letter, and Private Label Authorization Certificate*. Additionally, GOA’s *Certification Procedure (P008), Section 2, 2.3*, requires an annual inspection of all certified operations. *Section 4.1* of the same document provides timeframes for sending annual inspection reminder notices and due dates. The March 3, 2015 staff training also covered the certification procedure. Copies of all documents were provided to the NOP for review.

NP416800A.NC4 – 7 CFR §205.404 (b)(3) states, “The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified

operation.”

Comments: *Certificates are being issued for “Private Label” which is not one of the categories defined in the USDA National Organic Program regulations.*

Corrective Action: GOA’s *Certification Procedure (P008)*, Section 8.1 lists the information required on the certificate, including scope. GOA’s *Policy Manual*, Section 15.4.4 also states that the certificate will specify: “Scope of certification – crops, wild crop, livestock, processing, or handling.” Staff received training on the procedure on March 3, 2015. Copies of all documents were provided to the NOP. GOA also provided documentation to demonstrate that “Private Label” certificates being issued are visually distinct from organic certification certificates, and do not include the same information as organic certificates. GOA also provided to the NOP its Private Label application, request for co-packer’s current organic certificate, work instructions and approval letter.

NP416800A.NC5 – 7 CFR §205.501 (a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.”

Comments: *Five of the six employed personnel did not have a current conflict of interest disclosure report at the time of the assessment.*

Corrective Action: GOA has now added Conflict of Interest (COI) forms to staff semi-annual evaluation procedures to ensure that they are completed. The *Conflict of Interest* form will be a required portion of the April evaluation; The *Employee Performance Review* document now includes this statement and the requirement for the COI form to be attached to the blank evaluation form to prevent it from being overlooked. The President/Chief Executive Officer’s job description has been updated to include the responsibility for the annual completion of staff COI forms. Copies of all documents were provided to the NOP for review.

NP416800A.NC6 – 7 CFR §205.501 (a)(10) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program’s governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in §205.504(b)(5).”

Comments: *Five of the six employed personnel did not have a currently signed Confidentiality Statement. GOA Policy Manual, Section 3.4 states, “Individuals that review and/or evaluate applications/documents for certification or perform on-site inspections, make certification decisions and all parties responsibly connected to GOA must complete a Confidentiality Statement annually.”*

Corrective Action: GOA has now added Confidentiality Statements to staff semi-annual evaluation procedures to ensure that they are completed. *GOA Policy Manual AD001, Section 4.1*, has been updated to reflect this requirement. The *Confidentiality Statement* form will be a required portion of the April evaluation; The *Employee Performance Review* document now includes this statement and the requirement for the *Confidentiality Statement* form to be attached to the blank evaluation form to prevent it from being overlooked. The President/Chief Executive Officer's job description has been updated to include the responsibility for the annual completion of staff *Confidentiality Statement* forms. Copies of all documents were provided to the NOP for review.

NP416800A.NC7 – 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.”

Comments: *NOP 2027, Personnel Performance Evaluations, require inspectors to be annually evaluated during an onsite inspection by a supervisor or peer (another inspector). Annual field observations of contracted inspectors are not conducted.*

Corrective Action: GOA has revised its Policy Manual to reflect the requirement of an annual evaluation of all persons who perform on-site inspections. Additionally their *Inspector Evaluation Procedure P006D* was revised to require that all active inspectors be subject to an annual witness audit. Copies of these documents, as well as *Inspector Evaluation Form Annual F026F*, *Inspector Evaluation Form Certification F026B* and *Inspector Evaluation Form Operation F026C* were provided to the NOP for review. GOA has contracted with the International Organic Inspectors Association (IOIA) to conduct inspector witness audits to help GOA meet their goal for 100% annual evaluations.

NP416800A.NC8 – 7 CFR §205.404(b)(1) states, “The certifying agent must issue a certificate of organic operation which specifies the... Name and address of the certified operation...” Furthermore, NOP 2603, Organic Certificates, Section 3.2, states that “Certifying agents must identify only one “person” (typically a farm or business as defined in 7 CFR § 205.2) on the organic certificate...”

Comments: *GOA certified operations that are in a contractual selling relationship with a certified buyer have the name of certified buyer listed on their certificate, as well as the certified operation's name.*

Corrective Action: GOA has discontinued listing the contractor's name on the certificate; it will now be listed on the Certificate Profile that accompanies the certificate. The certificate now only lists the actual certified operation. GOA changed its template and its outside contract computer programmer set up the certificates so none can be changed or altered by in house staff. As a result, no "additional/new" training of staff was required. GOA's Policy Manual reflects that the certificate lists the name and address of the certified operation. A copy of an operation's certificate was provided to the NOP to verify this change.

NP416800A.NC9 – 7 CFR §205.403(c)(1) states, “The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part.”

Comments: *It was observed during the livestock inspection that fields used for pasturing the animals had no shade structures or trees that could provide shade. The operator indicated that animals were allowed access to the barn; however, this seems unlikely for the majority of the fields since the distance was too large for the cows to move back and forth to the barn. The inspector did not note this as a concern and GOA did not identify this as a noncompliance.*

Corrective Action: Rebuttal accepted. GOA respectfully rebutted this noncompliance; the inspector, who is well-versed in dairy animals, noted that the animals appeared in good health. Additionally, the President of GOA, also an expert in livestock, noted that adult dairy animals with access to indoors during the heat of the summer will not stray far from the shelter, preferring to graze in the pasture only during the very early morning and evening hours.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Global Organic Alliance, Inc.'s (GOA) organic program was conducted on June 17 & 19, July 9 and August 4-6, 2014. The National Organic Program (NOP) reviewed the auditor's report to assess GOA's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Global Organic Alliance, Inc. (GOA)
Physical Address	3185 Township Road 179, Bellefontaine, OH 43311-0530
Mailing Address	Same
Contact & Title	Betty Kananen, President/Chief Executive Officer
E-mail Address	goaorg@centurylink.net
Phone Number	937.593.1232
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer; Darrell Wilson & Lars Crail, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: September 22, 2014 Onsite audit: June 17 & 19, July 9 and August 4-6, 2014
Audit Identifier	NP4168OOA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of GOA's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	GOA's certification services in carrying out the audit criteria during the period: [date] through [date]

Global Organic Alliance (GOA) is a for-profit, privately owned organization incorporated by the state of Ohio in 1997. GOA offers organic certification to organic producers and processors/handlers. GOA has been accredited to the National Organic Program (NOP) as a certifying agent since April 29, 2002, for the scopes of crop, wild crop, livestock and handling. GOA has 828 clients certified to the NOP, including 288 crop, 451 livestock, 3 wild crop, and 64 handling operations. Clients are located throughout the US, and the Philippines. All certification

activities are conducted at the Bellefontaine office.

GOA also conducts certification services in Canada, US territories, and the Philippines. GOA is accredited to Canada Organic Regime (COR) and the USDA ISO 17065 Program. A USDA ISO Guide 17065 Program Reassessment was conducted concurrently with the NOP Mid-Term Assessment.

Nine administrative and technical staff members operate the GOA certification program. The staff consists of the Chief Executive Officer/President, a Certification Director/Quality Manager, three Certification Coordinators, a Certification Review Specialist and three Administrative Assistants. GOA has a four-member Advisory Board; it functions strictly as a source of advice and information and has no certification duties. GOA currently has 51 subcontracted inspectors for inspection activity.

Records and interviews with each staff member responsible for a certification activity concluded that a combination of formal GOA training, on the job training, witnessing inspections, and a well-documented mentoring program are the basis for the performance observed by the current staff. Interviews provided evidence of expertise in areas of responsibility for each staff member. All inspector profiles were complete and GOA maintains an inspector matrix that contains information on the scopes to which each inspector is qualified to inspect, and for each Standard to which they are allowed to inspect. Conflict of Interest Declarations and Confidentiality Agreements were complete for inspectors. Five of the staff members did not have current Conflict of Interest Declarations and Confidentiality Agreements.

CERTIFICATION PROCESS:

GOA provides information and application materials to potential applicants upon request. GOA sends potential applicants a copy of the NOP rule, fee schedule, materials list, GOA handbook, and an application. Upon receipt of a completed application, GOA will send out the appropriate Organic System Plan and addendums for the applicant to complete.

The Certification Coordinators complete the initial reviews of all applications for certification, including labels. Each application and organic system plan is reviewed for completeness and the ability to comply with the NOP regulations. When the initial review is complete, the file is assigned to a subcontracted inspector, with consideration of the inspector's expertise, location of the operation, potential inspector conflicts of interest, and availability of the inspector. The inspector forwards the inspection report and all pertinent materials collected during the inspection to GOA for review. All materials are reviewed for compliance and the Certification Director or the Certification Review Specialist makes the certification decision. A file checklist is maintained for each review to give evidence of compliance with the NOP regulations.

For continuation of certification, current clients receive a renewal packet. The packet includes an OSP update form and supplementary forms based on the previous year's certification, as well as an updated NOP final rule and GOA policy, if there have been any changes. Updated plans are due, annually, on April 15 for producers, and 90 days prior to the anniversary dates for handlers. The procedures for the review of the renewal applications are the same as for new applicants.

The Certification Director and Certification Coordinator review materials/input information submitted with applications (Organic System Plan –Input Log or Operation Product Profile forms) and annual updates for compliance. Operations can submit an “Input Review Request” form at any time for GOA to determine whether the material is compliant for use. GOA also utilizes the OMRI and WSDA lists to determine input compliance. GOA maintains an internal approved material list and compliance decisions for specific materials are recorded. GOA maintains an “Input Library” that includes supporting documents for all approved and disapproved materials. GOA publishes the National List of Allowed and Prohibited Substances, and the NOP published guidance documents on material inputs, for operators to use.

GOA oversees international exports for EU, COR, Taiwan, and JAS. A review of documents indicated they were being completed as required, with the exception of one TM 11 for Taiwan. A list is being maintained for all certificates issued. There have been no shipments for JAS since the equivalency arrangement has been implemented.

ADMINISTRATIVE RECORDS AND PROCESSES:

GOA’s certification program is outlined in their Program Manual, Quality Manual and supporting policies and procedures. Forms and letters reviewed for NOP certification activities were found to meet NOP requirements. GOA has completed their internal audits each year, with a management review of the results following. Annual updates to the Administrator have been submitted in a timely manner.

Since the last assessment there have been two denials of certification, and GOA has issued six suspensions. There have been no proposed revocations or revocations. Fifty nine operations surrendered their organic certificates. One request for mediation was requested and denied.

GOA’s fee schedule is available to interested parties and applicants in the application packet. The fees appear to be reasonable, and the application clearly identifies that registration fees are nonrefundable. If an application is withdrawn prior to an inspection, the applicant is only liable for the cost of services up to the notification of withdrawal. Records indicate that initial applicants are issued an estimate of fees based on the fee matrix. The estimates and final fees charged to clients were the same as in the fee schedule on file with the Administrator.

A review of personnel files indicate that both external and internal training is provided. GOA conducts annual training, which brings personnel up to date with any changes, and discusses areas where improvement is needed.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED:

As a part of the mid-term assessment there was one review audit and two witness inspections conducted, all of which were announced. The review audit was a handling operation located in Michigan, contracted to process frozen fruits. It is a mixed operation for which organic production is approximately 1.5% of their total production. The operation does not take ownership of the ingredients used in the process. The witness inspection, also located in Michigan, was a wild crop operation collection of leeks. The wild crop area is located in a wooded area adjacent to the main farm of the operation; the collection was being managed as wild crop. Harvest is conducted in such a way that there are enough plants remaining to reseed

the leeks. The other witness inspection - located in Virginia - is a family crop operation and dairy farm. There are approximately 52 acres, separated into several paddocks for rotational grazing. The inspectors did a very thorough inspection, except as indicated in the findings, and were very knowledgeable of the NOP regulations.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether GOA's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to GOA.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

AIA13339BJR.NC1 – Cleared - §205.662(a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

Comments: GOA did not provide a Notice of Noncompliance to a dairy operation in New York State, and GOA did not follow the approved adverse action procedures when it declared the operation's certificate invalid.

GOA's Corrective Actions: GOA stated that it will no longer invalidate an organic certificate without first going through adverse action procedures, as specified by §205.662. GOA modified its adverse action procedure to define failure to provide evidence of resolution of previous noncompliances from other certifiers as a major noncompliance. GOA will provide training to its certification staff during the 2014 annual training to review the requirements for operations transferring from another certifier. GOA is now tracking any transferred operations on a “Transferring Operation Spreadsheet” and will periodically check the NOP's list of suspended and revoked operations to verify their status. GOA will also send the operations the NOP 2604 instruction, Responsibilities of Certified Operations Changing Certifying Agents. As evidence, GOA submitted a revised adverse action procedure, a template for letters to new applicants who had been previously certified by other certifiers, and a blank spreadsheet for tracking these applicants.

Verification of Corrective Actions: There was no indication of invalidating of certificates. Training was conducted as stated in corrective actions.

AIA13339BJR.NC2 – Cleared - §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: (3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: GOA issued an organic certificate to a dairy operation which was in violation of §205.206 (f), which states, “The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with soil or livestock.”

GOA’s Corrective Actions: GOA asked the inspector to clarify the statements in the report. The inspector’s statements regarding the plans to install new treated wood in the pasture were apparently in error. The barn was 12 years old, and based on the amount of moss growing on the railroad ties in the pasture GOA judged them to be older than the date of the farmer’s initial certification. GOA will review the treated lumber regulations at the 2014 annual training, noting that any use of treated lumber must be investigated and documented by the inspector.

Verification of Corrective Actions: The subject was covered in annual training as specified in the corrective actions.

NP2219NNA.NC1 – Cleared - NOP §205.501 (a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” The NOP instruction, Issuance of Export Certificates to Japan, dated June 15, 2009, Section 1.04, Requirements for Authorization, states, “To be authorized to issue export certificates, a USDA accredited certifying agent must: 4. Assign a unique identification number to each export certificate... 5. Keep a paper- based or electronic control log that records and tracks the disposition of each export certificate including those issued, voided or destroyed.”

Comments: GOA has issued twelve certificates for export to Japan but has not assigned a unique number to each. Additionally, GOA is not maintaining a log of the certificates issued.

Corrective Action: GOA now maintains an export log, which has been updated to include all export certificates included in 2012. GOA provided an example of this log to the NOP, demonstrating unique identification numbers for each certificate. The Executive Director assigned an alternate TM-11 signatory and provided her with instructions for the completion of an export certificate to prevent future errors.

Verification of Corrective Actions: Files reviewed verified that they are assigning a unique number and are maintaining a log of the certificates.

NP2219NNA.NC2 – Cleared - NOP §205.406 (c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.”

Comments: Seven of twelve files reviewed contained a certification assessment letter that included “opportunities for improvement” (OFI). These OFIs each included a citation from the USDA organic regulations for all OFIs noted on the assessment. There was no deadline for corrective actions; instead, the operator was given until the next inspection to correct the OFIs. GOA is therefore not providing a written notification of noncompliance after identifying an operation’s noncompliance with the requirements of the Act and/or the regulations in 7 CFR 205.

Corrective Action: GOA stated that OFIs are similar to the category of “Minor Issues – Conditions for Certification” identified in the NOP’s 2612 Instruction, Recommended Penalties for Violations of Specific Regulatory Requirements. GOA revised its certification assessment template for its initial compliance reviews. The template includes a section to track updated information on previously issued Notices of Noncompliances, as well as Opportunities for Improvement (OFI), to note whether the issues were resolved. If an issue is outstanding, then GOA describes it in detail on the certification assessment form. GOA then requests additional information from the operator and informs him/her that failure to implement corrective actions may result in a delay in the certification process and/or an adverse action. GOA also revised its certification procedure, section 2.4, to state that operations who “fail to respond or submit requested additional information or documentation may be subject to an unannounced or additional inspection.” GOA will not move the file to the next stage of the certification process until the operator provides a response, as stated in section 5.2 of the certification procedure. The inspector evaluates the effectiveness of all corrective actions during the onsite inspection.

Verification of Corrective Actions: Interviews with certification coordinators verified that they are tracking Notices of Noncompliance as well as OFIs and providing inspectors with applicable instructions in regards to them.

NP2219NNA.NC3 – Cleared - NOP §205.662 (a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

Comments: GOA Certification Procedure P008 Section 4.1.1 states, “Production operations – April 15th is the deadline for submitting updated Organic System Plans (OSP) and pay applicable fees to avoid incurring additional late fees. Operations that fail to submit renewal documentation or a signed surrender/withdrawal will be subject to adverse actions applicable to the program.” As of September 2012, twenty-four operations had not submitted updated information or fees to GOA, which is required by the USDA organic regulations under § 205.406(a). At the time of the onsite assessment, GOA had not taken any adverse actions against these operators.

Corrective Action: On September 18, 2012, GOA sent late application/reminder notices to the twenty-four outstanding operations. On October 18, 2012, GOA sent Notices of Noncompliance to the five operations who had not responded to the late application notice. In order to prevent the noncompliance from recurring, GOA updated their Certification Procedure, Section 2.3, to include due dates for annual OSP updates, penalties for late submission, and dates on which adverse actions will commence. GOA also updated their fee schedule to reflect additional fees for late submissions. GOA will send these documents to all their certified operations in January 2012 as part of its certification renewal packet. GOA also wrote about updated OSP and annual fee deadlines, as well as deadlines for adverse actions and late fees, in its October 2012 newsletter to clients. In 2013, GOA will send reminder notices in June, July, and August. Notices of Noncompliance will be sent in late August, and Notices of Proposed Suspension will follow in late September for any operations who have not responded to the reminder notices.

Verification of Corrective Actions: Review of files verified that GOA is handling updates as outlined in the corrective actions.

NP2219NNA.NC4 – Cleared - NOP §205.662 (a)(1) states, “... A written notification of noncompliance shall be sent to the certified operation. Such notification shall provide a description of each noncompliance.”

Comments: A review of seven noncompliance letters that had been issued by GOA showed that GOA was identifying the noncompliance to the client by listing only the NOP citation (i.e. §205.205), without providing a description of the noncompliance or the facts on which the noncompliance was based.

Corrective Action: GOA submitted examples of modified Notices of Noncompliance and Notices of Noncompliance templates, which now include a description of each noncompliance and a citation of the relevant regulatory section(s). GOA discussed the requirements for this information with staff following the on-site assessment and will also address these requirements during its March 2013 annual training.

Verification of Corrective Actions: Noncompliance notifications reviewed found all contained the description of the noncompliance and the facts on which it was based.

Noncompliances Identified during the Current Assessment

NP4168OOA.NC1 – NOP §205.662 (c)(3) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state: The impact of a suspension or revocation on future eligibility for certification.”

Comments: *Notice of Proposed Suspension issued indicated a proposed suspension of 6 months. However, when the suspension was issued the suspension was for one year.*

NP4168OOA.NC2 – NOP §205.405 (a) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant.”

Comments: *In one of the reviewed files, fruit that originated from Chile, certified to the EU regulations, was being included in product being produced as NOP organic. There was no supporting documentation provided that indicated that the fruit was certified to NOP regulations. Certifier failed to identify the noncompliance and issue a Notice of Noncompliance.*

NP4168OOA.NC3 – NOP §205.403 (a)(1) states, “A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that

produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.”

Comments: *One of the six files reviewed was granted certification as “Private Label” without conducting an on-site inspection. Discussions with the CEO and the Certification Director indicated that certificates are being issued for all Private Label reviews without inspections.*

NP416800A.NC4 – NOP §205.404 (b)(3) states, “The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.”

Comments: *Certificates are being issued for “Private Label” which is not one of the categories defined in the USDA National Organic Program regulations.*

NP416800A.NC5 – NOP §205.501 (a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.”

Comments: *Five of the six employed personnel did not have a current conflict of interest disclosure report at the time of the assessment.*

NP416800A.NC6 – NOP §205.501 (a)(10) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in §205.504(b)(5).”

Comments: *Five of the six employed personnel did not have a currently signed Confidentiality Statement. GOA Policy Manual, Section 3.4 states, “Individuals that review and/or evaluate applications/documents for certification or perform on-site inspections, make certification decisions and all parties responsibly connected to GOA must complete a Confidentiality Statement annually.”*

NP416800A.NC7 – NOP §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.”

Comments: *NOP 2027, Personnel Performance Evaluations, require inspectors to be annually evaluated during an onsite inspection by a supervisor or peer (another inspector). Annual field observations of contracted inspectors are not conducted.*

NP416800A.NC8 – NOP §205.404(b)(1) states, “The certifying agent must issue a certificate of organic operation which specifies the... Name and address of the certified operation...” Furthermore, NOP 2603, Organic Certificates, Section 3.2, states that “Certifying agents must identify only one “person” (typically a farm or business as defined in 7 CFR § 205.2) on the organic certificate...”

Comments: *GOA certified operations that are in a contractual selling relationship with a certified buyer, have the name of certified buyer listed on their certificate as well as the certified operation’s name.*

NP416800A.NC9 – NOP – 205.403(c)(1) states, “The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part.”

Comments: *It was observed during the livestock inspection that fields used for pasturing the animals had no shade structures or trees that could provide shade. The operator indicated that animals were allowed access to the barn; however, this seems unlikely for the majority of the fields since the distance was too large for the cows to move back and forth to the barn. The inspector did not note this as a concern and GOA did not identify this as a noncompliance.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

SEP 30 2014

Betty Kananen
Global Organic Alliance, Inc. (GOA)
3185 Township Road 179
Bellefontaine, OH 43311-0530

Dear Ms. Kananen:

On June 17 & 19, July 9 and August 4-6, 2014, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Global Organic Alliance, Inc. (GOA) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On September 22, 2014 the NOP reviewed the results of the onsite audit to determine GOA's compliance to the USDA organic regulations. A copy of the assessment report, NP4168OOA, is enclosed for your reference.

As the report indicates six (6) corrective actions for prior noncompliances (AIA13339BJR.NC1-.NC2 and NP2219NNA.NC1-.NC4), were cleared and determined to be implemented and effective. No noncompliances remain outstanding from your previous audit. Nine (9) new noncompliances (NP4168OOA.NC1 through .NC9), were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice, indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the GOA management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Lars Crail, at (202) 205-5536 or Lars.Crail@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a renewal assessment of IBD Certification's (IBD). An onsite audit was conducted, and the audit report reviewed to determine IBD's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	IBD Certifications, Ltd.
Physical Address	Rua Amando de Barros 2275 – Centro, Botucatu, Sao Paulo, Brazil
Mailing Address	Rua Amando de Barros 2275 – Centro, Botucatu, Sao Paulo, Brazil
Contact & Title	Gwendal Bellocq, General Manager
E-mail Address	gwendal@ibd.com.br
Phone Number	55 (14) 3811-9800
Reviewer(s) & Auditor(s)	Graham Davis, NOP Reviewer; Penny Zuck and Miguel Caeres, Onsite Auditor(s).
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective actions review: July 31, 2017 NOP assessment review: June 13, 2017 Onsite audit: April 4-12, 2017
Audit Identifier	NP7093MMA
Action Required	None
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of [ACA acronym]'s certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	IBD's certification services in carrying out the audit criteria during the period:

NOP conducted an accreditation renewal onsite audit April 4-12, 2017.

IBD Certifications Ltd (IBD) is a limited liability company that was accredited on July 11, 2002, to the following scopes: crops, wild crops, livestock, and handling/processing. IBD certifies 243 operations: 116 crops, 17 wild crops, 22 livestock (only apiculture), and 143 handling. There are 17 grower groups. The majority of the USDA organic certified operations are located in Brazil, but there are certified operations in China. IBD certifies 21 trader/export operations.

IBD is accredited to provide certification to multiple organic certification schemes.

The IBD certification program staff includes an Executive Director, a Quality Manager, five Certification Managers, an Input Approval Program Manager, six Technical Reviewers, and two administrative staff. There are 41 subcontracted inspectors (21 in Brazil and 20 in China).

The onsite audit included one witness audit of a processor/handler located in Cordeiropolis, Sao Paulo, Brazil, and one witness audit of a grower group located in Parnaiba, Piaui, Brazil.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether IBD's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Noncompliances from Prior Assessments

Any noncompliance labeled as "**Cleared,**" indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP6308RKA.NC1 – Cleared.
NP5053RKA.NC1 – Cleared.
NP5053RKA.NC2 – Cleared.
NP5053RKA.NC3 – Cleared.
NP5053RKA.NC4 – Cleared.
NP5053RKA.NC5 – Cleared.

NP5053RKA.NC6 – Cleared. 7 CFR § 205.501(a)(21) states, "Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary."

Comments: *IBD did not conduct field evaluations for all inspectors in 2014.*

Corrective Action: IBD's previous guidance on field evaluations was realigned to understand annual field evaluations are to be completed for all inspectors. The IBD Quality Manager, is responsible for completing annual field evaluations and scheduled the evaluations in the Quality Department annual calendar. IBD has completed 13 annual field evaluations (60%) and scheduling the remaining 9 field evaluations of remote inspectors prior to December 31, 2015. This policy is supported by IBD's current Performance Evaluation Procedure, which correctly outlines the frequency, proper evaluation documentation, responsible persons.

2017 Verification of Corrective Action: Auditor reviewed documentation of field evaluations of inspectors during 2015. A field assessment of one inspector in northern Brazil was scheduled, but did not occur and the majority of inspectors in China were not evaluated. Field evaluations were

scheduled for all inspectors in 2016; however, one inspector was not evaluated. The evaluation is scheduled for next week.

2017 Corrective Action: IBD submitted alternative procedure to conduct NOP field evaluations for each inspector. Inspector's performance is evaluated for each audit by filling in the applicable fields of the audit performance evaluation in IBD's electronic system. Inspectors of the USDA NOP certification scheme who had a general performance (audit performance evaluation) below 70% must be evaluated at least once annually. Those who had a performance between 70% and 90% must be evaluated at least once every two years. IBD will implement a routine procedure (by July 2017) to monitor the shadow audit schedule at least every two months to ensure that field evaluations are being conducted on schedule. IBD has created a calendar reminder (two months prior to the field evaluation) that will appear in the Service Manager' Outlook calendar.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as “**Accepted**,” indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP7093MMA.NC1 – Accepted. 7 CFR §205.660(d) states, “Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.”

Comments: *Notifications are being sent to operations via email but do not include return receipt for confirmation of delivery.*

2017 Corrective Action: IBD has implemented an email delivery receipt confirmation system. IBD has revised and submitted their Certification Procedure to require staff so use the new system and save the delivery receipt confirmation with the email. In July of 2017, IBD conducted staff training regarding the procedure update and an activity on IBD's electronic system workflow to ensure that the confirmation of delivery is saved in IBD electronic database together with the corresponding notice. IBD submitted evidence that their staff has implemented the delivery confirmation system and that delivery confirmation receipts are being saved in IBD electronic system together with the corresponding notice.

NP7093MMA.NC2 – Accepted. 7 CFR §205.403(a)(2)(ii) states, “The Administrator...may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.” NOP 2609 section 4.1.9 states, “An unannounced inspection should not include prior notification of the inspector's arrival. However, there may be special cases where extenuating circumstances make it impossible to conduct an unannounced inspection of the operation without prior notification (e.g. biosecurity issues). In such cases, the certifying agent may notify the operation up to four (4) hours prior to the inspector arriving on-site to ensure that appropriate representatives are present.

Comments: *IBD's unannounced inspection procedure indicates the inspector can notify the operation 48 hours in advance.*

2017 Corrective Action: IBD revised and submitted their certification procedure to clarify that unannounced inspections cannot be announced to the client in any way, specifically excluding the possibility to inform the client until 48 hours before the inspection. IBD communicated the change in their certification procedure to the inspector's team, through a circulated letter (July 2017), and by online training. IBD plans reiterate NOP requirements for unannounced inspections during their next annual training for their inspection staff (October 2017).

NP7093MMA.NC3 – Accepted. 7 CFR § 205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart; Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” The NOP website provides instructions and the terms of international trade arrangements.

US – Canada Equivalency Arrangement: Labeling requirements. For retail products, labels or stickers must state the name of the U.S. or Canadian certifying agent and may use the USDA Organic seal or the Canada Organic Biologique logo. All product labels must be in English and French. Wholesale products only require lot numbers.

Comments: *IBD is not reviewing labels for products being exported to Canada under the US-Canada Equivalency Arrangement.*

2017 Corrective Action: IBD submitted a list of clients who exports to Canada and the results of their label reviews. IBD verified that the labels of the operations listed are compliant with the requirements of US-Canada Equivalence. IBD revised and submitted their transaction certificates issuance procedure to include the verification of exported products to Canada and that the products meet the labeling requirements of the equivalence agreement. In April and July of 2017, IBD provided training to their staff involved in the review of labels and transaction certificates procedure in order to review the requirements of product labels exported to Canada under the US-Canada Equivalency Arrangement.

NP7093MMA.NC4 – Accepted. 7 C.F.R. §205. 402(a)(2) states, “Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;...” §205.206(e) states that an Organic System Plan must include, “Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.”

Comments: *IBD did not assess the input material restriction (i.e. annotations) for compliance (when applicable) during a material input review of a nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”*

2017 Corrective Action: IBD obtained confirmation from the operation regarding the compliance of the material in question (citric acid). The operation confirmed that the citric acid in question is produced according to the restriction (produced by microbial fermentation of carbohydrate substances) required in NOP 205.605(a). In July of 2017, IBD provided training to their staff regarding this NOP 205.605(a). In July of 2017, IBD also provided training that included instruction regarding NOP requirements for input material restrictions. IBD circulated a letter (July 2017) to inform their staff that they need to check all restrictions applicable to inputs.

IBD plans to reinforce the NOP requirements regarding restrictions for input materials during their next annual training (October 2017) of their certification staff.

NP7093MMA.NC5 – Accepted. 7 CFR §205.402(a)(2) states, “Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;...” §205.201(a)(2) states that an Organic System Plan must include, “A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used.”

Comments: *The Organic System Plan for a grower group operation did not include a list of all inputs and materials allowed for use by the members. One member producer asked the IBD inspector during the inspection how to obtain an input approved. The IBD manager confirmed that IBD does not require the grower group to maintain a list of inputs.*

2017 Corrective Action: IBD revised and submitted their grower group report template to include the verification of all approved inputs and materials used by group members. In July of 2017, IBD provided training to their staff regarding this requirement of grower groups. A staff training was held on July 13, 2017 that included instructions regarding NOP grower group requirements. A letter (July 2017) was sent to all of IBD’s inspectors about update of the group inspection reports templates. IBD will provide additional training to reinforcement NOP requirements during the inspector’s annual training (October 2017).

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received IBD Certification's (IBD) accreditation renewal application to maintain U.S. Department of Agriculture (USDA) organic certifier accreditation on January 9, 2017. The NOP reviewed the application, conducted an onsite audit, and reviewed the audit report to determine IBD's capability to operate as a USDA accredited certifier.

ASSESSMENT INFORMATION

National Organic Program Assessment Review	
Reviewer	Graham Davis, NOP Reviewer(s)
Review Date	June 13, 2017
Action Required	Yes
National Organic Program Accreditation Assessment	
Assessment Date	April 4-7, 2017 and April 10-12, 2017 (Witness audit)
Assessment Identifier	NP7093MMA
Assessment Activity (select one)	<input type="checkbox"/> Documentation Adequacy Review <input type="checkbox"/> Pre-decisional Assessment <input type="checkbox"/> Initial Assessment <input type="checkbox"/> Mid-Term Assessment <input checked="" type="checkbox"/> Renewal Assessment <input type="checkbox"/> Compliance Assessment <input type="checkbox"/> Other
General Information	
Applicant Name	IBD Certifications, Ltd.
Physical Address	Rua Amando de Barros 2275 – Centro, Botucatu, Sao Paulo, Brazil
Mailing Address	Rua Amando de Barros 2275 – Centro, Botucatu, Sao Paulo, Brazil
Contact & Title	Gwendal Bellocq, General Manager
E-mail Address	gwendal@ibd.com.br
Phone Number	55 (14) 3811-9800
Assessment Team	
Lead Auditor	Penny Zuck
Second Auditor	Miguel Caceres
Other (Identify Role)	N/A
Program	USDA National Organic Program (NOP)
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the

	implementation and effectiveness of IBD’s certification
Audit & Review Scope	IBD’s certification services in carrying out the audit criteria during the period: March 1, 2015 through April 12, 2017.

NOP conducted an accreditation renewal onsite audit April 4-12, 2017.

IBD Certifications Ltd (IBD) is a limited liability company that was accredited on July 11, 2002, to the following scopes: crops, wild crops, livestock, and handling/processing. IBD certifies 243 operations: 116 crops, 17 wild crops, 22 livestock (only apiculture), and 143 handling. There are 17 grower groups. The majority of the USDA organic certified operations are located in Brazil, but there are certified operations in China. IBD certifies 21 trader/export operations.

IBD is accredited to provide certification to multiple organic certification schemes.

The IBD certification program staff includes an Executive Director, a Quality Manager, five Certification Managers, an Input Approval Program Manager, six Technical Reviewers, and two administrative staff. There are 41 subcontracted inspectors (21 in Brazil and 20 in China).

The onsite audit included one witness audit of a processor/handler located in Cordeiropolis, Sao Paulo, Brazil, and one witness audit of a grower group located in Parnaiba, Piaui, Brazil.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether IBD’s corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to IBD.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP6308RKA.NC1 – Cleared. 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: ... Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2603, *Organic Certificates*, section 3.1, Elements of the Organic Certificate, states that “Organic certificates should be issued in English and include the following: ... Effective date (when the current or initial certifying agent first certified the operation to the USDA organic regulations); ... Anniversary date (when the certified operation must submit its annual update). Organic certificates cannot include expiration dates.”

Comments: *The certificate issued to the operation does not indicate a complete “effective date” and “anniversary date.” The month and year are reported for those dates without the specific day.*

2017 Corrective Action: Since January 10, 2017, IBD began issuing certificates with effective and anniversary dates including the day, month and year. All certificates will be updated with the correct date format during the 2017 certification cycle. IBD trained its staff on the new work instruction regarding the change in date format on organic certificates. IBD submitted its training log and an example of an updated certificate.

2017 Verification of Corrective Action: Auditor reviewed current certificates for each certification scope. All required information was included in the certificates. Training records reviewed including a log of attendees was verified. No issued noted.

NP5053RKA.NC1 – Cleared. 7 CFR § 205.404(b) states, “The certifying agent must issue a certificate of organic operation” and NOP 2603 further describes the elements of the organic certificate such as the anniversary date.

Comments: *Certificates reviewed during the assessment currently indicate the effective date (date of initial certification) and the date of last update (date last issued from the certifier). The anniversary date (when the OSP is due) is missing from the certificates.*

Corrective Action: On March 9, 2015, IBD corrected the “NOP certificate template” to include an anniversary date. IBD identified and reissued 74 certified operations a corrected NOP Organic Certificate. IBD conducted and documented the staff training on March 11, 2015, covering the new NOP certificate template.

2017 Verification of Corrective Action: Auditor reviewed current certificates for each certification scope. All required information was included in the certificates. Training records reviewed including a log of attendees was verified. No issued noted.

NP5053RKA.NC2 – Cleared. 7 CFR § 205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;” Furthermore, NOP 4009 describes the types of operations that need to be certified.

Comments: *Based upon interviews with IBD staff and the review of a coffee roaster, considered by IBD to be a “service provider,” the certifier is allowing the distributor’s certification to include the organic coffee processing/packaging performed by the uncertified service provider or co-packer. IBD conducts a full annual inspection at the service provider’s facilities but it is not independently certified.*

Corrective Action: IBD has identified 22 subcontracting operations in need of individual certification. IBD is receiving and reviewing all certification documents from the subcontractors prior to inspection and NOP certification. Currently, IBD has not completed certification of all identified operations and estimates completing the remaining certifications in 60 days. IBD reviewed this noncompliance and policy corrections with staff in a training conducted and documented on March 11, 2015.

2017 Verification of Corrective Action: Auditor reviewed two files that were previously certified with “contracted operations” under one certification. Each operation has been individually certified. Training records for the training that took place on this topic and the log of attendees were verified.

NP5053RKA.NC3 – Cleared. 7 CFR § 205.670(d) states, “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.

Comments: *When samples are collected for routine analysis as part of the 5% requirement, the clients are charged for the testing of the sample. Clients are not charged for samples collected for an investigation conducted by IBD or during an unannounced inspection.*

Corrective Action: IBD amended its certification proposal template to state operations certified exclusively to the NOP standard will not be charged laboratory analysis fees. The staff training of the template changes occurred on August 26, 2015. Template changes were also distributed via email on August 26, 2015.

2017 Verification of Corrective Action: Auditor reviewed a recent fee estimate proposal that was sent to an operation and it clearly stated that the operator would not be charged for NOP residue sample collection and testing.

NP5053RKA.NC4 – Cleared. 7 CFR § 205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: *Below are two examples identified during the onsite audit that demonstrates errors in the application of USDA organic regulations and policy to the requirements of Organic System Plans (OSPs):*

- *A review of the certifier’s OSP template identified that the OSP does not address the self-monitoring compliance activities described in 205.201(a)(3), “A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented.” The current IBD OSP template does not include the requirement that the operation conducts and documents an internal review of its own organic program.*
- *A review of the certifier’s grower group OSP templates (other than for beekeeping operations) identified that it does not contain the requirement to provide sufficient maps of the collective group locations. 205.201(a) states “The producer or handler of a production or handling operation... must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling.” NOSB 2002 recommendation requires that “a list of information that the certifying agent must provide to the inspector prior to the inspection” include a, “General map of indicating the general region of each production zone,” and, “A more detailed map indicating the location of each of the communities to be inspected.” The current IBD OSP template does not require grower groups to submit general maps that identify all grower group sub-unit locations.*

Corrective Actions: IBD submitted seven amended OSP templates for review. The submitted templates ask the applicant to describe the operation’s internal audit procedures and provide a

map/sketch of the operation. On August 26, 2015, IBD documented staff training on the descriptions of audit procedures and site maps included in the new versions of the OSP templates. IBD also distributed the new OSP templates to inspectors via email on August 26, 2015.

2017 Verification of Corrective Action: Auditor reviewed operator files and verified the following internal audit section was added to the organic system plan and inspection checklist. Auditor reviewed a beekeeping grower group organic system plan and it included a section with a map of the GPS coordinates for all apiary locations. A map was also included for each bee keeper showing apiary locations specific to their operation.

NP5053RKA.NC5 – Cleared. 7 CFR 205.403(e)(2) states, “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.”

Comments: *According to IBD Quality Manual 12.6 Certification Decision, the inspection report is to be sent to the operation once the certification staff reviews the report. The inspection report from a December 2014 sugar mill unannounced inspection was not provided to the operation.*

Corrective Action: IBD sent a copy of the missing inspection report to the operation on March 6, 2015. IBD changed the certification procedure to make the IBD staff (inspection report reviewer) responsible for providing the inspection report to the applicant after reviewing the report. IBD has included an additional page to the inspection report template where the reviewer is to record the certification decision. On August 22, 2015, IBD emailed the new certification procedure to auditors and templates to auditors. On August 26, 2015, IBD trained staff on the new certification procedures and the new templates used to capture certification decision information.

2017 Verification of Corrective Action: Auditor confirmed that inspection reports are sent to the operators together with the certification decision notification.

NP5053RKA.NC6 – Outstanding. 7 CFR § 205.501(a)(21) states, “Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.”

Comments: *IBD did not conduct field evaluations for all inspectors in 2014.*

Corrective Action: IBD’s previous guidance on field evaluations was realigned to understand annual field evaluations are to be completed for all inspectors. The IBD Quality Manager, is responsible for completing annual field evaluations and scheduled the evaluations in the Quality Department annual calendar. IBD has completed 13 annual field evaluations (60%) and scheduling the remaining 9 field evaluations of remote inspectors prior to December 31, 2015. This policy is supported by IBD’s current Performance Evaluation Procedure, which correctly outlines the frequency, proper evaluation documentation, responsible persons.

2017 Verification of Corrective Action: Auditor reviewed documentation of field evaluations of inspectors during 2015. A field assessment of one inspector in northern Brazil was scheduled, but did not occur and the majority of inspectors in China were not evaluated. Field evaluations were scheduled for all inspectors in 2016; however, one inspector was not evaluated. The evaluation is scheduled for next week.

Noncompliances Identified during the Current Assessment

NP7093MMA.NC1 – 7 CFR §205.660(d) states, “Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.”

Comments: *Notifications are being sent to operations via email but do not include return receipt for confirmation of delivery.*

NP7093MMA.NC2 – 7 CFR §205.403(a)(2)(ii) states, “The Administrator...may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part.” NOP 2609 section 4.1.9 states, “An unannounced inspection should not include prior notification of the inspector’s arrival. However, there may be special cases where extenuating circumstances make it impossible to conduct an unannounced inspection of the operation without prior notification (e.g. biosecurity issues). In such cases, the certifying agent may notify the operation up to four (4) hours prior to the inspector arriving on-site to ensure that appropriate representatives are present.

Comments: *IBD’s unannounced inspection procedure indicates the inspector can notify the operation 48 hours in advance.*

NP7093MMA.NC3 – 7 CFR § 205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart; Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” The NOP website provides instructions and the terms of international trade arrangements. US – Canada Equivalency Arrangement: Labeling requirements. For retail products, labels or stickers must state the name of the U.S. or Canadian certifying agent and may use the USDA Organic seal or the Canada Organic Biologique logo. All product labels must be in English and French. Wholesale products only require lot numbers.

Comments: *IBD is not reviewing labels for products being exported to Canada under the US-Canada Equivalency Arrangement.*

NP7093MMA.NC4 - 7 C.F.R. §205. 402(a)(2) states, “Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;...” §205.206(e) states that an Organic System Plan must include, “Additional information deemed necessary by the certifying agent to evaluate compliance with the regulations.”

Comments: *IBD did not assess the input material restriction (i.e. annotations) for compliance (when applicable) during a material input review of a nonagricultural (nonorganic) substance allowed as an ingredient in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”*

NP7093MMA.NC5 - 7 CFR §205.402(a)(2) states, “Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;...” §205.201(a)(2) states that an Organic System Plan

must include, “A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used.”

Comments: *The Organic System Plan for a grower group operation did not include a list of all inputs and materials allowed for use by the members. One member producer asked the IBD inspector during the inspection how to obtain an input approved. The IBD manager confirmed that IBD does not require the grower group to maintain a list of inputs.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

JUN 14 2017

NOTICE OF NONCOMPLIANCE

Gwendal Belloq
IBD Certifications
Rua Amando de Barros, 2275 – Centro
Botucatu, Sao Paulo
18602-150
Brazil

Dear Mr. Belloq:

On April 4-12, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the IBD Certifications' (IBD) organic certification program as part of its USDA Renewal Accreditation Assessment. On June 13, 2017, the NOP reviewed the results of the onsite audit to determine IBD's compliance to the USDA organic regulations. A copy of the assessment report, NP7093MMA, is enclosed for your reference.

As the report indicates, one noncompliance, [NP5053RKA.NC6], remains outstanding from a previous audit. Five new noncompliances [NP7093MMA.NC1-NC5], were identified during the onsite audit. Please submit corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All corrective actions must indicate how the noncompliances will be corrected and how the IBD management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of IBD's USDA accreditation.

If you have questions regarding this notice, please contact, Graham Davis, Accreditation Manager, at Graham.Daivs@ams.usda.gov or (202) 692-0047.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney". The signature is written in a cursive, flowing style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report NP7093MMA

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The U.S. Department of Agriculture, Agricultural Marketing Service, National Organic Program (NOP) conducted an onsite mid-term accreditation assessment of the Iowa Department of Agriculture & Land Stewardship (IDALS) from June 23-27, 2014 in Des Moines, Iowa. The NOP reviewed the auditor's report on July 11, 2014 to determine IDALS' capability to operate as an USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Iowa Department of Agriculture & Land Stewardship (IDALS)
Physical Address	502 East 9th Street, Des Moines, IA 50319
Mailing Address	SAME
Contact & Title	Maury Wills, Program Director
E-mail Address	Maury.Wills@idals.state.us
Phone Number	515-281-5783
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer; Patricia Heckart and Alan Kohles, Onsite Auditors.
Program	USDA National Organic Program (NOP)
Audit & Review Date(s)	July 11, 2014: Noncompliances identified. August 20, 2014: Corrective Actions reviewed
Audit Identifier	NP4174NNA
Action Required	No
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of IDALS's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	IDALS's certification services in carrying out the audit criteria during the period: June 2011 – June 2014

Organizational Structure

IDALS is established under Iowa code chapter 159. It is established as the certification body pursuant to Iowa code Sections 190C.4.2. and 190C 13.1. The Agricultural Diversification and Market Development Bureau of IDALS is responsible for the administration of the Organic Certification Program.

IDALS is currently approved as a certifying agent to the USDA National Organic Program (NOP) for the scopes of crops, livestock, and handling/processing. IDALS currently has 348 clients certified to the NOP standard: 313 for crops, 53 for livestock, and 50 for handling.

IDALS certifies clients to the NOP in the United States with certified clients located in Iowa, Kansas, Minnesota, Missouri, Nebraska, South Dakota, and Wisconsin. IDALS does not currently certify any grower groups. All certification activities are conducted out of the main office in Des Moines, IA.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether IDAL's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP9201EEA.NC1 – Cleared

NP1164NNA.NC1 – Cleared

AIA4083BJR.NC1 – Cleared

AIA4083BJR.NC2 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4174NNA.NC1 – Accepted - 7 CFR §205.403 (c)(1-2) states, "The on-site inspection of an operation must verify: (1) the operation's compliance or capability to comply with the Act and the regulations in this part; (2) that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation." *Review of retail products available during the review audit found that the operation was using labels that had not been submitted or approved by the ACA and were not included in the OSP. The inspector had not reviewed the labels during the previous inspection. The labels in use were incorrect. There was no "Certified organic by" statement on the labels per §205.303 (b)(2). The operation had submitted a label for the popcorn, which was approved, however, this was not in use nor had its use been verified during an inspection. In addition, the farmer indicated that hay bales were ground by a service that brought equipment in to grind the hay bales on a custom basis. This was not described in the OSP nor did the inspector note this during the previous inspection.*

Corrective Action:

1. Label Review: IDALS conducted a follow-up witness inspection of the contract inspector. The contract inspector failed to review the farm's IDALS-approved labels, and neglected to report that the farm was not using the labels. The IDALS File Reviewer

contacted the farm to inform them that they needed to submit popcorn seed and egg labels for approval. The labels have since been submitted, reviewed and approved. Until more complete training can be provided at the winter training meeting, IDALS met with the inspector to review this aspect of the inspection process in an effort to increase his awareness to review labels used on farm products. IDALS also witnessed an on-farm inspection conducted by this inspector to ensure that he is conducting inspections appropriately. Additional training will be provided to all inspectors during an annual winter training meeting regarding the labeling of farm products for direct sales to consumers.

2. Service not included in OSP: IDALS conducted a follow-up witness inspection of the contract inspector. The inspector failed to report custom hay grinding service that was missing from the operation's OSP. The inspector also neglected to report this to IDALS. The operation has since updated their OSP to include sufficient information related to the custom service. IDALS met with inspector to discuss and emphasize the need to go over details of the OSP and view all aspects of farm practices in an effort to gain a more complete understanding of the farming operation. Additional training will be provided to all inspectors during their annual winter training meeting regarding the verification of any custom services provided to the operation.

NP4174NNA.NC2 – Accepted - 7CFR §205.403 (e)(1) states, “At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector.” *IDALS personnel collected samples for testing during 2013. A form was completed in each case that indicated what was collected, where and by whom. This form was signed by the operator. However, no receipt was left with the operators for the samples taken.*

Corrective Action: IDALS has made their Sampling Form in triplicate. Inspectors will leave a copy of the completed form with the operator as a receipt of the sample taken. Use of the new form began on July 22, 2014.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Maury Wills
Program Director, Organic Certification Program
Iowa Department of Agriculture & Land Stewardship (IDALS)
502 East 9th Street
Des Moines, IA 50319

Dear Mr. Wills:

On June 27, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a mid-term assessment of the Iowa Department of Agriculture & Land Stewardship's (IDALS) organic certification program. The objective of the assessment was to determine IDALS' compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4174NNA, is enclosed for your reference.

As the report indicates, two noncompliances, NP4174NNA.NC1 and NP4174NNA.NC2, were identified during the assessment. Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days of the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the IDALS' management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Betsy Rakola, at (202) 260-8209 or Betsy.Rakola@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

JUL 18 2014

Maury Wills
Program Director, Organic Certification Program
Iowa Department of Agriculture & Land Stewardship (IDALS)
502 East 9th Street
Des Moines, IA 50319

Dear Mr. Wills:

On June 27, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a mid-term assessment of the Iowa Department of Agriculture & Land Stewardship's (IDALS) organic certification program. The objective of the assessment was to determine IDALS' compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4174NNA, is enclosed for your reference.

As the report indicates, two noncompliances, NP4174NNA.NC1 and NP4174NNA.NC2, were identified during the assessment. Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days of the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the IDALS' management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Betsy Rakola, at (202) 260-8209 or Betsy.Rakola@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

MAR 28 2014

Maury Wills
Bureau Chief, Agricultural Diversification & Market Development
Iowa Department of Agriculture and Land Stewardship
502 East 9th St.
Des Moines, IA 50319
maury.wills@iowaagriculture.gov

Dear Mr. Wills:

On March 6, 2014, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) received the Iowa Department of Agriculture and Land Stewardship's (IDALS) review of AI+ Clear, a poultry litter treatment. IDALS approved this substance in 2005 and had not reviewed the formulation since. After IDALS reviewed the product in December 2013, you determined that the product contains prohibited substances and will no longer be allowed in organic production.

We have determined that the IDALS approval of AI+ Clear was noncompliant, as explained below.

AIA4083BJR.NC1: §205.403 (c)(3) states, "*The on-site inspection of an operation must verify that prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.* IDALS did not re-review the formulation of this product until 8 years after its initial approval. This indicates a systemic flaw in IDALS' materials evaluation program, as there was no procedure in place to ensure that materials continued to comply with the USDA organic regulations, such as a periodic evaluation of the product and its ingredients.

AIA4083BJR.NC2: §205.501 (a)(2) states, "*A private or governmental entity accredited as a certifying agent under this subpart must demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.*" In response to an NOP inquiry regarding the approval of AI+ Clear, IDALS sent a letter to all of its certified crop and livestock operations stating that the product was no longer allowed. The letter instructed operations to maintain records of any product applications and attached a form to verify that any sources of off-farm manure comply with the regulations.

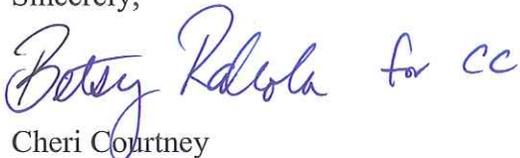
However, IDALS did not demonstrate the ability or the intention to verify that all of its certified operations have ceased using AI+ Clear. There was no plan for reviewing

organic system plans or conducting surveillance activities to ensure that the use of prohibited substances on certified organic land and livestock facilities has ceased.

Please submit proposed corrective actions to AIAInbox@ams.usda.gov within 30 days from the date of receipt of this letter, indicating how this noncompliance will be corrected. IDALS must propose and implement measures that will correct this action. The proposed corrective actions must also indicate how the IDALS management system will be modified to prevent a future noncompliance. Please refer to [NOP 2608](#), Responding to Noncompliances, for further instruction. Failure to promptly resolve this noncompliance may result in proposed adverse actions against IDALS as an accredited certifying agent for the USDA.

If you have questions regarding this notice, please contact your Accreditation Manager, Betsy Rakola, at Betsy.Rakola@ams.usda.gov or (202) 260-8209.

Sincerely,

A handwritten signature in blue ink that reads "Betsy Rakola for cc". The signature is written in a cursive style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: NOP Appeals
USDA Quality Assessment Division

Applicant Name:	Iowa Department of Agriculture and Land Stewardship (IDALS)
Physical Address:	502 East 9 th St., Des Moines, IA 50319
Mailing Address:	Same
Contact & Title:	Maury Wills, Organic Program Manager
E-mail Address:	maury.wills@iowaagriculture.gov
Phone Number:	(515) 281-5783
Auditor(s):	Meg Kuhn, Agricultural Marketing Specialist
Program:	USDA National Organic Program (NOP)
Audit Date(s):	May 2, 15, and 28, 2014
Audit Identifier:	AIA4083BJR
Action Required:	No
Audit Type:	Corrective Action
Audit Objective:	To verify review and approve corrective actions addressing the non-compliances identified during IDALS' review of A1+ Clear poultry litter.
Audit Criteria:	7 CFR Part 205, National Organic Program; as amended.
Audit Scope:	IDALS' April 28, 2014 and May 15 and 16, 2014 response letter and emails, respectively, to the March 28, 2014 Notice of Noncompliance
Location(s) Audited:	Desk

GENERAL INFORMATION

On March 28, 2014, the National Organic Program (NOP) issued a Notice of Noncompliance to Iowa Department of Agriculture and Land Stewardship (IDALS) for two violations to the USDA Organic regulations. See below for noncompliances, as well as IDALS' corrective actions, preventive actions, and objective evidence responses dated April 28 and May 15, 2014.

AUDIT INFORMATION

Two (2) noncompliances were cited in the March 28, 2014 Notice of Noncompliance. Corrective action responses for the noncompliances were reviewed during this desk assessment. Two of the corrective actions were accepted. Accepted responses will be reviewed and verified at IDALS' next on-site assessment, scheduled for June 2014 (Mid-Term assessment).

FINDINGS

1. **AIA4083BJR.NC1 – Accepted** – §205.403 (c)(3) states, *“The on-site inspection of an operation must verify that prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. IDALS did not re-review the formulation of this product until 8 years after its initial approval. This indicates a systemic flaw in*

IDALS' materials evaluation program, as there was no procedure in place to ensure that materials continued to comply with the USDA organic regulations, such as a periodic evaluation of the product and its ingredients.

Corrective Action: IDALS' corrective action response indicates that it is implementing a Material Review Team, comprised of existing reviewer staff, that will meet weekly or biweekly to make decisions about the compliance of materials in use at certified operations. Materials will be reviewed every three years; those that have not been reevaluated for at least three years will be listed as "inactive" in the IDALS material database. Inactive products cannot be used without being reevaluated. The IDALS material database can identify materials in use and operations using them; if listed as "inactive" IDALS will notify the operations in writing that the material is inactive and must be reevaluated before use. At that time, operations must send labels and material information to IDALS for review; if the MRT approves it, the material is logged as such in the database. Clients using an inactive product 45 days after inactive status is assigned will receive a Notice of Noncompliance. IDALS indicates the MRT will review materials on its own, as well as use resources such as OMRI, WSDA, and the PCO materials lists. Though IDALS has conceptualized this plan for a MRT, it has not finalized its policies or procedures and does not expect it to be fully implemented until June 30, 2014.

2. **AIA4083BJR.NC2 – Accepted** – §205. 501 (a)(2) states, "*A private or governmental entity accredited as a certifying agent under this subpart must demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.*" In response to an NOP inquiry regarding the approval of A1+ Clear, IDALS sent a letter to all of its certified crop and livestock operations stating that the product was no longer allowed. The letter instructed operations to maintain records of any product applications and attached a form to verify that any sources of off-farm manure comply with the regulations. However, IDALS did not demonstrate the ability or the intention to verify that all of its certified operations have ceased using A1+ Clear. There was no plan for reviewing organic system plans or conducting surveillance activities to ensure that the use of prohibited substances on certified organic land and livestock facilities has ceased. **Corrective Action:** IDALS responded with similar information that was received prior to issuing the Notice of Noncompliance; specifically, that IDALS' team verified A1+ Clear was prohibited on January 16, 2014 and notified affected operations on January 24, 2014. It also indicated it has revised its Off-farm Manure Verification from to more adequately ascertain whether a prohibited substance had been added to the manure intended for use. IDALS' response also states that it would, "review client OSPs for intended use of this product and our inspectors have been instructed to verify that this product is not being used." In the May 16, 2014 response email, IDALS indicated the OSP review of client materials has already begun, as of January 2014 when new and renewal OSPs arrived at the office. IDALS also indicated that its materials database is linked to certified operations using specific materials and, as such, IDALS was able to identify two producers that were using the A1+ Clear product – one was a conventional poultry producer that was also certified for crops with IDALS; another was a certified organic poultry producer, though the A1+ Clear product was not used on any of the operation's organic fields. Both operators have been notified through the client-wide letter sent

January 24, 2014, as well as through phone and email communications with IDALS staff and on-site inspectors; objective evidence of communication with clients was attached to the corrective action response. IDALS also provided evidence of training provided to staff and inspectors on March 4, 2014, at which time the specific issue regarding this material was discussed. At this time, it appears as though affected clients have been adequately notified and are no longer using the prohibited material; and all other clients, staff members, and inspectors have been notified of the material's prohibited status as well.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of Iowa Department of Agriculture and Land Stewardship (IDALS) organic program was conducted on July 24, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess IDALS' compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	two
Physical Address	502 East 9 th Street, Des Moines IA 50319
Mailing Address	502 East 9 th Street, Des Moines IA 50319
Contact & Title	Maury Wills, Bureau Chief, Ag. Diversification & Mkt. Dev. Bureau
E-mail Address	Maury.Wills@Iowaagriculture.gov
Phone Number	515-281-5783
Reviewer & Auditor	Rebecca Claypool, NOP Reviewer; Jason Lopez and Lars Crail, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: August 17, 2017 Onsite audit: July 24-28, 2017
Audit Identifier	NP7205JZA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of IDALS's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	IDALS's certification services in carrying out the audit criteria during the period: June 27, 2014 through July 24-28, 2017

The National Organic Program (NOP) conducted an accreditation renewal onsite audit of the Iowa Department of Agriculture and Land Stewardship (IDALS) on July 24-28, 2017.

IDALS is a state agency accredited on April 29, 2002 to the USDA National Organic Program for crops, livestock, handling, and wild crops. The IDALS Organic Certification Program certifies 390 operations to the following certification scopes: crops (330), livestock (53), and handlers (53). IDALS' office is located in Des Moines, Iowa, and provides certification services in the States of Iowa, Wisconsin, Minnesota, South Dakota, Nebraska, Missouri, and Kansas. As of January 2017, IDALS will no longer accept certification applications from outside Iowa.

Certification services are performed by the program director, three organic certification specialists, one administrative personnel, one staff inspector, and contract inspectors.

NOP auditors conducted two witness audits of annual inspections of crops/livestock operation and a handling operation. The two operations produced berries, commodity grains, pasture and hay. The livestock operation was a cow-calf beef cattle operation. The handling operation was a multi-ingredient feed processing facility.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether IDALS corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to IDALS.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared,**” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP4174NNA.NC1 – Cleared - 7 C.F.R. §205.403 (c)(1-2) states, “The on-site inspection of an operation must verify: (1) the operation's compliance or capability to comply with the Act and the regulations in this part; (2) that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.”

Comments: *Review of retail products available during the review audit found that the operation was using labels that had not been submitted or approved by the ACA and were not included in the OSP. The inspector had not reviewed the labels during the previous inspection. The labels in use were incorrect. There was no “Certified organic by” statement on the labels per §205.303 (b)(2). The operation had submitted a label for the popcorn, which was approved, however, this was not in use nor had its use been verified during an inspection. In addition, the farmer indicated that hay bales were ground by a service that brought equipment in to grind the hay bales on a custom basis. This was not described in the OSP nor did the inspector note this during the previous inspection.*

2014 Corrective Action:

1. **Label Review:** IDALS conducted a follow-up witness inspection of the contract inspector. The contract inspector failed to review the farm’s IDALS-approved labels, and neglected to report that the farm was not using the labels. The IDALS File Reviewer contacted the farm to inform them that they needed to submit popcorn seed and egg labels for approval. The labels have since been submitted, reviewed and approved. Until more complete training can be provided at the winter training meeting, IDALS met with the inspector to review this aspect of the inspection process in an effort to increase his awareness to review labels used on farm products. IDALS also witnessed an on-farm inspection conducted by this inspector to ensure that he is conducting inspections appropriately. Additional training will be provided to all

inspectors during an annual winter training meeting regarding the labeling of farm products for direct sales to consumers.

2. Service not included in OSP: IDALS conducted a follow-up witness inspection of the contract inspector. The inspector failed to report custom hay grinding service that was missing from the operation's OSP. The inspector also neglected to report this to IDALS. The operation has since updated their OSP to include sufficient information related to the custom service. IDALS met with inspector to discuss and emphasize the need to go over details of the OSP and view all aspects of farm practices in an effort to gain a more complete understanding of the farming operation. Additional training will be provided to all inspectors during their annual winter training meeting regarding the verification of any custom services provided to the operation.

2017 Verification of Corrective Actions: IDALS inspectors are provided access to the inspected operation's records which include previous inspection reports and the organic system plan (OSP). Auditors witnessed IDALS inspectors verify the approved OSP and make necessary updates onsite. Labels are reviewed and current copies of labels are clearly marked for inspector verification in files.

NP4174NNA.NC2 – Cleared – 7 C.F.R. §205.403 (e)(1) states, “At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector.”

Comments: *IDALS personnel collected samples for testing during 2013. A form was completed in each case that indicated what was collected, where and by whom. This form was signed by the operator. However, no receipt was left with the operators for the samples taken.*

2014 Corrective Action: IDALS has made their Sampling Form in triplicate. Inspectors will leave a copy of the completed form with the operator as a receipt of the sample taken. Use of the new form began on July 22, 2014.

2017 Verification of Corrective Actions: IDALS is using the triplicate sample receipt form. Sample receipts are provided to the operation on site at the time of sampling. The two remaining copies of the receipt are maintained in the operation file. One copy may be provided to the lab if needed.

Noncompliances Identified during the Current Assessment

NP7205JZA.NC1 – 7 C.F.R. §205.406(b) states “Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to §205.403: Except, That, when it is impossible for the certifying agent to conduct the annual on-site inspection following receipt of the certified operation's annual update of information, the certifying agent may allow continuation of certification and issue an updated certificate of organic operation on the basis of the information submitted and the most recent on-site inspection conducted during the previous 12 months: Provided, That, the annual on-site inspection, required pursuant to §205.403, is conducted within the first 6 months following the certified operation's scheduled date of annual update.”

Comments: *IDALS failed to inspect two operations within six months of the operations annual update. Inspections of these operations were conducted seven and eight months after the anniversary date. This resulted in an eleven month cycle to update and verify compliance.*

NP7205JZA.NC2 – 7 C.F.R. §205.504(b)(1) states “A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;”

Comments: *The IDALS quality manual does not have a procedure on mediation activities. Mediation is offered as a method of resolution to a notice of proposed suspension but no further information is available to IDALS personnel on this process or possible results of mediation.*

NP7205JZA.NC3 – 7 C.F.R. §205.662(a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

Comments: *IDALS issued a noncompliance notification for failure of an operation to submit its annual update. The noncompliance notification was issued eight months after the anniversary date and should have been issued shortly after the deadline.*

NP7205JZA.NC4 – 7 C.F.R. §205.662(c) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.”

Comments: *IDALS issued a notification of suspension four months after the proposed suspension effective date. IDALS should have issued the suspension shortly after the deadline to request mediation or file an appeal.*

Audit Resolution Chronology Log

Audit Identifier (if any): NP4258LCA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: IMOswiss AG
Accreditation Manager (who is working on the project): Janna Howley

Date	Activity
10/22/14	Docs submitted to AIA Inbox.
11/07/14	RM assigned to JH.
11/18/14	JH emailed LC w question about finding #3 and how findings were clustered together. LC responded back, and JH and LC decided it would be a good topic for the upcoming AM meeting.
11/20/14	AM meeting: group discussed.
11/21/14	LC sent reconfigured findings to JH (turned one finding into three separate ones).
11/24/14	<ul style="list-style-type: none"> • Renumbered findings based upon LC's revision of audit findings. So Finding 4 is now NC6, Finding 5 is now NC7, etc. • Please note: there is no NP2260AKA.NC9. Note from Julie Hartley's chrono log of 01/30/13: "Deletion of NP2260AKA.NC9, §205.670(d), as this noncompliance no longer applies with the new residue testing regulation of November 9, 2012. The noncompliance was that IMO had not reported results of analyses and tests to the Administrator."
12/03/14	Rcvd edits from RM.
12/04/14	Sent unclear sentence to LC (auditor) with question about how the sentence was intended to be understood. Made edits based upon his response. Updated letter and report and emailed back to RM.
12/8/14	<ul style="list-style-type: none"> • RM approved; emailed to CC for review. • Emailed to CC for review.
12/10/14	Rcvd edits from CC. Questions about some of the phrasing of the NCs and the intent.
12/12/14	<ul style="list-style-type: none"> • Emailed LC (lead auditor on audit) w questions. Rcvd response and edited report based upon his response. • Sent edited report to CC for review. Approved to print hard copies. Gave to CC.
12/15/14	Signed by CC. Sent to MM for review.
12/18/14	MM reviewed. Note from MM on Doc Router: "needs follow up verification of corrections in 2015."
12/19/14	JH emailed letter and report to IMO.
01/30/15	IMO sent CAs to Robert Yang, their AM, and AIA Inbox.
03/19/15	<ul style="list-style-type: none"> • JH sends email to CC and RY; upon reviewing the IMO file, noticed it contained no received CAs or completed CA report. • CC assigns CA report to JH. JH adds to WTL. RY forwards on IMO CAs to JH.
03/27/15	JH begins file review.

Audit Resolution Chronology Log

Audit Identifier (if any): NP4258LCA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: IMOswiss AG
Accreditation Manager (who is working on the project): Janna Howley

Date	Activity
03/30/15	<ul style="list-style-type: none"> • JH emailed Ingrid at IMO because the majority of their corrective actions had deadlines for implementation, and notification to clients, of March 2015. Requested that she confirm whether the deadlines had been met and items implemented. Deadline of 04/06/15. • Rcvd Ingrid out of office message until 04/01/15. Will follow up 04/10/15 since she was out of office for a few days. Set reminder in Outlook.
04/07/15	Rcvd email from Ingrid with additional information regarding JH questions.
04/14/15	<ul style="list-style-type: none"> • Emailed draft report and letter to RM for review. • Rcvd comments back from RM. NC3 needs some clarification.
04/14/15	JH reviewed IMO's submitted CAs and supporting documentation that addressed NC3. Updated the report (saved as new doc to preserve Track Changes). Resubmitted to RM.
04/20/15	RM reviewed and approved docs to go to CC. JH emailed docs to CC for review.
04/21/15	Email from CC with question regarding the sanction catalog mentioned in the CA. "Does the catalog outline the sanctions for NC's?"
04/22/15	JH replied, "I do not have a copy of the sanction catalog, since they are updating it, but my understanding is that, yes, the catalogue outlines the sanctions for various NCs, according to scope. I can contact Ingrid to get a previous version, or we can add a note for it to be reviewed during their next audit."
05/14/15	JH had been out on vacation for 2+ weeks (04/27-05/12); followed up with an email to CC to see if report can go final. Rcvd ok from CC to print docs. Printed and gave to CC.
05/18/15	Rcvd signed letter. Emailed to IMO. Closed in WTL.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of IMOsuisse AG (IMO). An onsite audit was conducted, and the audit report reviewed to determine IMO's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	IMOsuisse AG (IMO)
Physical Address	Weststrasse 51, Weinfelden, CH-8570, Switzerland
Mailing Address	Same
Contact & Title	Ms. Ingrid Hucke, Head of Department Europe/USA/NOP Scheme Manager
E-mail Address	ihu@imo.ch
Phone Number	+41-71-626 0 626
Reviewer & Auditors	Janna Howley, NOP Reviewer Lars Crail, On-site Auditor; Robert Yang, Auditor Trainee
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: April 20, 2015 Onsite audit: September 15-17, 2014
Audit Identifier	NP4258LCA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of IMO's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	IMO's certification services in carrying out the audit criteria during the period: November 2012 through September 2014.

The Institute for Marketecology (IMO) based in Weinfelden, Switzerland was legally spun off the Bio-Foundation in 2013 and embedded into a new independent legal entity as a stock corporation (AG) subject to Swiss law called IMOsuisse AG. The organization's name and legal form were changed, retroactive to January 1, 2013. The IMO main office is located in Weinfelden, Switzerland with a branch office in Germany. Key NOP certification activities are performed in the following IMO offices: Bolivia, Turkey, Chile, and Switzerland. In July 2013, IMO discontinued certification services at the following offices where key activities occurred: China and Brazil.

IMO was initially accredited by the USDA National Organic Program (NOP) on June 7, 2002 for crop, wild crop, livestock, and handling/processing operations. IMO currently has 671 NOP certified operations worldwide which includes 402 crop, 5 livestock, 37 wild crop, and 562 processor/handling operations in 50 countries. IMO certifies 161 grower groups, mainly in Turkey and Latin America.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether IMO's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP9180ACA.NC3 – Cleared
NP2260AKA.NC1 - Cleared
NP2260AKA.NC2 – Withdrawn
NP2260AKA.NC3 – Cleared
NP2260AKA.NC4 – Cleared
NP2260AKA.NC5 – Cleared
NP2260AKA.NC6 – Cleared
NP2260AKA.NC8 – Cleared
NP2260AKA.NC10 – Cleared
NP2260AKA.NC11 – Cleared
NP2260AKA.NC12 – Cleared
NP2260AKA.NC13 – Cleared
AIA091910LMC.NC3 – Cleared

NP2260AKA.NC7 – Accepted. 7 CFR §205.660(d) states, "Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663... and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts."

2012 Comments: *Per interviews with the NOP Program Scheme Deputy Manager, it was found that IMO is not currently meeting this requirement. Notifications are not sent via a delivery service that provides dated return receipts.*

2012 Corrective Action: As a temporary measure until June 2013, IMO used email delivery and read confirmations. Operations were requested to confirm receipt with a return email response. After June 2013, IMO implemented a registered email delivery system via an electronic service provider. IMO's 2013 annual program review will report on the implementation status of the

corrective actions.

2014 Verification of Corrective Action: IMO has not implemented a registered email delivery system via an electronic service provider. IMO continues to use email delivery and read confirmation.

2015 Corrective Action: IMO has selected a system that will allow it to receive dated return receipts via an electronic service provider. IMO provided the NOP with a copy of the electronic service provider service contract, which is scheduled to go into effect in May 2015. All NOP clients will be informed about the changed procedure via client newsletter once the system is in place. As soon as the procedure has been defined in detail the relevant QMH documents will be adapted and all staff members will receive further training on the revised procedure. IMO's internal NOP Annual Program Review will review and verify the use of the service providing Dated Return Receipts. Copies of the *Annex 2 Training confirmation on Audit results* and *Annex 3 DRAFT IMO I 5.2 G-e Internal Procedures NOP* were provided to the NOP for review.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as “**Accepted**,” indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4258LCA.NC1 – Accepted. 7 CFR §205.501(a)(15)(ii) states that a certifying agent must... “Submit to the Administrator a copy of... a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year.”

Comments: On January 2, 2014, IMO failed to submit a complete list of certified operations. The submitted list did not include certified operations located in Switzerland.

Corrective Action: IMO will now complete and submit annual lists of all certified operations. The 2014 annual list of certified operations was provided to the Administrator on January 2, 2015, including all information requested as per *NOP Instruction 2026: Submitting Annual Lists of Certified Operations*. A copy of the *2014 Annual List of Certified Operations* spreadsheet was provided to the NOP for review.

NP4258LCA.NC2 – Accepted. 7 CFR §205.501(a)(21) states that a certifying agent must... “Comply with, implement, and carry out any other terms or conditions determined by the Administrator to be necessary.” Furthermore, §205.403(a)(2)(ii-iii) states “The Administrator... may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and regulations in this part. Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator...”

Comments: IMO indicated that on January 2, 2013, there were 606 certified operations. During 2013, IMO conducted nine unannounced inspections which does not meet NOP's policy (NOP 2609) that a minimum of 31(5% of the total certified operations) unannounced inspections occur.

Corrective Action: For 2015, IMO will perform unannounced inspections of at least 5% of its NOP certified operations. All staff members concerned were updated on this requirement in

January 2015. The fulfillment of this requirement will be verified during IMO's 2015 internal NOP Annual Program Review. Copies of the *Annex 2 Training confirmation on Audit results*; *Annex 3 DRAFT IMO I 5.2 G-e Internal Procedures NOP*; *Annex 5 Template NOP Annual Program Review* were provided to the NOP for review.

NP4258LCA.NC3 – Accepted. 7 CFR §205.501(a)(3) states that a certifying agent must...
“Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and 205.670.”

Comments: *Below are several occurrences of noncompliant labeling and material issues where IMO certification staff granted approvals and inspectors did not identify noncompliances, during review or verification activities:*

- §205.304(a)(1)(ii) states that retail package labeling may indicate, “Made with organic (specified ingredients or specified food groups)”: provided, that the statement does not list more than three “organically produced ingredients; or, food groups.” **Comments:** *IMO approved a “Made with organic” retail label that did not specify ingredients or food groups; instead a percentage of organic content was indicated.*
- §205.304(b)(2) states that agricultural products in packages described in §205.301(c) must: “On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by ***,” or similar phrase, identify the name of the certifying agent...” **Comments:** *IMO approved a retail product label where the “Certified Organic by” statement was not below the name of the manufacturer or distributor.*
- §205.270(c)(2) states that a handling operation must not use in or on agricultural products intended to be sold as organic, “A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605...” **Comments:** *The salt ingredient in a “Made with organic...” product contained the anti-caking agent Sodium Ferronitrile, a prohibited material that is not listed on §205.605.*
- §205.301(b) states that “A raw or processed agricultural product sold, labeled, or represented as “organic” must contain...not less than 95 percent organically produced raw or processed agricultural products.” Furthermore, NOP 4012, Use of Brand or Company Names containing the word “Organic,” provides specific NOP policy on this topic. **Comments:** *IMO has approved at least one retail label with the word “Organic” in the brand name which is displayed on the primary product panel of a “Made with organic...” product.*

Corrective Action:

- **Labels:** *IMO Work Instruction No. 53, Annex I, NOP Labelling Requirements* outlined the requirements of “made with organic...” retail labels. The August 2014 *NOP Instruction: Use of Brand or Company Names Containing the Word “Organic”* requirements for labels containing the term “organic” were added to the *Work Instruction* in January 2015. Staff members then received training in January 2015 on all labeling requirements. Inspectors received training in March 2015. A Notice of Noncompliance was issued to the client with incorrect labels and prohibited material. Because IMO is in the process of developing and implementing an updated sanction system that will roll out in May 2015, all NOP certified operations will be informed about label requirements for “made with organic...” products through an April 2015 client letter that will update them

on the new system and requirements. IMO's internal NOP Annual Program Review will verify that rules are applied correctly during label approval. Copies of *Annex 2 Training confirmation on Audit results; Annex 6 Notice of Non-compliance to (the Client); Annex 7 Work Instruction No. 53 Annex I* were provided to the NOP for review.

- **Recipes.** All staff members received update training in January 2015 on the requirement of salt in multi-ingredient products. Inspectors received update training in March 2015. The IMO online training material for NOP inspectors and evaluators/certification officers covered the issue of review and verification of salt specifications. Noncompliances were issued to the specific client. Because IMO is in the process of developing and implementing an updated sanction system that will roll out in May 2015, IMO certified operators will be informed through an April 2015 client letter that will update them on the new system and requirements. IMO's internal NOP Annual Program Review will verify if the requirements have been followed correctly during recipe approval. Copies of *Annex 2, Training confirmation on Audit results; Annex 6, Notice of Non-compliance (Client)* were provided to the NOP for review.

NP4258LCA.NC4 – Accepted. 7 CFR §205.662(c) states, “When a rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent ... shall send the certified operation a written notification of proposed suspension...”

Comments: IMO issued a notice of proposed suspension before the Notice of Noncompliance deadline for an operation to submit a rebuttal or corrective actions.

Corrective Action: The internal instruction on how to use the template for Proposed Suspensions has been improved. All staff members concerned received update training on the NOP non-compliance procedure in January 2015. IMO's internal NOP Annual Program Review will follow up on the correct application of the NOP non-compliance procedure and the correct use of the updated template. Copies of *Annex 2 Training confirmation on Audit results; Annex 8 Template Proposed Suspension* were provided to the NOP for review.

NP4258LCA.NC5 – Accepted. 7 CFR §205.662(c)(4) states, “The notification of proposed suspension or revocation of certification shall state: The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: The template for Proposed Suspension states that an operation has the opportunity to submit a rebuttal to IMO within 14 days. USDA organic regulations only indicate that operations have the right to appeal or request mediation.

Corrective Action: The template for Proposed Suspensions has been corrected. All staff members concerned received update training in January 2015. IMO's internal NOP Annual Program Review will follow up on the correct use of this template. Copies of *Annex 2 Training confirmation on Audit results; Annex 8 Template Proposed Suspension* were provided to the NOP for review.

NP4258LCA.NC6 – Accepted. 7 CFR §205.501(a)(15)(i) states, states that a certifying agent must... “Submit to the Administrator a copy of: Any notice of...notification of noncompliance, notification of noncompliance correction...simultaneously with its issuance...”

Comments: IMO submits copies of notices of proposed suspension and suspension to the NOP; however, noncompliance and resolution notifications are not sent on a consistent basis.

Corrective Action: Along with the implementation of a service that provides dated return receipts, IMO began notifying the NOP in March 2015 of all notices of noncompliance and notices of non-compliance resolution. All staff members concerned were informed in January 2015 of this requirement. All NOP clients will be informed of IMO’s updated sanction system via client newsletter in late April 2015. As soon as the procedure has been defined in detail the relevant QMH documents will be adapted and all staff members will receive further training on the revised procedure. IMO’s internal NOP Annual Program Review will follow up on the correct implementation of this requirement. Copies of *Annex 2 Training confirmation on Audit results; Annex 3 DRAFT IMO I 5.2 G-e Internal Procedures NOP* were provided to the NOP for review.

NP4258LCA.NC7 – Accepted. 7 CFR §205.662 (a)(1) states, “... a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide...A description of each noncompliance.”

Comments: The following features were identified by auditors during a review of noncompliance notifications:

- *Issued noncompliances listed in the “Summary Assessment” document do not cite a specific regulation. There is no direct identifiable reference to the USDA organic regulations for noncompliances issue by IMO. Instead, reference numbers correspond to the operation’s OSP and inspection report.*
- *One proposed revocation notice did state the regulatory citation; however the citations were not appropriate to the noncompliances.*

Corrective Action: All sanction catalogues will be updated by indicating reference to the corresponding NOP paragraph for each control point. The catalogues will be available after the next Change Management update in May 2015. The sanction catalogues will be introduced gradually, starting in May with crop production and handling activities, followed by catalogues for wild collection and smallholder certification. All staff members concerned were informed in January 2015 of the requirement. As soon as the new sanction system catalogues are available all staff members concerned will receive further training. IMO’s internal NOP Annual Program Review will follow up on the correct use of the sanction catalogues. A copy of *Annex 2 Training confirmation on Audit results* was provided to the NOP for review.

NP4258LCA.NC8 - Accepted. 7 CFR §205.662 (a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

Comments: The review of two adverse action incidents revealed that proposed suspension notifications were issued without issuing noncompliance notifications.

Corrective Action: The template for Proposed Suspensions has been updated to include clearer instructions on how to use it. All staff members concerned received update training in January 2015 on NOP noncompliance procedures as detailed in *Work Instruction No. 165* and the instructions given in the *Proposed Suspensions Template*. IMO's internal NOP Annual Program Review will follow up on the correct use of this template. Copies of *Annex 2 Training confirmation on Audit results; Annex 8 Template Proposed Suspension* were provided to the NOP for review.

NP4258LCA.NC9 - Accepted. 7 CFR §205.670(e) states, "...Sample integrity must be maintained throughout the chain of custody..."

Comments: In one reviewed pesticide residue case, a sample was collected on July 10, 2013 and held for almost five months before received by the laboratory for analysis.

Corrective Action: All staff members at IMO received update training in January 2015 on the requirement to always ensure sample integrity. Inspectors were trained on the sample integrity requirement by email, or in-house, training, based upon availability. IMO's internal NOP Annual Program Review will review and verify the implementation of this requirement. A copy of *Annex 2 Training confirmation on Audit results* was provided to the NOP for review.

NP4258LCA.NC10 – Accepted. 7 CFR §205.501(a)(21) states that a certifying agent must... "Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." NOP 2603, Organic Certificates, indicates that the Anniversary Date on a certificate shall be the date the organic operation must submit its annual update.

Comments: The anniversary date listed on IMO certificates reflects a date one year after the issuing of the certificate. The date on the certificate is not the date which the operation must submit its annual update.

Corrective Action: The anniversary date has been set to March 31 of the following season, applicable for all certificates from the 2015 onwards. The NOP certificate template was updated in January 2015 and is available for use. All staff members were informed of the change in January 2015. All NOP clients will be informed on the changed procedure via client newsletter in April 2015. The NOP Annual Program Review will verify the correct use of the certificate template. Copies of *Annex 2 Training confirmation on Audit results* and *Annex 9 DRAFT IMO I 4.3.9 G-e NOP Certificate* were provided to the NOP for review.

NP4258LCA.NC11 – Accepted. 7 CFR §205.504(c)(2) states that a certifying agent must submit... "for all parties responsibly connected to the certifying agent, a conflict of interest disclosure report..."

Comments: Conflict of interest disclosures for the three board members were not completed.

Corrective Action: The members of the Board of Directors of IMOswiss AG signed 2014 Declarations of Conflicts of Interests and the information was entered into the staff database. The Board Members have been added to the list kept by the Human Resources Department to collect documents from all relevant personnel on an annual basis. Declarations of Conflicts of Interests will be collected annually by the HR Department from every staff member listed. The IMO

internal NOP Annual Program Review will verify the implementation of this requirement. A copy of *Annex 10 Declarations of Conflicts of Interests of Board Members; extract of HR staff list* was provided to the NOP for review.

NP4258LCA.NC12 – Accepted. 7 CFR §205.501(a)(5) states that a certifying agent must... “Ensure that its... contractors with inspection... have sufficient expertise in organic or handling techniques to successfully perform the duties assigned.” NOP 5012 Approval of Liquid Fertilizers for Use in Organic Production indicates that the material evaluation program of a certifying agent approving liquid fertilizers with a nitrogen analysis greater than 3 percent must “conduct a... review of all documented processes by a qualified inspector.”

Comments: IMO’s policy for inspector training and approval is to provide both in-house and, at minimum, one in-field inspection training specific to the type of inspection the inspector is being approved for. The review of training and inspection approval records for the inspector who conducted inspections of multiple operations involved in the production and handling of a liquid fertilizer product with a nitrogen analysis greater than 3 percent disclosed that the inspector was neither trained nor approved to conduct input materials inspections according to IMO’s policy.

Corrective Action: As of January 2015, IMO ceased to offer approval of operations involved in the production and handling of a liquid fertilizer product with a nitrogen analysis greater than 3 percent, due to lack of competent inspection personnel. *Work Instruction No. 116 (VA-116 G-e Off-farm Input Evaluation and Certification)* has been updated. Currently the entire input evaluation and certification procedure is under revision in order to harmonize it with Ecocert’s revised procedure. The complete update of the *Work Instruction* is scheduled for June 2015. However, all relevant personnel were notified that IMO will not offer approval of operations involved in the production and handling of a liquid fertilizer product with a nitrogen analysis greater than 3 percent. The contract with the only client concerned has been cancelled, effective date November, 2014. IMO’s QMH document has been revised (IMO I 3.2.2) and training, approval and supervision requirements have been clarified for each scheme/scope (IMO I 3.2.16). The NOP Annual Program Review will follow up on the correct implementation of the staff approval procedure. Copies *Annex 2 Training confirmation on Audit results; Annex 11 Update training of department leaders on staff approval procedure; IMO I 3.2.2 G-e IMO In-house Training; IMO I 3.2.16 Competencies personnel; and Cancellation letter IMO client* were provided to the NOP for review.

NP4258LCA.NC13 – Accepted. 7 CFR §205.501(a)(21) states that a certifying agent must... “Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” PM 11-4 Evaluation of Materials Used in Organic Crop, Livestock, and Handling Operations, indicates, “Organic producers and handlers must provide a complete list of substances used in production and handling in their Organic System Plan (OSP).”

Comments: The review of IMO’s policy for approval of pesticides (Policy No. 11 G-e Approval of Inputs) disclosed the following: When information about the inert ingredients in the pesticide is not disclosed by the input manufacturer, IMO is accepting in lieu of full disclosure, an affidavit (IMO I 4.4.14 G-e Declaration inert ingredients NOP) or self-declaration from the

manufacturer attesting to the fact that the” pesticide only contains the inert ingredients listed on EPA List 4 minus the revoked inerts.”

Corrective Action: Relevant changes in the corresponding policy for input approval were drafted and the document will be available after the next Change Management update in May 2015. Staff members received training on the requirement in January 2015, and inspectors received training in March 2015. All NOP clients will be informed on the changed procedure via client newsletter by April 2015. The NOP Annual Program Review will verify implementation of this requirement. Copies of *Annex 2 Training confirmation on Audit results; Annex 12 DRAFT Policy 11 G-e Approval of Inputs* and *DRAFT Policy 11 G-e; Annex I Approval of Inputs* were provided to the NOP for review.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Institute for Marketecology Switzerland (IMO). An onsite audit was conducted, and the audit report reviewed to determine IMO's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Institute for Marketecology Switzerland (IMO)
Physical Address	Weststrasse 51, Weinfelden, Switzerland
Mailing Address	Weststrasse 51, Weinfelden, Switzerland
Contact & Title	Ms. Ingrid Hucke, Head of Department Europe/USA/NOP Scheme Manager
E-mail Address	ihu@imo.ch
Phone Number	+41-71-626 0 626
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer Lars Crail, On-site Auditor; Robert Yang, Auditor Trainee
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: November 24, 2014 Onsite audit: September 15-17, 2014
Audit Identifier	NP4258LCA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of IMO's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	IMO's certification services in carrying out the audit criteria during the period: November 2012 through September 2014.

GENERAL INFORMATION:

IMO is a department of the Swiss Bio-Foundation, a non-profit foundation aimed to support the development of organic agriculture and consumer education. In September 2013, ECOCERT SA (France) acquired full ownership of IMO.

The IMO main office is located in Weinfelden, Switzerland with a branch office in Germany. Key NOP certification activities are performed in the following IMO offices: Bolivia, Turkey, Chile, and Switzerland. In July 2013, IMO discontinued certification services at the following offices where key activities occurred: China and Brazil.

IMO was initially accredited by the USDA National Organic Program (NOP) on June 7, 2002 for crop, wild crop, livestock, and handling/processing operations. IMO currently applies the NOP Standards and is certified for numerous Programs such as Bio Suisse, JAS, and the EU for the EC 834/2007 and 889/2008 Standards.

IMO currently has 671 NOP certified operations worldwide which includes 402 crop, 5 livestock, 37 wild crop, and 562 processor/handling operations in 50 countries. IMO indicated that they certify 161 grower groups mainly in Turkey and Latin America.

PERSONNEL:

The IMO main office in Weinfelden, Switzerland consists of the CEO who oversees all operations and 29 staff members who are involved in the NOP certification process. The technical staff consists of one Scheme Manager; 2 Deputy Scheme Managers; 2 Certification Managers; 14 Certification Officers some of which also act as inspectors and/or evaluators; 9 Inspectors/Evaluators; and one Evaluator.

CERTIFICATION PROCESS:

The initial request for certification and correspondence is handled by the IMO main office or a satellite office in the applicable country or region. The operation is provided with an application which they send back to IMO. There is an application for single operations, and a separate application for grower groups and wild crops. The submitted applications provide information on the scope requested and details of the operation (land area, previous certifications, etc.). Once IMO reviews the application, an Offer is submitted to the operation. The Offer is basically a cost estimate for certification and terms of service. An information and forms packet is also sent with the Offer which contains the contract for certification, the applicable organic system plans and the NOP standards or a link to the IMO webpage where the standards can be accessed.

Once the applicant returns the signed Offer, contract for certification, and organic system plans with relevant documentation, the review process can begin. The initial applications and organic system plans are reviewed by either the main office in Weinfelden, Switzerland or one of the satellite offices. When the initial review is completed, an inspector is assigned and the inspection is conducted by one of the staff inspectors. The inspectors are assigned based on the scope of the inspection, qualifications, and region of the country the inspection is to be conducted. All necessary information is sent to the inspector to conduct the inspection. When the inspection is completed, all documentation is returned to the main office in Switzerland for review. If all the documentation is in order and the information is found to be adequate, the packet is then sent to one of the NOP Department Managers (Asia Division, Latin American Division, Africa Division, or the Europe/USA Division) in Switzerland for the final certification decision. Labels are required to be submitted with the initial application and reviewed prior to the inspection. The labels are reviewed again by the inspector on-site based on the NOP requirements.

MATERIAL REVIEW

IMO has procedures in place for evaluation of both off-farm inputs and materials used by handlers. IMO maintains a database of all materials it has reviewed. Certification Officers use the database throughout the certification process to confirm the approved or prohibited status of a

material. IMO also provides input approval services for input manufacturers under its Off Farm Input Verification Program (OPV). Upon inspection of the operation and verification of compliance to the USDA organic regulations, the manufacturer is issued a certificate that states, “approval by IMO for use in organic production according to USDA, AMS 7 CFR Part 205, National Organic Program, Final Rule.” A list of products approved under the OPV can be found on the IMO website. The IMO seal can be used on labels of the approved products; the USDA organic seal cannot be used.

WITNESS AND REVIEW AUDITS

Two review audits and one witness audit were conducted in conjunction with this assessment. The one witness audit was an unannounced inspection of a processor located in Switzerland. One review audit was conducted of a Trader located in the United States and the other review audit was conducted on a processor located in Switzerland.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether IMO corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to IMO.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP9180ACA.NC3 - Cleared – 7 CFR §205.404 (b) (3) states, “The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.”

Comments: Several organic certificates reviewed did not specify the categories of organic operation.

2009 Corrective Action: The certificate template has been revised and the relevant certification staff informed. A copy of the revised certificate was submitted for review and included the categories of organic operation.

2012 NOP Verification of Corrective Action: Three of 16 files reviewed showed that IMO is not consistently issuing NOP certificates that list the category of certification. IMO updated its certificate template after the last on-site assessment, and again in March 2011; however, the new (compliant) template has not been effectively implemented.

2012 Corrective Action: IMO’s material submission for NOP’s review included a revised organic certificate template, training slides, proposed certification staff training dates, training confirmations, and IMO’s internal staff e-letter with NOP audit results and proposed corrections. Although IMO implemented measures to address the prior noncompliance, NOP auditors found

inconsistencies when sampling organic certificates. IMO training focused on identifying and listing the correct organic categories for each operation. All operation certificates will be reviewed and adjusted accordingly beginning June 2013 and concluding after one annual certification cycle. IMO's 2013 annual program review will report on the implementation status of the corrective actions.

2014 NOP Verification of Corrective Action: All organic certificates reviewed indicated the correct organic categories of Crops, Wild Crop, Livestock, and Handling.

NP2260AKA.NC1- Cleared - 7 CFR §205.402(a)(2) states, "Upon acceptance of an application for certification, a certifying agent must: Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part."

Comments: A handler listed on its OSP a supplier of organic ingredients identified as being certified by an Accredited Certifying Agent (ACA) that is no longer accredited by the NOP. Subsequent investigation during this assessment verified that the applicant is in fact now using another supplier for that ingredient which is certified under an accredited ACA. However, the OSP was evaluated and approved with the erroneous information listed. All information submitted by the applicant must be verified and approval must be granted only if the submitted application appears to comply or may be able to comply with the Act.

2012 Corrective Action: In addition to the IMO staff training materials, confirmations, and notifications provided for NOP review, IMO submitted revised quality manual procedures and reviewer checklists. IMO's efforts are to ensure that new applications, current OSPs, or annual updates are reviewed for compliance prior to conducting initial and annual inspections. IMO implemented the revised review procedures in March 2013 and training of all IMO certification staff will be completed by late 2013. IMO also corrected the specific deficiencies identified by NOP auditors regarding the sampled operations. IMO's 2013 annual program review will report on the implementation status of the corrective actions.

2014 NOP Verification of Corrective Action: IMO staff is conducting reviews of applications and annual updates. Documents reviewed appear to be complete and adequate to determine compliance to the USDA organic regulations and NOP policies.

NP2260AKA.NC2 – Withdrawn - 7 CFR §205.403(c)(1,2) states, "The on-site inspection of an operation must verify: (1) The operation's compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406 and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation...."

Comments: At the handler witness inspection, the inspector did not review or verify: sanitation, pest control, and commingling practices including materials used, as applicable, or the corrective actions from the previous on-site inspection. Regarding recordkeeping, the inspector did not conduct a traceability exercise to test the audit trail to ensure it meets the definition per the organic regulations.

Rebuttal: NOP issued this noncompliance as a result of a handler witness inspection.

According to IMO, the inspection was at a large and complex operation processing multi-ingredient products certified to multiple organic standards (e.g. NOP, EU, and Bio Suisse). Additionally, the inspection was not conducted in English. IMO submitted for NOP's review the operation's inspection report confirming that the inspector verified sanitation, pest control, controls to prevent commingling, and prior noncompliances. The inspection report included audit trail verification for several organic ingredients. Nevertheless, IMO submitted confirmation that the inspector completed additional training. During 2013 and 2014 IMO will provide training to all inspectors emphasizing inspection verification practices. IMO's quality manual was revised to include a new chapter describing the inspection verification of specific NOP practice standards. In the future IMO will provide a dedicated translator for NOP witness inspections and will also instruct inspectors to plan for additional time during inspections. This will allow inspectors to pause and explain verification practices to NOP auditors while the inspection is in progress. IMO's 2013 annual program review will report on the implementation status of the corrective actions. No verification required since this NC was withdrawn by the NOP.

NP2260AKA.NC3 – Cleared – 7 CFR §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: (2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments: Assessment of IMO's material review program found that there is no documented procedure or formal process for staff – evaluators and/or Certification Officers – to follow when reviewing, evaluating, and approving (or denying) materials for use in livestock and handling operations. For crop operations, IMO has a robust off-farm input material program, which also includes procedures addressing cleaning and sanitizing on-farm; but there is no same/similar program or review of other operational inputs such as livestock medications or vaccines or handling sanitizers, additives, or processing aids. Materials in use are checked against the National List and, as appropriate, non-GMO, irradiation and sewage sludge documentation is obtained and maintained in the client file; but verification that materials in use comply with designated National List annotations is not taken into account, except for winemaking clients. (For winemaking clients, there is a clear requirement in place to review additives, including a checklist for evaluators to demonstrate additives meet the USDA organic regulations.) For example, when reviewing a handler file, it was found that citric acid is being used as an ingredient to a Lime Juice product but there was no information in the file showing the material complied with the corresponding National List annotation; during interviews, it was found the evaluator/inspector and the NOP Program Scheme Deputy Manager were unaware of the annotation requirement in the regulations.

2012 Corrective Action: IMO clarified in its response to the noncompliance that record evidence regarding the citric acid compliance was in the operation's file, but could not be located on the day of the audit. IMO developed new annexes to the OSPs for operators to list all material inputs. The annexes will be reviewed and approved by IMO certification staff. Implementation of this new materials annex took place beginning June 2013. Training occurred during 2013 for the new procedures and forms. Training confirmations and presentation materials were provided for NOP review. IMO's 2013 annual program review will report on the implementation status of the corrective actions.

2014 NOP Verification of Corrective Action: IMO has implemented the corrective actions as

indicated which includes an OSP annex listing for materials. The new procedure appears to be effective and IMO's review of the materials appears to be adequate.

NP2260AKA.NC4 – Cleared - 7 CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: (3) Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: *The following issues were identified during a review of client files:*

- 1) *Review of 6 client files containing approximately 45 labels, both retail and bulk, spanning all claim categories revealed the following issues:*
 - *Retail labels (approximately 15 total) for a client producing spices displayed the IMO seal more prominently than the USDA seal, which is out of compliance with §205.303(a)(5). Specifically, the IMO seal was taller/bigger than the USDA seal.*
 - *A bulk label reviewed for an individually quick frozen (IQF) strawberry product displayed the USDA seal on the product box in a green/transparent scheme. Under the USDA organic regulations, transparent USDA seals can be combined only with black ink; alternately, green ink can be used if/when the USDA seal is displayed in the green/white/brown color scheme, per §205.311.*
 - *A bulk label reviewed for bulk coffee did not include a place for the display of the product lot number, as required when applicable under §205.307(b).*
- 2) *A number of certificates reviewed verified IMO allows certification of multiple distinct and separate operations under the scope of one certificate. Further, in these cases, the “certified entity” represented is a project owner or manager that oversees the individual production and processing units listed – together – on one overall certificate; however, this project owner/manager does not have an OSP, is not inspected, and is only – as noted – the overseer of the whole certification project.*
- 3) *IMO is certifying bees under the livestock scope; however, IMO is not requiring the land on which the bees feed to be certified organic. Because the land is not certified organic, the bees are not receiving certified organic feed, which is out of compliance with §205.237 requirements for livestock.*
- 4) *[China Satellite Office Audit Finding – NP2260ADA CN] IMO issued a certificate that lists two certified operations. IMO failed to comply with §205.401(a) by accepting an application for certification from an operation that did not complete an Organic System Plan. IMO failed to comply with 205.403(a) by not conducting an onsite inspection of a certified operation for which certification was requested. IMO granted certification to an operation when it had not determined that the operation complied with the USDA organic regulations.*

2012 Corrective Action: IMO provided objective evidence that label training was conducted and planned for future training sessions. Specific incidents of noncompliant labels were resolved with the operations. Regarding noncompliant certificates of several operations, IMO will no longer issue certificates with the “Mandator” or project owner listed, instead, certificates will list one operation as the certified entity. For the noncompliant bee keeping operations identified, certification staff and operators were informed that bee hive locations and foraging areas must be

certified organic. IMO requested a one-year transition period (completed June 2014) to fully implement this requirement. IMO submitted for review several revised procedures and forms that reflect implementation of the requirements. IMO's 2013 annual program review will report on the implementation status of the corrective actions.

2014 Verification of Corrective Action: The majority of labels reviewed were compliant. IMO has no livestock operations since all bee keeping operations surrendered their certification since the last assessment was conducted. All certificates reviewed indicated one operation and no "Mandator" was listed.

NP2260AKA.NC5 – Cleared - 7 CFR §205.501(a)(7) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliance's with the Act and the regulations in this part that are identified in the evaluation."

Comments: There is not an annual program review specific to certification activities for the NOP. Internal audits are performed annually by the Quality Management Department in conjunction with the Scheme Manager with the criteria of ISO 17020 and Guide 65. These internal audits encompass all schemes administered by IMO. Although the scheme of NOP is included in these internal audits and the specific requirements are addressed, not all areas of the program are reviewed annually.

2012 Corrective Action: IMO has revised its procedures to allow for an annual review addressing specific USDA organic regulation requirements. An annual review report template was provided for NOP's review.

2014 Verification of Corrective Action: IMO's 2014 Annual Review report does address IMO's compliance to USDA organic regulations and certification activities.

NP2260AKA.NC6 – Cleared – 7 CFR §205.642 states, "The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fee-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the non-refundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable."

Comments: IMO policy is to charge only fees incurred up to the point of withdrawal, however, this procedure is not listed on the fee schedule.

2012 Corrective Action: IMO submitted a revised fee schedule which indicates a refund policy for NOP's review.

2014 Verification of Corrective Action: The current IMO fee schedule includes a refund description.

NP2260AKA.NC7 – Outstanding - 7 CFR §205.660(d) states, "Each notification of

noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663... and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts."

Comments: Per interviews with the NOP Program Scheme Deputy Manager, it was found that IMO is not currently meeting this requirement. Notifications are not sent via a delivery service that provides dated return receipts.

2012 Corrective Action: As a temporary measure until June 2013, IMO used email delivery and read confirmations. Operations were requested to confirm receipt with a return email response. After June 2013, IMO implemented a registered email delivery system via an electronic service provider. IMO's 2013 annual program review will report on the implementation status of the corrective actions.

2014 Verification of Corrective Action: IMO has not implemented a registered email delivery system via an electronic service provider. IMO continues to use email delivery and read confirmation.

NP2260AKA.NC8 – Cleared - 7 CFR §205.661(a) states, "A certifying agent may investigate complaints of noncompliance with the Act or regulations of this part concerning production and handling operations certified as organic by the certifying agent. A certifying agent must notify the Program Manager of all compliance proceedings and actions taken pursuant to this part."

Comments: Two client files were requested for review of complaint proceedings. In both instances, it was found that IMO did not notify the NOP of results of the compliance proceedings and actions taken.

2012 Corrective Action: IMO provided materials for NOP's review as evidence of additional training and quality manual revisions. NOP will be notified of all complaints and proposed actions by IMO. The revised procedures were immediately implemented. IMO's 2013 annual program review will report on the implementation status of the corrective actions.

2014 Verification of Corrective Action: Since the last assessment, IMO has not received any complaints related to USDA organic certification or products. IMO has a procedure to report the results of complaint investigations and actions.

NP2260AKA.NC10 – Cleared – 7 CFR §205.402(a) states that "Upon acceptance of an application for certification, a certifying agent must: (1) Review the application to ensure completeness pursuant to §205.401; (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;.."

Comments: Crop witness audit observations revealed that IMO failed to identify compliance to the crop rotation practice standard (§205.205); failed to identify compliance to the crop pest, weed, and disease management practice standard (§205.206) and failed to identify how the operation was monitoring the effective implementation of the OSP (205.201(a)(3)). Additionally, the handler portion of this operation does not maintain adequate controls to prevent the shipment and sale of nonorganic product as organic. During the handling witness audit, 2011 processed dried Goji berry product was located in cold storage without clear

labeling identifying the organic standard: EU, JAS, or NOP. Since the operation's NOP certification was suspended during 2011, the inventory of stored 2011 harvested product is not certified to USDA organic regulations and cannot be sold, labeled, or represented as such. The Timeline of Events below shows that the operation was suspended between December 2010 to July 2012 and 2011 harvested processed products are ineligible for NOP organic status.

Timeline of Events:

- Nov 2010: The prior certifier proposes suspension due to alleged contaminated product.
- Dec 2010: The prior certifier suspends both operations.
- Aug 2011: IMO issued certification to the suspended operations without reinstatement approval and then subsequently retracted the certification.
- May 2012: NOP grants reinstatement to the operations.
- July 2012: IMO issues certification to the operations.

IMO's system of compliance review failed to identify the above mentioned noncompliances during the processing of the operation's reinstatement request.

2012 Corrective Actions: IMO revised its review procedure for Organic System Plans (OSP) in order to determine whether the OSPs are complete and the information therein is compliant to USDA organic regulations. IMO conducted training with seven relevant staff members on the revised review procedure.

2014 Verification of Corrective Action: A review of certified operation files indicated that OSPs were adequately completed and included sufficient information to determine compliance. IMO has implemented a process to review all OSP updates prior to conducting inspections.

NP2260AKA.NC11 – Cleared – 7 CFR §205.501(a)(13) states that certifiers “Accept the certification decisions made by another certifying agent accredited or accepted by USDA pursuant to §205.500.”

Comments: IMO granted certification to two suspended operations that were not approved for reinstatement by the NOP which then allowed the suspended operations to market (i.e. sell, label, and represent) organic products. See Timeline of Events in NP2260ADA.NC10.

2012 Corrective Actions: IMO revised its review procedure with regard to applications and Organic System Plans (OSP) in order to determine whether an operation is suspended or was reinstated prior to granting certification. IMO conducted training with staff members on the revised review procedure.

2014 Verification of Corrective Action: During the review of files or interviews with staff, there was no evidence that suspended operations were granted certification without requesting reinstatement.

NP2260AKA.NC12 – Cleared – 7 CFR §205.403(e)(2) states that “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.”

Comments: During both the crop and handler witness audits, a copy of the “Summary of Nonconformances/Noncompliances” was provided to the operation; however, a full inspection

report is not issued to the operation unless specifically requested. IMO certification procedures indicate that an operation will either receive a copy of the inspection report at the conclusion of the inspection or afterwards. A full inspection report must be provided to the inspected operation.

2012 Corrective Actions: IMO's response clarified existing procedures which indicate that an inspection report copy is provided to all operations after a certification decision is rendered. IMO conducted an internal review of China based operation files and verified that full inspection reports are provided to operations when issuing certification notifications. IMO conducted certification training for China satellite office staff which covered this topic.

2014 Verification of Corrective Action: Several certified operators were asked to show the auditors the inspection reports received from IMO and in all cases, a full and complete inspection report was provided to the operators.

NP2260AKA.NC13 – Cleared – 7 CFR §205.404(b)(1) states that “The certifying agent must issue a certificate of organic operation which specifies the: Name and address of the certified operation;..”

Comments: The 2011 List of Certified Operations submitted to the NOP by IMO does not correspond to the names listed on issued certificates.

2012 Corrective Actions: IMO issues certificates in China under the “Project Name,” not the certified operation's name. IMO corrected its database list of operations to indicate an operation name instead of “Project Name” and instructed its Chinese staff of the procedural change.

2014 Verification of Corrective Action: Several certificates issued for Chinese operations were reviewed and list only the certified operation's name.

AIA091910LMC.NC3 – Cleared – 7 CFR §205.403(c) states that “The on-site inspection of an operation must verify: (1) The operation's compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;”

Comments: During a witness audit of a newly planted tea production site, there was significant soil erosion observed due to rain and a lack of ground cover on this hilly site. The inspector did not question the operator about the erosion during the site visit and the inspector did not mention the erosion as an issue of concern during the exit interview. § 205.203(a) states “the producer must select and implement tillage and cultivation practices that maintain or improve the physical, chemical, and biological condition of soil and minimize soil erosion.” The operation's OSP does not mention any steps to prevent erosion.

Other NOP auditor observations during the IMO witness audits conducted in 2010:

- *The inspector failed to identify the lack of OSP descriptions and monitoring to prevent erosion. **2010 Corrective Action:** Regarding the lack of erosion discussion cited; IMO indicated that this component of the inspection may have occurred while NOP auditors were not present with the IMO inspector and client, “especially as the plot was very big*

and auditors were not around the inspection all the time. According to the memory of our inspector, he told the farm director about this problem of erosion.” Further, IMO required the farmer to “identify the risks of erosion, to take adequate measures against erosion, and to update the organic system plan accordingly.” **2012 Verification of Corrective Action:** The crop witness audit was conducted at a different production site and on flat terrain. There was no observed evidence of erosion.

- *The Inspector failed to verify that the operation is obtaining and maintaining current organic ingredient supplier certificates.* **2010 Corrective Action:** IMO notes this inspection was for an operation that has three suppliers, all of which are IMO-certified as part of the certified operation’s integrated supply system, and the certificates for which are provided to the operation directly through IMO. IMO noted that the inspector, familiar with IMO clients and this particular client’s certification structure, was aware that the suppliers were currently certified through IMO and, accordingly, current IMO certificates were available to demonstrate compliance. As such, this information was not requested on-site. However, IMO’s additional response indicated that September 2011 inspector training (for the IMO-China office) would include “review of the OSP” and “verification of information given in the OSP during inspection” (which would include review of suppliers, per §205.201(a)(2)) as topics for review. **2012 Verification of Corrective Action:** OSP review and verification of OSP information topic training occurred as scheduled. During the processing facility witness audit, the inspector reviewed supplier certificates.
- *Inspector failed to verify product recipes.* **2010 Corrective Action:** For system-wide issues, see other notes in this response regarding training planned for September 2011 for NOP inspectors at the IMO-China office. For this specific issue, IMO notes that the operation audited was for handling as a trader only and, as such, did not blend or process products. These activities would be verified at the individual sites conducting processing activities. IMO’s certification system requires the submission of product profiles for applicable operations, which must be verified at the inspection. **2012 Verification of Corrective Action:** Training occurred as scheduled in September 2011. During the processing facility witness audit, the inspector reviewed product recipes and confirmed production batches by conducting mass balance testing.
- *There was no evidence that the inspector conducted a records trace back test for any of the organic products.* **2010 Corrective Action:** IMO acknowledges inspectors working with the China office require further training on audit trail, recordkeeping, and traceability. IMO-Switzerland has planned training with IMO-China inspectors and an IMO-Switzerland inspector experienced with audit trail verification and review. Training is planned for September 2011. **2012 Verification of Corrective Action:** Training occurred as scheduled in September 2011. During the processing facility witness audit, the inspector conducted an adequate ingredient trace-back and review of records.

2012 Audit Findings: The following audit findings were identified as supporting evidence that AIA091910LMC.NC3 remains outstanding:

Comments: *During the crop witness audit:*

- *The inspector failed to verify a crop rotation plan or implementation of sod, cover cropping, green manure crops and catch crops pursuant to §205.205.*
- *The inspector failed to verify that the operation was using management practices and mechanical means to prevent crop pests pursuant to §205.206 (a) and (b). The operation*

was using a pyrethrum pesticide material to control aphids and no management practices or mechanical methods were discussed or identified as possible control measures in lieu of using input materials. This was not identified as a concern by the inspector during the exit meeting.

- *Compost is used as the only fertility input by this operation. During inspection of the composting site, the final compost product was not sufficiently processed. The material was unfinished compost and should be classified as manure. This issue was not identified as a concern by the inspector during the exit meeting.*

2012 Corrective Actions: All IMO Chinese inspectors will complete two IMO online training courses consisting of presentations, reading material, and exercises specifically to address the practice standards for crop rotation, pest management, and composting. Regarding the particular findings during the crop witness audit, IMO issued the operation a revised “Summary Assessment” or notice listing noncompliances for §205.205, §205.206 (a) and (b), and §205.203 (c). IMO will verify the operation’s corrective measures during the next onsite inspection. IMO published a newsletter to certified operations with a description of practice standards regarding crop rotation, pest management, and composting. The purpose of the newsletter is to remind, clarify and educate operations about the USDA organic regulations.

2014 Verification of Corrective Action: IMO conducted inspector training as outlined in their accepted corrective action; however, the IMO China Office partnership was discontinued and all China inspections are subcontracted with the ECOCERT China office.

Noncompliances Identified during the Current Assessment

NP4258LCA.NC1 – 7 CFR §205.501(a)(15)(ii) states that a certifying agent must... “Submit to the Administrator a copy of... a list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year.”

Comments: On January 2, 2014, IMO failed to submit a complete list of certified operations. The submitted list did not include certified operations located in Switzerland.

NP4258LCA.NC2 – 7 CFR §205.501(a)(21) states that a certifying agent must... “Comply with, implement, and carry out any other terms or conditions determined by the Administrator to be necessary.” Furthermore, §205.403(a)(2)(ii-iii) states “The Administrator... may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and regulations in this part. Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator...”

Comments: IMO indicated that on January 2, 2013, there were 606 certified operations. During 2013, IMO conducted nine unannounced inspections which does not meet NOP’s policy (NOP 2609) that a minimum of 31(5% of the total certified operations) unannounced inspections occur.

NP4258LCA.NC3 – 7 CFR §205.501(a)(3) states that a certifying agent must... “Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and 205.670.”

Comments: Below are several occurrences of noncompliant labeling and material issues where IMO certification staff granted approvals, and inspectors did not identify noncompliances, during review or verification activities:

- §205.304(a)(1)(ii) states that retail package labeling may indicate, “Made with organic (specified ingredients or specified food groups)”: provided, that the statement does not list more than three “organically produced ingredients; or, food groups.” **Comments:** IMO approved a “Made with organic” retail label that did not specify ingredients or food groups; instead a percentage of organic content was indicated.
- §205.304(b)(2) states that agricultural products in packages described in §205.301(c) must: “On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by ***,” or similar phrase, identify the name of the certifying agent...” **Comments:** IMO approved a retail product label where the “Certified Organic by” statement was not below the name of the manufacturer or distributor.
- §205.270(c)(2) states that a handling operation must not use in or on agricultural products intended to be sold as organic, “A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605:...” **Comments:** The salt ingredient in a “Made with organic...” product contained the anti-caking agent Sodium Ferronitrile, a prohibited material that is not listed on §205.605.
- §205.301(b) states that “A raw or processed agricultural product sold, labeled, or represented as “organic” must contain...not less than 95 percent organically produced raw or processed agricultural products.” Furthermore, NOP 4012, Use of Brand or Company Names containing the word “Organic,” provides specific NOP policy on this topic. **Comments:** IMO has approved at least one retail label with the word “Organic” in the brand name which is displayed on the primary product panel of a “Made with organic...” product.

NP4258LCA.NC4 – 7 CFR §205.662(c) states, “When a rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent ... shall send the certified operation a written notification of proposed suspension...”

Comments: IMO issued a notice of proposed suspension before the Notice of Noncompliance deadline for an operation to submit a rebuttal or corrective actions.

NP4258LCA.NC5 – 7 CFR §205.662(c)(4) states, “The notification of proposed suspension or revocation of certification shall state: The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: The template for Proposed Suspension states that an operation has the opportunity to submit a rebuttal to IMO within 14 days. USDA organic regulations only indicate that operations have the right to appeal or request mediation.

NP4258LCA.NC6 – 7 CFR §205.501(a)(15)(i) states, states that a certifying agent must... “Submit to the Administrator a copy of: Any notice of...notification of noncompliance, notification of noncompliance correction...simultaneously with its issuance...”

Comments: IMO submits copies of notices of proposed suspension and suspension to the NOP; however, noncompliance and resolution notifications are not sent on a consistent basis.

NP4258LCA.NC7 – 7 CFR §205.662 (a)(1) states, “... a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide...A description of each noncompliance.”

Comments: The following features were identified by auditors during a review of noncompliance notifications:

- *Issued noncompliances listed in the “Summary Assessment” document do not cite a specific regulation. There is no direct identifiable reference to the USDA organic regulations for noncompliances issue by IMO. Instead, reference numbers correspond to the operation’s OSP and inspection report.*
- *One proposed revocation notice did state the regulatory citation; however the citations were not appropriate to the noncompliances.*

NP4258LCA.NC8 - 7 CFR §205.662 (a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

Comments: The review of two adverse action incidents revealed that proposed suspension notifications were issued without issuing noncompliance notifications.

NP4258LCA.NC9 - 7 CFR §205.670(e) states, “...Sample integrity must be maintained throughout the chain of custody...”

Comments: In one reviewed pesticide residue case, a sample was collected on July 10, 2013 and held for almost five months before received by the laboratory for analysis.

NP4258LCA.NC10 – 7 CFR §205.501(a)(21) states that a certifying agent must... “Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2603, Organic Certificates, indicates that the Anniversary Date on a certificate shall be the date the organic operation must submit its annual update.

Comments: The anniversary date listed on IMO certificates reflects a date one year after the issuing of the certificate. The date on the certificate is not the date which the operation must submit its annual update.

NP4258LCA.NC11 – 7 CFR §205.504(c)(2) states that a certifying agent must submit... “for all parties responsibly connected to the certifying agent, a conflict of interest disclosure report....”

Comments: Conflict of interest disclosures for the three board members were not completed.

NP4258LCA.NC12 – 7 CFR §205.501(a)(5) states that a certifying agent must... “Ensure that its... contractors with inspection... have sufficient expertise in organic or handling techniques to successfully perform the duties assigned.” NOP 5012 Approval of Liquid Fertilizers for Use in Organic Production indicates that the material evaluation program of a certifying agent approving liquid fertilizers with a nitrogen analysis greater than 3 percent must “conduct a... review of all documented processes by a qualified inspector.”

Comments: IMO’s policy for inspector training and approval is to provide both in-house and, at minimum, one in-field inspection training specific to the type of inspection the inspector is being approved for. The review of training and inspection approval records for the inspector who conducted inspections of multiple operations involved in the production and handling of a liquid fertilizer product with a nitrogen analysis greater than 3 percent disclosed that the inspector was neither trained nor approved to conduct input materials inspections according to IMO’s policy.

NP4258LCA.NC13 – 7 CFR §205.501(a)(21) states that a certifying agent must... “Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” PM 11-4 Evaluation of Materials Used in Organic Crop, Livestock, and Handling Operations, indicates, “Organic producers and handlers must provide a complete list of substances used in production and handling in their Organic System Plan (OSP).”

Comments: The review of IMO’s policy for approval of pesticides (Policy No. 11 G-e Approval of Inputs) disclosed the following: When information about the inert ingredients in the pesticide is not disclosed by the input manufacturer, IMO is accepting in lieu of full disclosure, an affidavit (IMO I 4.4.14 G-e Declaration inert ingredients NOP) or self-declaration from the manufacturer attesting to the fact that the” pesticide only contains the inert ingredients listed on EPA List 4 minus the revoked inerts.”



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

DEC 19 2014

Ms. Ingrid Hucke
Institute for Marketecology - Switzerland
Weststrasse 51, Weinfelden
Switzerland

Dear Ms. Hucke:

On September 15-17, 2014 representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Institute for Marketecology Switzerland (IMO) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On November 24, 2014 the NOP reviewed the results of the onsite audit to determine IMO's compliance to the USDA organic regulations. A copy of the assessment report, **NP4258LCA**, is enclosed for your reference.

As the report indicates, twelve (12) corrective actions for prior noncompliances (NP9180ACA.NC3; NP2260AKA.NC1, NC3-NC6, NC8, NC10-NC13; AIA091910LMC.NC3), were cleared and determined to be implemented and effective. One noncompliance (NP2260AKA.NC2) was withdrawn. One noncompliance, (NP2260AKA.NC7), remains outstanding from your previous audit. Thirteen (13) new noncompliances (NP4258LCA.NC1-NC13) were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the IMO management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 690-4540 or RobertH.Yang@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Idaho State Department of Agriculture. An onsite audit was conducted, and the audit report reviewed to determine Idaho State Department of Agriculture's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Idaho State Department of Agriculture (ISDA)
Physical Address	2270 Old Penitentiary Road, Boise, ID 83712
Mailing Address	P.O. 790, Boise, ID 83701-0790
Contact & Title	Johanna Phillips, Organic Program Manager
E-mail Address	Johanna.Phillips@agri.idaho.gov
Phone Number	(208) 332-8539
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Miguel Caceres and Willy Horne, Onsite Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: September 30, 2014 Onsite audit: July 21-24, 2014
Audit Identifier	NP4202MMA
Action Required	Yes
Audit & Review Type	Mid-term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of ISDA's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	ISDA's certification services in carrying out the audit criteria during the period: July 15, 2014 through July 24, 2014.

ORGANIZATIONAL STRUCTURE:

The Idaho State Department of Agriculture (ISDA) is a State government agricultural office that operates an accredited USDA organic certification program. ISDA has been accredited as a certifying agent since April 29, 2002, to the National Organic Program (NOP) for the scopes of crop, wild crop, livestock, and handling. ISDA currently has 211 certified clients certified to the NOP, which include 149 crop, 27 livestock, one wild crop, and 85 handling operations. The clients are certified in U.S., with the majority being in Idaho, and certification activities are only to the USDA NOP standard.

All certification activities are conducted from the ISDA located in Boise, ID. The ISDA staff

consists of an administrator, a bureau chief, a section manager, an organic program manager, an agricultural program specialist, a senior agriculture investigator, and a technical records specialist. At the time of the mid-term assessment, ISDA was also utilizing seven contracted inspectors of which two were State employees involved with other programs, but contracted for conducting organic inspections. The ISDA administrator, bureau chief, and section manager are not directly involved with the ISDA organic certification program as they function in managerial positions that provide support and guidance for the staff. The agricultural program specialist and senior agriculture investigator are both staff inspectors. In addition, the organic program manager may also perform inspections. Through the interviews conducted, a review of the personnel records, and observations of the witness inspection, the onsite auditors verified ISDA staff and contracted inspectors had the necessary education, experience, and training to comply with and implement the organic certification program.

CERTIFICATION PROCESS:

For new applicants, ISDA sends the client an email with a link to ISDA website where the applicant may complete the Application for Organic Certification, an organic system plan (OSP) as applicable to the requested scope(s) of certification, and field history sheets. The email also contains links for OMRI, the NOP website, the NOP Handbook, the ISDA Organic Program homepage, the National Sustainable Agriculture Information Service, and a link to examples of other support documents (equipment clean out logs, previous land use forms, etc.). While most requests for certification are handled via email, ISDA will send hard copies of the documents and information if requested or the client does not have access to email. Fee estimates are provided to all applicants on the application itself. Once an application is received, the initial review for completeness is conducted by the technical records specialist, followed by a review by one of the two staff inspectors or the program manager to assess if the operation is in compliance or can comply with the requirements. The majority of inspections are conducted by the two ISDA staff inspectors, with a few inspections conducted by contracted inspectors. The contracted inspectors are assigned based on the location of the inspector and operation, the training and experience of the inspector, and client feedback. After the inspection, the certification decision is made based upon the final review conducted by the program manager or one of the two staff inspectors, if the program manager conducts the inspection.

For the annual update process, ISDA sends certified operations a certification renewal packet in hard copy at the beginning of February of each year. The packet includes a print out of the CFR organic standards, blank OSP form(s), an *Application for Organic Certification*, and a fee estimate specific to the operation. The fee estimate is in the letter “*Subject: Instructions for Continuing Organic Certification & Fee Estimate*,” which specifies the due date for submitting documents and fees. The application requires the certified operation to submit the full or updated portions of their OSP, including other items specified. The OSP requires an update for noncompliances identified during the previous year, if applicable. The certification renewal process is the same as for new applicants, but requires an annual update instead of an application.

In addition to the regularly scheduled inspections, ISDA conducted 11 unannounced inspections in calendar year 2013, which met the requirement of conducting unannounced inspections on five percent of the total certified operations for the year. No unannounced inspections had been conducted at the time of the 2014 mid-term. However, ISDA was planning on conducting 10 or more in August 2014.

Materials and labels are reviewed by the staff inspectors and/or the program manager. The program manager has the responsibility of making the final determination on materials. Label approval procedures are contained in the *Idaho State Department of Agriculture Organic Program Standard Operating Procedures* (ISDA SOP). The material review procedure in the ISDA SOP is the process for reviewing and approving materials requested for use by applicants and certified operations. The staff does not use a checklist for the materials review. However, labels are stamped as approved or denied after review and are maintained in the client files. In addition to the label procedure, the ISDA SOP contains a material approval procedure, which requires the completion of the “*Unregistered Material Review Form.*” This system places review information into the material tracker spreadsheet to include the product, its use, NOP annotations, and other information, such as what organic operation requested the review. ISDA also has a material registration program designed for material manufacturers/providers, which can apply directly to ISDA to have their material listed as approved for organic production. It is important to note that the material review procedure and the material registration process are not designed as a material evaluation program for liquid fertilizers with a nitrogen analysis greater than three percent, as described in NOP 5012.

The process for verification of the terms of the EU-US Organic Equivalency Arrangement is not documented. However, a process is followed for verifying the terms. There were three import certificates issued in 2013 and one thus far in 2014. All four were issued per the client’s request for product shipped to Norway; the forms do not reference that product shipped with this documentation was being traded under the EU-US Equivalency Arrangement. There were no certificates issued for any client exporting directly to an EU member state. The process for verification of the US-Canada Organic Equivalency Arrangement is not documented. However, a process is followed for verifying the terms. At the time of the mid-term assessment, there were four attestation statements issued. Attestation statements are contained on the *Canada Organic Regime Compliance Affidavit for ISDA Organic Producers*. Certificates reviewed also stated “*This is to attest that the above named is certified in accordance with 7 CFR Part 205 National Organic Program Final Rule & Canada Organic Regime.*” The process for verification of the US-Japan Organic Equivalency Arrangement and the Export Arrangement with Taiwan are documented. There were no requests for TM-11 Export Certificates for Japan and only one issued for Taiwan since the previous USDA assessment.

ADMINISTRATIVE RECORDS AND PROCESSES:

ISDA uses the ISDA SOP to address the procedures for organic certification from application through certification. As described under the “Certification Process” section, all forms from application to OSPs, and those the clients can use to record activities are available from the ISDA website for download and available from ISDA in hard copy.

The most recent annual program review was conducted between November 19 and December 19, 2013 by the previous organic program manager. The results were documented on the Organic Program Internal Audit Findings & Corrective Actions, which were submitted to the NOP. The annual program review was in the process of being assessed by an NOP accreditation manager and thus the auditor of record did not assess the contents of the ISDA annual program review. Training provided to the staff included external training by IOIA, OMRI, and on-the-job training. The ISDA internal training program for inspectors requires three shadow inspections for each scope of certification for inspectors newly assigned to the organic program. The observations made during the witness inspection verified the inspectors are well trained and knowledgeable.

SUMMARY OF WITNESS AND REVIEW AUDITS CONDUCTED:

A witness inspection of a crop and handling operation in Boise, ID was conducted. The operation consisted of four fields and two green houses with a total of 60 acres. This was a 100% organic operation that produced vegetables and flowers. Produce and flowers are marketed to a local co-op and a local CSA. All crops are hand harvested. Post-harvest handling consisted of cleaning, rinsing, cooling, bagging, and packing the produce into cardboard boxes. Product is stored in a cooler for no more than 24 hours before being shipped. The witness inspection was an actual inspection and an announced inspection. The witness inspection verified that 1) the inspector was knowledgeable of the operation, 2) a knowledgeable representative was present, 3) no prohibited substances were being used, 4) the OSP was an accurate description of the actual practices onsite, and 5) the operation was in compliance with the Act. The inspector was knowledgeable, thorough, and conducted a closing meeting with the operation’s representative.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether ISDA corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to ISDA.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the

corrective actions or that records reviewed and audit observations did not demonstrate compliance.

There are no noncompliances from prior assessments.

Noncompliances Identified during the Current Assessment

NP4202MMA.NC1 – NOP §205.403(a)(1) states, “A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.” *Comments: In one of six files reviewed, the inspector did not visit the wild crop harvest area. Furthermore, ISDA did not follow-up to ensure the wild harvest area was inspected.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

OCT 16 2014

Johanna Phillips
Idaho State Department of Agriculture
PO Box 790
Boise, ID 83707-0790

Dear Ms. Phillips,

On July 21-24, 2014, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Idaho State Department of Agriculture (ISDA) organic certification program as part of its USDA Mid-term Accreditation Assessment. On September 30, 2014, the NOP reviewed the results of the onsite audit to determine ISDA's compliance to the USDA organic regulations. A copy of the assessment report, NP4202MMA, is enclosed for your reference.

As the report indicates, there were no existing or outstanding noncompliances from your previous audit. One new noncompliance, NP4202MMA.NC1, was identified during the recent onsite audit. Please submit proposed corrective actions for the noncompliance to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the ISDA management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renée Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney". The signature is written in a cursive, flowing style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Johanna Phillips
Idaho State Department of Agriculture
PO Box 790
Boise, ID 83707-0790

Dear Ms. Phillips,

On July 21-24, 2014, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Idaho State Department of Agriculture (ISDA) organic certification program as part of its USDA Mid-term Accreditation Assessment. On September 30, 2014, the NOP reviewed the results of the onsite audit to determine ISDA's compliance to the USDA organic regulations. A copy of the assessment report, NP4202MMA, is enclosed for your reference.

As the report indicates, there were no existing or outstanding noncompliances from your previous audit. One new noncompliance, NP4202MMA.NC1, was identified during the recent onsite audit. Please submit proposed corrective actions for the noncompliance to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the ISDA management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renée Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

The National Organic Program (NOP) conducted a mid-term assessment of Idaho State Department of Agriculture. An onsite audit was conducted, and the audit report reviewed to determine Idaho State Department of Agriculture's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Idaho State Department of Agriculture (ISDA)
Physical Address	2270 Old Penitentiary Road, Boise, ID 83712
Mailing Address	P.O. 790, Boise, ID 83701-0790
Contact & Title	Johanna Phillips, Organic Program Manager
E-mail Address	Johanna.Phillips@agri.idaho.gov
Phone Number	(208) 332-8539
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Miguel Caceres and Willy Horne, Onsite Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action Review: December 15, 2014-January 15, 2015 NOP assessment review: September 30, 2014 Onsite audit: July 21-24, 2014
Audit Identifier	NP4202MMA
Action Required	Yes
Audit & Review Type	Mid-term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of ISDA's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	ISDA's certification services in carrying out the audit criteria during the period: July 15, 2014 through July 24, 2014.

ORGANIZATIONAL STRUCTURE:

The Idaho State Department of Agriculture (ISDA) is a State government agricultural office that operates an accredited USDA organic certification program. ISDA has been accredited as a certifying agent since April 29, 2002, to the National Organic Program (NOP) for the scopes of crop, wild crop, livestock, and handling. ISDA currently has 211 certified clients certified to the NOP, which include 149 crop, 27 livestock, one wild crop, and 85 handling operations. The clients are certified in U.S., with the majority being in Idaho, and certification activities are only to the USDA organic regulations. All certification activities are conducted from the ISDA located in Boise, ID. Through the interviews conducted, a review of the personnel records, and observations of the witness inspection, the onsite auditors verified ISDA staff and contracted

inspectors had the necessary education, experience, and training to comply with and implement the organic certification program.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether ISDA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Noncompliances from Prior Assessments

There are no noncompliances from prior assessments.

Noncompliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4202MMA.NC1 – Accepted – 7 CFR §205.403(a)(1) states, "A certifying agent must conduct an initial onsite inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An onsite inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue."

Comments: In one of six files reviewed, the inspector did not visit the wild crop harvest area. Furthermore, ISDA did not follow-up to ensure the wild harvest area was inspected.

Corrective Actions: The operation in question identified as part of this audit was suspended in October 2014 for failure to renew their certification. ISDA updated its certification decision procedures in November 2014 to specify that a certificate may not be issued to an operation if the inspection report is incomplete. Furthermore, the certificate may not be issued until the missing information or other issues identified as part of the inspection or final review have been resolved. These updates were communicated to staff and inspectors via a policy memo issued November 17, 2014.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

The National Organic Program (NOP) conducted a mid-term assessment of Idaho State Department of Agriculture. An onsite audit was conducted, and the audit report reviewed to determine Idaho State Department of Agriculture’s capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Idaho State Department of Agriculture (ISDA)
Physical Address	2270 Old Penitentiary Road, Boise, ID 83712
Mailing Address	P.O. 790, Boise, ID 83701-0790
Contact & Title	Johanna Phillips, Organic Program Manager
E-mail Address	Johanna.Phillips@agri.idaho.gov
Phone Number	(208) 332-8539
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Miguel Caceres and Willy Horne, Onsite Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action Review: December 15, 2014 NOP assessment review: September 30, 2014 Onsite audit: July 21-24, 2014
Audit Identifier	NP4202MMA
Action Required	Yes
Audit & Review Type	Mid-term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of ISDA’s certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	ISDA’s certification services in carrying out the audit criteria during the period: July 15, 2014 through July 24, 2014.

ORGANIZATIONAL STRUCTURE:

The Idaho State Department of Agriculture (ISDA) is a State government agricultural office that operates an accredited USDA organic certification program. ISDA has been accredited as a certifying agent since April 29, 2002, to the National Organic Program (NOP) for the scopes of crop, wild crop, livestock, and handling. ISDA currently has 211 certified clients certified to the NOP, which include 149 crop, 27 livestock, one wild crop, and 85 handling operations. The clients are certified in U.S., with the majority being in Idaho, and certification activities are only to the USDA NOP standard. All certification activities are conducted from the ISDA located in Boise, ID. Through the interviews conducted, a review of the personnel records, and observations of the witness inspection, the onsite auditors verified ISDA staff and contracted

inspectors had the necessary education, experience, and training to comply with and implement the organic certification program.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether ISDA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

There are no noncompliances from prior assessments.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4202MMA.NC1 – Accepted – 7 CFR §205.403(a)(1) states, "A certifying agent must conduct an initial onsite inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An onsite inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue."

Comments: In one of six files reviewed, the inspector did not visit the wild crop harvest area. Furthermore, ISDA did not follow-up to ensure the wild harvest area was inspected.

Corrective Actions: The operation in question identified as part of this audit was suspended in October 2014 for failure to renew their certification. ISDA updated its certification decision procedures in November 2014 to specify that a certificate may not be issued to an operation if the inspection report is incomplete. Furthermore, the certificate may not be issued until the missing information or other issues identified as part of the inspection or final review have been resolved. These updates were communicated to staff and inspectors via a policy memo issued November 17, 2014.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

The National Organic Program (NOP) conducted a mid-term assessment of Idaho State Department of Agriculture. An onsite audit was conducted, and the audit report reviewed to determine Idaho State Department of Agriculture’s capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Idaho State Department of Agriculture (ISDA)
Physical Address	2270 Old Penitentiary Road, Boise, ID 83712
Mailing Address	P.O. 790, Boise, ID 83701-0790
Contact & Title	Johanna Phillips, Organic Program Manager
E-mail Address	Johanna.Phillips@agri.idaho.gov
Phone Number	(208) 332-8539
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Miguel Caceres and Willy Horne, Onsite Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action Review: December 15, 2014-January 15, 2015 NOP assessment review: September 30, 2014 Onsite audit: July 21-24, 2014
Audit Identifier	NP4202MMA
Action Required	Yes
Audit & Review Type	Mid-term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of ISDA’s certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	ISDA’s certification services in carrying out the audit criteria during the period: July 15, 2014 through July 24, 2014.

ORGANIZATIONAL STRUCTURE:

The Idaho State Department of Agriculture (ISDA) is a State government agricultural office that operates an accredited USDA organic certification program. ISDA has been accredited as a certifying agent since April 29, 2002, to the National Organic Program (NOP) for the scopes of crop, wild crop, livestock, and handling. ISDA currently has 211 certified clients certified to the NOP, which include 149 crop, 27 livestock, one wild crop, and 85 handling operations. The clients are certified in U.S., with the majority being in Idaho, and certification activities are only to the USDA organic regulations. All certification activities are conducted from the ISDA located in Boise, ID. Through the interviews conducted, a review of the personnel records, and observations of the witness inspection, the onsite auditors verified ISDA staff and contracted

inspectors had the necessary education, experience, and training to comply with and implement the organic certification program.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether ISDA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Noncompliances from Prior Assessments

There are no noncompliances from prior assessments.

Noncompliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4202MMA.NC1 – Accepted – 7 CFR §205.403(a)(1) states, "A certifying agent must conduct an initial onsite inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An onsite inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue."

Comments: In one of six files reviewed, the inspector did not visit the wild crop harvest area. Furthermore, ISDA did not follow-up to ensure the wild harvest area was inspected.

Corrective Actions: The operation in question identified as part of this audit was suspended in October 2014 for failure to renew their certification. ISDA updated its certification decision procedures in November 2014 to specify that a certificate may not be issued to an operation if the inspection report is incomplete. Furthermore, the certificate may not be issued until the missing information or other issues identified as part of the inspection or final review have been resolved. These updates were communicated to staff and inspectors via a policy memo issued November 17, 2014.

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of BCS Oeko-Garantie GmbH. An onsite audit was conducted, and the audit report reviewed to determine BCS Oeko-Garantie GmbH's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	BCS Oeko-Garantie GmbH (BCS)
Physical Address	Marentorgraben 3-5, Nuremberg, D-90402, Germany
Mailing Address	Marentorgraben 3-5, Nuremberg, D-90402, Germany
Contact & Title	Tobias Fischer
E-mail Address	fischer@bcs-oeko.de
Phone Number	49 911 4 24 39 0
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Darrell Wilson, On-site Auditor. Lars Crail, Taiwan witness inspection; Mike Lopez, Peru grower group witness inspection.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: September 12, 2014 Onsite audit: July 21-24, 2014
Audit Identifier	NP4202OOA
Action Required	Yes
Audit & Review Type	Mid-term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of BCS's certification system.
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	BCS's certification services in carrying out the audit criteria during the period: July 7, 2013 through July 24, 2014.

ORGANIZATIONAL STRUCTURE:

BCS Öko-Garantie GmbH (BCS) is a private company under German law. It has been licensed as a private controlling agency since 1992 to implement the European Union (EU) Regulation on organic production. BCS offers services to companies worldwide, and the legal and technical supervision of work as a control office for organic farming is controlled by authorities of the region, Federal Government, and EU level.

BCS was initially accredited as a certifying agent by the NOP on April 29, 2002 for the scopes of crop, wild crop, livestock, and handling. BCS had approximately 1,124 NOP certified operations

worldwide with the majority certified for crops and handling. The NOP client breakdown for BCS included approximately 744 crop, 46 wild crop, 11 livestock (beekeeping only), 814 handling operations and 113 grower groups.

The main office for NOP certification for BCS is located in Nuremberg, Germany and includes National (German) and International Departments. All inquiries and certification activities for the NOP are conducted at the Nuremberg office. BCS is accredited as an ISO Guide 17065 certification body and approved for GLOBALGAP and EU organic certifications. BCS is also accredited for JAS, GOTS and all countries that they have certified operations that require accreditation to operate within the country. BCS has additional offices or representatives in 27 countries that provide a variety of other contract certification services.

The BCS list of personnel identified 12 staff members as certifiers/reviewers and two reviewers involved in the certification process. The certification program is divided into the International and National Departments. In addition, there are 61 staff inspectors and 46 subcontracted inspectors. Job descriptions for all positions are contained in the BCS quality management system.

Records were reviewed for annual performance evaluations, confidentiality agreements and conflict of interest statements. The file review indicated that all personnel had the required education, training and experience in organic agricultural production and handling to perform the duties assigned.

CERTIFICATION PROCESS:

Certifiers/reviewers conduct the initial and post inspection review of operator files for completeness and compliance, review material inputs, review labels, and make recommendations for non-compliances from information in inspection reports. Reviewers only review initial reviews for completeness and compliance, review material inputs, and review labels. A certifier reviews the complete file and makes the certification decision as well as issuing noncompliances and reviewing corrective actions.

BCS provides the operation seeking certification with general information about BCS, its services and the application form for certification. BCS maintains a website where any applicant seeking information has access to BCS documents and a link to the NOP website and NOP standards. When a completed application is accepted by BCS, a cost estimate (offer) based on details outlined in the application is prepared. If the applicant accepts the offer, BCS provides a contract and further specific information on the NOP standard. The applicant returns a signed contract whereupon BCS provides forms (organic system plans) and relevant documents for certification. A BCS certifier/reviewer or a reviewer reviews the completed organic system plans (OSPs) to verify that the client appears to comply with the NOP regulations and requests additional information if necessary. The inspection is assigned to a staff or subcontracted inspector based on geographic location and the inspector's expertise. The inspection report and additional information collected during the inspection are reviewed by a certifier/reviewer or a reviewer for completeness. If a certifier/reviewer reviews the inspection report and supporting documentation they may also make the certification decision. If a reviewer reviews the inspection report and supporting documentation then the material is forwarded to a

certifier/reviewer for final decision. Continuing certification follows a similar process as the initial certification process.

Material reviews are conducted during the certification process. BCS also conducts reviews of liquid nitrogen products with nitrogen content of 3% or greater. A list of materials approved by BCS is available on their website.

File reviews verified that BCS is conducting certification of grower groups in accordance with the NOSB recommendations on the Criteria of Certification of Grower Groups.

ADMINISTRATIVE RECORDS AND PROCESSES:

The primary documents for certification are the USDA NOP standards and the quality manual. The quality manual is comprised of various documents, each having their own revision status. Forms/templates are provided to the applicant/client based on the scope of their operation.

BCS has conducted an annual program review and annual updates have been submitted to the Administrator as required.

Reviews of personnel records verified that BCS provides opportunities for training both internal and external. All personnel performing certification activities pertinent to the NOP had training specific to the NOP standard.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED:

There were two witness inspections observed under the mid-term assessment. The first was an annual inspection for an importer and distributor of organic and conventional products located in Taiwan. The certified operation handles approximately 321 organic products and 65 conventional products. They are considered a “medium risk” operation by BCS. The inspector was very knowledgeable and familiar with the USDA organic regulations.

The second was an annual inspection for a processing operation in Germany. The operation blends and packages (in non-retail containers) dried vegetables, kitchen herbs, spices, and herbal teas/infusions. They strive for high quality herbal products which are mainly supplied to the food and herbal industry world-wide. Organic production (both NOP and EU) consists of 5% of their total production. The inspector did a very thorough inspection and was very knowledgeable of the USDA regulations.

One inspection is yet to be observed for a grower group in Peru. The witness inspection is scheduled to be conducted in October of 2014.

NOP DETERMINATION

The NOP auditors reviewed the onsite audit results to determine whether BCS corrective actions adequately addressed previous noncompliances. The NOP auditors also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to BCS.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

AIA091510LMC.NC2 - Cleared – 7 CFR § 205.501(a)(15)(i) states, “(a) A private or governmental entity accredited as a certifying agent under this subpart must: (15) Submit to the Administrator a copy of... (i) Any notice of denial of certification issued pursuant to § 205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to § 205.662 simultaneously with its issuance...” *Certifier correspondence to applicants granting certification often incorporates non-compliances, thereby functioning as notices of noncompliance. However, there is no record that copies of these documents were submitted to the NOP. For example, there is no “cc: NOP” or statement within the documents indicating submission to the NOP. Furthermore, there is no record to show that operations responded with corrective actions addressing the non-compliances and that the non-compliances were resolved (i.e. notice of resolution or correction of noncompliance) within the required timeframe.*

Corrective Actions (October 7, 2009): The corrective actions adequately address the noncompliance. BCS has established procedures for submitting notices of non-compliance, non-compliance resolution, proposed suspension / revocation or suspension / revocation to the NOP Administrator. BCS’s NOP Certification Quality Manual has been amended to include instruction for copies of any noncompliance notifications, and any adverse action notifications to be sent to the NOP Administrator. **Verification of Corrective Action:** BCS received notification of NOP’s acceptance of its corrective actions on June 24, 2011, just prior to the Renewal Assessment audit (November 23, 2011) but had not implemented the corrective actions as described. Therefore, implementation and effectiveness of corrective actions could not be verified. **Corrective Actions on the outstanding noncompliance (March 20, 2012):** BCS retroactively submitted prior notifications that were not forwarded to the Administrator and these notices have been received by NOP Appeals. Section 9.4.7 of BCS’s Quality Manual has been amended to indicate that notices of noncompliance and notices of adverse action will be routinely (weekly) submitted to the NOP Administrator. The corrective actions adequately address the noncompliance. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Verification of corrective actions (July 21, 2014):** BCS was able to demonstrate that notices have been submitted.

AIA091510LMC.NC3 – Cleared – 7 CFR § 205.670 (d) states, “Results of all analyses and tests performed under this section: (1) Must be promptly provided to the Administrator ...” *Although BCS China has a robust residue sampling regime, analyses and test results are not submitted to the NOP.* **Corrective Actions (March 13, 2009):** BCS has established procedures for submitting results of analysis and tests for residue testing to the NOP. BCS’s NOP Certification Quality Manual has been amended to include instruction on sampling and residue testing, including reporting results. This instruction requires that all test results will be forwarded to BCS Headquarters in Germany. BCS Headquarters will then forward the test results to the

NOP. The corrective actions adequately address the noncompliance. **Verification of Corrective Action:** BCS received notification of NOP's acceptance of its corrective actions on June 24, 2011, just prior to the Renewal Assessment audit (November 23, 2011) but had not implemented the corrective actions. Therefore, implementation and effectiveness of corrective actions could not be verified. **Corrective Actions on the outstanding noncompliance (March 20, 2012):** The corrective actions adequately address the noncompliance. BCS's Quality Manual, section 10, *Sample and Residue Testing*, describes residue testing procedures and instructions, including submitting analyses results to the NOP administrator. An internal review found that BCS has not been routinely submitting results to the NOP. BCS's Quality Manager will be responsible to ensure BCS staff provides residue analyses results to the NOP. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Verification of corrective actions (July 21, 2014):** NOP no longer requires sample results to be submitted. Sample results were available for review during the assessment.

AIA091510LMC.NC4 – Cleared – 7 CFR § 205.404(a) states, "...If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance with the requirements of this part and that the applicant is able to conduct operations in accordance with the plan, the agent shall grant certification. The certification may include requirements for the correction of minor non-compliances within a specified time period as a condition of continued certification." *The auditors' review of a new applicant file (Ref.: A-2007-00641_2/2009-05974 EK) revealed the issuance of a certificate prior to noncompliance correction. BCS identified the noncompliance as an incomplete OSP, noting incomplete plot descriptions and an inaccurate map of the certified land. This noncompliance is not considered a "minor" noncompliance and would require correction prior to issuance of a certification.* **Corrective Actions (March 13, 2009):** The corrective actions adequately address the noncompliance. BCS provided clarification on their determination of the minor noncompliance. Using the NOP interpretation described in the NOP Final Rule preamble - *Minor non-compliances are those infractions that, by themselves, do not preclude the certification or continued certification of an otherwise qualified organic producer or handler*, BCS determined that the operations non-compliances were correctable, and therefore minor. The operation's OSP was considered to be incomplete as a result of the operation's plot descriptions not providing clear indications of field sizes, and the scale of the inaccurate map did not provide a clear identification of the operation's fields. BCS obtained complete plot descriptions and requested the operation provide a more precise map. Verification of these corrective actions will be assessed at the next on-site audit. **Verification of Corrective Action:** BCS received notification of NOP's acceptance of its corrective actions on June 24, 2011, just prior to the Renewal Assessment audit (November 23, 2011) but had not implemented the corrective actions. Therefore, implementation and effectiveness of corrective actions could not be verified. In addition, these maps and plot descriptions of the operation cited in the noncompliance had not been inspected in 2011. The update to this information was due in August at the next scheduled inspection. **Corrective Actions on the outstanding noncompliance (March 20, 2012):** The corrective actions adequately address the noncompliance. The operation cited in the noncompliance surrendered its NOP certification to BCS. As a result, BCS did not obtain the operation's plot descriptions and field maps. BCS did amend its NOP certification procedures, section 9.1(e) in its quality manual, to require the OSP reviewer to evaluate an applicant's OSP's for completeness and compliance with the NOP regulations. BCS's OSP review will include an

operation's plot descriptions and field maps. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Verification of corrective actions (July 21, 2014):** It was determined through file reviews that OSPs were complete prior to conducting the inspection.

NP1199NNA.NC1 – Cleared – 7 CFR §205.501 (a)(8) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part.” *BCS is approved for the scope of livestock. Currently, BCS does not have any livestock clients; however, BCS has not addressed the Pasture practice standard under §205.240 and dry matter intake requirements under §205.237 with applicants or certified operations. The OSP form for livestock operations does not request sufficient information from a livestock applicant to determine whether or not the applicant would be able to comply with the NOP Pasture Rule. Corrective Actions (March 20, 2012):* The corrective actions adequately address the noncompliance. BCS revised its livestock OSP template, section 7, to assess an operation's pasture management practices including access to pasture, and also revised section 11, to assess dry matter intake requirements of ruminants. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Verification of corrective actions (July 21, 2014):** BCS still does not have any “traditional” livestock certified. Only bees are certified under livestock. Forms as reviewed during the CA review remain the same.

NP1199NNA.NC2 – Cleared – 7 CFR § 205.662 (a - c) states, “(a) When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: (1) A description of each noncompliance; (2) The facts upon which the notification of noncompliance is based; and (3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. (b) When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution. (c) When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.” *During the two witness inspections conducted in Germany, updated OSPs were not submitted prior to the inspections. Under § 205.406(a), operations continuing with NOP certification, must submit updated OSP's before inspections are scheduled. BCS did not issue Notices of Noncompliance to the operations for not submitting updated OSP's as required. In addition, review of files where noncompliance notifications had been issued with a time frame for correction indicated that BCS is not following up on the notices of noncompliance to determine whether an operator had submitted corrective action within the time frame stated in the original letter. Hence, notices of proposed suspension were not issued as required when the operators failed to submit corrective action. BCS indicated that in the case of foreign operators, corrective actions may have been received by the BCS contact in a foreign country and this*

information had not been passed on to the main office for review. **Corrective Actions (March 20, 2012):** The corrective actions adequately address the noncompliance. BCS conducted an internal review of its implementation of its noncompliance procedures. This review revealed that while procedures for issuing Notices of Noncompliance are established, the procedures are not being consistently implemented when noncompliances are observed. BCS has amended its procedures to issue notices of noncompliance when OSP's are not submitted prior to the inspection. BCS will establish procedures to verify that an operation's OSP has been submitted, and found to be NOP compliant, before inspections are scheduled. BCS's internal review also revealed that staff is following up on notices of noncompliance to determine whether there is resolution. However, the review determined that follow up on notices of noncompliance has not been consistently documented. BCS will assign additional staff to ensure that the noncompliance procedures for certified operations are implemented and that noncompliance follow up is effectively implemented and documented. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Verification of corrective actions (July 21, 2014):** BCS was able to provide evidence that notices were issued.

NP1199NNA.NC3 – Cleared – 7 CFR § 205.406 (a) 1-4 states, “To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: An updated organic production or handling system plan which includes: A summary statement, supported by documentation, detailing any deviations from, changes to, modifications to, or other amendments made to the previous year's organic system plan during the previous year; and any additions or deletions to the previous year's organic system plan, intended to be undertaken in the coming year, detailed pursuant to §205.200. Any additions to or deletions from the information required pursuant to §205.401(b); An update on the correction of minor non-compliances previously identified by the certifying agent as requiring correction for continued certification; and Other information as deemed necessary by the certifying agent to determine compliance with the Act and the regulations in this part.” *The BCS procedure states that all operators applying for continuation of certification must submit updated organic system plans (OSPs) and information regarding correction of non-compliances prior to an inspection. It was evident during the two witness inspections conducted in Germany that updated OSPs were not submitted prior to inspections. In both cases, the operators gave the inspector the updated OSP during the annual inspection. Further interviews with staff indicated that it is a problem with operators in Germany only.* **Corrective Actions (March 20, 2012):** The corrective actions adequately address the noncompliance. BCS amended its NOP certification procedures, quality manual section 9.1(e), to require the OSP reviewer to evaluate an applicant's OSP's for completeness and compliance with the NOP regulations. BCS will establish procedures to verify that an operation's OSP has been submitted, and found to be NOP compliant, before inspections are scheduled. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Verification of corrective actions (July 21, 2014):** File reviews and interviews verified that OSPs were complete prior to conducting the inspection.

NP1199NNA.NC4 – Cleared – 7 CFR § 205.501(a)(11)(vi) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.” *During the onsite review, seven of*

the ten client files reviewed revealed that the person who made the initial review of the operator's production plan also made the final certification decision. **Corrective Actions (March 20, 2012):** The corrective actions adequately address the noncompliance. BCS amended section 6.4 of its quality manual to state that conflicts of interest will be prevented by ensuring that three different persons will be involved in the OSP review, inspection, and in decisions on NOP certification. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Verification of corrective actions (July 21, 2014):** File reviews verified that at least 3 different individuals were involved with the certification process.

NP1199NNA.NC5 – Cleared – 7 CFR § 205.403 (c)(1) states, “The on-site inspection of an operation must verify: The operation’s compliance or capability to comply with the Act and the regulations in this part.” *The BCS inspector conducting the wild crop witness inspection did not review the buffer zones of the areas where inspections were conducted. The buffer zones were not adequately described on the maps provided with the Organic System Plans for the operations reviewed. The wild crop area covered a vast area in Poland, but the maps provided did not define buffer zones and any potential areas of concern for the wild crop collection areas. The inspector did not ask for information regarding the buffer zones during the inspection.* **Corrective Actions (March 20, 2012):** The corrective actions adequately address the noncompliance. BCS has modified sections 5.1 and 5.2 in its Wild Crop Collection OSP template to require information on wild collection area maps, areas of potential risk of contamination / pollution, and description of buffer zones. BCS also modified the Wild Crop Inspection Report template to include an assessment of potential risks and buffer zones. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Verification of corrective actions (July 21, 2014):** Review of files indicated that corrective actions were implemented and effective.

Noncompliances Identified during the Current Assessment

NP4202OOA.NC1 – 7 CFR § 205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.” *One of the labels reviewed contained the USDA seal which did not meet the color requirements as stated in §205.311 (b)(3). A notice of non-compliance was not issued to the operation requiring the label be corrected.*

NP4202OOA.NC2 – 7 CFR § 205.662 (a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: (1) A description of each noncompliance.” *Three notices of noncompliances reviewed made reference to NOSB recommendations as the standard violated instead of citing pertinent regulations in 7 CFR 205.*

NP420200A.NC3 – 7 CFR § 205.662 (c) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state: (2) The proposed effective date of such suspension or revocation; and (3) The impact of a suspension or revocation on future eligibility for certification.” *One Notice of Noncompliance/Notice of Proposed Suspension reviewed did not contain the proposed effective date of the suspension or the impact of the suspension. In reviewing this document, it was also determined that it was a combined notification of noncompliance/suspension. According to the training module for Noncompliance and Adverse Action Notices (dated January 24, 2012) the Notice of Noncompliance and/or Notice of Proposed Suspension need to be included in the Subject or Header but were not on the documents issued by BCS.*

NP420200A.NC4 – 7 CFR § 205.501 (a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP training module on Mediation Training, dated January 16, 2013, provided guidance for the use of settlement agreements as an informal way to settle disputes with certified operations. 7 CFR § 205.662 (e)(1) states, “If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of suspension or revocation.” *Two noncompliance resolutions reviewed contained terms for which both the operator and BCS would need to comply with in order to overcome the proposed suspension. By including these conditions, it constitutes a settlement agreement, which must be signed by both parties. There was no evidence provided to indicate that the operations agreed with the terms of the proposed settlement and no suspension was drafted or sent to the operations. In one case the client surrendered certification. BCS policies and procedures need to clarify this process to prevent future noncompliances.*

NP420200A.NC5 – 7 CFR § 205.501 (a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.” *A review of the personnel files found that there were 4 individuals that did not have current annual evaluations. Discussions with the Quality Manager revealed that inspectors are no longer receiving an annual evaluation. Inspectors, whether full-time or contracted staff, are considered part of certifying agent's personnel and are therefore subject to the personnel performance evaluations requirements.*

NOP420200A.NC6 – 7 CFR § 205.501 (a)(10) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in §205.504(b)(5).” BCS procedure D-EN_04-011 requires that document D-EN_4-031, which contains the confidentiality clause’ must be signed upon hiring. *One individual that was hired conducted certification activities without having signed the required form which contains the confidentiality clause.*

NOP420200A.NC7 – 7 CFR § 205.501 (a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.” *Three individuals did not have current conflict of interest disclosures on file as required.*

NOP420200A.NC8 – 7 CFR § 205.660 (d) states, “Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.” *Notifications are currently being sent to the operation’s place of business via email, which does not provide dated returned receipts or confirm receipt of the notification by the legally responsible party.*

NOTICE OF NONCOMPLIANCE

Tobias Fischer
BCS Oeko-Garantie GmbH
Marentorgraben 3-5
Nuremberg, #-90402
Germany

SEP 24 2014

Dear Mr. Fischer,

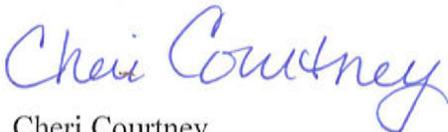
On July 21-24, 2014, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the BCS Oeko-Garantie GmbH (BCS) organic certification program as part of its USDA Mid-term Accreditation Assessment. On September 12, 2014, the NOP reviewed the results of the onsite audit to determine BCS's compliance to the USDA organic regulations. A copy of the assessment report, NP4202OOA, is enclosed for your reference.

As the report indicates eight corrective actions for prior noncompliances (AIA091510LMC.NC2 through 4 and NP1199NNA.NC1 through 5), were cleared and determined to be implemented and effective. Eight new noncompliances (NP4202OOA.NC1 through 8), were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the BCS management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renée Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,



Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of the LACON GmbH (LACON) organic program was conducted on June 26-28, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess LACON's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	LACON GmbH
Physical Address	Moltkestrasse 4 D-77654 Offenburg, Germany
Mailing Address	Moltkestrasse 4 D-77654 Offenburg, Germany
Contact & Title	Dr. Joachim Kopp, Director
E-mail Address	j.kopp@lacon-institut.org
Phone Number	49 781 966 79 242
Reviewer & Auditor	Graham Davis, NOP Reviewer; Penny Zuck, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: July 14, 2017 Onsite audit: June 26-28, 2017
Audit Identifier	NP7177PZA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of LACON's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	LACON's certification services in carrying out the audit criteria during the period: October 23, 2015 through June 26, 2017

LACON GmbH is a limited liability company that conducts certification and compliance verification of agricultural products, food, and livestock feed with national, international, and private quality standards. LACON was initially accredited to the USDA National Organic Program on October 21, 2002 for crops, wild crops, livestock, and handling. LACON currently certifies 143 operations including: 79 crops, 15 wild crops, 8 livestock (apiculture only), and 78 handling operations. LACON certifies 12 grower groups. LACON is also accredited for other organic standards, including the European Union (EC 834/2007), BioSuisse, and Naturland.

LACON maintains individual or partner offices with certification bodies in Austria, Brazil, Bulgaria, Cyprus, Morocco, Romania, and India. The offices serve currently certified and

prospective operations. The regional offices provide documents and other communications in the language of the respective country. All certification reviews and decisions are conducted at the main LACON office in Offenburg, Germany. LACON's NOP organic certification program staff consists of the General Manager, Executive Director, 7 reviewers/certifiers, and 18 inspectors.

This is the Renewal Assessment Audit for LACON. The current LACON accreditation certificate is valid until October 21, 2017. The audit consisted of an office audit only and did not include witness or review audits. The witness and review audits will be scheduled in the near future.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether LACON corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to LACON.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2281EEA.NC3 – Cleared – 7 CFR § 205.662(a) states, “*Notification*. When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program’s governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: (1) A description of each noncompliance; (2) The facts upon which the notification of noncompliance is based; and (3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible.”

Comments: *Eight of the ten files reviewed included 2 to 14 “Measures” with no noncompliances issued. Examples of “measures” included: 1.) No documents available to verify organic seedling, sale of untreated seed, delivery notices, etc.; 2.) No traceability of product from delivery to the field of origin – records of dates of harvesting, cutting, bagging, etc., and cleaning records for dual purpose equipment; 3.) No documentation to show the 3 year previous history of fields included in the OSP; and 4.) No clean out verifications concerning cleanliness of containers used for delivery. Measures from the previous year are still open regarding record keeping. There is no record of a noncompliance being issued to any certified operation since the previous assessment.*

Corrective Action: LACON explained that it previously used the term “measure” instead of the term “noncompliance” and that the inspector notified the operation of the measure (now called

deficiency/noncompliance) and proposed a deadline for resolution. This information was then confirmed by the reviewer and the reviewer conducted follow-up. The NOP determined that this procedure was not compliant with 7 CFR §205.501(a)(11)(vi). In response, LACON changed its exit interview form (called a Noncompliance Report, form Y037) to state that the noncompliance is *proposed* by the inspector, that the reviewer must review the noncompliance, and that the notice of noncompliance created by the reviewer must be sent to the operator and the USDA. LACON also changed its “Review of evaluation report Project inspection” (form Y009) to state that measures *proposed* during the inspection by the auditor must be confirmed by the staff reviewer as noncompliances in report Y037. As evidence of corrective actions, LACON submitted documents showing that it had issued a notice of noncompliance to one of its operations; the noncompliance was also submitted to the proper email address of the USDA for submission of adverse actions. LACON will present training on this topic to its inspectors at the next in-person training in January 2014.

2015 Verification of Corrective Action: LACON continues to use the Noncompliance Report, form Y037. The version of the form used states that the noncompliance is *observed* by the inspector instead of *proposed* by the inspector as indicated in their corrective actions. The auditors noted that both the old and revised forms contain the same revision numbers and dates.

2016 Corrective Actions: LACON revised the noncompliance report forms for operations inside (form U-NOP-24_r00) and outside (form U-F-20e r1) of Germany. The forms reflect updated revision dates and version numbers, and now state that noncompliances are *proposed* by the inspector.

Verification of Corrective Action: The auditor verified the Noncompliance Report forms were revised and email notification was sent to inspectors and reviewers. The old version of the noncompliance report was archived and replaced with the revised documents on the portal. Inspectors access this portal for current forms.

N529900A.NC1 – Cleared – 7 CFR § 205.404(b)(1) states, “The certifying agent must issue a certificate of organic operation which specifies the: Name ... of the certified operation ... Effective date of certification ... categories of organic operation.” NOP 2601 Instruction Organic Certificates states, “Organic certificates should ... include the following ... Anniversary date (when the certified operation must submit its annual update); Categories of organic certification (crops, wild crops, livestock, and handling/processing) ... The statement, “Once certified, a production or handling operation’s organic certification continues in effect until surrendered, suspended or revoked. Certifying agents must identify only one “person” (typically a farm or business as defined in 7 CFR § 205.2) on the organic certificate; this “person” must be certified organic. Each certified organic operation must have its own organic certificate.”

Comments: *The review of organic certificates, observations during the witness audit of a wild crops/handling operation, and interview with certification staff indicated that LACON’s certificates do not comply in the following manner:*

- *The certificate states “Certificate Renewal Date” in lieu of “Anniversary Date.”*
- *The scopes (i.e. categories of operation) on the certificate template include the option “Trade.”*
- *All certificates reviewed contained the statement “Once certified, the organic certification of the above mentioned company continues in effect until surrendered by the organic operation or suspended or revoked by LACON*

GmbH.” The LACON certificate template includes this same incorrect statement. The USDA regulations, however, state that “A production or handling operation’s organic certification may be suspended or revoked by the certifying agent, the State organic program’s governing State official (if applicable), or the Administrator.”

- *On the current organic certificate of the wild crops/handling operation, the certified operation is listed as the certified identity, and its contracted processor is listed as a second entity (“unit”) on the certificate annex. The operation was verified to be processing products under contract for the certified operation. An interview with certification staff indicated that LACON allows its certified operations to contract with such operations to produce or handle products for them. The contracted operations are added to the certified operation’s organic system plan and individually inspected, but not individually certified.*
- *The review of a tea grower group’s certificate revealed that the certified grower group was listed as the certified identity, and its contracted producers were also listed on the certificate. The producers were verified to be operations producing under contract for the grower group. The contracted operations were added to the certified operation’s organic system plan and individually inspected, but not individually certified.*

Corrective Actions: LACON’s revised USDA NOP organic certificate template reflects the correct scopes (crops, wild crops, livestock, handling) and now includes the statement “A production or handling operation’s organic certification may be suspended or revoked by the certifying agent, the State organic program’s governing State official (if applicable), or the Administrator.” The certificate template also includes the effective date, issue date and anniversary date. The instructions for issuing the USDA NOP organic certificate state that “a certificate must be issued for each NOP certified operation.”

Verification of Corrective Action: The auditor reviewed a number of certificates issued in 2017. Current certificates include all required information as outlined in the USDA organic regulations and NOP 2601. The auditor reviewed the current certification of the tea group operation and all producers are individually certified and the main operation is certified separately for handling. The producers are identified on the handler certificate, however, producers are certified to the ‘crops’ scope.

N529900A.NC2 – Cleared – 7 CFR § 205.671 states, “ When residue testing detects prohibited substances at levels that are greater than 5 percent of the EPA’s tolerance for the specific residue detected ... the agricultural product must not be sold, labeled, or represented as organically produced.” Additionally, the instruction NOP 2613 “Responding to Results from Pesticide Residue Testing,” 5.3.3.a states that if there is no EPA or FDA tolerance level, and testing detects a residue of prohibited pesticides above 0.01 parts per million (ppm), the certifying agent should “immediately notify the certified operation of the test results and indicate that the product may not be sold as organic.”

Comments: *The review of two positive pesticide residue analysis files revealed that in one instance an EPA or FDA detection level did not exist for the two prohibited substances detected, and the detection levels exceeded 0.01 ppm. LACON did not inform the operation that the product may not be sold, labeled, or represented as organic. In the second instance the detection*

level for the prohibited substance, which did not have an EPA or FDA detection level, was reported by the testing lab as “less than 0.02 ppm.” LACON did not take any further action to determine whether the test results exceeded 0.01 ppm. An interview with certification staff indicated that staff was not fully aware of the instructions in NOP 2613.

Corrective Actions: LACON provided evidence that staff have been informed via e-mail that all test results must be provided to the client. LACON’s current procedure U-NOP-12e “Sample Taking and Residues,” last revised in 2013, does not fully align with USDA requirements or NOP 2613, sections 5.1, 5.2, or 5.3. Staff training on responding to pesticide residues was also not addressed in this corrective action response.

Verification of Corrective Action: LACON conducted residue test results process training for personnel conducting reviews. The auditor reviewed the training log of participants and the training agenda. Revisions were made to U-NOP-12e ‘Sample Taking and Residues’ by adding a section on residues detected at less than .01 ppm and actions to be taken. The revision also references NOP 2613 as the procedure to follow.

N529900A.NC3 – Cleared – 7 CFR § 205.501(a)(9) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Maintain all records pursuant to § 205.510(b) and make all such records available for inspection.”

Comments: *During the audit it was not possible to verify that residue test results were provided to operations in Bulgaria and Madagascar because records were not available for review at LACON’s head office. An interview with certification staff indicated that records of communication and notices issued in countries where LACON has a local contact person are not kept at LACON’s head office.*

Corrective Actions: LACON issued an e-mail to staff in foreign offices reminding them that official communications and notices, such as residue results and reports, shall be shared with the LACON headquarters staff.

Verification of Corrective Action: The auditor reviewed a residue test result for an operation located in Madagascar. The residue test result was provided to the operation.

N529900A.NC4 – Cleared – 7 CFR § 205.402(a)(2) states, “a certifying agent must: determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part;” Also, § 205.403(c)(1) states, “The onsite inspection of an operation must verify: the operation’s compliance or capability to comply with the Act and the regulations in this part.”

Comments: *LACON’s form entitled Organic System Plan Processing/Handling in Foreign Countries does not request that the applicant provide information needed in order for a LACON reviewer to determine whether an operation complies with the following:*

- *The USDA facility pest management practice standards of § 205.271(c) – (e): Section 14 “Pest Control” on the OSP form does not ask the applicant to provide information regarding how the operation meets the requirements of § 205.271(c) – (e) prior to use of a nonsynthetic substance or synthetic substance consistent with the National List or a synthetic substance not on the National List. Furthermore, the form does not instruct the inspector to verify an operation’s compliance with the requirements of § 205.271(c) – (e), if applicable.*

- *The USDA labeling requirements of § 205.307: Section 10 “Labeling” on the OSP form does not ask that bulk (non-retail) labels be submitted for review in order to determine compliance.*

Corrective Actions: LACON revised its inspection report form and now requires inspectors to verify pest control procedures of the operation prior to the use of nonsynthetic or synthetic substances. LACON revised its handler OSP to require that operations 1) describe their pest control measures in compliance with 205.271, and 2) submit retail and non-retail labels for review.

Verification of Corrective Action: The revised processor OSP has a section (10) requiring the operator to submit all product labels for review. U-F-15e ‘Inspection Report for Processing’ was revised June 2016 to include a section for the inspector to verify pest control procedures of the operation. The auditor reviewed certified operations files to verify the revised forms are currently in use. No issues were noted by the auditor.

NP529300A.NC5 – Outstanding – 7 CFR §205.501(a)(21) states “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” The instruction NOP 2027, “Personnel Performance Evaluations,” section 3.2 (b) states “Inspectors should be evaluated during an onsite inspection by a supervisor or peer (another inspector) at least annually. This field evaluation should be conducted at the certifying agent’s expense.”

Comments: *LACON’s current policy for evaluating inspector field performance is on a five year cycle instead of annually. There are provisions for conducting field evaluations more frequently if deemed necessary.*

Corrective Actions: LACON updated its inspector policies (U-NOP-04e r1) and now requires annual inspector field evaluations for personnel involved in USDA NOP inspection activities. In addition, LACON provided documentation showing that six inspectors have already been subject to a field evaluation.

Verification of Corrective Action: From the auditor’s review of personnel evaluations, 4 out of 18 active NOP inspectors were not field evaluated in 2016. LACON has revised their procedure for conducting field evaluations of inspectors and intends to submit it to the NOP for review according to NOP 2027.

NP529300A.NC6 – Cleared – 7 CFR §205.660 (d) states “Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.”

Comments: *Notifications are sent via email with no service that provides a dated delivery receipt.*

Corrective Actions: LACON updated its procedures to require that staff send an advance e-mail followed by a fax or registered letter for any adverse actions. LACON provided documentation that staff were informed via e-mail of the updated procedures regarding delivery confirmation of adverse action notices.

Verification of Corrective Action: LACON is using the outlook email feature which provides a record of sent emails and requires recipients to respond when emails are read. Each notice is also sent via postal service with a tracking number and return receipt.

NP529300A.NC7 – Cleared – 7 CFR § 205.402(a)(3) states, “Upon acceptance of an application for certification, a certifying agent must: Verify that an applicant who previously applied to another certifying agent and received a notification of noncompliance or denial of certification, pursuant to §205.405, has submitted documentation to support the correction of any noncompliances identified in the notification of noncompliance or denial of certification, as required in §205.405(e).”

Comments: *LACON’s Application Form Agricultural Production (U-F-02e) instructs the applicant to disclose if they received a notification of noncompliance combined with certification denial and whether any corrective actions were implemented to address the noncompliances. The form does not address notices of noncompliances that may have been issued to applicants without a denial of certification.*

Corrective Actions: LACON revised the application for certification form, which now requires clients to disclose any prior noncompliances received through a denial of certification, or during their previous certification.

Verification of Corrective Action: LACON’s application form has been revised. Email notification of the revised application was sent to all reviewers, satellite offices, and inspectors. The revised application has been uploaded to the platform (shared folder) and the old version has been archived. No issues identified by the auditor.

NP529300A.NC8 – Cleared – 7 CFR § 205.501(a)(21) states “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” Additionally, the instruction NOP 4009 “Who Needs to Be Certified?” states, “When organically producing or handling agricultural products, a certified operation may not: Allow an uncertified operation to produce or handle agricultural products, under contract or other arrangement on the uncertified operation’s land or premises (i.e., at units, facilities, or sites not explicitly subject to inspection or compliance action by the NOP or a certifying agent).”

Comments: *The following observations were identified by a review of two operation files:*

- *The current organic certificate for a wild crops/handling operation indicates that the wild crop operation is listed as the certified entity, with its contracted processor is listed as a second entity (“unit”) on the certificate annex. The handling operation was determined to be processing products under contract for the certified wild crop operation. An interview with LACON certification staff revealed that LACON allows its certified operations to contract with such operations to produce or handle products for them. The contracted operations are added to the certified operation’s OSP and individually inspected, but not individually certified.*
- *The certificate for a tea operation indicates the operation is grower group and lists the producers on the certificate. The auditors verified that the tea handling operation is not an actual grower group but is instead a single certified entity that contracts with uncertified producers to provide product. An interview with*

LACON certification staff revealed that LACON allows its certified operations to contract with such operations to produce or handle products for them. The contracted operations are added to the certified operation's OSP and individually inspected, but not individually certified.

Corrective Actions: LACON issued letters to the wild crop and tea operations explaining that subcontractors who provide organic product must be individually certified per the USDA organic regulations and instruction NOP 4009. This corrective action response did not address staff training or measures to prevent this issue from reoccurring.

Verification of Corrective Action: LACON sent a letter to all NOP certified operations on May 3, 2016 referencing NOP 4009, which requires contracted operations to be certified. As part of this corrective action, email notifications were sent to staff in the Germany office, and other foreign offices in 2016.

Noncompliances Identified during the Current Assessment

NP7177PZA.NC1 – 7 C.F.R. §205.662(a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program’s governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

NOP 2613 Section 5.3.3 (3) states, “If appropriate, consider a notice of noncompliance for the following violations:

- § 205.202(b): application of prohibited substances. The notice should propose to suspend or revoke the operation’s certification.

- § 205.202(c): inadequate buffer zones to prevent the unintended application of prohibited substances. The notice should require corrective actions to prevent future contamination.

- § 205.272: inadequate measures to prevent commingling or contamination of organic products. The notice should require corrective actions to prevent future contamination. If suspensions, revocations, or civil penalties are appropriate, coordinate adverse actions with the NOP.”

Comments:

- 1. Following a residue testing result without EPA or FDA levels, LACON issued a notification to the operation indicating the results; the product could not be sold, labeled, or represented as organic; and requiring measures to reduce the risk of contamination in the future. The notice was not an official Notice of Noncompliance nor did it contain the required elements according to the USDA organic regulations. After receiving insufficient corrective actions, LACON did issue a Notice of Proposed Suspension and subsequently a Notice of Suspension, however, these notices did not include the required elements according to the USDA organic regulations.*
- 2. LACON provides each operation with a Review of Evaluation Report following the final certification review. This report includes measures that must be addressed by the operation, however, some of the measures reviewed by the auditor should be identified as noncompliances. LACON is not issuing Notices of Noncompliance to operations.*
- 3. LACON does not have an Adverse Action process/procedure in place to demonstrate compliance with the USDA organic regulations.*

NP7177PZA.NC2 – 7 C.F.R. §205.501(a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must... Prevent conflicts of interest by... Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.”

Comments: *Three LACON inspectors did not have Conflict of Interest statements on file for 2016 or 2017.*

NP7177PZA.NC3 – 7 C.F.R. §205.401(a) states, “A person seeking certification of a production or handling operation under this subpart must submit an application for certification to a certifying agent. The application must include the following information: An organic production and handling system plan, as required in §205.200;...”

NOP 2615 provides details of how producers and handlers can comply with these requirements. Organic System Plan (OSP) templates are available in the NOP Handbook. 7 C.F.R.

§205.201(a)(3) states, “The producer or handler of a production or handling operation,... must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:... A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;...”

Comments: *LACON’s OSPs do not include the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify the plan is effectively implemented. LACON’s inspection reports do not provide verification of the monitoring practices and procedures.*

NP7177PZA.NC4 - 7 C.F.R. §205.501(a)(18) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliances;...”

Comments: *LACON is not notifying inspectors of its decision regarding certification of the operations inspected and any requirements for the correction of minor noncompliances.*

NP7177PZA.NC5 – 7 C.F.R. §205.402(b)(2) states, “The certifying agent shall within a reasonable time:... Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed; and...”

Comments: *LACON is not consistently providing copies of inspection reports to operations from the LACON office. On some occasions, the inspector provides the operator with a copy during the inspection.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

H.-Joachim Kopp
LACON GmbH
Moltkestrasse 4, D-77654 Offenburg
Germany

Dear Dr. Kopp:

On June 26-28, 2017, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the LACON GmbH (LACON) organic certification program as part of its USDA Renewal Accreditation Assessment. On July 14, 2017, the NOP reviewed the results of the onsite audit to determine LACON's compliance to the USDA organic regulations. A copy of the assessment report, NP7177PZA, is enclosed for your reference.

As the report indicates, one noncompliance, (NP529300A.NC5) remains outstanding from a previous audit. Five new noncompliances (NP7177PZA.NC1 through NC5), were identified during the onsite audit. Please submit corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All corrective actions must indicate how the noncompliances will be corrected and how the LACON management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of LACON's USDA accreditation.

If you have questions regarding this notice, please contact, Graham Davis, Accreditation Manager, at Graham.Davis@ams.usda.gov or (202) 692-0047.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report NP7177PZA

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

JUL 27 2017

NOTICE OF NONCOMPLIANCE

H.-Joachim Kopp
LACON GmbH
Moltkestrasse 4, D-77654 Offenburg
Germany

Dear Dr. Kopp:

On June 26-28, 2017, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the LACON GmbH (LACON) organic certification program as part of its USDA Renewal Accreditation Assessment. On July 14, 2017, the NOP reviewed the results of the onsite audit to determine LACON's compliance to the USDA organic regulations. A copy of the assessment report, NP7177PZA, is enclosed for your reference.

As the report indicates, one noncompliance, (NP5293OOA.NC5) remains outstanding from a previous audit. Five new noncompliances (NP7177PZA.NC1 through NC5), were identified during the onsite audit. Please submit corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All corrective actions must indicate how the noncompliances will be corrected and how the LACON management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of LACON's USDA accreditation.

If you have questions regarding this notice, please contact, Graham Davis, Accreditation Manager, at Graham.Davis@ams.usda.gov or (202) 692-0047.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report NP7177PZA

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Monterey County Certified Organic. An onsite audit was conducted, and the audit report reviewed to determine Monterey County Certified Organic's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Monterey County Certified Organic (MCCO)
Physical Address	1428 Abbott Street, Salinas, CA 93901
Mailing Address	Same
Contact & Title	Richard Ordonez, Chief Deputy Agricultural Commissioner
E-mail Address	ordonezr@co.monterey.ca.us
Phone Number	(831) 759-7322
Reviewer & Auditors	NOP Reviewer: Janna Howley On-site Auditors: Nikki Adams (Lead Auditor) and Robert Yang (Auditor Trainee)
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: February 25, 2015 Onsite audit: October 2-3 and October 14-15, 2014
Audit Identifier	NP4275ADA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MCCO's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	MCCO's certification services in carrying out the audit criteria during the period: May 2012 through October 2014.

Monterey County Certified Organic (MCCO) is a county program, initially accredited on April 29, 2002 as a USDA National Organic Program (NOP) certifying agent. MCCO is currently accredited to provide organic certification in crops, wild crops and processing/handling to the NOP standard only in Monterey County of California. The MCCO list of NOP certified operations included 16 operations, consisting of 5 crops and 11 handlers. Of the handler operations, 10 are processors and 3 are distributors (1 handler distributor and 2 handler/processor/ distributors).

MCCO has one office located in Salinas, CA based within the Monterey County Agriculture

Commissioner's Office. MCCO provides accreditation services under the USDA NOP Program, as well as equivalency under the EU and COR.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether MCCO's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP1284ADA.NC1 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4275ADA.NC1 – Accepted - 7 CFR §205.403(e)(1) states, "At the time of inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector."

Comments: *A review of the procedures, sample results, and interviews conducted found that no receipt is left with the authorized representative at the time the sample is taken.*

Corrective Action: MCCO has a procedure in the *MCCO Certification Handbook, 2.2.2 Annual Inspection* for leaving receipts of sampling with the operator. In December 2014, MCCO also developed a *MCCO Sampling Receipt* form to be used by the inspector when conducting the sampling. This was inserted into MCCO's Field Sampling Notebook for use by inspectors. The *MCCO Sampling Receipt* form instructs the inspector to complete the sample receipt for each sample taken and have the operator sign this receipt before leaving the operation. It also instructs the inspectors to provide a copy to the operator on the day of sampling and keep the original for MCCO's file. This instruction is then reiterated in the *Inspector Residue Sampling Preparation & Tools Checklist*. MCCO updated its Quality Manual to include the *MCCO Sampling Receipt* as part of the MCCO Field Sampling Notebook. In January 2015, MCCO circulated a training memorandum, which included copies of the new form, to MCCO staff.

NP4275ADA.NC2 – Accepted - 7 CFR §205.403(d) states, “Exit Interview: The inspector must conduct an exit interview... to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.”

Comments: *A review of files, the exit interview template, observation at the witness inspection and interviews conducted found that 1) the Exit Interview form asks for ‘Recommended Corrective Actions’ and states these are for Minor Non-compliances or recommended areas of improvement, which could imply giving advice for identifying overcoming barriers to certification; and 2) MCCO inspectors are issuing an ‘Organic Compliance Agreement’ at the conclusion of the inspection when minor issues are noted (such as OSP corrections, organic certificates not available during the inspection), which requires the operator to perform immediate correction based on the inspector’s determination. This is being used in place of a ‘Notification of Minor Issues’ that requires the operator to provide corrective actions. Two of eight files reviewed did not have Notifications of Minor Issues given to the client when it was warranted.*

Corrective Action: In December, 2014, the *Organic Inspection Exit Interview* document was updated from referencing "recommended corrective actions/minor noncompliance(s) or recommended areas of improvement" to state, "issues of concern and follow-up information." In December 2014, the *Organic Compliance Agreement* was made obsolete. Inspectors no longer issue an *Organic Compliance Agreement*. The updates to the *Organic Inspection Exit Interview* were document controlled and notification thereof was issued on December 2, 2014 to MCCO staff.

NP4275ADA.NC3 – Accepted - 7 CFR §205.662(c)(1-4) states, “Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.... The notification of proposed suspension or revocation of certification shall state: 1) The reasons for the proposed suspension or revocation; 2) The proposed effective date of such suspension or revocation; 3) The impact of a suspension or revocation on future eligibility for certification; and 4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *A review of the Proposed Suspension template, interviews conducted, and the only Proposed Suspension issued includes an opportunity to submit corrective actions to clear the proposed suspension. Additionally, this is a combined template for Proposed Suspension and Proposed Revocation. This phrasing was removed from the template during the assessment, prior to the closing meeting.*

Corrective Action: In October 2014 the *MCCO Proposed Suspension or Revocation* letter was updated to include: 1) the reasons for the proposed suspension or revocation; 2) the proposed effective date of such suspension or revocation; 3) the impact of a suspension or revocation on future eligibility for certification; and 4) the right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681. The updates to the *MCCO Proposed Suspension or Revocation* letter were document controlled and notification thereof was issued on October 20, 2014 to MCCO staff.

NP4275ADA.NC4 – Accepted - 7 CFR §205.501(a)(5) states, “Ensure that its reasonably connected persons, employees, and contractors with inspection, analysis, and decision making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.”

Comments: *Interviews conducted, and training records reviewed, found that one of the two final decision makers did not have organic training in 2011 or 2013. Two inspectors did not have training in 2014 and another did not have training in both 2013 and 2014. Additionally, in house training is not being documented.*

Corrective Action: MCCO made updates to its Quality Manual to clarify that the qualifications listed are required of both Inspectors and Reviewers, and that IOIA organic training "and/or an equivalent organic training" are required. MCCO maintains a Training Log to demonstrate that MCCO is actively committed to ongoing training of its personnel in the organic program. In the past, the training log has not been inclusive of all trainings. Personnel were responsible for tracking trainings by their own logging system (i.e. calendars, email, etc.). To improve this process, MCCO will now request that personnel provide evidence of their trainings so the Training Log can be updated accordingly. MCCO has implemented the *MCCO In-House Training Form*. This tool is used to document trainings that occur during meetings, or provided by staff sharing information from individually-attended trainings, meetings, seminars, scheduled webinars, and other formal or informal training opportunities. Additionally, every month the Monterey County Agricultural Commissioner's Office updates a binder that contains industry periodicals, agricultural group newsletters, internal and external memos, regulation updates, departmental notices and other informative resources. This binder is circulated to the Monterey County Agricultural Commissioner's Office supervisors and managers, who review the information and share relevant items with their staff. MCCO will now document this review and subsequent training on the *MCCO In-House Training Form*. On February 1, 2015 MCCO began their annual request for Human Resource records. A request for updating training records was included in the request; this request will now occur annually.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Monterey County Certified Organic. An onsite audit was conducted, and the audit report reviewed to determine Monterey County Certified Organic's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Monterey County Certified Organic (MCCO)
Physical Address	1428 Abbott Street, Salinas, CA 93901
Mailing Address	Same
Contact & Title	Richard Ordonez, Chief Deputy Agricultural Commissioner
E-mail Address	ordonezr@co.monterey.ca.us
Phone Number	(831) 759-7322
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer Nikki Adams (Lead Auditor) and Robert Yang (Auditor Trainee), On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: December 10, 2014 Onsite audit: October 2-3 and October 14-15, 2014
Audit Identifier	NP4275ADA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MCCO's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	MCCO's certification services in carrying out the audit criteria during the period: May 2012 through October 2014.

Organizational Structure:

Monterey County Certified Organic (MCCO) is a county program, initially accredited on April 29, 2002 as a USDA National Organic Program (NOP) certifying agent. MCCO is currently accredited to provide organic certification in crops, wild crops and processing/handling to the NOP standard only in Monterey County of California. The MCCO list of NOP certified operations included 16 operations, consisting of 5 crops and 11 handlers. Of the handler operations, 10 are processors and 3 are distributors (1 handler distributor and 2 handler/processor/ distributors).

MCCO has one office located in Salinas, CA based within the Monterey County Agriculture Commissioner's Office. MCCO provides accreditation services under the USDA NOP Program, as well as equivalency under the EU and COR.

The MCCO organic certification program is operated with a staff of five, consisting of 1 Deputy Agriculture Commissioner (MCCO Manager), 1 Chief Deputy Agricultural Commissioner (MCCO Supervisor) and 3 staff inspector/biologists. The MCCO staff all has multiple functions as reviewers and inspectors. There are also 2 sub-contracted Quality Managers who perform the annual program review, aid in making revisions, and respond to any NOP requests or corrective actions.

Certification Process:

Certification information and application material can be obtained by contacting MCCO via phone, e-mail, or fax. Upon receiving a request for information regarding certification from a potential client, MCCO sends to the client the following: NOP Rule or a current link; certification packet; application form; applicable OSP; and the MCCO Handbook, which includes the fee schedule. Documents are usually sent electronically but may be sent in hardcopy if requested. The applicant then submits a completed application for certification to MCCO that must contain the following information: an organic production or handling system plan; the application fee; any labels developed; land history; CDFA registration information; and any information and documentation about the previous activity of the firm in organic production if previously certified. The OSP and applications for certification are reviewed by an assigned Inspector/Reviewer to determine if the application is complete and whether the applicant appears to comply with the Final Rule. After the initial review, the inspection is scheduled by the same Inspector/Reviewer. The inspector is assigned based on qualification and availability, but are rotated between the 3 staff inspectors. Upon completion of the inspection, the inspection report is submitted and reviewed by a different Inspector/Reviewer, and then given to the Final Reviewer, who makes the certification decision. The MCCO Supervisor may also make the final decision, based on need. Certificates are issued upon initial certification and updated annually or as required.

The inspection schedule is reviewed for the assigned qualified inspector. A matrix of all inspection activities provides information to the inspector as to whether the inspection is announced, unannounced, the scope (NOP, EU, etc.), if sampling needs to occur, and in what quarter the inspection is to be performed. Inspectors have secure access to the files and/or computer database to retrieve the most recent documents and updates. The inspector performs the inspection using the NOP specific checklist. If necessary, or as assigned, the inspector takes samples, conducts an exit interview, and submits a written report to the evaluator. The inspection report and the analysis results (if any) are reviewed by the evaluator, who then submits the proposal of certification to the MCCO Manager.

For continuing certification (annual updates), updated packets are sent to the client one to three months prior to their anniversary date, and followed up at the deadline to request the necessary information. If the client has not submitted the annual update information by the anniversary date, and no response to requests have been made, a notice of non-compliance is issued. When

updated documents are received, the certification process follows the same process as initial certification.

Clients submit labels to MCCO with the initial application, or at other times during the year, as applicable. MCCO reviews and approves the label prior to use by the client. MCCO does have its own seal, but it is not required for use. Clients generally use the 'Certified Organic by MCCO' or similar statement on labels.

MCCO utilizes the Organic Materials Review Institute (OMRI) and WSDA Material Review List Registry for review and approval of inputs. MCCO staff was trained and knowledgeable of inputs and the NOP National List.

MCCO performed the minimum residue testing for 2013 (1 operation with 6 residue tests taken). MCCO had not yet taken any samples for 2014, but were in the process of scheduling at the time of the assessment. The pesticide residue sample kit and procedures includes a sample form, receipt, sample method, sterile gloves and bags, marking pen, and sample labels for mailing to the appropriate lab. MCCO sends all samples to the Primus Laboratory; it was verified that this is an ISO Accredited Laboratory. No results exceeded the EPA or FDA limits.

Administrative Records and Processes:

The basis of certification for the MCCO certification program is outlined in the MCCO Organic Certification Handbook, Certification Procedures, and the Organic Quality Manual. These documents along with the forms needed for certification are sent to the applicant/client upon request in either a paper or electronic format.

Staff members receive training sessions in NOP training and other agricultural related areas. Most of the training was from outside sources, such as the annual NOP training, IOIA and Eco-Farm Conference. Documentation of the training is being maintained and was available for review. Training is ongoing and is conducted when changes to the program occur.

MCCO has issued Notices of Minor Issues, Notices of Non-Compliances, Notices of Proposed Suspensions, Notices of Suspension and Notices of Resolution since the previous assessment, and also had certified operations surrender their certification. There have been no Notices of Proposed Revocation issued since the last assessment. There have been no withdrawals, appeals, requests for mediation, complaints, Notices of Proposed Revocation or Notices of Denials since the previous assessment. One Settlement Agreement was issued in July 2013.

Summary of Witness Inspections and Review Audits Conducted:

A review audit was conducted of a seed coating and priming operation in Soledad, CA. The small operation has only one site. The facility, material inputs, records, equipment, seeds, seed certificates and maps were reviewed and verified as accurate to the OSP and the latest inspection. There was no evidence of any prohibited substances used. It was verified that MCCO is providing the inspection report, certificate, and updates to the Final Rule and is available to answer any questions from the client. The client was pleased with the services provided by MCCO. There were no issues of concern.

A witness inspection was conducted at an organic vegetable crop operation in Soledad, CA. The inspection was an additional inspection (as the annual inspection was previously conducted earlier this year). The operation is also certified under the terms of the US-Canada equivalence arrangement. The farm is a parallel production operation on 257 acres, with 5% dedicated to 100% organic. The organic sites contract with three external certified operations. The external certified operations plant the crop on the client's fields, and later harvest, package (in the field), and transport the product to their own storage facilities. The crop operation is responsible for managing the crops until harvest. Only one product is planted, managed, harvested, and transported in bulk by the crop operation. The crop client does not package any products in final retail packaging; therefore, no labeling takes place. All areas were verified during the inspections. Buffer zones, inputs, planting stock, records, and maps were verified. Inputs, compost and seeds were verified as compliant. At the completion of the inspection, an exit interview was conducted with a knowledgeable representative of the company. However, the inspector did not present the two issues of concern to the operator as potential noncompliances. They were instead relayed as corrective action measures. Such issues of concern were noted in the "Recommended Corrective Actions" section of MCCO's Organic Inspection Exit Interview form (see findings). No samples were taken and there was no evidence of prohibited substance used.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether MCCO corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to MCCO.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP1284ADA.NC1 – Cleared – 7 CFR §205.404 (b)(3) states, "The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock or processed products produced by the certified operation."

Comments: MCCO has five crop clients. A review of the three certificates issued so far in 2011 found that all three stated the scope as Producer instead of Crops. The template was corrected in the database prior to the conclusion of the audit.

2011 Corrective Action: The MCCO Organic Certification Form was revised to specify the term "Crop" rather than "Grower" or "Producer." The MCCO Organic Certification Addendum was also similarly revised. These documents will continue to be used by MCCO, now and in the future.

2014 Verification of Corrective Action: A review of current crop client certificates found that the scope is listed appropriately as 'Crop.'

Noncompliances Identified during the Current Assessment

NP4275ADA.NC1 - 7 CFR §205.403(e)(1) states, “At the time of inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector.”

Comments: *A review of the procedures, sample results, and interviews conducted found that no receipt is left with the authorized representative at the time the sample is taken.*

NP4275ADA.NC2 – 7 CFR §205.403(d) states, “Exit Interview: The inspector must conduct an exit interview... to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.”

Comments: *A review of files, the exit interview template, observation at the witness inspection and interviews conducted found that 1) the Exit Interview form asks for ‘Recommended Corrective Actions’ and states these are for Minor Non-compliances or recommended areas of improvement, which could imply giving advice for identifying overcoming barriers to certification; and 2) MCCO inspectors are issuing an ‘Organic Compliance Agreement’ at the conclusion of the inspection when minor issues are noted (such as OSP corrections, organic certificates not available during the inspection), which requires the operator to perform immediate correction based on the inspectors determination. This is being used in place of a ‘Notification of Minor Issues’ that requires the operator to provide corrective actions. Two of eight files reviewed did not have Notifications of Minor Issues given to the client when it was warranted.*

NP4275ADA.NC3 – 7 CFR §205.662(c)(1-4) states, “Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.... The notification of proposed suspension or revocation of certification shall state: 1) The reasons for the proposed suspension or revocation; 2) The proposed effective date of such suspension or revocation; 3) The impact of a suspension or revocation on future eligibility for certification; and 4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *A review of the Proposed Suspension template, interviews conducted, and the only Proposed Suspension issued includes an opportunity to submit corrective actions to clear the proposed suspension. Additionally, this is a combined template for Proposed Suspension and Proposed Revocation. This phrasing was removed from the template during the assessment, prior to the closing meeting.*

NP4275ADA.NC4 – 7 CFR §205.501(a)(5) states, “Ensure that its reasonably connected persons, employees, and contractors with inspection, analysis, and decision making

responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.”

Comments: *Interviews conducted, and training records reviewed, found that one of the two final decision makers did not have organic training in 2011 or 2013. Two inspectors did not have training in 2014 and another did not have training in both 2013 and 2014. Additionally, in house training is not being documented.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

DEC 19 2014

Mr. Richard Ordonez
Monterey County Certified Organic
1428 Abbott Street
Salinas, CA 93901

Dear Mr. Ordonez:

On October 2-3 and 14-15, 2014, representatives of the United States Department of Agriculture (USDA), National Organic Program (NOP), completed an onsite audit of the Monterey County Certified Organic (MCCO) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On December 10, 2014 the NOP reviewed the results of the onsite audit to determine MCCO's compliance to the USDA organic regulations. A copy of the assessment report, **NP4275ADA**, is enclosed for your reference.

As the report indicates, one corrective action for a prior noncompliance (**NP1284ADA.NC1**) was cleared and determined to be implemented and effective. Three new noncompliances (**NP4275ADA.NC1-NC3**) were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the MCCO management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 690-4540 or RobertH.Yang@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Minnesota Crop Improvement Association (MCIA). An onsite audit was conducted, and the audit report reviewed to determine MCIA's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Minnesota Crop Improvement Association (MCIA)
Physical Address	1900 Hendon Avenue, St. Paul, MN 55108
Mailing Address	Same
Contact & Title	Cindy Wippler, General Manager
E-mail Address	Wipl001@umn.edu
Phone Number	612-625-7766
Reviewers & Auditors	Janna Howley, NOP Reviewer Lars Crail, On-site Auditor; Renee Gebault-King, Auditor Trainee
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: December 23, 2014 Onsite audit: September 2-5, 2014
Audit Identifier	NP4245LCA
Action Required	No
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MCIA's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	MCIA's certification services in carrying out the audit criteria during the period: April 2012 through September 2014.

MCIA is a 501(c)(5) not for profit association that has been accredited to the National Organic Program as a certifying agent since April 29, 2002. MCIA was initially accredited for the scopes of crops and handling; on June 4, 2004 a scope extension for wild crops was granted, and on October 19, 2007 a scope extension for livestock was granted.

As of August 2014, MCIA had 170 certified operations to the following scopes: 105 crops, 2 wild crops, 11 livestock, and 66 handlers. The majority of the operations are certified in Minnesota, with some operations in Indiana, Iowa, Michigan, Illinois, North Dakota, South Dakota, Missouri, and Wisconsin. All certification activities are conducted at the St. Paul, MN office. MCIA does not have any other accreditations at this time.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether MCIA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4245LCA.NC1 – Accepted - 7 CFR §205.662(c) states, "When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification."

Comments: *MCIA issued an operator a combined notice of noncompliance and proposed suspension for not submitting a timely annual update and fees, which is a correctable noncompliance.*

Corrective Action: The combined *Notice of Noncompliance and Proposed Suspension* was issued February 12, 2014. MCIA addressed this issue in May 2014 by developing letter templates for its notices. The first letter issued to clients is the *Notice of Renewal Deadline*, issued two weeks after the annual update and fees due date. If no response is provided within two weeks, MCIA issues a *Notice of Noncompliance*. If no response is received within two weeks to this second notice, the *Notice of Proposed Suspension*, which gives the client a six week response period, is issued. Templates of the letters were provided to the NOP. MCIA maintains a master list which contains links to its controlled documents, including the revised letter templates. All full-time staff has access to this list and has been trained to refer to it to access the most current documents. MCIA also updated its *Work Instruction – Noncompliance*, which also includes additional examples of notices. Staff has reviewed this revised work instruction, and the updated version will be added to the master list.

NP4245LCA.NC2 – Accepted - 7 CFR §205.662(c)(4) states, "The notification of proposed suspension or revocation of certification shall state: The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681."

Comments: *Some of the notices reviewed either did not include the right to mediate or included only the regulatory section number for the right to request mediation or to file an appeal. During the assessment on May 7, 2014, MCIA updated its noncompliance and adverse action notice templates to align with examples in the 2012 NOP Adverse Action Notice Review training module.*

Corrective Action: MCIA developed a *Notice of Proposed Suspension* in May 2014 that contains language regarding the right to request mediation or file an appeal. In September 2014, MCIA revised the letter again to correct the address for the submission of written appeals. MCIA continues to have a Final Certifier approve the proposed suspensions prior to issuance. A copy of a proposed suspension issued since the onsite audit was provided to the NOP, demonstrating that the correct mediation and appeal rights were communicated to MCIA's client. All full-time staff has access to the revised letter templates via MCIA's master document control system. MCIA

also updated its *Work Instruction – Noncompliance* which includes directions to add the right to request mediation or appeal to *Notification of Proposed Suspension or Revocation* letters. A copy of this document was provided to the NOP. This work instruction also contains additional examples of notices. Staff has reviewed this revised work instruction, and the updated version was added to the master list.

NP4245LCA.NC3 - Accepted - 7 CFR §205.501(a)(9) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Maintain all records pursuant to §205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary...” Furthermore, §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector.”

Comments: *MCIA has written procedures to provide the operator with a receipt for pesticide residue samples taken during an inspection, but there are no records at the MCIA office of receipts issued to the operator, or maintained in operator files.*

Corrective Action: In April 2014 MCIA created a *Residue Testing Sampling Collection Record*. The document was developed to allow the sampler to leave a copy of the form with the operation (MCIA: white copy, Certified Operation: pink copy). MCIA updated the document in October 2014 to address the issued noncompliance. MCIA added an additional form (Certified Operation’s Folder: yellow copy). MCIA prints the form on three-part paper (white, yellow, pink). As of the Fall of 2014, when MCIA collects samples it ensures the yellow copy is put in the operation’s folder. MCIA updated its residue testing sampling written procedure and staff was trained on this new procedure in October 2014.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of MCIA. An onsite audit was conducted, and the audit report reviewed to determine MCIA's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	MCIA – Minnesota Crop Improvement Association
Physical Address	1900 Hendon Avenue, St. Paul, MN 55108
Mailing Address	Same
Contact & Title	Cindy Wippler, General Manager
E-mail Address	Wipl001@umn.edu
Phone Number	612-625-7766
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer; Lars Crail On-site Auditor, and Renee Gebault-King, Auditor Trainee.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: October 8, 2014 Onsite audit: September 2-5, 2014
Audit Identifier	NP4245LCA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MCIA's certification
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	MCIA's certification services in carrying out the audit criteria during the period: April 2012 through September 2014.

Organizational Structure:

Minnesota Crop Improvement Association (MCIA) is a 501(c)(5) not for profit association that has been accredited to the National Organic Program (NOP) as a certifying agent since April 29, 2002. MCIA was initially accredited for the scopes of crops and handling; on June 4, 2004 a scope extension for wild crops was granted, and on October 19, 2007 a scope extension for livestock was granted.

As of August 2014, MCIA had 170 certified operations to the following scopes: 105 crops, 2 wild crops, 11 livestock, and 66 handlers. The majority of the operations are certified in Minnesota, with some operations in Indiana, Iowa, Michigan, Illinois, North Dakota, South Dakota, Missouri, and Wisconsin. All certification activities are conducted at the St. Paul, MN office. MCIA does not have any other accreditations at this time.

The most current organizational structure for MCIA indicated that the following positions are relevant to NOP certification: A governing Board of Directors; a President/CEO; a General Manager/Manager Organic Services; an Organic Communications Coordinator; two Organic Certification Specialists; an Organic Manager of Special Services/Inspector; two Organic Certification Field Supervisors; two Organic Field Supervisors/Inspectors; one part-time Organic Inspector; and 13 contract Organic Inspectors. The staff members also conduct organic inspections. Each of the administrative staff and contract inspectors has documented IOIA training.

Records indicated that each employee possesses the required education and experience in organic agricultural production and handling techniques to perform the duties assigned. These employees include those responsible for assigning inspections, initial reviews, label and input reviews, and decisions on certification. Confidentiality, conflict of interest declarations and performance evaluations were on file for each of those performing work.

Contract employees include 13 full- and part-time inspectors. Three contract inspectors are approved to perform inspections for all scopes; six are approved for crops, livestock, and handling only; and four inspectors are approved for crops only. Records indicated that each contracted person possesses the required education and experience in organic agricultural production and handling techniques to perform the duties assigned. Except for two inspectors, confidentiality, conflict of interest declarations and performance evaluations were on file for each of the contract inspectors. However, MCIA management stated that these two inspectors are prohibited from contracting for additional inspections until they update their required documents. The review of files confirmed that no inspector performed services outside the scopes of inspection for which they are approved.

The MCIA management conducts and documents internal and external staff training. Internal training occurs when new issues arise that need to be shared with staff and the inspectors, either on an individual basis or at regular meetings (as needed). External training includes participation in webinars, conferences, ACA meetings, IOIA trainings and other experiences beneficial to the organic certification and/or inspection staff.

Certification Process:

Requests for certification are handled by the organic certification specialist and received primarily by phone or email. When requests for certification are received, the applicant is provided a certification packet either by mail or electronically. The packet of information is also available on the MCIA website, along with a link to the most current USDA organic regulations. When the completed documents are received, MCIA office staff conducts an initial review for completeness and the ability of the operation to comply. The initial review is recorded on a checklist and specific inspector instructions are listed.

An inspector, either MCIA staff or a contractor, is assigned based on location, knowledge, skills, and experience, to arrange and conduct the inspection. Once an inspection report is completed and submitted to the MCIA office, one or more of the office staff conduct a post-inspection review of the report and all associated documents, including changes to the organic system or handling plan made during the inspection. A recommendation can be one of three options: (1)

issuing certification; (2) issuing certification with conditions that must be met within a certain time frame; or (3) requesting additional information from the operation or the inspector. If additional information is needed, the certification process does not continue until all information is received and reviewed. When the review staff determines there is enough information to make a certification decision, the operation's file is forwarded to the General Manager for the certification decision and issuance of the certificate.

During the file review of several operations, annual updates and subsequent annual inspections were conducted in a process similar to initial applicants and in accordance with the USDA organic regulations. MCIA allows operators to complete and submit a shorter version of the applicable Organic Systems Plan (OSP) that captures changes from the prior year.

MCIA conducts both unannounced inspections and pesticide residue sampling. In 2013 MCIA conducted more than the five percent minimum of certified operations.

The materials review process at MCIA is very comprehensive. It incorporates product reviews from OMRI, WSDA, PCO and other certifiers, in addition to an in-house review, as needed. Annual lists of approved/prohibited substances are maintained for crop, livestock and handling. The lists note the operations that requested approval for various materials, dates and decisions (receipt of request, approval or denial), and other pertinent notes. Under their current system, MCIA and individual operations communicate efficiently about the current status of materials, including whether the operation will continue or cease to use the reviewed materials (determined on an annual basis). This system also allows MCIA to keep a robust database of materials that have been evaluated.

Labels are reviewed by MCIA personnel for compliance with the regulations and their policy requires the labels be approved prior to use. Labels are maintained in their database and are clearly identifiable as single ingredient or multi-ingredient product labels. Procedures and records are in place to document all ingredients, sources, and to calculate the percentage of ingredients for 100% Organic, Organic and "Made with..." label categories. A review of a variety of product labels demonstrated that labels comply with the NOP requirements.

MCIA has no certified private label operations; however, MCIA does certify processors that conduct handling services for private label operations certified by other certifying agents.

MCIA does not currently certify grower groups.

International certification activities were not reviewed during this audit.

Administrative Records and Processes:

MCIA maintains both an electronic and paper based system for records. Certified operation and applicant files are well organized and maintained. Certification activities are adequately recorded and were auditable. MCIA's quality manual is in the process of revision. There is a certification manual published on their website. OSP and inspection report templates are comprehensive, well designed, and adequately cover compliance requirements.

Fees

The MCIA fee schedule is supplied to applicants as required. The fee schedule includes non-refundable information. The fee schedule outlines the various set costs for the certified operations. The fees appear to be reasonable and the schedule is understandable.

MCIA provides estimated certification and inspection costs to initial and continuing operations.

Summary of Witness Inspection:

One witness audit was conducted on a recently certified hydroponic operation in St. Paul, Minnesota. The inspection was unannounced and allowed MCIA to observe production and verify that the record keeping system described in the OSP was implemented. MCIA adequately demonstrated the ability to carry out unannounced inspections.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether MCIA corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to MCIA.

Noncompliances Identified during the Current Assessment

NP4245LCA.NC1 – 7 CFR §205.662(c) states, “When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification.”

Comments: *MCIA issued an operator a combined notice of noncompliance and proposed suspension for not submitting a timely annual update and fees, which is a correctable noncompliance.*

NP4245LCA.NC2 – 7 CFR §205.662(c)(4) states, “The notification of proposed suspension or revocation of certification shall state: The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *Some of the notices reviewed either did not include the right to mediate or included only the regulatory section number for the right to request mediation or to file an appeal. During the assessment on May 7, 2014, MCIA updated its noncompliance and adverse action notice templates to align with examples in the 2012 NOP Adverse Action Notice Review training module.*

NP4245LCA.NC3 - 7 CFR §205.501(a)(9) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Maintain all records pursuant to §205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary...” Furthermore, §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector.”

Comments: *MCIA has written procedures to provide the operator with a receipt for pesticide residue samples taken during an inspection, but there are no records at the MCIA office of receipts issued to the operator, or maintained in operator files.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

OCT 16 2014

Cindy Wippler
Minnesota Crop Improvement Association (MCIA)
1900 Hendon Avenue
St. Paul, MN 55108

Dear Ms. Wippler:

On September 2-5, 2014 representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the MCIA organic certification program as part of its USDA Mid-Term Accreditation Assessment. On October 8, 2014, the NOP reviewed the results of the onsite audit to determine MCIA's compliance to the USDA organic regulations. A copy of the assessment report, **NP4245LCA**, is enclosed for your reference.

As the report indicates, three (3) new noncompliances (**NP4245LCA.NC1 through NC3**), were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the MCIA management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Janna Howley, at (202) 692-0047 or JannaB.Howley@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink, appearing to read "Cheri M".

for Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: AIA Inbox

NOTICE OF NONCOMPLIANCE

Chris Grigsby
MOFGA Certification Services LLC
210 Crosby Brook Rd.
Unity, Maine 04988

Dear Mr. Grigsby:

On May 23, 2017, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) was informed that MOFGA Certification Services (MCS) failed to complete an annual onsite inspection of 100% of its certified operations. We have determined that MCS is noncompliant with the USDA organic regulations, 7 CFR Part 205, as follows:

AIA17145JL.NC1 – 7 CFR §205.403(a)(1) states, “... An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.”

Comments: *MCS failed to conduct a 2016 onsite inspection of a livestock operation. The operation refused MCS access to complete the onsite inspection.*

AIA17145JL.NC2 – 7 CFR §205.662(a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:...”

Comments: *MCS did not issue a notice of noncompliance to a livestock operation that did not permit an on-site inspection to be conducted in 2016. The operation remained certified for over a year without an annual onsite inspection as required.*

MCS must submit corrective actions to AIAInbox@ams.usda.gov within 30 days from the date of this Notice. The corrective actions should indicate how each noncompliance will be corrected and how the MCS management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut the noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions. Failure to resolve the noncompliances may result in proposed suspension or revocation of MCS’s USDA accreditation.

Page 2

If you have questions regarding this notice, please contact Jason Lopez, Accreditation Manager, at JasonJ.Lopez@ams.usda.gov or (202) 620-9445.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Chris Grigsby
MOFGA Certification Services LLC
210 Crosby Brook Rd.
Unity, Maine 04988

Dear Mr. Grigsby:

On May 23, 2017, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) was informed that MOFGA Certification Services (MCS) failed to complete an annual onsite inspection of a certified operation. We have determined that MCS is noncompliant with the USDA organic regulations, 7 CFR Part 205, as follows:

AIA17145JL.NC1 – 7 CFR §205.403(a)(1) states, "... An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue."

Comments: *In 2016, MCS failed to conduct an annual onsite inspection of a certified operation.*

AIA17145JL.NC2 – 7 CFR §205.662(a) states, "When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide:..."

Comments: *MCS did not issue a notice of noncompliance to an operation that refused MCS access to perform an annual onsite inspection in 2016. The operation remained certified for over a year without an annual onsite inspection as required.*

MCS must submit corrective actions to AIAInbox@ams.usda.gov within 30 days from the date of this Notice. The corrective actions should indicate how each noncompliance will be corrected and how the MCS management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut the noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions. Failure to resolve the noncompliances may result in proposed suspension or revocation of MCS's USDA accreditation.

Page 2

If you have questions regarding this notice, please contact Jason Lopez, Accreditation Manager, at JasonJ.Lopez@ams.usda.gov or (202) 620-9445.

Sincerely,



Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Mary Yurlina
Certification Director
MOFGA Certification Services, LLC
210 Crosby Brook Rd.
Unity, ME 04988

Dear Ms. Yurlina:

On June 13, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a mid-term assessment of the MOFGA Certification Services, LLC organic certification program. The objective of the assessment was to determine MOFGA's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4160BJR, is enclosed for your reference.

As the report indicates, five noncompliances, NP4160BJR.NC1 through NC5, were identified during the assessment. Three noncompliances, NP2155ACA.NC1, NP2155ACA.NC6, and NP2155ACA.NC7, remain outstanding from your previous audit. Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the MOFGA management system will be modified to prevent future noncompliances. Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions.

Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Betsy Rakola, at (202) 260-8209 or Betsy.Rakola@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

JUL 7 2014

Mary Yurlina
Certification Director
MOFGA Certification Services, LLC
210 Crosby Brook Rd.
Unity, ME 04988

Dear Ms. Yurlina:

On June 13, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a mid-term assessment of the MOFGA Certification Services, LLC organic certification program. The objective of the assessment was to determine MOFGA's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4160BJR, is enclosed for your reference.

As the report indicates, five noncompliances, NP4160BJR.NC1 through NC5, were identified during the assessment. Three noncompliances, NP2155ACA.NC1, NP2155ACA.NC6, and NP2155ACA.NC7, remain outstanding from your previous audit. Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the MOFGA management system will be modified to prevent future noncompliances. Please refer to NOP 2608, Responding to Noncompliances, for further instructions.

Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Betsy Rakola, at (202) 260-8209 or Betsy.Rakola@ams.usda.gov.

Sincerely,

A handwritten signature in cursive script that reads "Cheri Courtney for CC".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The U.S. Department of Agriculture, Agricultural Marketing Service, National Organic Program (NOP) conducted a mid-term accreditation assessment of MOFGA Certification Services, LLC (MOFGA) from June 9-12, 2014 in Unity, Maine. The NOP reviewed the auditor's report on Jun 26, 2014 to determine MOFGA's capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	MOFGA Certification Services, LLC
Physical Address	210 Crosby Brook Rd., Unity, ME 04988
Mailing Address	210 Crosby Brook Rd., Unity, ME 04988
Contact & Title	Mary Yurlina, Certification Director
E-mail Address	Yurlina@mofga.org
Phone Number	207-568-4142
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer; Betsy Rakola Onsite Auditor(s).
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Review of Corrective Actions Date: October 21, 2014; Audit Date: June 26, 2014
Audit Identifier	NP4160BJR
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MOFGA's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	MOFGA's certification services in carrying out the audit criteria during the period: June 2012 – June 2014

MOFGA Certification Services, LLC (MOFGA) was formed by the Maine Organic Farmers and Gardeners Association in 2002 in order to provide USDA-accredited organic certification services to Maine farmers and food processors. MOFGA was accredited as a certifying agent on June 3, 2002 to the USDA National Organic Program (NOP) for crops, wild crops, livestock, and handling operations.

The MOFGA organic program currently includes 435 operations certified to the NOP, consisting of 345 crops, 51 wild crop, 113 livestock (of which several also have crops), and 114 handlers. All operations are located in the United States. The vast majority are located in the State of Maine, with between 5-10 operations located in Vermont, Massachusetts, and New Hampshire.

All activities are conducted out of MOFGA's office in Unity, ME.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether MOFGA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2155ACA.NC2 – Cleared

NP2155ACA.NC3 – Cleared

NP2155ACA.NC4 – Cleared

NP2155ACA.NC5 – Cleared

AIA13354BJR.NC1 – Cleared

AIA4087MMK.NC1 – Cleared

AIA4087MMK.NC2 – Cleared

NP2155ACA.NC1 – Accepted – 7 CFR §205.402 (a)(1) & (2) states, "Upon acceptance of an application for certification, a certifying agent must: Review the application to ensure completeness pursuant to §205.401; Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part."

Comments: *The review of the certification files found that 3 of the 8 files demonstrated that applications and updates reviewed by the initial reviewer did not have enough information to conduct a complete review of the file. The files moved forward for inspection without being complete and it was requested that the inspector obtain OSP details during the on-site audit. Some examples of missing information included: product labels, commingling descriptions, last date of prohibited material applications, etc. With the information missing, the ACA was not able to determine compliance or capability to comply.*

2012 Corrective Action: MOFGA provided some explanation to the history and culture of MOFGA certification. In an historical aspect, inspectors provided this type of service – helping the farmer with his/her OSP; obtaining information about the OSP for the certifier – for years. Once the NOP was established and prohibited this practice, MOFGA has been continually working with the farmers and the parent organization that maintains an expectation that MOFGA certification services, especially inspectors, be able to help the farmers in any/every way. MOFGA understands this is a non-compliant component of their program. MOFGA held a training session with staff in Oct 2012 to discuss NOP requirements, including complete OSPs before inspection is scheduled. MOFGA intends to enlist their parent company, a non-profit cooperative extension, for assistance in consulting with the farmers and helping them in the ways the inspectors cannot. MOFGA is also going to print an article in their member newsletter

detailing the USDA audit and why this “change” to their system is so important. Finally, MOFGA has created a staff role for a QC/QA Manager; one of the main duties will be to check review documents generated by multiple staff to ensure continuity and compliance with NOP, and MOFGA policies and procedures.

June 2014 NOP Verification: One of the six files reviewed was incomplete, since it did not have any information on the handler’s recordkeeping for organic certificates, tracking of ingredients, or their lot numbers. In addition, the inspector on the slaughterhouse witness audit did not have the most updated copy of the operation’s labels.

October 2014 Corrective Action: MOFGA updated their procedure document, “Administration of Organic Crop System Plan Renewals on Paper” to include a step by step process for Specialists to follow to ensure that a consistent system is in place to process OSPs and receive final approval from Executive Director. All mail, email and phone calls with clients are tracked in MOFGA’s FileMaker database. MOFGA also created a “Farm Review Checklist 2014” for Specialists to ensure that OSPs, and inspector files, are complete prior to inspections. MOFGA provided NOP copies of these two new documents.

NP2155ACA.NC6 – Accepted - 7 CFR §205.501 (a)(11)(iv) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification.”

Comments: *The review of the certification files found that 2 of the 8 files showed use of commanding language in the inspection report that appear to instruct the client on how to address or fix issues of concern, rather than documenting observations to the certifier and indicating how the observations yield, or could yield, a potential non-compliance.*

- *One of the eight files reviewed instructed the operation to do “XYZ” rather than documenting the observation of what was lacking in the system and how that yielded an issue of concern or non-compliance.*
- *One of the eight files reviewed had a certification decision letter for 2012 which stated “continuing improvement points” and included a citation to wild crop regulation 205.207, then cited “MCS tapping guidelines.” The ACA cannot cite findings to their own guidelines or rules unless the rules are in the NOP regulation.*

2012 Corrective Action: MOFGA’s response indicates a need to train staff on inspector roles and language vs. reviewer roles and language; this training was conducted in October 2012. MOFGA also indicated that language appropriate for inspection reports and not using consulting or commanding language was a topic of discussion at the December 2012 inspector training. Further, the creation of the QC/QA Manager position, responsible for overall program compliance through quality control, would provide an additional layer of verification that policies and procedures are being properly followed throughout the certification year. Also, regarding citing “MCS Guidelines” for maple operators, MOFGA stated that it would only use the NOP regulations for non-compliance citations. If effectively implemented, MOFGA’s response demonstrates capability to comply with NOP accreditation requirements.

June 2014 NOP Verification: MOFGA showed significant improvement in this area. The MOFGA Certification Services, LLC parent company, Maine Organic Farmers and Gardeners, includes an “Agricultural Services” division which provides consulting services to organic farmers, and the certification staff regularly make referrals to these consultants in response to questions from operations. MOFGA also showed documentation of its 2012 inspector training session, which specifically discussed refraining from the use of “commanding language.” However, the 2014 initial review letter for a dairy operation suggested to the operator how he could change his protocols in order to bring his temporary confinement procedures into compliance. Therefore, the documentation showed that MOFGA provided advice to the operation on how to overcome barriers to certification, rather than citing the practice as either a minor issue or a noncompliance.

October 2014 Corrective Action: MOFGA sent a notice to its staff to explain that the specific language in the 2014 initial review letter for the dairy operation was considered consulting. MOFGA regularly conducts reviews of its staff and inspectors’ work and the staff conducts peer-reviews of each other’s work. These reviews will include a review of documents for consulting language.

NP2155ACA.NC7 – Accepted - 7 CFR §205.662(a) states, “*Notification:* When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

Comments: *The review of the certification files found that 2 of the 8 files showed “continuous improvement points” were issued instead of noncompliances to operations where issuance of noncompliance was warranted.*

- *One of the eight files reviewed had a certification decision letter for 2012 which listed “continuing improvement points” rather than citing these issues as noncompliances.*
- *One of the eight files reviewed had a “Findings” letter which provided a copy of the inspection report and “continuing improvement points.” These continuous improvement points should have been issued as noncompliances, specifically the recordkeeping issue of not having any compost records on file.*

2012 Corrective Action: MOFGA’s response indicated a necessary change in interpretation of the regulation, including discontinued use of the term “continuous improvement point.” Training for staff was conducted October 2012 to address what is a minor non-compliance as a condition for continued certification vs. non-compliance vs. major non-compliance. MOFGA has provided the new NOP Penalty Matrix to all staff as a guideline for citing non-compliance issues. MOFGA has also created a staff role for Quality Control and Quality Assurance Manager, who will be responsible for overall program compliance and quality checks; a copy of the job description for this position has been provided as objective evidence. If the Penalty Matrix and staff training are effectively implemented, MOFGA’s response demonstrates capability to comply with NOP accreditation requirements.

June 2014 NOP Verification: Three files showed that the operations had used a prohibited sanitizer. One operation also had significant problems with outdoor access for pigs and

chickens. MOFGA addressed these issues through continuing improvement points. The reviewers did not issue Notices of Noncompliance, but instead explained to the operations that they could choose to use an additional sanitizer as an intervening event or change to a different type of sanitizer.

October 2014 Corrective Action: The MCS Director and Associate Director attended the ACA/NOP training in San Diego in February 2014 where NOP's revised, one-page Penalty Matrix was introduced. This training was brought back and shared with MCS staff. Non-conformities such as the ones described here clearly fit the type of violation described in the new one-page Penalty Matrix as ones that need to be addressed by issuing notices of non-compliance instead of compliance inquiry or continuing improvement point letters.

MOFGA has also created a staff role for Quality Control and Quality Assurance Manager, who will be responsible for overall program compliance and quality checks; a copy of the job description for this position has been provided as objective evidence. If the Penalty Matrix and staff training are effectively implemented, MOFGA's response demonstrates capability to comply with NOP accreditation requirements. The Director has already implemented weekly individual meetings with specialists, to review their clients' status and the specialists' approaches to the issues their clients have complying with the regulation. MOFGA is also using weekly staff meetings to discuss, as a team learning exercise, compliance issues encountered in inspection reports or OSP reviews, and whether or not non-compliance notices are in order. MOFGA is also conducting sessions with small groups of specialists, to foster cross-training and consistent interpretations of internal guidelines and NOP regulations.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4160BJR.NC1 - Accepted – 7 CFR §205.404(b)(2) states, "The certifying agent must issue a certificate of organic operation which specifies the:... effective date of certification."

Comments: *Not all certificates contained the additional information and statements as recommended by NOP 2603. The certificates do not include the next anniversary date or the issue date. In addition, the certificate addenda contain an "effective through" date, which could be misinterpreted as an expiration date (however, this date appears on the organic product verification, not on the certificate itself). Although certificates reference the USDA NOP standards, they do not specifically reference 7 CFR 205.*

Corrective Action: Certificates and product verifications have been updated to contain the required information. MOFGA attached copy of updated certificates. Certificates are now a standard layout and produced by their database, which prints out the Certificate and the Product Verification.

NP4160BJR.NC2 - Accepted - 7 CFR §205.403(b)(2) "All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the

operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.”

Comments: *MOFGA does not conduct all inspections during a time when the activities that demonstrate the operation’s compliance can be observed. One file review showed that all vegetables had been harvested prior to the inspector’s visit, and another showed that an inspection of a ruminant livestock operation was conducted after the grazing season had concluded. MOFGA stated that if an annual update inspection for a producer was late in the season one year, they try to schedule them earlier for the next year. MOFGA also stated that initial applicants are always inspected during the production season.*

Corrective Action: MOFGA will reduce the occurrence of “late season” inspections by hiring more staff inspectors. Since the audit in June 2014, MOFGA trained a new dairy/livestock inspector. This inspector has been trained by staff and is now performing inspections. The inspector’s resume and signed Conflict of Interest statement were provided to the NOP. Additionally, the Executive Director gave additional assignments to three contract inspectors in August and September. MOFGA is also considering managing three part-time professional staff members so they work full time schedules during summer months and reduced hours in the winter. This will allow them to perform more inspections during the summer. MOFGA continues to also pursue a 2015 budget that will allow them to afford additional staff resources.

NP4160BJR.NC3 - Accepted - 7 CFR §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.”

Comments: *MOFGA stated that not all contract inspectors attend annual inspector training. If an inspector does not attend the training, there is no mechanism for providing them with the training information or requiring additional training in order to ensure that they maintain the necessary expertise on organic regulations.*

Corrective Action: MOFGA will use a web-based meeting format like GoToMeeting or Readytalk for their next training this fall. This will eliminate the travel issue, which has been the chief factor for not being able to attend trainings. Inspectors will continue to assign homework or a self-test, but MOFGA will now keep their completed work on file to be used as verification of training. MOFGA has set up a Google Group for email announcements and discussions amongst staff and inspectors. This is intended to facilitate fast information dissemination and clarification. Inspectors who do not participate will not be called upon to inspect. MOFGA has 100% participation in the Google Group. The Director posted a message to the group explaining that inspectors need to participate in training if they are to receive inspection work.

NP4160BJR.NC4 - Accepted - 7 CFR §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations

concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”

Comments: *The Certification Director’s inspections are not evaluated. The Management Committee evaluates her overall performance, but her certification functions (such as inspections) are not evaluated.*

Corrective Action: On October 7, 2014, the MOFGA Management Committee came to the decision that the Director will no longer do inspections, but instead delegate this activity. A greater separation of levels and duties within the staff structure is desired; removing this job task from the Director's work plan will enhance the integrity of the program. It will also effectively resolve this non-compliance. The decision was effective immediately. An internal MOFGA policy was developed that clearly stated that the Director will not be part of the inspection process, and the Director’s job description has been updated to reflect this change. The Director’s two remaining 2014 scheduled inspections have been given to other inspectors.

NP4160BJR.NC5 - Accepted – 7 CFR §205.501(a)(18) states, “A private or governmental entity accredited as a certifying agent under this subpart must: provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliances.”

Comments: *During the handler witness inspection, the inspector did not have the most updated labels. MOFGA had the operation’s most recent labels in the certification file, but it did not provide copies of these labels to the inspector prior to the witness inspection.*

Corrective Action: MOFGA has an established label review process; they used this process for a few years, but had not recently. They are conducting a focused label review training in November. MOFGA provided a copy of the updated SOP for Inspection Folders. MOFGA explained that it is printing labels that are placed on the outside of each inspection folder. MOFGA staff assembling the inspector folders check off each item once it is enclosed in the inspector folder. The label has a specific checkbox for the presence of labels. Unchecked boxes indicate that the folder may be incomplete and not ready to be sent to the inspector. Those folders will be flagged for inquiry. The labels will be renewed annually. MOFGA will continue to put copies of all labels in the inspection file as part of the review process. MOFGA provided NOP a copy of their revised procedure document, “Protocol: Client and Inspection Files.”

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

The U.S. Department of Agriculture, Agricultural Marketing Service, National Organic Program (NOP) conducted an onsite mid-term accreditation assessment of the Maryland Department of Agriculture (MDA) from June 23-25, 2014 in Annapolis, MD. The NOP reviewed the auditor's report on July 11, 2014 to determine IDALS' capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name:	Maryland Department of Agriculture (MDA)
Physical Address:	50 Harry S. Truman Parkway, Annapolis, MD 21401
Mailing Address:	50 Harry S. Truman Parkway, Annapolis, MD 21401
Contact & Title:	Deanna Baldwin, Program Manager
E-mail Address:	Deanna.Baldwin@maryland.gov
Phone Number:	410-841-5769
Auditor(s) and Reviewer (s):	Betsy Rakola, NOP Reviewer; Betsy Rakola, On-site Auditor.
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	Reviewed July 11, 2014: noncompliances identified.
Audit Identifier:	NP4147BJR
Action Required:	Yes: corrective actions requested.
Audit and Review Type:	Mid-Term Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of the MDA's certification system.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	The MDA's certification services in carrying out the audit criteria during the period: August 2012 – June 2014

Organizational Structure

The Maryland Department of Agriculture (the MDA) Organic Certification Program is part of the State of Maryland's Food Quality Assurance Program. It operates with employees whose areas of responsibility are not dedicated entirely to the organic program, but to various other responsibilities or activities within the Department, such as egg and poultry inspections. The MDA was accredited as a certifying agent on April 29, 2002 to the USDA National Organic Program (NOP) for crops, wild crops, livestock, and handling operations. The MDA organic program currently includes 101 operations certified to the NOP, consisting of 78 crops, 20

livestock, and 24 handlers. All operations are located in the State of Maryland. The MDA does not certify any grower groups.

The MDA staff for the NOP Program consists of the Program Manager, Program Administrator (also an inspector), and two other part-time staff inspectors. The MDA is training an additional inspector/reviewer. The MDA does not use independent inspectors for NOP inspections. Records reviewed verified that the MDA is meeting the requirements for annual performance evaluations, annual confidentiality agreements and conflict of interest statements. Personnel files reviewed and interviews conducted indicated that all had the required education, training and experience in organic agricultural production and handling to perform the duties assigned, except as noted in the findings.

Certification Process

After January 1 of each year, the Program Manager or Program Administrator post current procedures, notification of certification applicability and exceptions and fees for obtaining certification on the MDA website. Upon request, the MDA sends a potential applicant a complete packet of information for the type of certification that applies. This includes all pertinent forms and OSP's along with the NOP Rule or a notice where to find the most recent version of the Rule. When applications are received, the Program Administrator does the initial review and notes any questions or concerns. The Program Administrator then either conducts the on-site inspection or assigns the inspection to another staff inspector. After the inspection is completed, the inspection report is submitted to the Program Administrator or another inspector for review. After the review, the completed file is submitted to the Program Manager, who makes the final certification decision.

Upon certification, the MDA issues a certificate which includes the required information, along with a letter summarizing any minor issues. The MDA requires information to be updated annually or as changes are made to the OSP. The MDA also requires and conducts annual renewal inspections for continuing NOP certification. Operations submit a summary annual update form, and the MDA requests a fully completed OSP from each operation once every 5 years. The MDA issues new certificates annually.

The MDA has a Material Review Contract and Recognition Agreement with the Organic Materials Review Institute (OMRI) to assist in all material reviews. They also purchased the Pennsylvania Certified Organic materials list and use information from the Washington State Department of Agriculture. The Program Manager has the final say in approving the product, and the program has approved basic products such as mined lime or compost.

Labels are required to be submitted to the MDA prior to usage. The labels are reviewed by one of the inspectors and then are passed to the Program Manager, who makes the final decision. Not all labels are reviewed on-site or compared with labels in the file, as noted in the findings.

The MDA is approved to issue TM-11 export certificates to Japan and Taiwan, but they have not received any requests to do so. Interviews and file reviews confirmed that the MDA is appropriately implementing the terms of the US-Canada equivalency arrangement. The MDA

has not received any requests for exports or imports under the US-European Union equivalency arrangement.

Administrative Records and Processes

The MDA has a Quality Manual and additional forms, procedures, and documents used for NOP certification activities. The MDA conducts internal audits and has an annual program review relating to requirements that are specific to the NOP program. Non-conformances are identified and corrective actions are implemented as needed.

The MDA has policies and procedures in place for investigation of complaints, as well as denials, proposed suspension and revocation. File reviews indicated that the MDA is following the NOP regulations for adverse actions, except as noted in the findings. Two operations have appealed Notices of Proposed Suspension, and the NOP has concluded these appeals.

The MDA charges a flat fee of \$500 per applicant, and this fee is published on their website and on all of their organic system plan and annual update forms. The fee schedule does not explain refundable portions or when fees become non-refundable, as noted in the findings. The fees appear to be reasonable. The fee schedule supplied to clients or prospective clients is the same as that filed with the Administrator.

Witness Inspections

The audit included an annual renewal witness audit of a fresh fruit and vegetable handler in Lancaster, MD. The handler cut, repacked, and distributed both organic and conventional produce. The inspection verified that the operation was complying with the USDA organic regulations, except as noted in the findings.

NOP DETERMINATION

NOP's review of the MDA's onsite audit report was conducted. NOP has determined the following status of the prior noncompliance correction actions, the current identified noncompliances, and any observations:

Noncompliances from Prior Assessments – Cleared

NP2226ACA.NC1 – Cleared. NOP § 205.404(b)(3) states, “The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.” *The eight (8) certification files reviewed during the assessment found that all eight (8) organic certificates in the files did not have the scope of certification listed. Corrective Action:* The MDA updated its database that generates organic certificates to include the scope of certification, provided new certificates to certified operations since August 2012, and submitted a template of its organic certificate for review. **2014 NOP Verification:** all of the certificates reviewed listed the correct scope of certification.

Noncompliances Identified during the Current Assessment

NP2226ACA.NC2 – Outstanding –NOP § 205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.” *The eight (8) certification files reviewed during the assessment found that continuation of certification was granted with “conditions of certification” for two (2) of the files which were clearly violations of certain sections of the rule. The 2 files indicated that the clients were in violation of NOP §205.303 (b) (2) and that the labels should be corrected prior to the next onsite inspection. Corrective Action:* The MDA had the certified operations correct the two labels to be compliant with USDA organic regulations. The MDA also revised its procedure document, MDA_SOP_011, *Handling Noncompliances/Non-conformities*, to define and address the implementation of the procedures concerning conditions of certification and noncompliances. Staff meetings were held April 23, 2013, and May 28, 2013, to review the procedure amendments and updated SOPs were provided to all organic program employees. **2014 NOP Verification:** Two of the eight files reviewed included a letter with conditions for certification where the operations clearly violated the requirements. In the first file, the operator violated §205.103(b)(3) by maintaining records for only 3 years, §205.400(f)(2) by not notifying the MDA of changes to his organic system plan, and §205.239(c) by allowing heifers access to a stream in such a way that could contribute to the contamination of water. In a second file, the crop operation listed continuous corn production on two of its fields, which does not comply with §205.206(a)(1). In the second file, the MDA did not address this issue in the certification decision letter, which listed other conditions for certification, and they did not issue a Notice of Noncompliance.

NP4174BJR.NC1. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.” *The MDA doesn’t have a consistent system to track approved product labels. Approvals are stored in the folder corresponding to the year in which they were submitted, but this information isn’t easily accessible. Staff were not certain which copies of labels were the most recent, approved copies; and the inspector did not have copies of the approved labels during the witness audit.*

NP4174BJR.NC2. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” *The MDA only conducted one unannounced inspection since 2012. Therefore, they have not conducted unannounced inspections of 5% of their certified operations, as recommended by instruction NOP 2609, “Unannounced Inspections,” under the authority of §205.403(a)(2)(iii).*

NP4174BJR.NC3. §205.402(b)(3), “The certifying agent shall within a reasonable time: provide the applicant with a copy of the test results for any samples taken by an inspector.” *As of June 23, 2014, the MDA had not provided a copy of test results from residue testing to the operations which it had sampled. The MDA received the test results in February 2014. The MDA had submitted these samples to the state laboratory in May 2012.*

NP4174BJR.NC4. §205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.” *Certification fees are refundable prior to the inspection, but not after the inspection. Neither the MDA’s website nor its application for certification explain at what stage during the certification process fees become nonrefundable.*

NP4174BJR.NC5. §205.405(a) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant.” *The MDA did not provide a Notice of Noncompliance to two operations who were issued a proposed denial of certification.*

NP4174BJR.NC6. §205.405(c)(2) states, “After issuance of a notification of noncompliance, the certifying agent must: issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.” *The MDA did not issue a written notice of denial of certification to applicants that failed to respond to the notification of noncompliance. Instead, the MDA issued a “proposed denial of certification” but took no further action. However, there is no provision in the regulations for “proposed denial of certification”.*

NP4174BJR.NC7. §205.662(c)(4) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state: the right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.” *The MDA adverse action procedure stated that all Notices of Proposed Suspension or Revocation must include “the date by which any rebuttal or corrective actions must be submitted.” One Notice of Proposed Suspension included the option to submit a rebuttal of the noncompliance for approval by the MDA. However, operations may not respond to a Notice of Proposed Suspension with a rebuttal or corrective actions. The only remedies at this stage of the process are appeals and/or mediation.*

NP4174BJR.NC8. §205.403(c)(2) states, “The on-site inspection of an operation must verify: that the information, including the organic production or handling system plan, provided in

accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.” *The inspector did not fully verify the operation’s compliance during the witness inspection, as described below.*

- *The inspector only verified five product labels for a fruit and vegetable handler which handled more than fifty organic products. These labels did not represent all of the product lines handled by the operation. The inspector did not compare the labels viewed onsite to the ones which were approved by MDA to determine whether there were any changes.*
- *The inspector reviewed a selection of certificates for the operation’s suppliers, which verified that the suppliers were certified to produce crops. However, the inspector did not review any of the product profiles to verify that the suppliers were actually producing the fruits and vegetables that the handler was purchasing.*
- *The inspector did not view procedures for receiving incoming product, bills of lading, or clean truck affidavits. The operation stated that they had these records available, but the inspector did not ask to review them. Therefore, he did not verify the integrity of organic products during receiving or shipping.*

NP4174BJR.NC9. §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.” *The MDA did not have a sufficient number of adequately trained staff to conduct certification activities according to the USDA organic regulations. The lead inspector and the program manager had not participated in the NOP’s annual training, and they have not reviewed the training slides. Interviews showed staff were not aware of recent updates to NOP policies and had not reviewed recent guidance. In half the certification files reviewed the MDA did not make a certification until 12-14 months after the application was received. During interviews, personnel stated that they have difficulty recruiting and retaining qualified staff, which results in a slow certification process.*

NP4174BJR.NC10. §205.501(a)(9) states, “A private or governmental entity accredited as a certifying agent under this subpart must maintain all records pursuant to §205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official.” *The MDA was not able to locate several of the records requested for certification file reviews during the audit. For example, a dairy operation’s certification file was missing dry matter intake worksheets, and a processor’s file was missing organic certificates for ingredients and product verification forms. The MDA’s records showed that staff had previously reviewed the records, but they could not be located or made available for the audit. These records are necessary to demonstrate compliance with the organic regulations.*

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

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Mailing Address:	50 Harry S. Truman Parkway, Annapolis, MD 21401
Contact & Title:	Deanna Baldwin, Program Manager
E-mail Address:	Deanna.Baldwin@maryland.gov
Phone Number:	410-841-5769
Auditor(s) and Reviewer (s):	Betsy Rakola, NOP Reviewer; Betsy Rakola, On-site Auditor.
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	Reviewed July 11, 2014: noncompliances identified.
Audit Identifier:	NP4147BJR
Action Required:	Yes: corrective actions requested.
Audit and Review Type:	Mid-Term Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of the MDA's certification system.
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NP4174BJR.NC2. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” *The MDA only conducted one unannounced inspection since 2012. Therefore, they have not conducted unannounced inspections of 5% of their certified operations, as recommended by instruction NOP 2609, “Unannounced Inspections,” under the authority of §205.403(a)(2)(iii).*

NP4174BJR.NC3. §205.402(b)(3), “The certifying agent shall within a reasonable time: provide the applicant with a copy of the test results for any samples taken by an inspector.” *As of June 23, 2014, the MDA had not provided a copy of test results from residue testing to the operations which it had sampled. The MDA received the test results in February 2014. The MDA had submitted these samples to the state laboratory in May 2012.*

NP4174BJR.NC4. §205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.” *Certification fees are refundable prior to the inspection, but not after the inspection. Neither the MDA’s website nor its application for certification explain at what stage during the certification process fees become nonrefundable.*

NP4174BJR.NC5. §205.405(a) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant.” *The MDA did not provide a Notice of Noncompliance to two operations who were issued a proposed denial of certification.*

NP4174BJR.NC6. §205.405(c)(2) states, “After issuance of a notification of noncompliance, the certifying agent must: issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.” *The MDA did not issue a written notice of denial of certification to applicants that failed to respond to the notification of noncompliance. Instead, the MDA issued a “proposed denial of certification” but took no further action. However, there is no provision in the regulations for “proposed denial of certification”.*

NP4174BJR.NC7. §205.662(c)(4) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state: the right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.” *The MDA adverse action procedure stated that all Notices of Proposed Suspension or Revocation must include “the date by which any rebuttal or corrective actions must be submitted.” One Notice of Proposed Suspension included the option to submit a rebuttal of the noncompliance for approval by the MDA. However, operations may not respond to a Notice of Proposed Suspension with a rebuttal or corrective actions. The only remedies at this stage of the process are appeals and/or mediation.*

NP4174BJR.NC8. §205.403(c)(2) states, “The on-site inspection of an operation must verify: that the information, including the organic production or handling system plan, provided in

accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.” *The inspector did not fully verify the operation’s compliance during the witness inspection, as described below.*

- *The inspector only verified five product labels for a fruit and vegetable handler which handled more than fifty organic products. These labels did not represent all of the product lines handled by the operation. The inspector did not compare the labels viewed onsite to the ones which were approved by MDA to determine whether there were any changes.*
- *The inspector reviewed a selection of certificates for the operation’s suppliers, which verified that the suppliers were certified to produce crops. However, the inspector did not review any of the product profiles to verify that the suppliers were actually producing the fruits and vegetables that the handler was purchasing.*
- *The inspector did not view procedures for receiving incoming product, bills of lading, or clean truck affidavits. The operation stated that they had these records available, but the inspector did not ask to review them. Therefore, he did not verify the integrity of organic products during receiving or shipping.*

NP4174BJR.NC9. §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.” *The MDA did not have a sufficient number of adequately trained staff to conduct certification activities according to the USDA organic regulations. The lead inspector and the program manager had not participated in the NOP’s annual training, and they have not reviewed the training slides. Interviews showed staff were not aware of recent updates to NOP policies and had not reviewed recent guidance. In half the certification files reviewed the MDA did not make a certification until 12-14 months after the application was received. During interviews, personnel stated that they have difficulty recruiting and retaining qualified staff, which results in a slow certification process.*

NP4174BJR.NC10. §205.501(a)(9) states, “A private or governmental entity accredited as a certifying agent under this subpart must maintain all records pursuant to §205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official.” *The MDA was not able to locate several of the records requested for certification file reviews during the audit. For example, a dairy operation’s certification file was missing dry matter intake worksheets, and a processor’s file was missing organic certificates for ingredients and product verification forms. The MDA’s records showed that staff had previously reviewed the records, but they could not be located or made available for the audit. These records are necessary to demonstrate compliance with the organic regulations.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Deanna Baldwin
Program Manager, Organic Certification Program
Maryland Department of Agriculture (MDA)
50 Harry S. Truman Parkway
Annapolis, MD 21401

Dear Ms. Baldwin:

On June 25, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a mid-term assessment of the Maryland Department of Agriculture's (MDA) organic certification program. The objective of the assessment was to determine the MDA's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4147BJR, is enclosed for your reference.

As the report indicates, ten noncompliances (NP4147BJR.NC1 through 10) were identified during the assessment. One noncompliance, NP2226ACA.NC2, remains outstanding from your previous audit. Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the MDA's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Betsy Rakola, at (202) 260-8209 or Betsy.Rakola@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

JUL 18 2014

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Program Manager, Organic Certification Program
Maryland Department of Agriculture (MDA)
50 Harry S. Truman Parkway
Annapolis, MD 21401

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If you have questions regarding this notice, please contact your Accreditation Manager, Betsy Rakola, at (202) 260-8209 or Betsy.Rakola@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney". The signature is written in a cursive, flowing style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The U.S. Department of Agriculture, Agricultural Marketing Service, National Organic Program (NOP) conducted an onsite mid-term accreditation assessment of the Maryland Department of Agriculture (MDA) from June 23-25, 2014 in Annapolis, MD. The NOP reviewed the auditor's report on July 11, 2014 to determine MDA's capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Maryland Department of Agriculture (MDA)
Physical Address	50 Harry S. Truman Parkway, Annapolis, MD 21401
Mailing Address	Same
Contact & Title	Deanna Baldwin, Program Manager
E-mail Address	Deanna.Baldwin@maryland.gov
Phone Number	410-841-5769
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer; Betsy Rakola, Onsite Auditor.
Review & Audit Date(s)	Corrective actions reviewed: October 9, 2014 Audit Date: July 11, 2014
Audit Identifier	NP4147BJR
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MDA's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	The MDA's certification services in carrying out the audit criteria during the period: August 2012 – June 2014

The Maryland Department of Agriculture (the MDA) Organic Certification Program is part of the State of Maryland's Food Quality Assurance Program. It operates with employees whose areas of responsibility are not dedicated entirely to the organic program, but to various other responsibilities or activities within the Department, such as egg and poultry inspections. The MDA was accredited as a certifying agent to the USDA National Organic Program (NOP) for crops, wild crops, livestock, and handling operations on April 29, 2002. MDA's organic program currently includes 101 operations certified to the NOP, consisting of 78 crops, 20 livestock, and 24 handlers. All operations are located in Maryland. MDA does not certify any grower groups.

MDA staff for the NOP Program consists of the Program Manager, Program Administrator (also an inspector), and two other part-time staff inspectors. MDA is training an additional inspector/reviewer. MDA does not use independent inspectors for NOP inspections. Records reviewed verified that MDA is meeting the requirements for annual performance evaluations, annual confidentiality agreements and conflict of interest statements. Personnel files reviewed and interviews conducted indicated that all had the required education, training and experience in organic agricultural production and handling to perform the duties assigned, except as noted in the findings.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether MDA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2226ACA.NC1 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP2226ACA.NC2 – Accepted - NOP §205.406(c) states, "If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662."

2012 Comments: *Eight (8) certification files reviewed during the assessment found that continuation of certification was granted, with "conditions of certification" for two (2) of the files which were clearly violations of certain sections of the rule. The two files indicated that the clients were in violation of NOP §205.303(b)(2) and that the labels should be corrected prior to the next onsite inspection.*

2012 Corrective Action: MDA had the certified operations correct the two labels to be compliant with USDA organic regulations. MDA also revised its procedure document, MDA-SOP-011, *Handling Noncompliances/Nonconformities*, to define and address the implementation of the procedures concerning conditions of certification and noncompliances. Staff meetings

were held April 23, 2013 and May 28, 2013, to review the procedure amendments, and updated SOPs were provided to all organic program employees.

2014 NOP Verification: Two of the eight files reviewed included a letter with conditions for certification where the operations clearly violated the requirements. In the first file, the operator violated §205.103(b)(3) by maintaining records for only 3 years, §205.400(f)(2) by not notifying the MDA of changes to his organic system plan, and §205.239(c) by allowing heifers access to a stream in such a way that could contribute to the contamination of water. In a second file, the crop operation listed continuous corn production on two of its fields, which does not comply with §205.206(a)(1). In the second file, MDA did not address this issue in the certification decision letter, which listed other conditions for certification, and they did not issue a Notice of Noncompliance.

2014 Corrective Action: MDA-SOP-011, *Handling Noncompliances/Nonconformities*, has been revised. Reviewers and inspectors are to notify the Administrator and Program Manager of any potential noncompliances noted during reviews and/or inspections within five days of the review and/or inspection. This will assist the Administrator and Program Manager in investigating potential noncompliances as soon as they are noted and taking more timely action.

The Program Manager and Administrator are developing a more comprehensive document to clarify the difference between conditions of certification (i.e., soil test due, records disorganized) and non-compliances (example - records not kept for required time period). After the document is completed, a training session for all reviewers and inspectors will be conducted will be held by October 30, 2014 that will review identifying noncompliances, the clarifying document and NOP guidance on noncompliances. The Program Manager and Administrator will spot check certification files at different stages (after initial review, after inspection, after final review) to verify noncompliances are being identified and Notices of Noncompliance issued as appropriate. All Notices of Noncompliance will be issued as noncompliances are identified, rather than waiting for the certification decision. A template for noncompliance letters that includes the required instructions to certified operations was developed.

NP4174BJR.NC1 – Accepted - §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: *MDA doesn't have a consistent system to track approved product labels. Approvals are stored in the folder corresponding to the year in which they were submitted, but this information isn't easily accessible. Staff was not certain which copies of labels were the most recent, approved copies; and the inspector did not have copies of the approved labels during the witness audit.*

Corrective Action: MDA adopted a new system to track approved product labels to ensure approved product labels are tracked and the information on current approved labels is easily accessible. The new procedure (MDA-SOP-024) and tracking document (revised MDA-DOC-056) were provided to the NOP. The procedure requires inspectors to be provided with copies of all currently approved labels prior to conducting an inspection for comparison to labels used at the inspected operation. The new procedure has been reviewed with staff who receive labels by

email and/or regular mail. In August 2014, instructions were issued to inspectors clarifying that they will be provided copies of all currently approved labels prior to an inspection, and verification of each label must be conducted and documented during the inspection. The Administrator and/or Program Manager will begin to review inspection reports and take corrective actions with inspectors that are not following the new SOP.

NP4174BJR.NC2 – Accepted - §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.”

Comments: *MDA only conducted one unannounced inspection since 2012. Therefore, they have not conducted unannounced inspections of 5% of their certified operations, as recommended by instruction NOP 2609, “Unannounced Inspections,” under the authority of §205.403(a)(2)(iii).*

Corrective Action: MDA revised procedure MDA-SOP-002 to add procedures for ensuring that 5% of MDA certified operations are selected and receive annually unannounced inspections. The Administrator and the Program Manager reviewed NOP 2609 Instruction “Unannounced Inspections” and incorporated it by reference in MDA-SOP-002. The Administrator and Program Manager will ensure 5% of the certified operations have received an unannounced inspection by December 31, 2014.

NP4174BJR.NC3 – Accepted - §205.402(b)(3), “The certifying agent shall within a reasonable time: provide the applicant with a copy of the test results for any samples taken by an inspector.”

Comments: *As of June 23, 2014, the MDA had not provided a copy of test results from residue testing to the operations which it had sampled. The MDA received the test results in February 2014. The MDA had submitted these samples to the state laboratory in May 2012.*

Corrective Action: MDA’s Program Manager reviewed procedure MDA-SOP-016 *Testing Requirements, Soil Samples*. The SOP did not specifically detail the procedure for providing test results to certified operations. MDA revised the SOP and reviewed it with staff responsible for providing the test results to certified operations.

NP4174BJR.NC4 – Accepted - §205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable. The certifying agent shall provide all persons inquiring about the application process with a copy of its fee schedule.”

Comments: *Certification fees are refundable prior to the inspection, but not after the inspection. Neither MDA's website nor its application for certification explain at what stage during the certification process fees become nonrefundable.*

Corrective Action: MDA added the refund policy to certification applications and cover sheets (MDA-DOCS-002 thru -004, and MDA-DOCS-015 thru -018,). Copies of the updated documents were provided to the NOP. MDA will have this information on its website before December 31, 2014.

NP4174BJR.NC5 – Accepted - §205.405(a) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant.”

Comments: *MDA did not provide a Notice of Noncompliance to two operations who were issued a proposed denial of certification.*

Corrective Action: MDA's procedure MDA-SOP-005 has been revised to include a required response date; a noncompliance will be issued to any applicant that does not respond by the due date. Failure to resolve the noncompliance will result in a Denial of Certification. The Program Manager will review the revised SOP with the Administrator and all reviewers.

NP4174BJR.NC6 – Accepted - §205.405(c)(2) states, “After issuance of a notification of noncompliance, the certifying agent must: issue a written notice of denial of certification to an applicant who fails to respond to the notification of noncompliance.”

Comments: *The MDA did not issue a written notice of denial of certification to applicants that failed to respond to the notification of noncompliance. Instead, the MDA issued a “proposed denial of certification” but took no further action. However, there is no provision in the regulations for “proposed denial of certification”.*

Corrective Action: MDA-SOP-005 has been revised to require response dates and the issue of a noncompliance for failure to submit additional information. The current SOP did not include a “Proposed denial of certification.” The Administrator and Program Manager reviewed MDA-SOP-005 and will follow it in the future. A template for Denial of Certification letters, that includes the required standard information, will be developed.

NP4174BJR.NC7 – Accepted - §205.662(c)(4) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed

suspension or revocation of certification shall state: the right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *The MDA adverse action procedure stated that all Notices of Proposed Suspension or Revocation must include “the date by which any rebuttal or corrective actions must be submitted.” One Notice of Proposed Suspension included the option to submit a rebuttal of the noncompliance for approval by the MDA. However, operations may not respond to a Notice of Proposed Suspension with a rebuttal or corrective actions. The only remedies at this stage of the process are appeals and/or mediation.*

Corrective Action: MDA-SOP-011 was revised to remove the option of submitting corrective actions or rebuttals for proposed suspensions, suspensions, proposed revocations and revocations. The Program Manager and Administrator reviewed the new procedure. A template that includes the required standard information for proposed suspension, suspension, proposed revocation and revocation letters will be developed.

NP4174BJR.NC8 – Accepted - §205.403(c)(2) states, “The on-site inspection of an operation must verify: that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.”

Comments: *The inspector did not fully verify the operation’s compliance during the witness inspection, as described below.*

- *The inspector only verified five product labels for a fruit and vegetable handler which handled more than fifty organic products. These labels did not represent all of the product lines handled by the operation. The inspector did not compare the labels viewed onsite to the ones which were approved by MDA to determine whether there were any changes.*
- *The inspector reviewed a selection of certificates for the operation’s suppliers, which verified that the suppliers were certified to produce crops. However, the inspector did not review any of the product profiles to verify that the suppliers were actually producing the fruits and vegetables that the handler was purchasing.*
- *The inspector did not view procedures for receiving incoming product, bills of lading, or clean truck affidavits. The operation stated that they had these records available, but the inspector did not ask to review them. Therefore, he did not verify the integrity of organic products during receiving or shipping.*

Corrective Action: MDA-SOP-007 *Inspection Protocols* was revised to include MDA-DOC-056 to verify the labeling, product profiles, and NOP compliance of all ingredients. The new protocol will be reviewed with all inspectors by the Administrator and the Program Manager. MDA-SOP-007 already stated that all required records must be reviewed at the inspection; this would include procedures for incoming product, bills of lading, or clean truck affidavits. The Administrator and/or Program Manager will review the revised inspection protocol, and the requirement to review all required records, with all inspectors. Verification that inspectors are following these procedures will be conducted during their next supervisory witness inspections.

NP4174BJR.NC9 – Accepted - §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.”

Comments: *The MDA did not have a sufficient number of adequately trained staff to conduct certification activities according to the USDA organic regulations. The lead inspector and the program manager had not participated in the NOP’s annual training, and they have not reviewed the training slides. Interviews showed staff were not aware of recent updates to NOP policies and had not reviewed recent guidance. In half the certification files reviewed the MDA did not make a certification until 12-14 months after the application was received. During interviews, personnel stated that they have difficulty recruiting and retaining qualified staff, which results in a slow certification process.*

Corrective Action: The Program Manager and Administrator will review all NOP training slides currently available on the NOP website. MDA-SOP-015 was revised to require the Program Manager, Administrator and Reviewers to attend the annual NOP training or review the training slides and to review all NOP guidance as it is issued. The Program Manager and/or Administrator will determine the relevance of training slides and guidance documents to the duties of other personnel; they will then be required to review these training slides and guidance.

MDA SOPs and documents will be updated by the Program Manager and/or Administrator as needed after the training, and/or reviewing the guidance documents. Delays in certification decisions are caused by a “bottleneck”; only the Program Manager is able to make certification decisions and write all letters concerning certification. The bulk of MDA’s inspections must be conducted during the growing season from May to September. MDA currently has three inspectors (one of which is also the Administrator) and two reviewers (both are also inspectors). MDA currently has two inspectors in training; the plan is to have one of the inspectors in training transition to a position to make certification decisions after receiving adequate training in inspection, and review procedures and policies. The transition should take place by December 31, 2014. Two final certification decision makers will be able to reduce the time it takes MDA to make certification decisions.

NP4174BJR.NC10 – Accepted - §205.501(a)(9) states, “A private or governmental entity accredited as a certifying agent under this subpart must maintain all records pursuant to §205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official.”

Comments: *The MDA was not able to locate several of the records requested for certification file reviews during the audit. For example, a dairy operation’s certification file was missing dry matter intake worksheets, and a processor’s file was missing organic certificates for ingredients and product verification forms. The MDA’s records showed that staff had previously reviewed the records, but they could not be located or made available for the audit. These records are necessary to demonstrate compliance with the organic regulations.*

Corrective Action: MDA's policy and procedures require all records required to demonstrate compliance with the organic regulations to be kept in the certification file. To improve MDA's recordkeeping, a new procedure for maintaining product profiles, organic certificates for ingredients and labels was developed (MDA-SOP-024). MDA receives records by regular mail and electronically; a comprehensive filing system that makes records easy to locate is not possible without printing all records received by email.

MDA will immediately begin printing all records received by email and include them in the file of the certified operation. The current Administrator for the program moved a year ago; his new home is several hours away from the MDA main office. Previously he was in the office two to three days; currently he is now in the office two to three days per month. Many records are emailed to him or taken with him to review off site. One of the current inspectors in training – who will be moving into the Administrator position once she has received adequate experience and training - will be in the office two to three days per week. Records will be emailed to her by certified operations and printed for the files. If any records need to be taken off site, they will be copied and the originals will remain in the files. Until this transition takes place, MDA will discontinue the practice of taking originals records off site. All records taken off site will be copies of originals; originals will remain in the certified operation's file at the main office.

NATIONAL ORGANIC PROGRAM

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Marin Organic Certified Agriculture (MOCA). An onsite audit was conducted, and the audit report reviewed to determine MOCA's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Marin Organic Certified Agriculture (MOCA)
Physical Address	1682 Novato Blvd. Suite 150A; Novato, CA 94947
Mailing Address	1682 Novato Blvd. Suite 150A; Novato, CA 94947
Contact & Title	Jeffrey Stiles, Inspector/Biologist III
E-mail Address	jstiles@marincounty.org
Phone Number	(415) 473-6700
Reviewer(s) & Auditor(s)	Robert Yang, NOP Reviewer; Nikki Adams, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: October 23, 2014 Onsite audit: August 18-20, 2014
Audit Identifier	NP4230ADA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MOCA's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	MOCA's certification services in carrying out the audit criteria during the period: October, 2011 through August, 2014.

Organizational Structure:

Marin Organic Certified Agriculture (MOCA) operates as a program of the Marin County Department of Agriculture, providing organic certification services to operations in Marin and Sonoma counties. MOCA has been accredited by the National Organic Program (NOP) since April 29, 2002 for the scopes of crop, wild crop, livestock, and handling. MOCA currently certifies 51 operations. The certified operations consist of 49 crops, 22 livestock, 2 wild crops, and 3 handling operations, of which 1 is a processor and 2 are distributors. All certification activities are conducted at MOCA's office, which is located in the Marin County Agriculture Weights and Measures office.

The MOCA organic certification program is operated with six full-time staff. The staff consists

of one program administrator, one inspector/program coordinator, three additional inspectors, and one residue sampling specialist. Two sub-contracted quality managers perform the annual program review and assist with making revisions and responding to requests for corrective actions from the NOP. A review of the personnel files indicated that personnel had a sufficient combination of education, experience and/or training in organic production and handling practices. A review of certification files and personnel records did not identify any conflicts of interest. Annual confidentiality statements and performance evaluations were verified to be on-file.

Certification Process:

Requests for certification are received via telephone or email. The initial request for certification and correspondence is handled by an assigned inspector who also conducts the initial review of the application for certification. New applicants are provided an application affidavit form; MOCA's Certification Handbook, which includes the fee schedule; appropriate Organic System Plan(s); and a copy of the USDA organic regulations. After the initial review, the inspection is conducted by the same inspector/reviewer. The inspection report is reviewed by a different inspector/reviewer who makes the final certification decision. Certificates are issued upon initial certification and updated annually.

For continuing certification, update packets are sent out quarterly, which is generally 1-3 months prior to the certified operation's anniversary date. Update documents are reviewed by an inspector/reviewer to verify completeness and compliance prior to conducting the inspection. The inspection report is subsequently reviewed by another inspector/reviewer. Certified operations are issued an updated certificate upon completion of their annual inspection.

Labels are submitted by clients to MOCA with their initial application and throughout the year, as needed, for review and approval. A review of various approved labels found all to be in compliance. MOCA does not currently have their own seal, and therefore clients generally use the 'Certified Organic by MOCA', or similar statement on labels.

MOCA utilizes the Organic Materials Review Institute (OMRI) and WSDA Material Review List Registry for review and approval of inputs. MOCA staff was found to be knowledgeable of input-use requirements and the NOP National List.

MOCA has performed the minimum 5% residue testing for 2013 and has established a schedule to ensure they meet the minimum requirements in 2014 also. MOCA sends all samples to the California Department of Agriculture Analytical Laboratory, an ISO accredited laboratory. There were no results which exceeded the EPA or FDA limits. MOCA's residue sampling specialist oversees their sampling program and conducts annual training on pesticide residue sampling for MOCA staff.

Administrative Records and Processes:

A review of personnel qualifications indicated that all staff had participated in various NOP trainings. Training records were readily available for review. Training is ongoing and conducted

when certification program changes occur.

MOCA has issued Notices of Non-Compliances, Notices of Proposed Suspensions and Notices of Resolution since the previous assessment and processed surrenders of certification. A review of files indicated that all notices issued contained the required information and that the procedures for issuance of the notices and for surrendering certification were followed properly. There have been no withdrawals, appeals, requests for mediation, complaints, investigations, or Notices of Suspension, Notices of Proposed Revocation, and Notices of Denials issued since the previous assessment. As such, there were no settlement agreements.

Summary of Review Audit Conducted:

A review audit was conducted of a 100% organic crop operation in Petaluma, CA. The operation included 2 sites on a combined 40 acres. Certified crops included hay, silage, beans, beets, cabbage, carrots, cauliflower, celery, chard, sweet corn, cucumber, fennel, greens, kale, lettuce, melons, parsnip, peas, peppers, potatoes, pumpkin, radish, squash, tomatoes, turnip and watermelon. The fields, farm stand, cold storage, records, equipment and maps were reviewed and verified to be accurate with the OSP and the latest inspection. There was no evidence of prohibited substance use. MOCA provided the operation with a copy of their inspection report and updated certificate. There were no issues of concern.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether MOCA's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to MOCA.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP1290AKA.NC1 – Cleared. NOP §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector.” *The inspector(s) did not provide the operation with a receipt for pasture samples at the time they were drawn in response to a complaint of possible pesticide drift. The operation was later provided the test results, but no receipt was issued at the time of sampling. Although the client was present during the sampling procedure (the client was the complainant) and was aware of the samples being taken, a receipt must be issued to comply with the regulations.*

Corrective Action: The MOCA Quality Manual states that “MOCA shall provide the operation with a receipt for all samples taken by the inspector and a copy of the test results” (MOCA Quality Manual, Pesticide Residue Sampling section). Pesticide residue training and review of the MOCA Quality Manual was held for MOCA staff on November 1, 2011 (2011 Training Log). Specific instruction was given to ensure all inspectors provide operations with a receipt for samples taken (Pesticide Residue Sample Receipt).

Verification of Corrective Action: Training records and interviews confirmed that staff were trained and aware of the requirement to provide clients with a receipt for any samples taken. A review of client files confirmed that clients were provided with a receipt for samples collected.

NP1290AKA.NC2 – Cleared. NOP §205.670(d)(1) states, “Results of all analyses and tests performed under this section: Must be promptly provided to the Administrator; *Except, that, where a State organic program exists, all test results and analyses shall be provided to the State organic program’s governing State official by the applicable certifying party that requested testing.*” *Results of the pesticide residue testing initiated in April of 2011, have not been provided to the Administrator or the State organic program governing official. MOCA was waiting until the investigation was complete to submit the results. The results of the analyses indicated that although a pesticide residue was detected, it was far below the 5% of EPA tolerance.*

Corrective Action: The MOCA Quality Manual was revised to state “All test results and analysis shall be promptly provided to the USDA Administrator and the CDFA organic program...” (MOCA Quality Manual, Pesticide Residue Sampling section). Pesticide residue training and review of the MOCA Quality Manual was held for MOCA staff on November 1, 2011 (2011 Training Log). Specific attention was given to review the procedure for residue sample test results and analysis to be sent promptly to the State organic program’s governing official.

Verification of Corrective Action: Training records and interviews confirmed that staff were trained and aware of the requirement to provide the State Organic Program with test results and analyses.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of Marin Organic Certified Agriculture (MOCA) organic program was conducted on March 20, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess MOCA's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Marin Organic Certified Agriculture (MOCA)
Physical Address	1682 Novato Bldg, Suite 150-A, Novato, CA 94947
Mailing Address	1682 Novato Bldg, Suite 150-A, Novato, CA 94947
Contact & Title	Jeffery Stiles, Program Coordinator
E-mail Address	jstiles@marincounty.org
Phone Number	415-473-6700
Reviewer & Auditors	Rebecca Claypool, NOP Reviewer; Jason Lopez and Devon Pattillo, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: July 21, 2017 Onsite audit: March 20 – 24, 2017
Audit Identifier	NP7079JZA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MOCA's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	MOCA's certification services in carrying out the audit criteria during the period: August 18, 2014 through March 20, 2017

The NOP conducted an onsite audit of Marin Organic Certified Agriculture (MOCA) on March 20-24, 2017, as part of their accreditation renewal audit. MOCA program is within the Marin County Department of Agriculture, and was initially accredited as a USDA certifying agent on April 29, 2007 to the scopes of crops, wild crops, livestock, and handling. MOCA's office is located in Novato, California. MOCA certifies 52 operations to the following scopes: crops (50), livestock (22), wild crops (1), and handling (1). MOCA certifies organic operations located in Marin, Humboldt, Riverside, and Sonoma counties in California. MOCA's staff consists of five individuals: Program Coordinator (1), Certification reviewers/inspectors (4).

During the onsite accreditation audit, four witness audits were conducted on operations with the following certification scopes: Crops, Livestock, Wild Crops, and Handling/Processing.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether MOCA corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to MOCA.

Noncompliances Identified during the Current Assessment

NP7079JZA.NC1 – 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670;” §205.303(b)(2) states, “On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product....”

Comments: *In one reviewed label that was approved by MOCA, the label does not identify the final handler or distributor. Another reviewed label did not place the “Certified organic by ***” statement below the name of the certified operation or distributor.*

NP7079JZA.NC2 - 7 C.F.R. §205.501(a)(21) states, “A certifying agent...must... Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2603, Organic Certificates, Section 3.1, indicates the elements to be included on an organic certificate.”

Comments: *The following MOCA organic certificate elements are incorrect or missing on issued organic certificates:*

1. “Anniversary date” is incorrectly displayed as “Renewal” date.
2. “Certified to the USDA organic regulations, 7 CFR Part 205.” is not stated accurately.
3. “Issue Date” is not identified.
4. Specific certified organic products are not identified with brand names.
5. Labeling categories for products for the handling/processing category are not indicated.

NP7079JZA.NC3 - 7 C.F.R. §205.642 states, “...The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable...”

Comments: *MOCA’s fee schedule does not explain what fees are nonrefundable and at what stage in the certification process the fees become nonrefundable.*

NP7079JZA.NC4 - 7 C.F.R. §205.501(a)(8) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;”

Comments: *The MOCA organic system plan (OSP) templates do not require operations to provide information on the following topics and/or activities:*

1. *Are operations selling, shipping, buying, or receiving products and/or ingredients traded under the international arrangements with Korea, Japan, EU, Canada and/or Switzerland. There is only mention of international import/export activities on MOCA's processing OSP, and is limited to the Canadian and European Union trade arrangements.*
2. *Two files reviewed have products with a private label, however the OSP does not include information regarding private label agreements.*

NP7079JZA.NC5 – 7 C.F.R. §205.501(a)(9) requires that certifiers “Maintain all records pursuant to §205.510(b) and make all such records available for inspection and copying during normal business hours...” Interim Instruction NOP 3012 Material Review (Section 4) states, “maintain documentation to support its determinations about the status of a product’s compliance with the regulations, including those products that are based on prior determination by another certifier, MRO, or the EPA...”

Comments: *MOCA conducts material reviews and maintains an excel spreadsheet of approved materials. The reviewed documentation on the materials is not readily available, and is presumably contained within the OSP of the operation that initially submitted the material for review.*

NP7079JZA.NC6 – 7 C.F.R. §504(b)(2) states, “A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part...”

Comments: *MOCA does not have a written procedure describing the re-review of their internal list of approved materials.*

NP7079JZA.NC7 - 7 C.F.R. §205.403(c)(1) and (2) states, “The on-site inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part; That the information, including the organic production or handling system plan, provided in accordance with...§205.406...accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;

Comments: *During a witness audit, the inspector did not verify the input materials listed in the OSP. Chemical storage locations were not visited during the inspection.*

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Midwest Organic Services Association. An onsite audit was conducted, and the audit report reviewed to determine Midwest Organic Services Association's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Midwest Organic Services Association (MOSA)
Physical Address	122 W. Jefferson St., Viroqua, WI 54665
Mailing Address	122 W. Jefferson St., Viroqua, WI 54665
Contact & Title	Cori Skolaski, Executive Director
E-mail Address	cskolaski@mosaorganic.org ; mosa@mosaorganic.org
Phone Number	608-637-2526
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Darrell Wilson, Lead Onsite Auditor, and Kathy Matejovsky, Trainee; Alan Kohles, Witness Inspection Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: September 19, 2014 Onsite audit: August 19-21, 2014 Witness inspection: June 19, 2014
Audit Identifier	NP147000A
Action Required	Yes
Audit & Review Type	Mid-term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MOSA's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	MOSA's certification services in carrying out the audit criteria during the period: May 2, 2013 through August 21, 2014

ORGANIZATIONAL STRUCTURE:

The Midwest Organic Services Association (MOSA) is a non-profit, non-stock corporation registered in the state of Wisconsin, offering a third-party certification program and verification services to organic producers and processors/handlers. MOSA has been accredited as a certifying body since April 29, 2002 to the National Organic Program (NOP) for the scopes of crop, wild crop, livestock, and handling. MOSA currently has approximately 1,506 certified clients, which include 651 crops, 704 livestock, 36 wild crops, and 139 handling operations certified to the NOP; no grower groups are currently part of MOSA's client base. The clients are

certified in U.S., mostly in the Midwestern section of the country. All certification activities are conducted at the Viroqua office. MOSA does not have any other accreditations at this time.

The MOSA certification program staff consists of an Executive Director, a Quality Manager, an Administrative Manager, 3 Administrative Specialists, 1 Compliance Manager, 1 Certification Manager, an Inspector Manager/Inspector, an Inspection Coordinator, a Certification Specialist, 7 Certification Specialists/Inspectors, 2 Staff Inspectors, and 33 contracted inspectors.

A review of the files and interviews conducted verified that the organic certification staff had sufficient experience, training, and education or a combination thereof in agriculture, organic production, and organic handling. A review of the personnel files confirmed that annual conflicts of interest forms and confidentiality statements were current for all employees and contracted inspectors. However, performance evaluations for contract inspectors did not include an annual onsite evaluation as stated in the NOP 2027.

MOSA is governed by a Board of Directors comprised of experienced and qualified individuals from the organic community. The board functions include oversight and decision making (not certification decisions) responsibilities. There is also an Advisory committee, which is made up of experienced and qualified individuals including major stockholder groups representing crop and livestock producers, handlers, consumers and organic industry technical experts. The Advisory Committee functions to review and develop policies and make recommendations for new or revised policies to the Board of Directors.

CERTIFICATION PROCESS:

MOSA provides information and application materials to potential applicants upon request. All certification materials may be mailed in hard copy to an applicant or downloaded from the MOSA website. Information packets, which include a request for certification, application packet, and schedule of fees, are also available on the MOSA website.

Once completed application documents are submitted, an administrative member of MOSA reviews the information for completeness, making sure that all forms required for the scope of the applicant applying have been submitted. A Certification Specialist reviews the application for compliance. When the initial review is completed, the file is then submitted to the inspection manager who assigns an inspector with consideration given to location of the operation, scope the inspector is approved for and potential inspector conflicts of interest and availability of the inspector. The inspections are assigned to MOSA staff inspectors or contracted inspectors. After the completion of the inspection, the final review of the inspection report and organic system plan is performed by a Certification Specialist who also makes the final certification decision. The reviewer completes an evaluation record to give evidence of compliance with the NOP Regulations for each final review completed.

For continuation of certification, current clients receive an update packet in January. The packet includes an organic system plan and supplementary forms based on the previous year's certification as well as the updated National Organic Program final rule and MOSA Program Manual (if either has been revised) and an invoice for fees. Updated plans are due on May 1 for producers, and handler updates are due 90 days prior to the anniversary of the effective date of their certification. The procedures for the review of renewal applications are the same as those

for new applicants.

MOSA has conducted 23 unannounced inspections in 2013 and 5 thus far in 2014. They are continuing to work toward a goal of 5% which is suggested in the NOP 2609. MOSA also conducted 254 surveillance inspections, had 6 denials of certification, 237 Notices of Proposed Suspensions, of which 18 resulted in Suspension, 1 Proposed Revocation, 6 willful violations, and 6 settlement agreements; there were 6 reinstatements.

MOSA does not currently have any grower groups certified. MOSA does have policies and procedures in place in the event that there would be an interest for this type of certification.

The MOSA certification staff created a database of approved and prohibited materials as a reference tool for input review. The materials are evaluated by a Certification Specialist using the National List of Allowed and Prohibited Substances, WSDA list and the OMRI List. Applicants provide product ingredient information to the MOSA staff for approval. Label reviews are also conducted by the Certification Specialist as part of the review of the client's organic system plan.

MOSA oversees international exports. There have been exports for EU, Taiwan, and JAS since the last assessment. A review of documents indicated that they were being completed as required. A list is being maintained for all certificates issued.

ADMINISTRATIVE RECORDS AND PROCESSES:

The main basis of certification for the NOP is the MOSA Program Manual. This manual is available on the MOSA website and can be obtain by regular post or email if so requested. All forms for certification are also available on the MOSA website.

MOSA's annual review consists of an internal audit. A review of these audits verified that they are being conducted in accordance with their procedures and that corrective actions are being taken as applicable.

Training can be external or internal. Records reviewed indicated that all personnel have had various training in organic agricultural related areas.

SUMMARY OF WITNESS AND REVIEW AUDITS CONDUCTED:

As a part of the mid-term assessment there were two announced witness inspections conducted. One of the witness inspections was conducted at a handling operation located in St. Ansgar, IA that manufactures organic feeds (grinding, mixing, and pelletizing of organic grains or grain by-products) in addition to product storage and transfer. The operation produces organic feeds in either a ground or pelletized form based on customer specifications. The second witness inspection was a crop and livestock operation located in Chaseburg, WI. This was a beef operation of approximately 19 organic cows plus young stock and a bull. The animals are all grass fed. The crops grown were pasture, hay, vegetables, and corn. The corn crop will be marketed as a cash crop. Inspectors were MOSA staff inspectors who demonstrated knowledge of the USDA NOP regulations and conducted a thorough inspection.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether MOSA corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to MOSA.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP9222OOA.NC4 – Cleared -7 CFR §205.501 (a)(6) General requirements for accreditation states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.” *4 of 21 evaluations reviewed for contracted inspectors had not been completed annually.* **Corrective Action:** Reviewers evaluate the inspectors on each inspection report. The evaluations are entered into a computer data base and the Inspection Manager consolidated the information annually by hand. The computer data base has been upgraded to enable this information to be sorted by the computer thus eliminating the chance of missing any inspector’s evaluations in the future. Evaluations for three of the four contracted inspectors have been completed. The other contracted inspector will be evaluated at the end of the 2009 inspection season since he only performed one inspection in 2008. **Reassessment Finding:** Due to a complaint regarding the evaluation process, the MOSA Board of Directors suspended evaluations of employees to allow reassessment of the evaluation process. Records indicated that 18 of 25 performance evaluations were not conducted in 2012. **Corrective Action:** The MOSA Board of Directors hired a consultant to develop a new performance evaluation process for personnel which was implemented October 31, 2012. The new evaluation process, which includes a quarterly employee check-in and annual review with a manager, has been incorporated into a draft of the MOSA Personnel Manual, and was explained to employees at a full staff meeting. MOSA created new forms to conduct performance evaluations, and developed an Employee Evaluation Schedule to return employees to a regular evaluation schedule based on their date of hire. **Corrective Action Verification:** A review of the personnel records on file verified that evaluations are being conducted as described in corrective actions.

NP2240NNA.NC1 – Cleared -7 CFR §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector.” *In 2010, samples were collected at an operation as part of an investigation. There is no record that a receipt was issued to the operator at the time of the sample collection.* **Corrective Action:** MOSA submitted receipts for recent samples taken to

verify that MOSA is following its Administrative Manual's procedure (Section IV: Inspectors and Inspections, Part 3: Residue Testing, D. Procedures for Sample Collection) which states "The sample collector must provide a receipt to the operator from whom the sample is taken...." MOSA also revised its Program Manual, Section X Certification Program Policies, Part D. Residue Testing Policy and Exclusion from Organic Sale to state that the operator will be issued a receipt for samples taken if residue testing is conducted. The revised Program Manual will be sent with other annual mailing materials to all certified operations in 2013. Training for inspectors responsible for collecting residue samples will occur in April, 2013 to review residue testing procedures, including the requirement to provide a sample receipt to the operation. **Corrective Action Verification:** The auditor confirmed the use of the Residue Sample Log, which is signed by both the inspector and representative of the operation and a copy is left as a receipt for samples taken. The Residue Sample Log describes the sampling, and, where applicable, shows the field locations from which samples were collected.

NP2240NNA.NC2 – Cleared -7 CFR §205.501(a)(15)(i) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Submit to the Administrator a copy of: Any notice of denial of certification issued pursuant to §205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance." *MOSA issues notices of non-compliance in certification decision letters after review of inspection documents. In 3 of 5 files reviewed with such non-compliances, the notices were not forwarded to the Administrator. The MOSA's Administrative Manual Part III. Section V Part I.J.5 states, "Minor noncompliances do not require notification of the NOP," which does not comply with NOP requirement for notification.* **Corrective Action:** MOSA has amended its understanding of what constitutes a noncompliance and revised its Administrative Manual and Decision Log database to be aligned with NOP 2612, Recommended Penalties for Violations of Specific Regulatory Requirements and Penalty Matrix. An email was issued to MOSA staff describing the revisions made to the Administrative Manual and Decision Log. MOSA will now include noncompliances once deemed minor but not categorized as a condition for continued certification to also be sent to the NOP as it has done in the past for all major noncompliances. MOSA sent six staff members to the January 2013 NOP certifier training, which included training on NOP Instruction 2612. **Corrective Action Verification:** All adverse action notifications were verified to have been sent to the NOP Administrator.

NP2240NNA.NC3 – Cleared -7 CFR §205.662 (a) and (b) state, "(a) When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation. Such notification shall provide: (1) A description of each noncompliance; (2) The facts upon which the notification of noncompliance is based; and (3) The date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. (b) *Resolution.* When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution." *MOSA's Administrative Manual Part III. Section V Part I.J.5 outlines a time frame for correction of minor noncompliances to be "on the update application*

or at the next inspection.” The notification issued provides a description of the noncompliance and the facts upon which the notification of noncompliance is based; however, the date for rebuttal or correction is indeterminate since the operator is allowed to correct the noncompliance “Prior to the next inspection.” Secondly, operators may implement corrective actions during the time prior to the next inspection that is included as part of an updated organic system plan or verified as part of an inspection; however, MOSA does not send the certified operation a written notice of non-compliance resolution. File reviews and observations during the handling witness inspection, showed that MOSA implemented the noncompliance procedures described in its program manual. **Corrective Action:** MOSA amended its definition of a noncompliance to include noncompliances once deemed minor but now aligned with NOP 2612 as stated above, but not to include minor issues categorized as conditions for continued certification. MOSA will implement noncompliance procedures under its new definition of noncompliance as it has done in the past for all major noncompliances, which includes providing a date for rebuttal or correction and providing a written notice of noncompliance resolution. MOSA sent 6 staff members to the January 2013 NOP certifier training, which included training on NOP Instruction 2612. **Corrective Action Verification:** A review of the noncompliances verified that the date of rebuttal or correction was included in the notice. In addition, noncompliance resolutions were being sent to the operation.

NP2240NNA.NC4 – Cleared - 7 CFR §205.403 (c)(1) & (d) states, “The on-site inspection of an operation must: verify the operation's compliance or capability to comply with the Act and the regulations in this part; (d) The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.” *During the livestock and crop witness inspection, the inspector reviewed the organic system plans with the operator to verify that the information in the plan was correct. He concluded this portion of the inspection with an exit interview and the operator signed the MOSA affirmation document at this point. The inspector then proceeded to review the pastures and livestock after the exit interview. He neglected to review some of the cattle that were in a far pasture and also bypassed some buildings on the site. He did not conclude with a summary of all activities to confirm the completeness of the inspection observations. The MOSA inspection procedure also requires that an inspection be concluded with an exit interview.*

Corrective Action: MOSA provided email correspondence to the inspector noted in the noncompliance and to all other inspectors reiterating the MOSA policy outlined in the Administrative Manual concerning proper Exit Interview procedures. MOSA also developed an Inspector Shadowing Checklist, which includes a section to review exit interview processes, for the Inspection Manager to use when conducting periodic field evaluations of the inspectors.

Corrective Action Verification: The auditor’s observation of witness inspections conducted during this assessment verified that exit interviews were being conducted at the completion of the each inspection.

Noncompliances Identified during the Current Assessment

NP41700OA.NC1 – 7 CFR §205.404 (b)(1) states “The certifying agent must issue a certificate of organic operation which specifies the: Name and address of the certified operation;”

Furthermore, NOP 2603, Organic Certificates, Section 3.2, states, “Certifying agents must identify only one “person” (typically a farm or business as defined in 7 CFR § 205.2) on the organic certificate.” *One of the files reviewed consisted of 9 operations contracted to produce products for another certified operation was issued a certificate which contained the name of the entity contracting and the names of the 9 contracted entities.*

NP417000A.NC2 – 7 CFR §205.406 (c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.” *During the witness inspection of the crop and livestock operation it was observed that the label being used for cucumbers contained the USDA Seal which did not meet the requirements outlined in section §205.311 of the NOP rule. It was further determined that this issue was known by at least some of the MOSA staff since the inspector indicated to the operator that he would be allowed to use up the remaining inventory of the noncompliant labels.*

NP417000A.NC3 – 7 CFR §205.403 (a)(1) states, “A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.” *It was observed during the witness inspection of the crop and livestock operation that the inspector did not visit all of the fields associated with the certified operation and therefore did not verify their compliance with the regulations.*

NP417000A.NC4 – NOP §205.501 (a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” The training module, International Trade Arrangement, dated February 20, 2014, states that the certifiers must verify certified operations’ compliance to USDA organic trade arrangements during certification process, including during onsite inspections. *Compliance requirements of the applicable JAS and EU trade arrangements have not been incorporated into the quality manual. A review of the export documents for organic products exported to Japan revealed that labels were not being verified for compliance and there was no verification that operations had a contract with a JAS certified importer. Bulk labels for product destined to the EU were not verified for compliance to the EU or the NOP labeling requirements.*

NP107000A.NC5 – NOP §205.501 (a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.” NOP 2027 further states, “Inspectors should be evaluated during an onsite inspection by a supervisor or peer (another inspector) at least annually. This

field evaluation should be conducted at the certifying agent's expense." *Interviews with MOSA personnel revealed that contract inspectors are not being evaluated during onsite inspections.*

NP417000A.NC6 –7 CFR §205.402 (b)(3) states, "The certifying agent shall within a reasonable time: Provide the applicant with a copy of the test results for any samples taken by an inspector." *A review of the sampling and testing procedures for randomly selected samples revealed that only analyses with positive results were being sent to the operations from which they were collected, but negative results were not disclosed to the operations.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Cori Skolaski
Midwest Organic Services Association
122 W. Jefferson St.
Viroqua, WI 54665

SEP 30 2014

Dear Ms. Skolaski,

On August 19-21, 2014, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Midwest Organic Services Association (MOSA) organic certification program as part of its USDA Mid-term Accreditation Assessment. On September 18, 2014, the NOP reviewed the results of the onsite audit to determine MOSA's compliance to the USDA organic regulations. A copy of the assessment report, NP14700OA, is enclosed for your reference.

The report indicates five corrective actions, for prior noncompliances (NP92220OA, NC4 and NP2240NNA.NC1 through 4), were cleared and determined to be implemented and effective. Six new noncompliances (NP41700OA.NC1 through 6), were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the MOSA management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renée Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NC Report Chronology Log

Audit Identifier (if any): NP4161EEA

Audit Type: Mid-term assessment

Accredited Certifying Agent Name: MT Dept. of Ag

Accreditation Manager: Renée Gebault King (RGK)

Date	Activity
10/22/14	Assigned to RGK.
11/18/14	RGK reviewed NOP audit checklists and prepared NC Report.
11/19/14	RGK completed NC Report (no new NCs were observed during this audit). RGK prepared both a NoNC letter and a NoConAccred letter for this situation because no CA report or follow-up is required by MTDA per this audit. Submitted all documents electronically to R Mann for review.
11/22/14	<p>RGK received suggested edits from RM</p> <ul style="list-style-type: none"> • Directed to follow-up with R. Skinner (QAD) to obtain more clarification on verification of cleared NCs from audit. • Use Notice of Continuing Accreditation letter, delete NC letter
11/26/14	<p>RGK sent e-mail to R Skinner requesting clarification on NCs cleared as a result of the recent audit:</p> <ul style="list-style-type: none"> • NP2191ZZA.NC2: Verification of Corrective Action (2014): The OSP and associated documents has been modified to include additional information necessary for continuing the certification cycle. OSP reviewed were completed prior to inspection. Documented staff training in 2013 was verified and interviews conducted verified that the personnel were knowledgeable that OSP must be complete prior to inspections. <i>RGK: Could you specify the "new written procedures" implemented by MTDA to address incomplete OSPs prior to conducting inspections? Did Montana update its OSP forms or requirements in any way?</i> • NP2191ZZA.NC3: Verification of Corrective Action (2014): Training was completed in 2013 for reviewers and inspectors. The training covered the scope of inspection and the authority with producers and handlers. <i>RGK: Could you clarify the second sentence with more detail? I'm not sure what the "authority with producers and handlers" exactly means?</i> • NP2191ZZA.NC4: Verification of Corrective Action (2014): Records showed that the corrective actions submitted have been performed and implemented. Staff and inspector trainings and updated templates have been incorporated into the certification. <i>RGK: Please explain how "staff and inspector trainings" are incorporated into the process that resolves this prior issue (Were trainings conducted? When? Other details?). Are updated OSPs being developed or used? Was there training associated with this?</i> • NP2191ZZA.NC5: Verification of Corrective Action (2014): There is no

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Montana Department of Agriculture. An onsite audit was conducted, and the audit report reviewed to determine Montana Department of Agriculture's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Montana Department of Agriculture (MTDA)
Physical Address	302 North Roberts Street, Helena, MT 59601
Mailing Address	302 North Roberts Street, Helena, MT 59601
Contact & Title	Georgana Webster
E-mail Address	gwebster@mt.gov ; angray@mt.gov
Phone Number	406-444-9421
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Rick Skinner and Willy Horne, On-site Auditors
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: November 18, 2014 Onsite audit: June 10-12, 2014
Audit Identifier	NP4161EEA
Action Required	No
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of MTDA's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	MTDA's certification services in carrying out the audit criteria during the period: August 16, 2013 through June 12, 2014.

ORGANIZATIONAL STRUCTURE:

The Montana Department of Agriculture (MTDA) is a state agency that is divided into the Agricultural Sciences, Agricultural Development, and Central Services Divisions. The Agricultural Sciences Division is directed by a Division Administrator and consists of the Commodity Services Bureau, Laboratory Bureau, and Agricultural Services Bureau. The MTDA Organic Certification Program is located in the Commodity Services Bureau under the oversight of the Commodity Services Bureau Chief and management by the Organic Certification Program Manager.

MTDA is currently approved as a certifying agent to the USDA National Organic Program (NOP) for the scopes of crops, wild crops, livestock, and handling. The MTDA State program currently has 192 operations certified to the USDA NOP standard; 118 for crops, 2 for wild crop, 25 for livestock, and 49 for handling (all are processors). MTDA provides organic certification to operators in Montana and adjoining states. MTDA does not currently certify any grower groups. All certification activities are carried out of the main office in Helena, Montana. Several staff inspectors and reviewers are located in various department offices throughout the state; however, all information passes through the Helena office.

MTDA certification program staff consists of a Commodity Services Bureau Chief, an Organic Certification Program Manager, an administrative assistant, two staff reviewers/inspectors, and seven contracted reviewer/inspectors. Resumes were provided for all staff and contracted employees that documented their education, experience, and training. Through records reviewed and interviews conducted, the auditors verified that personnel had the qualifications to perform their organic certification duties as assigned. Records reviewed verified that MTDA was meeting the requirements for confidentiality and annual conflict of interest disclosure reports for all personnel, and has also completed annual performance evaluations for all personnel.

MTDA's program includes an Organic Commodity Advisory Council, which is appointed by the Director of the Department of Agriculture. This council has representatives from the public, certified organic producers, processors, and handlers, and the Department itself. While the committee may be asked to advise the MTDA regarding program policies, procedures, and standards, the Advisory Council does not make certification decisions. The council members are required to complete confidentiality and conflict of interest disclosures reports annually. New members are required to complete confidentiality and conflict of interest disclosure reports during their first meeting and annually thereafter for the term of their appointment.

CERTIFICATION PROCESS:

Requests for initial certification are received via phone and/or electronically. The initial request for certification and correspondence is handled by the administrative assistant in the MTDA office. New applicants are provided a certification packet that includes the following items: the MTDA quality manual, policy manual (which is currently being integrated into the quality manual), certification procedures, application forms, a fee schedule, general requirements for certification and continuation of certification, the organic system plan template (based on the requested scope) and a copy of the NOP Rule. All certification information is also available for download from the MTDA website. When completed applications are received, the documents are reviewed for completeness by the administrative assistant and then forwarded to the Organic Certification Program Manager for assignment to a staff or contracted reviewer/inspector. The initial review is typically assigned to the same person that is scheduled to conduct the inspection.

Following inspection, the report and the supporting documents are reviewed by either a staff or contracted reviewer that was not involved in the initial review or the inspection. The final reviewer makes a recommendation for certification along with identifying noncompliances that may have been identified during the inspection. The certification decision is made by the Organic Certification Program Manager or the Commodity Services Bureau Chief. Certificates

are issued upon initial certification and updated annually following an acceptable inspection and resolution of any noncompliances.

MTDA's annual (renewal) process requires an operation to submit any changes to the approved organic system plan (OSP). The OSP update also includes an explanation of actions taken to correct all noncompliances from the previous certification cycle, and all updates are reviewed for compliance. The procedures for the review of renewal applications are the same as those for new applicants.

Inputs are reviewed and approved prior to use by MTDA staff or contracted reviewers. MTDA conduct their own reviews and also reference OMRI and the WSDA lists to assist in evaluating and/or approving inputs.

MTDA has a procedure for the review and approval of all labels prior to use. There have been instances in the past where this has not occurred, resulting in noncompliances. Since 2012, however, the certifier has enhanced its training and review process to ensure the owners of the labels submit the label drafts for approval prior to use. Labels may be reviewed by the initial reviewers, but all label approvals are performed by the Organic Certification Program Manager.

MTDA has issued TM-11 Export Certificates for Taiwan and certificates of inspection for the EU. A random review of these documents verified that they were being properly executed. MTDA maintains a list of these documents it issues.

ADMINISTRATIVE RECORDS AND PROCEDURES:

MTDA has a quality manual and a procedures manual describing procedures for the certification process. The manuals are being updated to combine them into one Quality Management Document. The manuals cover the process for certification for all applicants and renewals, and also compliance and adverse actions. MTDA has detailed organic system plan (OSP) templates and forms for other support documents.

Training records were available for staff members. MTDA conducts internal training for its staff members and inspectors. Records of outside training sessions attended by staff were also available for review.

Records reviewed verified that the notifications of noncompliance, notifications of proposed suspension, notifications of suspension, notification of proposed revocation, and notification of revocation issued by MTDA were in accordance with the NOP regulation. Unlike in previous assessments, MTDA no longer issues letters containing "potentially compliant issues." Each noncompliance is treated as an independent adverse action. MTDA does forward notices of noncompliance and other adverse action notification to the NOP as required.

WITNESS INSPECTIONS:

One witness inspection and one review audit were performed during the assessment. The inspection was conducted at a dairy, crop (pasture/forage), vegetable and processing (cheese) operation. The inspection was performed by a contract inspector who displayed a very thorough knowledge of the USDA NOP regulations as they pertain to aspects of this complex operation.

The review audit of the brewing company verified the results of the previous inspection conducted by a MTDA staff inspector. The review audit confirmed the results of the previous inspection and that MTDA was completing the organic certification and renewal process as required by the NOP Regulations. There were no noncompliances associated with this audit.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether MTDA corrective actions adequately addressed previous noncompliances. The NOP also reviewed the onsite audit report to determine whether noncompliances should be issued to MTDA. No noncompliances were identified as a result of the most recent onsite audit.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2191ZZA.NC1 – Cleared – 7 CFR §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification...” *No performance evaluation was conducted in 2011 for one of the five staff reviewers/inspectors. The performance evaluations for three of five staff reviewer/inspectors did not include the reviewer activities (i.e. only the inspector role was evaluated).*

Corrective Actions: MTDA completed the 2012 performance evaluations for the entire staff by December 18, 2012 and submitted a list of the performance evaluation completion dates for each employee. MTDA created a master spreadsheet to facilitate the tracking of performance evaluations of staff, including annual performance evaluations for inspectors and reviewers. The Annual Staff Evaluation Master Spreadsheet Record lists name, position, region, qualifications, planned evaluation date, evaluation date, and evaluation report completed date. However, MTDA did not submit a copy of the revised performance evaluation forms identifying the reviewer activities.

Verification of Corrective Actions (2014): The audit verified that MTDA completed a evaluations for all of its staff, contract inspectors and reviewers. MTDA is using its revised performance evaluation forms, which document the evaluation criteria for each review.

NP2191ZZA.NC2 – Cleared - 7 CFR §205.402 (a)(1)(2) states, “Upon acceptance of an application for certification, a certifying agent must: (1) Review the application to ensure completeness pursuant to §205.401; (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part.” *All four witness audits and four of six additional files reviewed in the office revealed the organic system plans (OSP) were incomplete. The initial*

reviews identified numerous “potentially non-compliant” areas; however, the required information is not being submitted prior to the on-site inspection. The inspectors are conducting the initial reviews and many items that should be addressed prior to the inspection are being completed during the inspection (no clear separation between initial review activity and inspection). Examples of incomplete OSPs identified as “potentially non-compliant” by MTDA reviewers that were not further addressed prior to inspection included the following:

- Statement in an OSP that non-organic products are not handled, but other information in that same OSP identifies non-organic products.
- Process flow chart and method for maintaining organic integrity not included for cider molasses and apple juice.
- Updated product profile sheets not completed.
- Method for calculating dry matter demand not identified for ruminant livestock; and calculations do not appear to be correct.
- Number of non-organic livestock not identified.
- Updated field maps not submitted.
- Inputs for greenhouse production of seedlings not identified.
- Labels for all inputs not submitted.
- Organic Seed Non-Availability affidavit not completed for use of non-organic seeds.
- Wild Crop Addendum not completed.

Corrective Actions: MTDA advised that on two separate meetings, held on 7/20/12 and 10/25/12, the staff was instructed to obtain complete versions of the OSPs prior to inspection and, if the information is incomplete, to issue a written request for information. To prevent future noncompliances, new written procedures are in place and a training class is set for March 2013 to discuss the handling of initial reviews and inspections.

Verification of Corrective Actions (2014): The auditor confirmed that MTDA is using an updated procedure to ensure that staff obtains completed OSPs during initial reviews. OSPs reviewed during the audit had been completed prior to inspection. MTDA had conducted staff training in 2013. The auditor interviewed MTDA personnel and verified that the personnel were knowledgeable that OSPs must be complete prior to inspections.

NP2191ZZA.NC3 – Cleared - 7 CFR §205.403(c)(1)states, “Verification of information. The on-site inspection of an operation must verify: (1) The operation’s compliance or ability to comply with the Act and the regulations in this part.” *During the witness audit of the wild crop operation, the inspector reviewed the herb products to the point of transfer to the handling operation. The certified crop and wild crop operation is located on the same property and under the same ownership as the non-certified handling operation. The inspector stated that traceability stopped at this point of product transfer since the handling operation was not certified. It was also stated that the operation was previously certified by MTDA for various beauty and health care products, but had voluntarily surrendered their handling certification. The inspector did not question the operator or investigate any further how the products were labeled or if any were labeled as organic or with any organic ingredients. Upon further review by the auditor, it was discovered that many products were labeled with organic ingredients and several were observed labeled as organic (e.g. Antioxidant Lotion with Organic Green Tea & Organic Shea Butter; 100% Organic African Shea Butter). The auditor conducted a follow-up review of the file at the MTDA office and discovered that the operation had surrendered their handling certification in 2009. The company stated that they would only be listing organic*

ingredients in the ingredients list and not making any label claims of 100% organic, organic, or made with organic. MTDA had previously informed the operation of the requirements for certification if they made any of these label claims in the future. However, MTDA had not instructed inspectors to observe labels during the inspections of the crop/wild crop operation, and the inspector did not consider this to be within the scope of the inspection.

Corrective Actions: On October 29, 2012 MTDA issued a notice of noncompliance to the certified crop/wild crop operation affiliated with a non-certified handler found using organic labels. Subsequently, the certified producer submitted a response and reached a resolution on this matter. MTDA recognizes the importance of training to discuss the scope of inspection and authority with producers and handlers. The training class for reviewers and inspectors is set for March 2013.

Verification of Corrective Actions (2014): The auditor verified that MTDA issued Notices of Noncompliance to the operations with noncompliant labeling identified through the previous audit. In addition, MTDA conducted training for reviewers and inspectors in 2013, which focused on inspector responsibilities for documenting potential noncompliances at the exit interview.

NP2191ZZA.NC4 – Cleared - 7 CFR §205.403(c)(2) states, “Verification of information. The on-site inspection of an operation must verify: That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;” and NOP §205.403(d) states, “...The inspector must also address...any issues of concern.” *All four witness inspections and four of six additional files reviewed identified areas where the OSP did not accurately reflect the practices used by the applicant. However, the inspectors did not identify issues of concern for the missing, incomplete, or inaccurate information. In most cases, the inspectors simply updated the OSP during the inspection, which corresponded with statements by the previous Organic Certification Program Manager that MTDA made the decision not to identify issues of concern or noncompliances for information that could be corrected during the inspection in order to speed up the process. Examples of missing, incomplete, or inaccurate information with no issue of concern being identified included the following:*

- *For the handling witness audit, the pest management plan had been revised with a new type of mouse trap and new person responsible for oversight without updating the OSP; the operation had not documented the cleanout procedure between conventional and organic coffee roasting in their OSP; the section for identifying non-organic products was not complete; and the organic product profile for vanilla-flavored coffee was missing.*
- *For the livestock witness audit, the use of the antibiotic LA 200 and procedure for removal of these cattle from organic production was not identified in the OSP; and the method for calculating dry matter demand was not identified in the OSP.*
- *For the crop witness audit, three inputs (insecticidal soap, potting soil, and seaweed powder) only had the generic name and not the specific product name in the OSP. The use of mulch, plastic sheeting for weed management, and the method and equipment for vegetable washing was not included in the OSP.*

Correction Actions: MTDA will provide more training in March 2013 to the reviewers and inspectors. The staff was advised to review the OSPs and any missing information must be

obtained prior to conducting the inspection. MTDA developed new samples of OSPs for the various scopes as guidelines for the certified operations.

Verification of Corrective Actions (2014): The auditor verified that MTDA conducted training for reviewers and inspectors in 2013, which covered the procedures for obtaining complete OSPs prior to inspections and inspector responsibilities for documenting potential noncompliances.

NP2191ZZA.NC5 – Cleared - 7 CFR §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.” *MTDA is not issuing notices of noncompliance (NONC) in accordance with §205.662 when OSPs are incomplete (8 of 10 files reviewed). Noncompliances are instead simply being identified as “potentially non-compliant” items in the inspection notification letter and then updated by the inspector. The majority of NONC issued by MTDA are for certified operations not submitting an annual update at all or not paying the required fees.*

Corrective Actions: This non-compliance required similar corrective actions as previous non-compliances. This process now requires the issuance of a letter requesting that any missing information be added to the OSPs prior to conducting the inspection. MTDA implemented new procedures in the review of OSPs, such as the addition of dry matter demand calculations for the livestock OSP and updates to the crop OSP forms. To prevent its occurrence, MTDA will make sure that the notice of inspection letter is only sent after receipt of a complete OSP. MTDA will provide more training in March 2013 to the reviewers and inspectors.

Verification of Corrective Actions (2014): The auditor did not observe the use of “potentially non-compliant” items in the inspection notification letter of any of the files reviewed. Interviews with MTDA staff indicated that this is no longer a part of the certification process. All forms and templates have been updated and are in use. All operators were required to complete an updated OSP this certification year. A letter requesting missing information to the OSPs is being sent prior to conducting the inspection. Training was conducted in 2013, which addressed this issue with staff.

NP2191ZZA.NC6 – Cleared - 7 CFR §205.504(b)(1), states, “A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques... A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates.” *MTDA’s label approval procedure does not adequately address the method used to identify the approval or disapproval of labels. The labels in the files do not document the date of approval or the name of the individual approving the label. MTDA provided an example of the method they intend to use in the future (e.g. received date, review/approval date, and approver initials); however, this had not yet been implemented.*

Corrective Actions: MTDA implemented new procedures to be used by the program assistant, program manager, field inspector and reviewer for label reviews. The new label review procedures and approval letter template seem appropriate to correct this non-compliance.

Verification of Corrective Actions (2014): All labels reviewed had the date of review and the initials of the reviewer. This updated procedure is being followed for every label reviewed.

NP2191ZZA.NC7 – Cleared - 7 CFR §205.402(b)(3) states, “The certifying agents shall within a reasonable time: Provide the applicant with a copy of the test results for any samples taken by the inspector.” *MTDA collected samples and conducted testing on samples from five operations in 2011; however, they did not provide a copy of the test results to any of the certified operations. The laboratory test results were dated December 2011 and as of July 2012, they had not been sent to the certified operations. The samples were tested for the compounds listed in NOP 2011-11 and the results were all “non-detected,” so MTDA simply informed the operations verbally.*

Corrective Actions: MTDA submitted evidence that certified operations were provided copies of the test results not issued previously in 2011. MTDA revised the Pesticide Residue Testing procedures to clarify that positive or negative test results shall be sent to the certified operations within 30 days of receiving results. MTDA provided samples of notice of negative/positive results letters.

Verification of Corrective Actions (2014): Test results are provided to the operations as required.

NP2191ZZA.NC8 – Cleared - 7 CFR §205.504(b)(5)(iii) states, “A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques... A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request: The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years.” *MTDA’s policy/procedures do not adequately address public requests for laboratory analyses for residues of pesticides and other prohibited substances. Their Policy Manual (Section 3, B.7.d.2) states the results will be available upon request; however, there are no details on the process for public requests, the authorized individuals with MTDA that can release the information, etc. MTDA has not received any requests from the public for this type of information.*

Corrective Actions: MTDA revised the Organic Program Policy Manual Section 3, B.7.(d)(2) and identified the roles of the organic program staff in the review of public information requests.

Verification of Corrective Actions (2014): Records showed that one request for all of the test results was received and the information was provided as per the revised MTDA procedure.

NP2191ZZA.NC9 – Cleared - 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” Issuance of Export Certificates under an Export Arrangement with Taiwan (April 16, 2009) section 1.04 states, “To be authorized to issue export certificates, a USDA accredited certifying agent must: 1. Incorporate the compliance requirements of the applicable export arrangement into its quality manual under the heading “Requirements for export of U.S. organic raw and processed agricultural products to (insert country name).” *MTDA has not incorporated the compliance requirements for issuance of export certificates for Taiwan into their Quality Manual under the required heading. The requirements are listed in their Policy Manual (Section 11) under the heading “Terms of the USDA-Taiwan Export Arrangement” instead of in the Quality Manual and not all requirements are listed. MTDA issued 7 TM-11s for Taiwan in 2011 and 2 to date in 2012. A review of the TM-11s issued for Taiwan verified they were in compliance to the*

requirements and contained the correct compliance statement.

Corrective Actions: MTDA revised the quality manual to meet the NOP export criteria and updated the manual's heading for this procedure as follows: "Requirements for export of U.S. organic raw and processed agricultural products to..."

Verification of Corrective Actions (2014): The quality and procedures manual now includes the export certificate compliance requirements and the required heading. The actual export activities that were performed were evaluated and met the requirements.

Noncompliances Identified during the Current Assessment

No noncompliances were identified as a result of the current assessment.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Montana Department of Agriculture. An onsite audit was conducted, and the audit report reviewed to determine Montana Department of Agriculture's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Montana Department of Agriculture (MTDA)
Physical Address	302 North Roberts Street, Helena, MT 59601
Mailing Address	302 North Roberts Street, Helena, MT 59601
Contact & Title	Georgana Webster
E-mail Address	gwebster@mt.gov ; angray@mt.gov
Phone Number	406-444-9421
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Rick Skinner and Willy Horne, On-site Auditors
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: November 18, 2014 Onsite audit: June 10-12, 2014
Audit Identifier	NP4161EEA
Action Required	No
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MTDA's program includes an Organic Commodity Advisory Council, which is appointed by the Director of the Department of Agriculture. This council has representatives from the public, certified organic producers, processors, and handlers, and the Department itself. While the committee may be asked to advise the MTDA regarding program policies, procedures, and standards, the Advisory Council does not make certification decisions. The council members are required to complete confidentiality and conflict of interest disclosures reports annually. New members are required to complete confidentiality and conflict of interest disclosure reports during their first meeting and annually thereafter for the term of their appointment.

CERTIFICATION PROCESS:

Requests for initial certification are received via phone and/or electronically. The initial request for certification and correspondence is handled by the administrative assistant in the MTDA office. New applicants are provided a certification packet that includes the following items: the MTDA quality manual, policy manual (which is currently being integrated into the quality manual), certification procedures, application forms, a fee schedule, general requirements for certification and continuation of certification, the organic system plan template (based on the requested scope) and a copy of the NOP Rule. All certification information is also available for download from the MTDA website. When completed applications are received, the documents are reviewed for completeness by the administrative assistant and then forwarded to the Organic Certification Program Manager for assignment to a staff or contracted reviewer/inspector. The initial review is typically assigned to the same person that is scheduled to conduct the inspection.

Following inspection, the report and the supporting documents are reviewed by either a staff or contracted reviewer that was not involved in the initial review or the inspection. The final reviewer makes a recommendation for certification along with identifying noncompliances that may have been identified during the inspection. The certification decision is made by the Organic Certification Program Manager or the Commodity Services Bureau Chief. Certificates

are issued upon initial certification and updated annually following an acceptable inspection and resolution of any noncompliances.

MTDA's annual (renewal) process requires an operation to submit any changes to the approved organic system plan (OSP). The OSP update also includes an explanation of actions taken to correct all noncompliances from the previous certification cycle, and all updates are reviewed for compliance. The procedures for the review of renewal applications are the same as those for new applicants.

Inputs are reviewed and approved prior to use by MTDA staff or contracted reviewers. MTDA conduct their own reviews and also reference OMRI and the WSDA lists to assist in evaluating and/or approving inputs.

MTDA has a procedure for the review and approval of all labels prior to use. , The certifier has a review process to ensure the owners of the labels submit the label drafts for approval prior to use. Labels may be reviewed by the initial reviewers, but all label approvals are performed by the Organic Certification Program Manager.

MTDA has issued TM-11 Export Certificates for Taiwan and certificates of inspection for the EU. A random review of these documents verified that they were being properly executed. MTDA maintains a list of these documents it issues.

ADMINISTRATIVE RECORDS AND PROCEDURES:

MTDA has a quality manual and a procedures manual describing procedures for the certification process. The manuals are being updated to combine them into one Quality Management Document. The manuals cover the process for certification for all applicants and renewals, and also compliance and adverse actions. MTDA has detailed organic system plan (OSP) templates and forms for other support documents.

Training records were available for staff members. MTDA conducts internal training for its staff members and inspectors. Records of outside training sessions attended by staff were also available for review.

Records reviewed verified that the notifications of noncompliance, notifications of proposed suspension, notifications of suspension, notification of proposed revocation, and notification of revocation issued by MTDA were in accordance with the NOP regulation. Each noncompliance is treated as an independent adverse action. MTDA does forward notices of noncompliance and other adverse action notification to the NOP as required.

WITNESS INSPECTIONS:

One witness inspection and one review audit were performed during the assessment. The inspection was conducted at a dairy, crop (pasture/forage), vegetable and processing (cheese) operation. The inspection was performed by a contract inspector who displayed a very thorough knowledge of the USDA NOP regulations as they pertain to aspects of this complex operation.

The review audit of the brewing company verified the results of the previous inspection conducted by a MTDA staff inspector. The review audit confirmed the results of the previous inspection and that MTDA was completing the organic certification and renewal process as required by the NOP Regulations. There were no noncompliances associated with this audit.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether MTDA corrective actions adequately addressed previous noncompliances. The NOP also reviewed the onsite audit report to determine whether noncompliances should be issued to MTDA. No noncompliances were identified as a result of the most recent onsite audit.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2191ZZA.NC1 – Cleared – 7 CFR §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification...” *No performance evaluation was conducted in 2011 for one of the five staff reviewers/inspectors. The performance evaluations for three of five staff reviewer/inspectors did not include the reviewer activities (i.e. only the inspector role was evaluated).*

Corrective Actions: MTDA completed the 2012 performance evaluations for the entire staff by December 18, 2012 and submitted a list of the performance evaluation completion dates for each employee. MTDA created a master spreadsheet to facilitate the tracking of performance evaluations of staff, including annual performance evaluations for inspectors and reviewers. The Annual Staff Evaluation Master Spreadsheet Record lists name, position, region, qualifications, planned evaluation date, evaluation date, and evaluation report completed date. However, MTDA did not submit a copy of the revised performance evaluation forms identifying the reviewer activities.

Verification of Corrective Actions (2014): The audit verified that MTDA completed an evaluation for all of its staff, contract inspectors and reviewers. MTDA is using its revised performance evaluation forms, which document the evaluation criteria for each review.

NP2191ZZA.NC2 – Cleared - 7 CFR §205.402 (a)(1)(2) states, “Upon acceptance of an application for certification, a certifying agent must: (1) Review the application to ensure completeness pursuant to §205.401; (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part.” *All four witness audits and four of six additional files reviewed in the office revealed the organic system plans (OSP) were incomplete. The initial*

reviews identified numerous “potentially noncompliant” areas; however, the required information is not being submitted prior to the on-site inspection. The inspectors are conducting the initial reviews and many items that should be addressed prior to the inspection are being completed during the inspection (no clear separation between initial review activity and inspection). Examples of incomplete OSPs identified as “potentially noncompliant” by MTDA reviewers that were not further addressed prior to inspection included the following:

- Statement in an OSP that non-organic products are not handled, but other information in that same OSP identifies non-organic products.
- Process flow chart and method for maintaining organic integrity not included for cider molasses and apple juice.
- Updated product profile sheets not completed.
- Method for calculating dry matter demand not identified for ruminant livestock; and calculations do not appear to be correct.
- Number of non-organic livestock not identified.
- Updated field maps not submitted.
- Inputs for greenhouse production of seedlings not identified.
- Labels for all inputs not submitted.
- Organic Seed Non-Availability affidavit not completed for use of non-organic seeds.
- Wild Crop Addendum not completed.

Corrective Actions: MTDA advised that on two separate meetings, held on 7/20/12 and 10/25/12, the staff was instructed to obtain complete versions of the OSPs prior to inspection and, if the information is incomplete, to issue a written request for information. To prevent future noncompliances, new written procedures are in place and a training class is set for March 2013 to discuss the handling of initial reviews and inspections.

Verification of Corrective Actions (2014): The auditor confirmed that MTDA is using an updated procedure to ensure that staff obtains completed OSPs during initial reviews. OSPs reviewed during the audit had been completed prior to inspection. MTDA had conducted staff training in 2013. The auditor interviewed MTDA personnel and verified that the personnel were knowledgeable that OSPs must be complete prior to inspections.

NP2191ZZA.NC3 – Cleared - 7 CFR §205.403(c)(1) states, “Verification of information. The on-site inspection of an operation must verify: (1) The operation’s compliance or ability to comply with the Act and the regulations in this part.” *During the witness audit of the wild crop operation, the inspector reviewed the herb products to the point of transfer to the handling operation. The certified crop and wild crop operation is located on the same property and under the same ownership as the non-certified handling operation. The inspector stated that traceability stopped at this point of product transfer since the handling operation was not certified. It was also stated that the operation was previously certified by MTDA for various beauty and health care products, but had voluntarily surrendered their handling certification. The inspector did not question the operator or investigate any further how the products were labeled or if any were labeled as organic or with any organic ingredients. Upon further review by the auditor, it was discovered that many products were labeled with organic ingredients and several were observed labeled as organic (e.g. Antioxidant Lotion with Organic Green Tea & Organic Shea Butter; 100% Organic African Shea Butter). The auditor conducted a follow-up review of the file at the MTDA office and discovered that the operation had surrendered their handling certification in 2009. The company stated that they would only be listing organic*

ingredients in the ingredients list and not making any label claims of 100% organic, organic, or made with organic. MTDA had previously informed the operation of the requirements for certification if they made any of these label claims in the future. However, MTDA had not instructed inspectors to observe labels during the inspections of the crop/wild crop operation, and the inspector did not consider this to be within the scope of the inspection.

Corrective Actions: On October 29, 2012 MTDA issued a notice of noncompliance to the certified crop/wild crop operation affiliated with a non-certified handler found using organic labels. Subsequently, the certified producer submitted a response and reached a resolution on this matter. MTDA recognizes the importance of training to discuss the scope of inspection and authority with producers and handlers. The training class for reviewers and inspectors is set for March 2013.

Verification of Corrective Actions (2014): The auditor verified that MTDA issued Notices of Noncompliance to the operations with noncompliant labeling identified through the previous audit. In addition, MTDA conducted training for reviewers and inspectors in 2013, which focused on inspector responsibilities for documenting potential noncompliances at the exit interview.

NP2191ZZA.NC4 – Cleared - 7 CFR §205.403(c)(2)states, “Verification of information. The on-site inspection of an operation must verify: That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;” and NOP §205.403(d) states, “...The inspector must also address...any issues of concern.” *All four witness inspections and four of six additional files reviewed identified areas where the OSP did not accurately reflect the practices used by the applicant. However, the inspectors did not identify issues of concern for the missing, incomplete, or inaccurate information. In most cases, the inspectors simply updated the OSP during the inspection, which corresponded with statements by the previous Organic Certification Program Manager that MTDA made the decision not to identify issues of concern or noncompliances for information that could be corrected during the inspection in order to speed up the process. Examples of missing, incomplete, or inaccurate information with no issue of concern being identified included the following:*

- *For the handling witness audit, the pest management plan had been revised with a new type of mouse trap and new person responsible for oversight without updating the OSP; the operation had not documented the cleanout procedure between conventional and organic coffee roasting in their OSP; the section for identifying non-organic products was not complete; and the organic product profile for vanilla-flavored coffee was missing.*
- *For the livestock witness audit, the use of the antibiotic LA 200 and procedure for removal of these cattle from organic production was not identified in the OSP; and the method for calculating dry matter demand was not identified in the OSP.*
- *For the crop witness audit, three inputs (insecticidal soap, potting soil, and seaweed powder) only had the generic name and not the specific product name in the OSP. The use of mulch, plastic sheeting for weed management, and the method and equipment for vegetable washing was not included in the OSP.*

Correction Actions: MTDA will provide more training in March 2013 to the reviewers and inspectors. The staff was advised to review the OSPs and any missing information must be

obtained prior to conducting the inspection. MTDA developed new samples of OSPs for the various scopes as guidelines for the certified operations.

Verification of Corrective Actions (2014): The auditor verified that MTDA conducted training for reviewers and inspectors in 2013, which covered the procedures for obtaining complete OSPs prior to inspections and inspector responsibilities for documenting potential noncompliances.

NP2191ZZA.NC5 – Cleared - 7 CFR §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.” *MTDA is not issuing notices of noncompliance (NONC) in accordance with §205.662 when OSPs are incomplete (8 of 10 files reviewed). Noncompliances are instead simply being identified as “potentially non-compliant” items in the inspection notification letter and then updated by the inspector. The majority of NONC issued by MTDA are for certified operations not submitting an annual update at all or not paying the required fees.*

Corrective Actions: This non-compliance required similar corrective actions as previous non-compliances. This process now requires the issuance of a letter requesting that any missing information be added to the OSPs prior to conducting the inspection. MTDA implemented new procedures in the review of OSPs, such as the addition of dry matter demand calculations for the livestock OSP and updates to the crop OSP forms. To prevent its occurrence, MTDA will make sure that the notice of inspection letter is only sent after receipt of a complete OSP. MTDA will provide more training in March 2013 to the reviewers and inspectors.

Verification of Corrective Actions (2014): The auditor did not observe the use of “potentially non-compliant” items in the inspection notification letter of any of the files reviewed. Interviews with MTDA staff indicated that this is no longer a part of the certification process. All forms and templates have been updated and are in use. All operators were required to complete an updated OSP this certification year. A letter requesting missing information to the OSPs is being sent prior to conducting the inspection. Training was conducted in 2013, which addressed this issue with staff.

NP2191ZZA.NC6 – Cleared - 7 CFR §205.504(b)(1), states, “A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques... A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates.” *MTDA’s label approval procedure does not adequately address the method used to identify the approval or disapproval of labels. The labels in the files do not document the date of approval or the name of the individual approving the label. MTDA provided an example of the method they intend to use in the future (e.g. received date, review/approval date, and approver initials); however, this had not yet been implemented.*

Corrective Actions: MTDA implemented new procedures to be used by the program assistant, program manager, field inspector and reviewer for label reviews. The new label review procedures and approval letter template seem appropriate to correct this non-compliance.

Verification of Corrective Actions (2014): All labels reviewed had the date of review and the initials of the reviewer. This updated procedure is being followed for every label reviewed.

NP2191ZZA.NC7 – Cleared - 7 CFR §205.402(b)(3) states, “The certifying agents shall within a reasonable time: Provide the applicant with a copy of the test results for any samples taken by the inspector.” *MTDA collected samples and conducted testing on samples from five operations in 2011; however, they did not provide a copy of the test results to any of the certified operations. The laboratory test results were dated December 2011 and as of July 2012, they had not been sent to the certified operations. The samples were tested for the compounds listed in NOP 2011-11 and the results were all “non-detected,” so MTDA simply informed the operations verbally.*

Corrective Actions: MTDA submitted evidence that certified operations were provided copies of the test results not issued previously in 2011. MTDA revised the Pesticide Residue Testing procedures to clarify that positive or negative test results shall be sent to the certified operations within 30 days of receiving results. MTDA provided samples of notice of negative/positive results letters.

Verification of Corrective Actions (2014): Test results are provided to the operations as required.

NP2191ZZA.NC8 – Cleared - 7 CFR §205.504(b)(5)(iii) states, “A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques... A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request: The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years.” *MTDA’s policy/procedures do not adequately address public requests for laboratory analyses for residues of pesticides and other prohibited substances. Their Policy Manual (Section 3, B.7.d.2) states the results will be available upon request; however, there are no details on the process for public requests, the authorized individuals with MTDA that can release the information, etc. MTDA has not received any requests from the public for this type of information.*

Corrective Actions: MTDA revised the Organic Program Policy Manual Section 3, B.7.(d)(2) and identified the roles of the organic program staff in the review of public information requests.

Verification of Corrective Actions (2014): Records showed that one request for all of the test results was received and the information was provided as per the revised MTDA procedure.

NP2191ZZA.NC9 – Cleared - 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” Issuance of Export Certificates under an Export Arrangement with Taiwan (April 16, 2009) section 1.04 states, “To be authorized to issue export certificates, a USDA accredited certifying agent must: 1. Incorporate the compliance requirements of the applicable export arrangement into its quality manual under the heading “Requirements for export of U.S. organic raw and processed agricultural products to (insert country name).” *MTDA has not incorporated the compliance requirements for issuance of export certificates for Taiwan into their Quality Manual under the required heading. The requirements are listed in their Policy Manual (Section 11) under the heading “Terms of the USDA-Taiwan Export Arrangement” instead of in the Quality Manual and not all requirements are listed. MTDA issued 7 TM-11s for Taiwan in 2011 and 2 to date in 2012. A review of the TM-11s issued for Taiwan verified they were in compliance to the requirements and contained the correct compliance statement.*

Corrective Actions: MTDA revised the quality manual to meet the NOP export criteria and updated the manual's heading for this procedure as follows: "Requirements for export of U.S. organic raw and processed agricultural products to..."

Verification of Corrective Actions (2014): The quality and procedures manual now includes the export certificate compliance requirements and the required heading. The actual export activities that were performed were evaluated and met the requirements.

Noncompliances Identified during the Current Assessment

No noncompliances were identified as a result of the current assessment.

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted the New Hampshire Department of Agriculture, Marketing and Food's (NHDAMF) mid-term assessment. The NOP reviewed NHDAMF's submitted certification program materials, conducted an onsite audit, and reviewed the results of the onsite audit to determine NHDAMF's capability to continue to operate as a USDA accredited certifying agent.

GENERAL INFORMATION

Applicant Name:	New Hampshire Department of Agriculture, Marketing and Food (NHDAMF)
Physical Address:	25 Capitol Street, Rm. 218, Concord, NH 03302
Mailing Address:	PO Box 2042, Concord, NH 03302
Contact & Title:	Jennifer Gornnert, Director, Division of Regulatory Services
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Phone Number:	603-271-7761
Reviewer (s) and Auditor(s):	Renée Gebault King, NOP Reviewer; Martin Friesenhahn, Onsite Auditor
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	NOP Review: August 7, 2014 Onsite audit: July 7-9, 2014
Audit Identifier:	NP4188BBA
Action Required:	Yes
Audit and Review Type:	Mid-term Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of NHDAMF's certification system.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	NHDAMF's certification program activities in carrying out the audit criteria during the period: April 22, 2013 - July 7, 2014

ORGANIZATIONAL STRUCTURE:

NHDAMF Organic Certification Program (hereafter referred to as NHDAMF) is under the New Hampshire State Division of Regulatory Services. NHDAMF was accredited as a certifying agent on April 29, 2002, to the USDA National Organic Program (NOP) for crops, wild crops, livestock, and handling operations. NHDAMF currently includes 162 operations certified to the

NOP: 111 crops, 30 livestock, 0 wild crops, and 21 processor/handling operations. Per New Hampshire State Law, all clients and operations are only certified in the state of New Hampshire. The NHDAMF also conducts other audits and reviews such as for Country of Origin Labeling requirements.

NHDAMF consists of one office located in Concord, New Hampshire. The certification program staff consists of the Director, the Certification Coordinator (also an inspector), one other full time staff Agricultural Inspector, and one part time Agricultural Inspector. Future plans include the hiring of an additional Agricultural Inspector when allowed by the State budget. The current conflict of interest disclosure reports and confidentiality statements were completed for certification staff members. Annual performance evaluations were completed for the Certification Coordinator and the Agricultural Inspector. However, the annual performance evaluations were not completed for the Director and the part time Agricultural Inspector (see NP4188BBA.NC1). A review of the files and interviews conducted confirmed that the organic certification staff had sufficient experience, training, and education or a combination thereof in agriculture, organic production, and organic handling. A review of training records indicated that all organic certification staff had received current training on the USDA organic regulations and guidance.

CERTIFICATION PROCESS:

The Certification Coordinator or an Agricultural Inspector conducts an initial review of certification applications or the annual update for completeness and compliance. The assigned onsite inspector will also conduct a review of the certification application or annual update. The inspection report and certification materials are then reviewed by the Director, who makes the final certification decision. The Director will consult with the inspector if necessary.

NHDAMF requires certified operations to submit the following:

- Annual updates or changes in response to USDA organic regulation requirements; a revision in NHDAMF procedures will allow certified operations to update only the portions of the Organic System Plan (OSP) that change or require revision.
- Annual inspections for continuing USDA organic certification; organic certificates are issued after each inspection or when changes to the certification status occurs.
- Labels are submitted by operations with their initial certification application or by certified operations if new labels are developed. The Certification Coordinator or Inspector review and approve labels prior to use by the operator; labels are also verified during the annual update and onsite inspections.

NHDAMF has submitted their Annual Report. NHDAMF does not currently certify any grower groups. NHDAMF has conducted annual unannounced inspections on a minimum 5% of their certified clients. There is a Material Review Contract and Recognition Agreement with OMRI. Additional material reviews are also utilized, as applicable, from Washington State Department of Agriculture, Pennsylvania Certified Organic, or by consulting with local certifying agents. Final approval decisions regarding materials are made by the Director in consultation with the Certification Coordinator or an inspector if necessary. NHDAMF has completed verification and oversight activities of export and import activities of at least one operation where product was traded under the US/ Canada and the US/European Union arrangements. NHDAMF staff

demonstrated familiarity with the export requirements or was capable of finding the applicable export information.

ADMINISTRATIVE RECORDS AND PROCESSES:

NHDAMF has a Policies and Procedures Manual that is provided to operations; they also provide forms (e.g. OSP). NHDAMF forms and letters were reviewed and found to meet USDA organic regulations except as identified in the Findings section of this report (see NP4188BBA.NC2). An annual program review is completed and reviewed by the NHDAMF staff. Corrective actions and improvements are implemented as applicable. Training is both internal and external; training records and documentation are maintained. Refresher training or additional training is completed as needed, which includes shadow and witness inspections for evaluations and training.

SUMMARY OF WITNESS AUDITS AND REVIEW AUDITS CONDUCTED:

The audit included one witness audit, which was an inspection of an organic processor in Concord, New Hampshire that produces “organic” and “made with organic...” meat/pot pies. The annual inspection was conducted by the Certification Coordinator/Agricultural Inspector. A detailed inspection was observed including the verification of the OSP to the USDA organic regulations. An exit interview was conducted providing a summary of the inspection results. The inspector was very knowledgeable of the USDA regulations and the process of conducting an organic inspection.

NOP DETERMINATION

NOP reviewed the onsite audit results to determine whether NHDAMF corrective actions adequately addressed previous noncompliances. NOP also reviewed the Findings identified during the onsite audit to determine whether noncompliances should be issued to NHDAMF.

Noncompliances from Prior Assessments

Any noncompliance labeled as “Cleared,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “Outstanding” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

All 5 previous NC’s corrective actions were reviewed and determined to be implemented and effective and therefore were cleared.

NP2191ACA.NC1 – CLEARED – 7 CFR §205.402(a)(1) and (2) state, “Upon acceptance of an application for certification, a certifying agent must: Review the application to ensure completeness pursuant to §205.401; and (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply....” *A review of the 10 client files identified that the Organic System Plans*

(OSP) and labels are not being adequately reviewed. Four of ten OSP's were found to be incomplete. In three cases, the processors or producers indicated that there were no changes to their OSP when in fact there were significant changes. Inspectors conduct an initial review of the OSPs prior to the inspection; however, significant missing information regarding inputs, procedures and other required information is not addressed with the operation prior to the onsite inspection. The following issues were identified during the file review and witness inspection:

- During the witness inspection at the livestock/crop operation, the inspector found significant updates or changes to the OSP. There were many feed supplements and medications that were identified by the inspector that were not documented on the OSP.*
- Of the 10 labels reviewed, two labels from the same processor had the placement of the "Certified organic by NHDAMF" statement located above the distributor's name.*
- During the witness inspection, the inspector indicated that a need for a buffer zone had been discussed with the operation manager during the previous year's inspection. The current OSP did not include the buffer zones that had been discussed and required from the previous inspection.*
- One OSP did not have the seeds and planting stock practice standard section completed.*
- One operator's OSP was incomplete for the livestock living conditions. The operator did not include all cases of temporary confinement for breeding, calving, illness, etc.*
- One OSP had an incomplete pasture plan that did not address the proposed DMI calculations for the entire grazing season; field maps were incomplete and did not identify details such as neighboring land use, water, sources, buffers, natural areas, etc.; the type of grazing methods used in the pasture system; and no information on erosion control and protection of natural wetlands and riparian areas practices.*

Corrective Action: NHDAMF received and reviewed missing information necessary to complete OSPs and also issued an operation a notice of noncompliance to resolve subsequent findings. The noncompliance bullet point listed above concerning labels was addressed by NHDAMF implementing the NOP Policy Memo 12-2, *Placement of "Certified Organic by ****" Statement*. NHDAMF created a Standard Operation Procedure (SOP) for reviewing organic system plans that involves a three-person review process. Staff meetings were held in March 2013, to review proper procedure for reviewing applications and the requirement of obtaining all required information and documentation prior to conducting onsite inspections. NHDAMF revised its Livestock OSP to emphasize USDA organic Pasture Rule requirements. Certified operations were informed of changes to the revised forms and that completed OSPs are required to be submitted prior to an onsite inspection. DRS staff participated in IOIA training on August 22, 2012, to better understand the Pasture Rule and DMI calculation verification and will provide subsequent training to other staff members.

Verification of corrective actions: There is a two person review in place prior to inspection and the Director conducts the final review. Files confirmed that the new review form is in use. OSP's are updated and reviewed. NHDAMF is ensuring that

OSP's are complete and compliant during the initial review. File reviews, observation during a witness audit, and interviews of NHDAMF staff confirmed that corrective measures were implemented and effective.

NP2191ACA.NC2 – CLEARED- 7 CFR §205.403(c)(1) states, “The onsite inspection of an operation must verify: The operation’s compliance or capability to comply with the Act and the regulations in this part.” *NHDAMF does not require inspectors to conduct trace-back and input/output sampling activities, nor does the inspection report or checklist provide for a section that documents these inspection verification activities.*

Corrective Action: NHDAMF revised its inspection report forms to include sections for ‘audit back track’ to verify trace-back activities and ‘product in/product out balance audit’ to verify input/output activities and submitted its processor inspection report. Inspectors also review crop operations’ yield and sales information and harvest records as documented in an operation’s application and OSP to verify compliance. Internal training was held in March, 2013, for staff and inspectors and included procedures for conducting verification activities.

Verification of corrective actions: The auditor’s observations and file reviews during inspection verified that the new form was being used for trace-back audits.

NP2191ACA.NC3 – CLEARED- 7 CFR §205.403(d) states, “The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the onsite inspection. The inspector must also address the need for any additional information as well as any issues of concern.” *During 1 of 3 witness inspections observed by NOP auditors, the inspector did not conduct an exit interview.*

Corrective Action: An NHDAMF letter documenting findings from the onsite inspection noted above was sent to the operation on July 24, 2012. NHDAMF standard procedure for onsite inspections is to conduct an exit interview at the end of an inspection, and noted that this was an isolated incident. Staff meetings held in August and November, 2012, provided clarification of the procedure including the requirement of completing a summary exit interview narrative in the inspection report. The NHDAMF Director will accompany inspectors periodically to verify the exit interview procedure is being implemented.

Verification of corrective actions: An exit interview was observed by the auditor during the witness audit and a review of operation files demonstrated that exit interview records were present. Also the Standard Operating Procedure (SOP) for exit interviews was confirmed during the audit.

NP2191ACA.NC4 – CLEARED- 7 CFR §205.501(a)(7) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Have an annual program review of its certification activities conducted by the certifying agent’s staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation.” *During the assessment, NHDAMF provided a one page document dated January 1, 2011, titled “2011 Annual NHDAMF*

Organic Program Review” to the NOP auditors for review. The document listed four actions or changes that have been implemented to NHDAMF organic program. Additionally, there were five recommendations listed. The document does not reference the Act when identifying noncompliances; consequently, there is no basis or reference to develop a plan to implement corrective measures to address deficiencies in the program.

Corrective Action: NHDAMF created an SOP for completing an annual program review. A DRS staff person will conduct an annual program review using the NOP 2005, Accreditation Assessment Checklist which references citations of the USDA organic regulations. The NHDAMF annual program review and corrective actions will be submitted to the NOP with its annual report in April, 2013.

Verification of corrective actions: The annual program review was reviewed and indicated greater information about the process and identification of nonconformances including implemented corrective actions and a plan of action to address deficiencies.

NP2191ACA.NC5 – CLEARED- 7 CFR §205.501(a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform onsite inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.” *No annual signed conflict of interest disclosure reports are on file within the NHDA Division of Market and Regulatory Affairs.*

Corrective Action: NHDAMF submitted its 2012 Annual Conflict of Interest (COI) Disclosure Report which all employees signed, and created an SOP to indicate procedures for completion of an annual COI. The COI is to be renewed annually by each employee in November.

Verification of corrective actions: The auditor reviewed the NHDAMF staff filed COI documents completed in December 2013.

Noncompliances Identified during the Current Assessment

NP4188BBA.NC1 – 7 CFR § 205.501 (a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform onsite inspections, review certification documents...” *The Director has not received a written performance evaluation since starting the position in July 2012, and a part time inspector has not received a written performance evaluation since 2012. An interview with the Director during the audit indicated she is scheduled to receive an evaluation on July 14, 2014 and that the part time inspector was evaluated during an inspection, but the event was not recorded.*

NP4188BBA.NC2 – 7 CFR § 205.662 (c) states, “Proposed suspension or revocation...When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification...”

NHDAMF issued a combined Notice of Non-compliance and Proposed Suspension to several clients that had not submitted the required renewal Organic System Plan (OSP) for organic crops by the March 1 deadline. This non-compliance is correctable and NHDAMF should issue a noncompliance and allow the operation to submit corrective actions before proposing adverse actions.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted the New Hampshire Department of Agriculture, Marketing and Food's (NHDAMF) mid-term assessment. The NOP reviewed NHDAMF's submitted certification program materials, conducted an onsite audit, and reviewed the results of the onsite audit to determine NHDAMF's capability to continue to operate as a USDA accredited certifying agent.

GENERAL INFORMATION

Applicant Name:	New Hampshire Department of Agriculture, Marketing and Food (NHDAMF)
Physical Address:	25 Capitol Street, Rm. 218, Concord, NH 03302
Mailing Address:	PO Box 2042, Concord, NH 03302
Contact & Title:	Jennifer Gornert, Director, Division of Regulatory Services
E-mail Address:	Jennifer.Gornert@agr.nh.gov
Phone Number:	603-271-7761
Reviewer (s) and Auditor(s):	Renée Gebault King, NOP Reviewer; Martin Friesenhahn, Onsite Auditor
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	NOP Corrective Action Review: October 7, 2014 NOP Audit Review: August 7, 2014 Onsite audit: July 7-9, 2014
Audit Identifier:	NP4188BBA
Action Required:	Yes
Audit and Review Type:	Mid-term Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of NHDAMF's certification system.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	NHDAMF's certification program activities in carrying out the audit criteria during the period: April 22, 2013 - July 7, 2014

ORGANIZATIONAL STRUCTURE:

NHDAMF Organic Certification Program (hereafter referred to as NHDAMF) is under the New Hampshire State Division of Regulatory Services. NHDAMF was accredited as a certifying agent on April 29, 2002, to the USDA National Organic Program (NOP) for crops, wild crops,

livestock, and handling operations. NHDAMF currently includes 162 operations certified to the NOP: 111 crops, 30 livestock, 0 wild crops, and 21 processor/handling operations. Per New Hampshire State Law, all clients and operations are only certified in the state of New Hampshire. The NHDAMF also conducts other audits and reviews such as for Country of Origin Labeling requirements.

NHDAMF consists of one office located in Concord, New Hampshire. The certification program staff consists of the Director, the Certification Coordinator (also an inspector), one full time staff Agricultural Inspector, and one part-time Agricultural Inspector. A review of the files and interviews conducted confirmed that the organic certification staff had sufficient experience, training, and education or a combination thereof in agriculture, organic production, and organic handling. A review of training records indicated that all organic certification staff had received current training on the USDA organic regulations and guidance.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether NHDAMF's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Noncompliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2191ACA.NC1 – Cleared
NP2191ACA.NC2 – Cleared
NP2191ACA.NC3 – Cleared
NP2191ACA.NC4 – Cleared
NP2191ACA.NC5 – Cleared

Noncompliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4188BBA.NC1 – Accepted – 7 CFR § 205.501 (a)(6) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance

evaluation of all persons who review applications for certification, perform onsite inspections, review certification documents...”

Comments: *The Director has not received a written performance evaluation since starting the position in July 2012, and a part time inspector has not received a written performance evaluation since 2012. An interview with the Director during the audit indicated she is scheduled to receive an evaluation on July 14, 2014 and that the part time inspector was evaluated during an inspection, but the event was not recorded.*

Corrective Action: NHDAMF has created a policy as part of its quality management system that states new employees will have their annual review conducted no later than the anniversary date of their hire, while senior staff annual performance reviews will be conducted in August or September. The State of New Hampshire Employee Performance-Technical Staff Form will be used for these evaluations, with copies issued to the employee and retained in the personnel files.

NP4188BBA.NC2 – Accepted – 7 CFR § 205.662 (c) states, “Proposed suspension or revocation...When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification...”

Comments: *NHDAMF issued a combined Notice of Noncompliance and Proposed Suspension to several clients that had not submitted the required renewal Organic System Plan (OSP) for organic crops by the March 1 deadline. This noncompliance is correctable and NHDAMF should issue a noncompliance and allow the operation to submit corrective actions before proposing adverse actions.*

Corrective Action: NHDAMF updated its policies and procedures to reflect that a Notice of Noncompliance will be issued to operations that fail to submit annual OSPs by the March 1 deadline.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Jennifer Gornert
Director, Division of Regulatory Services
New Hampshire Department of Agriculture, Marketing and Food
PO Box 2042
25 Capitol Street
Concord, NH 03302

Dear Ms. Gornert:

On July 7-9, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service, National Organic Program (NOP), completed an onsite audit of the New Hampshire Department of Agriculture, Marketing and Food's (NHDAMF) organic certification program. The onsite audit was conducted as a function of the NOP Mid-term Accreditation Assessment process. The objective of the assessment was to determine NHDAMF's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4188BBA, is enclosed for your review.

As the report indicates, five noncompliances, NP2191ACA.NC1 through NC5, from your previous assessment are cleared. Two noncompliances, NP4188BBA.NC1 and NC2, were identified as a result of the onsite audit. Please submit proposed corrective actions for the two noncompliances within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how NHDAMF's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Janna Howley, at (202) 690-0047 or JannaB.Howley@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

AUG 28 2014

NOTICE OF NONCOMPLIANCE

Jennifer Gornnert
Director, Division of Regulatory Services
New Hampshire Department of Agriculture, Marketing and Food
PO Box 2042
25 Capitol Street
Concord, NH 03302

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If you have questions regarding this notice, please contact your Accreditation Manager, Janna Howley, at (202) 690-0047 or JannaB.Howley@ams.usda.gov.

Sincerely,

for Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Ave. SW
Room 2603- South
Washington, D.C. 20250

Steven B. Steinborn
Hogan Lovells US LLP
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004
Transmitted via email: Steven.Steinborn@hoganlovells.com

MAR 12 2015

RE: APL-033-14; National Organic Program Appeal Denied

Dear Mr. Steinborn:

The evaluation of the appeal regarding the June 12, 2014 Notice of Proposed Suspension of Accreditation your client, Nature's International Certification Services (NICS), received from The National Organic Program (NOP) has concluded. The United States Department of Agriculture (USDA) Agricultural Marketing Service (AMS) Administrator has issued a decision denying NICS' appeal, determining that the NOP was correct in proposing suspension of NICS' accreditation. A copy of the Administrator's decision is enclosed.

NICS is entitled to a hearing before an USDA Administrative Law Judge as allowed by the USDA organic regulations at 7 CFR 205.681(a)(2). If you choose this option, the Department will initiate the hearing, and it will be conducted according to the USDA's Uniform Rules of Practice, 7 CFR, Part 1, Subpart H. The hearing will be held in the United States. If NICS would like to request this hearing, please sign and return the enclosed "Request for Hearing" form. This form must be returned to the address above within 30 days of receipt.

Alternatively, NICS may waive a hearing and accept the decision of the AMS Administrator to suspend NICS' accreditation due to an inability to comply as a certifying agent. As a result of this action, NICS may apply for reinstatement of accreditation; however, it must wait one (1) year, the timeframe cited in NOP's Notice of Proposed Suspension, before seeking organic accreditation. If NICS would like to waive the hearing, please sign and return the enclosed "Waiver of Hearing" form. This would acknowledge waiving the opportunity for a hearing and accept the decision of the AMS Administrator in its entirety. **If you or NICS does not return either form within 30 days of receipt of this letter, we will accept the Administrator's Decision as a final action without a hearing.**

For more information, please review the appeal decision and forms enclosed.

Sincerely,

A handwritten signature in black ink, appearing to read "Michael Sheats".

Michael Sheats
National Organic Program Appeals Program
Division Director, Agriculture Analytics Division
Livestock, Poultry, and Seed Programs
Agricultural Marketing Service

cc: NOP Accreditation Manager; David Engel (dave@naturesinternational.com)

Enclosures: Administrator's Decision; Request for Hearing Form, Waiver of Hearing Form

UNITED STATES DEPARTMENT OF AGRICULTURE
AGRICULTURAL MARKETING SERVICE
BEFORE THE ADMINISTRATOR

In re:) **Administrator's Decision**
)
Nature's International Certification Services) **APL-033-14**

This Decision is in response to an appeal, APL-33-14, filed by Nature's International Certification Services (NICS), a USDA-accredited certifying agent. NICS is appealing a Notice of Proposed Suspension of Accreditation from the U.S. Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), concluding that NICS is not in compliance with the Organic Foods Production Act of 1990 (Act)¹ and the USDA organic regulations.²

BACKGROUND

The Act authorizes the Secretary to accredit agents to certify crop, livestock, wild crop, and/or handling operations pursuant to the USDA organic regulations (7 C.F.R. Part 205). Accreditation of certifying agents is done by the NOP, which also initiates compliance actions to enforce program requirements. Noncompliance procedures for certifying agents are set forth in §205.665 of the USDA organic regulations. Persons subject to the Act who believe that they are adversely affected by a noncompliance decision of the NOP may appeal such decision to the AMS Administrator, pursuant to §205.680 and §205.681 of the USDA organic regulations.

¹ 7 U.S.C. 6501-6522

² 7 C.F.R. Part 205

FINDINGS OF FACT

1. NICS is currently a USDA-accredited certifying agent.
2. On April 1, 2014, the NOP issued NICS a Notice of Noncompliance citing multiple violations of accreditation requirements.
3. On April 29, 2014, NICS submitted a corrective action plan in response to the Notice of Noncompliance to the NOP.
4. On June 12, 2014, the NOP issued NICS a Notice of Proposed Suspension of Accreditation because the NOP determined that NICS' corrective actions did not adequately or completely resolve the violations.
5. On July 10, 2014, NICS appealed the June 12, 2014 Notice of Proposed Suspension, which was accepted as timely.
6. On August 22, 2014, NICS submitted additional information to support its appeal.

DISCUSSION

The April 1, 2014, Notice of Noncompliance issued to NICS cited multiple violations of accreditation requirements. These included: §205.501(a)(7), for not properly or completely conducting an internal annual program review of its certification activities or resolving issues identified within the annual review; §205.501(a)(6), for not conducting performance evaluations of all certification staff, specifically the Executive Director; §205.505(a)(1), for not accepting the certification decisions made by other accredited certifying agents and/or the NOP; §205.662(f)(1), for granting reinstatement to suspended organic operations without first requesting reinstatement through the NOP; and §205.403(c)(1-2), for not properly verifying that

previously issued noncompliances had been resolved, or that no organic sales had occurred during suspension, prior to issuing organic certification to new or suspended operations.

NICS submitted a corrective action plan on April 29, 2014, responding to the noncompliance determinations. However, the NOP determined that these corrective actions did not adequately or completely resolve the cited violations. Therefore, on June 12, 2014, the NOP issued NICS a Notice of Proposed Suspension of Accreditation. This notice also cited a violation that was not included in the April 1, 2014, Notice of Noncompliance, citing §205.501(a)(3), for not carrying out the provisions of the Act and the USDA organic regulations.

On July 10, 2014, NICS appealed the Notice of Proposed Suspension. In this appeal, NICS argued that the “new” violation in the Notice of Proposed Suspension was inappropriately cited, because it was not included in the original Notice of Noncompliance. NICS argued that the NOP should have cited the new violation in a separate Notice of Noncompliance, and given NICS an opportunity to provide corrections. NICS argued that NOP did not afford NICS due process by including the new violation in the Notice of Proposed Suspension without first issuing a Notice of Noncompliance. NICS stated that the NOP inaccurately identified the new violation as non-correctable. NICS contends that in fact it is correctable, and, therefore, NOP should have cited it in a Notice of Noncompliance instead of a Notice of Proposed Suspension. On August 22, 2014, NICS also submitted additional information to support its appeal. The additional information included a number of proposed corrective actions for the outstanding violations in the Notice of Proposed Suspension.

In response to the NICS’ contention regarding the “new” violation in the Notice of Proposed Suspension, the NOP included this violation in the notice because a response to a violation alleged in the April 1, 2014, Notice of Noncompliance revealed another violation. In

its April 29, 2014, corrective actions, NICS provided the results of its internal certification activities annual review. This review indicated that NICS's annual review was not completed in compliance with the regulations, and was therefore derivative of the initial citation in the Notice of Noncompliance. The citation in the Notice of Proposed Suspension was directly derived from NICS' response to the Notice of Noncompliance; therefore, NICS' claim that it was not afforded due process is incorrect.

NICS also argued that the NOP inappropriately cited violations in the Notice of Proposed Suspension as "willful," without providing evidence or explanation of willful activity. The NOP's Notice states, "I [sic] have reason to believe that you have willfully violated the USDA organic regulations, based on the evidence summarized by the attached corrective action report, numbered AIA13350BJR. Therefore, under 7 CFR §205.665(c) and (d) of the USDA Organic regulations, *Proposed suspension or revocation of Willful Violations*, I [sic] am proposing to suspend your accreditation as a certifying agent."

Willfulness in this case is indicated by the repeated nature of the violation related to certification of suspended operations, and communication records between NICS, its clients, and NOP. First, NICS certified four separate suspended operations without following the appropriate reinstatement procedures; the repeated incorrect actions demonstrate that this was not an isolated mistake. Furthermore, NICS had followed appropriate procedures in past cases, demonstrating that NICS did know what the procedures were, and chose not to follow them.

Second, in two of the cases where NICS failed to follow proper procedure, NICS specifically documented in an inspection report and in communication with the NOP that it disagreed with prior decisions made in this case. This shows that NICS disagreed with previous

decisions related to the cases, and willfully carried out subsequent actions in violation of the regulations.

Beyond these two points, NICS' appeal did not include any arguments as to why it was correct in its actions, or why the NOP was inappropriate or incorrect in issuing the adverse action for the remaining violations. Rather, NICS provided additional corrective actions to resolve the violations that were cited first in the April 1, 2014, Notice of Noncompliance and continued in the June 12, 2014, Notice of Proposed Suspension.

A review of the corrective actions submitted with the appeal indicates that NICS still had not fully resolved the outstanding violations at the time it submitted its appeal.

First, NICS was cited for issuing organic certificates to operations previously suspended by other certifying agents; this is a violation of §205.662(f)(1), Noncompliance procedure for certified operations, and NOP 2605 Instruction, Reinstating Organic Operations. Only the Secretary has the authority to reinstate the organic certification of suspended operations. In its April 29, 2014, corrective action response, NICS included letters it sent to the four (4) operators in question, informing them that their certification was suspended and they could only be reinstated by the NOP. In its August 22, 2014, appeal response, NICS provided a new "Reinstatement Request" form, but no implementation plan, or preventive management plan to ensure the violation would not recur. This violation remains unresolved.

Second, NICS was cited for a noncompliance with §205.501(a)(6), General requirements for accreditation, relating specifically to the performance evaluations of the Executive Director, who is responsible for the oversight of all certification activities, but who also conducts application reviews, inspections, and inspection report reviews. NICS did not provide a copy of a performance evaluation for the Executive Director in its 2013 annual report. In its April 29,

2014, corrective action response, NICS verified that two of the Executive Director's direct reports, a Certification Director and the Inspection Operations Director, performed the performance evaluation. This is not an objective perspective of performance, as an employee evaluating a supervisor is a conflict of interest. In its August 22, 2014, appeal response, NICS indicated the Executive Director's performance evaluation was conducted by an outside party; however, it did not include objective evidence of the conducted evaluation. As such, this violation remains unresolved.

Third, NICS was cited for not accepting the certification decision, such as a suspension of an operation, made by another certifier or the NOP, a noncompliance of §205.505(a)(1). Evidence of this violation is that NICS certified four (4) operations that had been previously suspended by another USDA-accredited certifying agent. By overturning the suspensions, NICS did not accept the other certifiers' decisions to suspend.

In its April 29, 2014, corrective action response, NICS corrected the violation by issuing letters to the operations informing them of their suspensions and their requirement to be reinstated by the NOP. However, these letters did not reflect a change to the NICS quality management system to prevent these violations from occurring again. In its August 22, 2014, appeal response, NICS provided a copy of a new policy memo, "Accepting the certification decisions of another certifier." This addresses the need to accept decisions made by other certifiers, but does not explicitly reference the need to accept and follow NOP decisions. This expansion would be required for this issue to be fully resolved.

Fourth, NICS was cited for a noncompliance of §205.403(c)(1-2), for not properly conducting on-site inspections of operations seeking certification, specifically those related to reinstatement process. In seven (7) instances, the NOP found that NICS did not conduct required

activities prior to issuing organic certificates or recommending reinstatement. Specifically, NICS failed to verify that operations' outstanding noncompliances had been resolved, failed to adequately address discrepancies between the inspection report and information within an operation's Organic System Plan, and failed to verify that no organic sales had occurred during suspension timeframes.

The NICS April 29, 2014, response to the Notice of Noncompliance provided an inspector training document for review; however, the NOP found this draft was not sufficiently clear to meet the requirements. In its August 22, 2014, appeal response, NICS stated that it issued a new policy memo to address verifying organic sales during suspension, as well as a new policy to inspectors for how to submit complete inspection reports. NICS did not, however, provide a corrective mechanism for verifying organic sales after suspension. NICS also stated it was retracting the earlier inspector training document deemed insufficient by NOP, yet provided no replacement for correction. This violation remains unresolved.

CONCLUSION

The NICS appeal of the Notice of Suspension argued two points: first, the Notice of Proposed Suspension incorrectly included a new and correctable noncompliance; and second, that there was no evidence that the violations were willful. The NOP responded to these two points as follows. First, the "new" noncompliance was a derivative of a noncompliance in the original Notice of Noncompliance. As such, NICS had been provided an opportunity to respond in full, and was afforded due process. Second, the NOP supported its argument that the NICS violations were willful because of the repeated certification of suspended operations, and

because of the communications between NICS and its clients and the NOP indicated that it disagreed with decisions made by other certifiers and the NOP.

Beyond these two points, the NICS appeal consists primarily of corrective actions responding to the citations in the initial Notice of Noncompliance and subsequent Notice of Proposed Suspension. The appeals process is not a corrective action process; however, AMS did fully consider the submitted corrective actions, to determine whether they would fully resolve the Notice of Proposed Suspension. This review revealed that even after two separate corrective action submittals, NICS remained out of compliance with four accreditation requirements. These remaining outstanding noncompliances indicate that the NOP Combined Notice of Noncompliance and Proposed Suspension was appropriate, and that at the time of the appeal, NICS had demonstrated an inability or unwillingness to comply with the USDA organic regulations accreditation requirements.

DECISION

The appeal is denied. NICS' organic accreditation for crops, wild crops, handling, and livestock scopes is to be suspended for one (1) year. Attached to this formal Administrator's Decision is a Request for Hearing form. NICS has thirty (30) days to request an administrative hearing before an Administrative Law Judge. If NICS does not request a hearing in that period, this Decision will be implemented and the NOP will suspend NICS' organic accreditation.

In accordance with §205.665(g)(1) of the USDA organic regulations, "A certifying agent whose accreditation is suspended by the Secretary under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its accreditation. The request must be accompanied by evidence demonstrating

correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.”

Done at Washington, D.C., on this 11
day of MARCH, 2015.



Rex A. Barnes

Associate Administrator

Applicant Name:	Nature's International Certification Services
Physical Address:	22 East State Highway 56, Viroqua, WI 54665
Mailing Address:	22 East State Highway 56, Viroqua, WI 54665
Contact & Title:	Dave Engel, Executive Director
E-mail Address:	dave@naturesinternational.com
Phone Number:	608-637-7080
Auditor(s):	Betsy Rakola, Accreditation Manager
Program:	USDA National Organic Program (NOP)
Audit Date(s):	May 9 – 30, 2014
Audit Identifier:	AIA13350BJR
Action Required:	Outstanding noncompliances
Audit Type:	Corrective Action Audit
Audit Objective:	To evaluate the corrective actions submitted by the certifying agent in response to the non-compliances identified during reinstatement and annual report reviews.
Audit Criteria:	7 CFR Part 205, National Organic Program; as amended.
Audit Scope:	NICS' April 29, 2014 corrective action plan, in response to the Notice of Noncompliance issued on April 1, 2014.
Location(s) Audited:	Desk

GENERAL INFORMATION

NICS is a for-profit operation which was initially accredited as a certifying agent to perform certification activities on behalf of the USDA under the National Organic Program (NOP) on February 12, 2007 for crop and livestock; March 17, 2008 for wild crops; and May 26, 2010 for handling. At the time of the renewal assessment, NICS had 462 certified operations, which included 451 crops, 1 wild crop, 149 livestock, and 14 handling operations certified to the NOP. The clients are certified in U.S., mostly in the Midwestern section of the country. NICS applies the NOP Rule and the USDA Grass (Forage) Fed Standard under Guide 65.

BACKGROUND INFORMATION

NICS submitted four reinstatement requests to the NOP in the fall of 2013. While reviewing these requests, the NOP discovered noncompliances in NICS certification processes. The NOP also identified a noncompliance during the review of NICS' 2013 annual report. On April 1, 2014, the NOP issued NICS a Notice of Noncompliance. NICS responded with corrective actions on April 29, 2014. This report summarizes the NOP's assessment of NICS' response.

FINDINGS

The findings below describe the NOP's issues of concern and identify the relevant section of the regulation for each issue. We also outline the certifying agent's response to these issues, which describe how they will correct the problem and prevent it from recurring in the future. Overall,

NICS' corrective action plan failed to address the underlying causes of the Notice of Noncompliance. During the next on-site assessment, the NOP will review the corrective actions below.

Non-Compliances – Certifier Response Accepted

AIA13350BJR.NC2 – Accepted. 7 CFR §205.501 (a)(7) states: *“Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation.”* NICS's 2013 annual report did not include an annual review of its certification activities or describe implemented measures to correct any noncompliances with the Act and its regulations. The outside auditor's report stated that the report was limited in scope and did not include an assessment of NICS's compliance the USDA Organic Regulations. **NICS corrective action:** NICS submitted their 2013 internal audit plan and report. The internal audit listed several serious and recurring noncompliances. In response to the internal audit findings, NICS' submitted a limited corrective action plan which focused mainly on inspector training. NICS provided a copy of its April 22, 2014 memo to inspectors addressing the findings of the annual report.

NOP May 2014 Determination: the evidence proved that NICS conducted an internal program review, as required by the regulations. However, the program review showed evidence of multiple, serious violations, as outlined below in AIA4150BJR.NC1.

Non-Compliances – Certifier Response Not Accepted

AIA4150BJR.NC1 – New. 7 CFR §205.501(a)(3) states, *“A private or governmental entity accredited as a certifying agent under this subpart must carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”* NICS 2013 internal audit report documented several serious and recurring noncompliances. These included:

- NICS did not issue noncompliances to several operations for potentially serious violations, which is required by §205.406(c) and §205.662(a). These violations included:
 - Selling products as organic which were not included in the operation's organic system plan (§205.201(a)(1,6)),
 - Failing to notify NICS of the accidental application of prohibited substances due to pesticide drift (§205.400(f)(2)),
 - Recurring lack of an organic seed search, no crop rotation, and persistent failure to manage diseases (§205.206(a) and (§205.204(a)), and
 - Using nonorganic agricultural ingredients, not listed on §205.606, in products labeled as “organic” and thereby reducing the organic content below 95% (§205.301(b)).
- One file did not include enough information to determine when the last application of prohibited substances occurred (§205.403(a)(2)).

- Maple syrup producers were not inspected at a time when activities that demonstrate the operation's compliance could be observed (§205.403(b)(2)).
- Two inspections did not verify whether storage facilities separated conventional and organic products. The NOP also cited this as a noncompliance when reviewing James Penoyer's request for reinstatement (§205.403(c)(1)).
- Mass balance and trace-back audits are inadequate to verify that the products sold as organic could have been reasonably produced by the operations applying for certification (§205.403(c)(2)).
- Inspection reports included conflicting statements and did not always state whether the inspector verified activities onsite (§205.403(c)(2)).
- Both an inspector and a reviewer failed to conduct a sufficient review of sanitizing materials, including required intervening steps (§205.403(c)(3)).
- In exit interview and report forms, inspectors wrote instructions to operations on how to change their practices to comply with the regulations and overcome barriers to certification, instead of simply describing the evidence at hand (501(a)(11)(iv)).
- Two staff resumes did not include evidence of the necessary qualifications to conduct organic inspection and review activities, and NICS did not keep training records to demonstrate additional qualifications (§205.501(a)(5)).

In response to the internal audit findings, NICS' submitted a limited corrective action plan which focused mainly on inspector training. NICS provided a copy of its April 22, 2014 memo to inspectors addressing the findings of the annual report.

NOP May 2014 Determination: While the memo summarized areas for improvement, it did not provide sufficient training for in-out balances or trace-back audits. Moreover, the memo stated that audits were not always necessary, but it did not provide any objective criteria for determining when one would be necessary. The memo did not use plain language that could be easily understood by all readers. There was no evidence of a plan to address the noncompliant products or operations which were identified by the auditor.

AIA13350BJR.NC1 – Outstanding. 7 CFR §205.501 (a)(6) states: *“Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”* NICS's 2013 annual report did not include staff performance evaluations of all persons involved in certification activities. The 2013 performance evaluation of NICS's Executive Director was limited to business management practices and did not evaluate certification activities performed by the Director. The evaluation did not describe measures implemented to correct any deficiencies in certification services.

NICS corrective action: the Certification Director and the Inspection Operations director completed performance evaluations of the Executive Director.

NOP May 2014 Determination: NICS stated that this evaluation will occur annually, but there was no supporting evidence for this claim. Since these positions report to the Executive Director, an evaluation by direct reports has an inherent conflict of interest that prevents an

unbiased evaluation. As outlined in NOP 2027, *Personnel Performance Evaluations*, certifiers should use supervisor or peer reviews during evaluations.

AIA13350BJR.NC3: Outstanding. 7 CFR §205.505 (a)(1) states: “A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including: Accept the certification decisions made by another certifying agent accredited or accepted by USDA...”

- The Midwest Organic Services Association (MOSA) suspended James Penoyer’s dairy farm in Gilman, Wisconsin on July 16, 2013. Penoyer had appealed MOSA’s proposed suspension in 2012, and the NOP upheld the suspension by denying the appeal in June 2013. NICS granted certification to the farmer on May 23, 2013 and renewed his certification on October 15, 2013. Both NICS’ letters stated that the certification process was complete and that a certificate was enclosed. Neither stated that the farmer’s suspension from MOSA remained in effect until the NOP granted reinstatement, thereby overturning the decisions of MOSA and the NOP. In addition, the inspector stated that MOSA and the NOP had made erroneous and conflicting statements, indicating that he did not accept either decision.

NICS corrective action: On April 25, 2014, NIC sent a Notice of Continuing Suspension to Mr. Penoyer to inform him that his operation was still suspended and therefore was not eligible to sell, label, or represent products as organic.

- Organic Crop Improvement Association (OCIA) issued a Notice of Noncompliance to the Cunningham operation in Twin Lakes, Minnesota on November 11, 2011, placing 16 acres of the producer’s operation in transition due to contamination from flooding on July 15, 2011. NICS is required to accept this certification decision and verify that the 16 acres remain in transition until July 15, 2014. The operation was subsequently suspended by OCIA on July 3, 2012 for other noncompliances. NICS included these 16 acres in the operation’s request for reinstatement and argued in an email communication to NOP staff that the 16 acres should not have been removed from certification.

NICS corrective action: On November 14, 2013 and February 6, 2014, NICS sent a letter to Mr. Cunningham stating that the 15 acres contaminated by flooding would not be eligible for certification until November 11, 2014. NICS also submitted a training memo to reviewers on April 23, 2014 reminding them of the need to verify the status of all acres requested for certification.

NOP May 2014 Determination: NICS’ corrective action did not address their refusal to accept the certification decisions of the NOP and other certifiers.

AIA13350BJR.NC4: Outstanding. 7 CFR §205.662 (f)(1) states: “A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each

noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.”

- NICS issued a decision granting reinstatement of certification to James Penoyer on October 15, 2013. MOSA suspended Mr. Penoyer on July 8, 2013, and NICS included MOSA’s suspension notice in its request to the NOP. NICS did not submit a reinstatement request for the farmer to the NOP until October 18, 2013. Therefore, NICS granted certification to an operation which was not eligible for certification.
- NICS issued a decision granting reinstatement of certification to Kyle Buchholz on December 31, 2013 prior to submitting Kyle Buchholz’s request for reinstatement on January 2, 2014. Mr. Buchholz’s operation was suspended by MOSA on July 29, 2011 and NICS included MOSA’s suspension notice in its request to the NOP. Therefore, NICS granted certification to an operation which was not eligible for certification.
- NICS issued a decision granting reinstatement of certification to the Cunningham operation in Twin Lakes, Minnesota on August 22, 2013, and submitted his request for reinstatement on the same day. The operation was suspended by MOSA on May 24, 2012, and NICS included MOSA’s suspension notice in its request to the NOP. Therefore, NICS granted certification to an operation which was not eligible for certification.

NICS corrective action: NICS updated its procedures manual to state the following:

“The USDA’s Secretary requires NICS to provide a letter of support for the reinstatement request, which can only be done after NICS performs an on-site inspection and conducts a review of the operation’s paperwork and supporting documentation to ensure that the operation requesting reinstatement is in compliance and is capable of ongoing compliance. This letter of support is then sent to the USDA’s Secretary for reinstatement consideration. If the USDA provides a decision to reinstate the suspended operation, then NICS will issue an organic certificate for the reinstatement operation, once notification from the USDA has been received in the NICS office. Operations who wish to request reinstatement should contact the NICS office to request information about the reinstatement process and associated fees for the process.”

On April 25, 2014, NICS issued Notices of Continuing Suspension Mr. Buchholz and Mr. Penoyer that their prior suspensions remained in effect and that he may not sell, label, or represent his products as organic until he has been reinstated. On November 14, 2013 and February 6, 2014, NICS sent a letter to Mr. Cunningham stating that the 15 acres contaminated by flooding would not be eligible for certification until November 11, 2014. As proof of its plan to verify this corrective action, NICS submitted a copy of its request for an internal audit, which asked the auditor to emphasize a review of suspended or revoked operations. NICS’ Inspection Operations Director and Certification Director will also monitor the handling of suspended operations.

NOP May 2014 Determination: NICS did not state whether these three operations sold, labeled, or represented products as organic while suspended. Certifiers must verify this

information when reviewing suspended operations. There was no evidence of staff training or communication on the revised procedure. Certifiers must provide evidence to the NOP on how they will implement corrective actions throughout their organizations, and how they will monitor them to ensure that they are effective.

AIA13350BJR.NC5: Partially accepted; three out of four points outstanding. 7 CFR §205.403 (c)(1-2) states: “*The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part; [and] that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.*”

- NICS granted two certification decisions to James Penoyer, which had outstanding noncompliances without sufficient evidence of corrective actions. NICS’ inspection report did not verify full compliance by the operation, as noted below.
1. NICS did not verify the Penoyer operation’s compliance with §205.105, *Allowed and prohibited substances, methods, and ingredients in organic production and handling*.
 - a. Mr. Penoyer had an outstanding noncompliance from January 5, 2012 for the use of the prohibited products Sulmet and Resorb. The NICS inspector stated that the operation did not intend to use the products on certified calves, but that it was possible that one or two calves may have been treated with these products. NICS noted that very detailed health records for 2008-2012 were present, raising questions as to why the farmer could not verify whether Sulmet or Resorb were used.
NICS corrective action: In its April 25, 2014 Notice of Continuing Suspension, NICS notified Mr. Penoyer that Sulmet is prohibited for use in organic livestock production. NICS also noted that Mr. Penoyer would need to submit additional documentation on livestock production in any future certification application.

NOP May 2014 Determination: NICS did not address the discrepancy in the inspection report.

- b. In response to the question, “§205.601: If micro-nutrients are applied, are micro-nutrient deficiencies documented through testing?” the inspector marked “not applicable.” However, the operation had a previous noncompliance for failing to provide evidence of such deficiencies through testing, and the operation provided evidence of use of synthetic micro-nutrients.
NICS corrective action: NICS’ April 25, 2014 Notice stated that Mr. Penoyer would need to submit soil or tissue tests with any future certification application. NICS also submitted a soil test for Mr. Penoyer’s operation dated May 2013.

NOP May 2014 Determination: It is not clear whether NICS had this information at the time the inspection report was marked “not applicable.” NICS did not address the discrepancy in the inspection report.

- c. The inspector noted that the farmer used dried poultry litter from an off-farm source. The report did not show sufficient evidence that the litter had not been treated with prohibited substances. Instead, the inspector commented that the farmer stated that his supplier told him that the litter was “the ‘OMRI’ one.” **NICS corrective action:** NICS’ April 25, 2014 Notice stated that Mr. Penoyer would need to submit information on all livestock and crop inputs with any future application for certification.

NOP May 2014 Determination: this response adequately addresses the noncompliance.

2. The inspector marked record-keeping requirements for crop storage and records for non-organic production as “not applicable.” However, the report stated that storage facilities were described in the OSP, and the farmer had been cited a previous noncompliance for failing to disclose his non-organic production activities. **NICS corrective action:** NICS’ April 25, 2014 Notice stated that Mr. Penoyer would need to submit a complete organic system plan with any future certification application.

NOP May 2014 Determination: NICS did not mention storage facilities in the letter to Mr. Penoyer. The corrective actions did not address the discrepancy in the inspection report.

3. In response to the question, “If animals are temporarily confined, are the reasons for temporary confinement accurately and completely described?” the inspector marked “yes. However, the inspector marked the question on records for temporary confinement as “not applicable.” The inspector did not state how he was able to verify compliance with §205.239(b-c), *Livestock Living Conditions*, without viewing a record of the dates and reasons for temporary confinement. **NICS corrective action:** NICS’ April 25, 2014 Notice stated that Mr. Penoyer would need to submit documentation of outdoor pads, pasture, and temporary confinement with any future certification application.

NOP May 2014 Determination: Although the corrective actions appeared effective to address compliance concerns with Mr. Penoyer’s operation, they did not address the discrepancies in the inspection report.

- In submitting Joseph and Noah Miller’s request for reinstatement, NICS determined that 84 acres were eligible for certification and issued a notice granting certification of this acreage on November 13, 2013. However, the NICS inspection report on the Miller operation and a statement submitted by Joseph Miller indicated 16 of the 84 acres were not eligible for certification due to the use of treated seed on the land. **NICS corrective action:** NICS submitted a certificate showing that only 69 acres of the Miller’s land were certified. NICS also submitted a memo to certification file reviewers instructing them to verify the organic status of all land under the management of an applicant.

NOP May 2014 Determination: NICS calculated the number of acres incorrectly, since 84 minus 16 equals 68. The certificate still shows an inaccurate number of acres.

- In submitting Kyle Bucholz's request for reinstatement, NICS noted that Mr. Bucholz was not aware that his operation was suspended by MOSA in 2011. Mr. Bucholz continued production in 2012 and 2013. NICS's inspection report on the Bucholz operation did not verify if harvested product was sold as organic while the operation was suspended. The inspection reported noted that the organic and nonorganic sales records from 2012 – 2013 were not applicable. The inspection report also noted that the operation had not maintained records for five years, including when the operation had been certified by MOSA. **NICS corrective action:** On April 25, 2014, NICS issued a Notice of Continued Suspension to Mr. Bucholz. The Notice stated that all certification records must be kept for at least 5 years, and that all organic and nonorganic sales records from 2011 forward would need to be available at his next on-site inspection.

NOP May 2014 Determination: NICS has not investigated whether Mr. Bucholz sold, labeled, or represented products as organic since his 2011 suspension and appears to consider the reinstatement request closed. Neither the reinstatement procedure nor the inspector training addressed the need to investigate whether suspended operations continued to sell products labeled as organic.

NICS Corrective Action Response: in order to address the underlying causes of NC 5 , the Inspection Operations Director will now monitor inspection evaluations and certification decisions. NICS submitted a copy of an evaluation form that will allow final reviewers to comment on the clarity and completeness of inspection reports. NICS also submitted a form to evaluate whether certification decisions answered all questions appropriately, reviewed previous noncompliances, contained sufficient information, and were generally appropriate based on the available evidence.

NOP May 2014 Determination: The inspector training document was long and unclear, with a lot of colloquialisms and acronyms. Given that its purpose was to provide guidance on clear and accurate inspection reports, it does not adequately address the problem. It appears that there was no verbal discussion or follow-up conversation with any of the inspectors about the instructions.

The Executive Director wrote all of the inspection reports which the NOP cited for noncompliances. He also supervises the two staff who will be evaluating the inspection reports and certification decisions. As stated in NC1, employees are unable to provide unbiased of their supervisor's performance. Therefore, the proposed evaluation system cannot guarantee effective monitoring and feedback.

Applicant Name:	Nature's International Certification Services
Physical Address:	22 East State Highway 56, Viroqua, WI 54665
Mailing Address:	22 East State Highway 56, Viroqua, WI 54665
Contact & Title:	Dave Engel, Executive Director
E-mail Address:	dave@naturesinternational.com
Phone Number:	608-637-7080
Auditor(s):	Betsy Rakola, Accreditation Manager
Program:	USDA National Organic Program (NOP)
Audit Date(s):	May 9 – 30, 2014
Audit Identifier:	AIA13350BJR
Action Required:	Outstanding noncompliances
Audit Type:	Corrective Action Report
Audit Objective:	To evaluate the corrective actions submitted by the certifying agent in response to the non-compliances identified during reinstatement and annual report reviews.
Audit Criteria:	7 CFR Part 205, National Organic Program; as amended.
Audit Scope:	NICS' April 29, 2014, corrective action plan, in response to the Notice of Noncompliance issued on April 1, 2014.
Location(s) Audited:	Desk

GENERAL INFORMATION

NICS is a for-profit operation which was initially accredited as a certifying agent to perform certification activities on behalf of the USDA under the National Organic Program (NOP) on February 12, 2007, for crop and livestock; March 17, 2008, for wild crops; and May 26, 2010, for handling. At the time of the renewal assessment, NICS had 462 certified operations, which included 451 crops, 1 wild crop, 149 livestock, and 14 handling operations certified to the NOP. The clients are certified in U.S., mostly in the Midwestern section of the country. NICS applies the USDA organic rule and the USDA Grass (Forage) Fed Standard under ISO Guide 65.

BACKGROUND INFORMATION

NICS submitted four reinstatement requests to the NOP in the fall of 2013. While reviewing these requests, the NOP discovered noncompliances in NICS certification processes. The NOP also identified a noncompliance during the review of NICS' 2013 annual report. On April 1, 2014, the NOP issued NICS a Notice of Noncompliance. NICS responded with corrective actions on April 29, 2014. This report summarizes the NOP's assessment of NICS' response.

FINDINGS

The findings below describe the noncompliances identified with the relevant section of the USDA organic regulation for each issue. For each noncompliance identified we summarize NICS' response. Finally we make a determination on whether NICS response is adequate to

resolve the noncompliance or whether NICS' response is unsuccessful in resolving the noncompliance. Overall, NICS' corrective action plan was unsuccessful in resolving the noncompliances. In addition, new noncompliances were identified during this review.

Noncompliances – Certifier Response Accepted

AIA13350BJR.NC2 – Accepted. 7 CFR §205.501 (a)(7) states: *“Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation.”* NICS's 2013 annual report did not include an annual review of its certification activities or describe implemented measures to correct any noncompliances with the Act and its regulations. The outside auditor's report stated that the report was limited in scope and did not include an assessment of NICS's compliance with the Act and the USDA Organic Regulations.

NICS corrective action: NICS submitted their 2013 internal audit plan and report. The internal audit listed several serious and recurring noncompliances. In response to the internal audit findings, NICS' submitted a limited corrective action plan which focused mainly on inspector training. NICS provided a copy of its April 22, 2014, memo to inspectors addressing the findings of their 2013 internal audit report.

NOP May 2014 Determination: The evidence provided by NICS demonstrated that NICS conducted an internal program review, as required by the regulations. However, the program review showed evidence of multiple, serious violations, as outlined below in AIA4150BJR.NC1.

Noncompliance – New finding based on NICS Internal Audit Findings

AIA4150BJR.NC1 – New. 7 CFR §205.501(a)(3) states, *“A private or governmental entity accredited as a certifying agent under this subpart must carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”* NICS' 2013 internal audit report documented several serious and recurring noncompliances. These included:

- NICS did not issue noncompliances to several operations for potentially serious violations, which is required by §205.406(c) and §205.662(a). These violations included:
 - Selling products as organic which were not included in the operation's organic system plan (§205.201(a)(1,6)),
 - Failing to notify NICS of the accidental application of prohibited substances due to pesticide drift (§205.400(f)(2)),
 - Recurring lack of an organic seed search, no crop rotation, and persistent failure to manage diseases (§205.206(a) and (§205.204(a)), and
 - Using nonorganic agricultural ingredients, not listed on §205.606, in products labeled as “organic” and thereby reducing the organic content below 95% (§205.301(b)).
- One file did not include enough information to determine when the last application of prohibited substances occurred (§205.403(a)(2)).

- Maple syrup producers were not inspected at a time when activities that demonstrate the operation's compliance could be observed (§205.403(b)(2)).
- Two inspections did not verify whether storage facilities separated conventional and organic products. The NOP also cited this as a noncompliance when reviewing James Penoyer's request for reinstatement (§205.403(c)(1)).
- Mass balance and trace-back audits are inadequate to verify that the products sold as organic could have been reasonably produced by the operations applying for certification (§205.403(c)(2)).
- Inspection reports included conflicting statements and did not always state whether the inspector verified activities onsite (§205.403(c)(2)).
- Both an inspector and a reviewer failed to conduct a sufficient review of sanitizing materials, including required intervening steps (§205.403(c)(3)).
- In exit interview and report forms, inspectors wrote instructions to operations on how to change their practices to comply with the regulations and overcome barriers to certification, instead of simply describing the evidence at hand (501(a)(11)(iv)).
- Two staff resumes did not include evidence of the necessary qualifications to conduct organic inspection and review activities, and NICS did not keep training records to demonstrate additional qualifications (§205.501(a)(5)).

In response to the internal audit findings, NICS' submitted a limited corrective action plan which focused mainly on inspector training. NICS provided a copy of its April 22, 2014, memo to inspectors addressing the findings of the internal audit checklist and report.

NOP May 2014 Determination: NICS did not submit any plan to address its failure to issue Notices of Noncompliance to operations which had violated the USDA organic regulations. While the memo summarized areas for improvement, it did not provide sufficient training for in-out balances or trace-back audits. Moreover, the memo stated that audits were not always necessary, but it did not provide any objective criteria for determining when one would be necessary. The memo did not use plain language that could be easily understood by all readers. There was no evidence of a plan to address the noncompliant products or operations which were identified by the auditor.

Non-Compliances – Certifier Response Not Accepted

AIA13350BJR.NC1 – Outstanding. 7 CFR §205.501 (a)(6) states: *“Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”* NICS's 2013 annual report did not include staff performance evaluations of all persons involved in certification activities. The 2013 performance evaluation of NICS's Executive Director was limited to business management practices and did not evaluate certification activities performed by the Director. The evaluation did not describe measures implemented to correct any deficiencies in certification services.

NICS corrective action: the Certification Director and the Inspection Operations director completed performance evaluations of the Executive Director.

NOP May 2014 Determination: NICS stated that this evaluation will occur annually, but there was no supporting evidence for this claim. Since these positions report to the Executive Director, an evaluation by direct reports has an inherent conflict of interest that prevents an unbiased evaluation. As outlined in NOP 2027, *Personnel Performance Evaluations*, certifiers should use supervisor or peer reviews during evaluations.

AIA13350BJR.NC3: Outstanding. 7 CFR §205.505 (a)(1) states: *“A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including: Accept the certification decisions made by another certifying agent accredited or accepted by USDA...”* Further, 7 U.S.C. 6515(f) of the Organic Foods Production Act states: *“Any certifying agent shall fully comply with the terms and conditions of the applicable organic certification program implemented under this title.”*

- The Midwest Organic Services Association (MOSA) suspended James Penoyer’s dairy farm in Gilman, Wisconsin on July 16, 2013. Penoyer had appealed MOSA’s proposed suspension in 2012, and the NOP upheld the suspension by denying the appeal in June 2013. NICS granted certification to the farmer on May 23, 2013, and renewed his certification on October 15, 2013. Both NICS’ letters stated that the certification process was complete and that a certificate was enclosed. Neither stated that the farmer’s suspension from MOSA remained in effect until the NOP granted reinstatement, thereby overturning the decisions of MOSA and the NOP. In addition, the inspector (who is also NICS’ Executive Director) stated that MOSA and the NOP had made erroneous and conflicting statements, indicating that he did not accept either decision.

NICS corrective action: On April 25, 2014, NICS sent a Notice of Continuing Suspension to Mr. Penoyer to inform him that his operation was still suspended and therefore was not eligible to sell, label, or represent products as organic.

- Organic Crop Improvement Association (OCIA) issued a Notice of Noncompliance to the Cunningham operation in Twin Lakes, Minnesota on November 11, 2011, placing 16 acres of the producer’s operation in transition due to contamination from flooding on July 15, 2011. NICS is required to accept this certification decision and verify that the 16 acres remain in transition until July 15, 2014. The operation was subsequently suspended by OCIA on July 3, 2012, for other noncompliances. NICS included these 16 acres in the operation’s request for reinstatement and argued in an email communication to NOP staff that the 16 acres should not have been removed from certification.

NICS corrective action: On November 14, 2013 and February 6, 2014, NICS sent a letter to Mr. Cunningham stating that the 16 acres contaminated by flooding would not be eligible for certification until November 11, 2014. NICS also submitted a training memo to NICS reviewers on April 23, 2014, reminding them of the need to verify the status of all acres requested for certification.

NOP May 2014 Determination: NICS' corrective action did not address their refusal to accept the certification decisions of the NOP and other certifiers.

AIA13350BJR.NC4: Outstanding. 7 CFR §205.662 (f)(1) states: *“A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.”* **Further, 7 U.S.C. 6515(d) of the Organic Foods Production Act states:** *“Any certifying agent shall enter into an agreement with the Secretary under which such agent shall (1) agree to carry out the provisions of this title; and (2) agree to such other terms and conditions as the Secretary determines appropriate.”* **Instruction NOP 2605, Reinstating Suspended Operations, states the following in Section 3:** *“Certifiers may not approve or deny certification of a suspended operation without the NOP’s written approval.”*

- NICS issued a decision granting reinstatement of certification to James Penoyer on October 15, 2013. MOSA suspended Mr. Penoyer on July 8, 2013, and NICS included MOSA’s suspension notice in its request to the NOP. NICS did not submit a reinstatement request for the farmer to the NOP until October 18, 2013. Therefore, NICS granted certification to a suspended operation which was not eligible for certification.
- NICS issued a decision granting reinstatement of certification to Kyle Buchholz on December 31, 2013, prior to submitting Kyle Buchholz’s request for reinstatement on January 2, 2014. Mr. Buchholz’s operation was suspended by MOSA on July 29, 2011, and NICS included MOSA’s suspension notice in its request to the NOP. Therefore, NICS granted certification to a suspended operation which was not eligible for certification.
- NICS issued a decision granting reinstatement of certification to the Cunningham operation in Twin Lakes, Minnesota on August 22, 2013, and submitted his request for reinstatement on the same day. The operation was suspended by MOSA on May 24, 2012, and NICS included MOSA’s suspension notice in its request to the NOP. Therefore, NICS granted certification to a suspended operation which was not eligible for certification.

NICS corrective action: NICS updated its procedures manual to state the following:

“The USDA’s Secretary requires NICS to provide a letter of support for the reinstatement request, which can only be done after NICS performs an on-site inspection and conducts a review of the operation’s paperwork and supporting documentation to ensure that the operation requesting reinstatement is in compliance and is capable of ongoing compliance. This letter of support is then sent to the USDA’s Secretary for reinstatement consideration. If the USDA provides a decision to reinstate the suspended operation, then NICS will issue an organic certificate for the reinstatement operation, once notification from the USDA has been received in the NICS office. Operations who wish to request reinstatement should contact the NICS office to request information about the reinstatement process and associated fees for the process.”

On April 25, 2014, NICS issued Notices of Continuing Suspension to Mr. Bucholz and Mr. Penoyer that their prior suspensions remained in effect and that he may not sell, label, or represent his products as organic until he has been reinstated. On November 14, 2013, and February 6, 2014, NICS sent a letter to Mr. Cunningham stating that the 16 acres contaminated by flooding would not be eligible for certification until November 11, 2014. As proof of its plan to verify this corrective action, NICS submitted a copy of its request for an internal audit, which asked the auditor to emphasize a review of suspended or revoked operations. NICS' Inspection Operations Director and Certification Director will also monitor the handling of suspended operations.

NOP May 2014 Determination: NICS did not state whether these three operations sold, labeled, or represented products as organic while suspended. Certifiers must verify this information when reviewing suspended operations. There was no evidence of staff training or communication on the revised procedure. Certifiers must provide evidence to the NOP on how they will implement corrective actions throughout their organizations, and how they will monitor them to ensure that they are effective.

AIA13350BJR.NC5: Partially accepted; three out of four points outstanding. 7 CFR §205.403 (c)(1-2) states: *“The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part; [and] that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.”*

1. NICS granted two certification decisions to James Penoyer, which had outstanding noncompliances without sufficient evidence of corrective actions. NICS' inspection report did not verify full compliance by the operation, as noted below.
1. NICS did not verify the Penoyer operation's compliance with §205.105, *Allowed and prohibited substances, methods, and ingredients in organic production and handling.*
 - a. Mr. Penoyer had an outstanding noncompliance from January 5, 2012 for the use of the prohibited products Sulmet and Resorb. The NICS inspector stated that the operation did not intend to use the products on certified calves, but that it was possible that one or two calves may have been treated with these products. NICS noted that very detailed health records for 2008-2012 were present, raising questions as to why the farmer could not verify whether Sulmet or Resorb were used.

NICS corrective action: In its April 25, 2014, Notice of Continuing Suspension, NICS notified Mr. Penoyer that Sulmet is prohibited for use in organic livestock production. NICS also noted that Mr. Penoyer would need to submit additional documentation on livestock production in any future certification application.

NOP May 2014 Determination: NICS did not address the discrepancy in the inspection report.

- b. In response to the question, “§205.601: If micro-nutrients are applied, are micro-nutrient deficiencies documented through testing?” the inspector marked “not applicable.” However, the operation had a previous noncompliance for failing to provide evidence of such deficiencies through testing, and the operation provided evidence of use of synthetic micro-nutrients.

NICS corrective action: NICS’ April 25, 2014, Notice stated that Mr. Penoyer would need to submit soil or tissue tests with any future certification application. NICS also submitted a soil test for Mr. Penoyer’s operation dated May 2013.

NOP May 2014 Determination: It is not clear whether NICS had this information at the time the inspection report was marked “not applicable.” NICS did not address the discrepancy in the inspection report.

- c. The inspector noted that the farmer used dried poultry litter from an off-farm source. The report did not show sufficient evidence that the litter had not been treated with prohibited substances. Instead, the inspector commented that the farmer stated that his supplier told him that the litter was “the ‘OMRI’ one.”
- d. **NICS corrective action:** NICS’ April 25, 2014, Notice stated that Mr. Penoyer would need to submit information on all livestock and crop inputs with any future application for certification.

NOP May 2014 Determination: this response adequately addresses the noncompliance.

2. The inspector marked record-keeping requirements for crop storage and records for non-organic production as “not applicable.” However, the report stated that storage facilities were described in the OSP, and the farmer had been cited a previous noncompliance for failing to disclose his non-organic production activities.
3. **NICS corrective action:** NICS’ April 25, 2014, Notice stated that Mr. Penoyer would need to submit a complete organic system plan with any future certification application.

NOP May 2014 Determination: NICS did not mention storage facilities in the letter to Mr. Penoyer. The corrective actions did not address the discrepancy in the inspection report.

4. In response to the question, “If animals are temporarily confined, are the reasons for temporary confinement accurately and completely described?” the inspector marked “yes. However, the inspector marked the question on records for temporary confinement as “not applicable.” The inspector did not state how he was able to verify compliance with §205.239(b-c), *Livestock Living Conditions*, without viewing a record of the dates and reasons for temporary confinement.

5. **NICS corrective action:** NICS' April 25, 2014, Notice stated that Mr. Penoyer would need to submit documentation of outdoor pads, pasture, and temporary confinement with any future certification application.

NOP May 2014 Determination: Although the corrective actions appeared effective to address compliance concerns with Mr. Penoyer's operation, they did not address the discrepancies in the inspection report.

2. In submitting Joseph and Noah Miller's request for reinstatement, NICS determined that 84 acres were eligible for certification and issued a notice granting certification of this acreage on November 13, 2013. However, the NICS inspection report on the Miller operation and a statement submitted by Joseph Miller indicated 16 of the 84 acres were not eligible for certification due to the use of treated seed on the land.
3. **NICS corrective action:** NICS submitted a certificate showing that only 69 acres of the Miller's land were certified. NICS also submitted a memo to certification file reviewers instructing them to verify the organic status of all land under the management of an applicant.

NOP May 2014 Determination: NICS calculated the number of acres incorrectly, since 84 minus 16 equals 68. The certificate still shows an inaccurate number of acres.

4. In submitting Kyle Bucholz's request for reinstatement, NICS noted that Mr. Bucholz was not aware that his operation was suspended by MOSA in 2011. Mr. Bucholz continued production in 2012 and 2013. NICS's inspection report on the Bucholz operation did not verify if harvested product was sold as organic while the operation was suspended. The inspection reported noted that the organic and nonorganic sales records from 2012 – 2013 were not applicable. The inspection report also noted that the operation had not maintained records for five years, including when the operation had been certified by MOSA.
- 5.
6. **NICS corrective action:** On April 25, 2014, NICS issued a Notice of Continued Suspension to Mr. Bucholz. The Notice stated that all certification records must be kept for at least 5 years, and that all organic and nonorganic sales records from 2011 forward would need to be available at his next on-site inspection.

NOP May 2014 Determination: NICS has not investigated whether Mr. Bucholz sold, labeled, or represented products as organic since his 2011 suspension and appears to consider the reinstatement request closed. Neither the reinstatement procedure nor the inspector training addressed the need to investigate whether suspended operations continued to sell products labeled as organic.

NICS Corrective Action Response: in order to address the underlying causes of NC 5 , the Inspection Operations Director will now monitor inspection evaluations and certification decisions. NICS submitted a copy of an evaluation form that will allow final reviewers to comment on the clarity and completeness of inspection reports. NICS also submitted a form to

evaluate whether certification decisions answered all questions appropriately, reviewed previous noncompliances, contained sufficient information, and were generally appropriate based on the available evidence.

NOP May 2014 Determination: The inspector training document was long and unclear, with a lot of colloquialisms and acronyms. Given that its purpose was to provide guidance on clear and accurate inspection reports, it does not adequately address the problem. It appears that there was no verbal discussion or follow-up conversation with any of the inspectors about the instructions.

The Executive Director wrote all of the inspection reports which the NOP cited for noncompliances. He also supervises the two staff who will be evaluating the inspection reports and certification decisions. As stated in NC1, employees are unable to provide unbiased evaluations of their supervisor's performance. Therefore, the proposed evaluation system cannot guarantee effective monitoring and feedback.

Applicant Name:	Nature's International Certification Services
Physical Address:	22 East State Highway 56, Viroqua, WI 54665
Mailing Address:	22 East State Highway 56, Viroqua, WI 54665
Contact & Title:	Dave Engel, Executive Director
E-mail Address:	dave@naturesinternational.com
Phone Number:	608-637-7080
Auditor(s):	Betsy Rakola, Accreditation Manager
Program:	USDA National Organic Program (NOP)
Audit Date(s):	May 9 – 30, 2014
Audit Identifier:	AIA13350BJR
Action Required:	Outstanding noncompliances
Audit Type:	Corrective Action Report
Audit Objective:	To evaluate the corrective actions submitted by the certifying agent in response to the non-compliances identified during reinstatement and annual report reviews.
Audit Criteria:	7 CFR Part 205, National Organic Program; as amended.
Audit Scope:	NICS' April 29, 2014, corrective action plan, in response to the Notice of Noncompliance issued on April 1, 2014.
Location(s) Audited:	Desk

GENERAL INFORMATION

NICS is a for-profit operation which was initially accredited as a certifying agent to perform certification activities on behalf of the USDA under the National Organic Program (NOP) on February 12, 2007, for crop and livestock; March 17, 2008, for wild crops; and May 26, 2010, for handling. At the time of the renewal assessment, NICS had 462 certified operations, which included 451 crops, 1 wild crop, 149 livestock, and 14 handling operations certified to the NOP. The clients are certified in U.S., mostly in the Midwestern section of the country. NICS applies the USDA organic rule and the USDA Grass (Forage) Fed Standard under ISO Guide 65.

BACKGROUND INFORMATION

NICS submitted four reinstatement requests to the NOP in the fall of 2013. While reviewing these requests, the NOP discovered noncompliances in NICS certification processes. The NOP also identified a noncompliance during the review of NICS' 2013 annual report. On April 1, 2014, the NOP issued NICS a Notice of Noncompliance. NICS responded with corrective actions on April 29, 2014. This report summarizes the NOP's assessment of NICS' response.

FINDINGS

The findings below describe the noncompliances identified with the relevant section of the USDA organic regulation for each issue. For each noncompliance identified we summarize NICS' response. Finally we make a determination on whether NICS response is adequate to

resolve the noncompliance or whether NICS' response is unsuccessful in resolving the noncompliance. Overall, NICS' corrective action plan was unsuccessful in resolving the noncompliances. In addition, new noncompliances were identified during this review.

Noncompliances – Certifier Response Accepted

AIA13350BJR.NC2 – Accepted. 7 CFR §205.501 (a)(7) states: *“Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation.”* NICS's 2013 annual report did not include an annual review of its certification activities or describe implemented measures to correct any noncompliances with the Act and its regulations. The outside auditor's report stated that the report was limited in scope and did not include an assessment of NICS's compliance with the Act and the USDA Organic Regulations.

NICS corrective action: NICS submitted their 2013 internal audit plan and report. The internal audit listed several serious and recurring noncompliances. In response to the internal audit findings, NICS' submitted a limited corrective action plan which focused mainly on inspector training. NICS provided a copy of its April 22, 2014, memo to inspectors addressing the findings of their 2013 internal audit report.

NOP May 2014 Determination: The evidence provided by NICS demonstrated that NICS conducted an internal program review, as required by the regulations. However, the program review showed evidence of multiple, serious violations, as outlined below in AIA4150BJR.NC1.

Noncompliance – New finding based on NICS Internal Audit Findings

AIA4150BJR.NC1 – New. 7 CFR §205.501(a)(3) states, *“A private or governmental entity accredited as a certifying agent under this subpart must carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”* NICS' 2013 internal audit report documented several serious and recurring noncompliances. These included:

- NICS did not issue noncompliances to several operations for potentially serious violations, which is required by §205.406(c) and §205.662(a). These violations included:
 - Selling products as organic which were not included in the operation's organic system plan (§205.201(a)(1,6)),
 - Failing to notify NICS of the accidental application of prohibited substances due to pesticide drift (§205.400(f)(2)),
 - Recurring lack of an organic seed search, no crop rotation, and persistent failure to manage diseases (§205.206(a) and (§205.204(a)), and
 - Using nonorganic agricultural ingredients, not listed on §205.606, in products labeled as “organic” and thereby reducing the organic content below 95% (§205.301(b)).
- One file did not include enough information to determine when the last application of prohibited substances occurred (§205.403(a)(2)).

- Maple syrup producers were not inspected at a time when activities that demonstrate the operation's compliance could be observed (§205.403(b)(2)).
- Two inspections did not verify whether storage facilities separated conventional and organic products. The NOP also cited this as a noncompliance when reviewing James Penoyer's request for reinstatement (§205.403(c)(1)).
- Mass balance and trace-back audits are inadequate to verify that the products sold as organic could have been reasonably produced by the operations applying for certification (§205.403(c)(2)).
- Inspection reports included conflicting statements and did not always state whether the inspector verified activities onsite (§205.403(c)(2)).
- Both an inspector and a reviewer failed to conduct a sufficient review of sanitizing materials, including required intervening steps (§205.403(c)(3)).
- In exit interview and report forms, inspectors wrote instructions to operations on how to change their practices to comply with the regulations and overcome barriers to certification, instead of simply describing the evidence at hand (501(a)(11)(iv)).
- Two staff resumes did not include evidence of the necessary qualifications to conduct organic inspection and review activities, and NICS did not keep training records to demonstrate additional qualifications (§205.501(a)(5)).

In response to the internal audit findings, NICS' submitted a limited corrective action plan which focused mainly on inspector training. NICS provided a copy of its April 22, 2014, memo to inspectors addressing the findings of the internal audit checklist and report.

NOP May 2014 Determination: NICS did not submit any plan to address its failure to issue Notices of Noncompliance to operations which had violated the USDA organic regulations. While the memo summarized areas for improvement, it did not provide sufficient training for in-out balances or trace-back audits. Moreover, the memo stated that audits were not always necessary, but it did not provide any objective criteria for determining when one would be necessary. The memo did not use plain language that could be easily understood by all readers. There was no evidence of a plan to address the noncompliant products or operations which were identified by the auditor.

Non-Compliances – Certifier Response Not Accepted

AIA13350BJR.NC1 – Outstanding. 7 CFR §205.501 (a)(6) states: *“Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”* NICS's 2013 annual report did not include staff performance evaluations of all persons involved in certification activities. The 2013 performance evaluation of NICS's Executive Director was limited to business management practices and did not evaluate certification activities performed by the Director. The evaluation did not describe measures implemented to correct any deficiencies in certification services.

NICS corrective action: the Certification Director and the Inspection Operations director completed performance evaluations of the Executive Director.

NOP May 2014 Determination: NICS stated that this evaluation will occur annually, but there was no supporting evidence for this claim. Since these positions report to the Executive Director, an evaluation by direct reports has an inherent conflict of interest that prevents an unbiased evaluation. As outlined in NOP 2027, *Personnel Performance Evaluations*, certifiers should use supervisor or peer reviews during evaluations.

AIA13350BJR.NC3: Outstanding. 7 CFR §205.505 (a)(1) states: “A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including: Accept the certification decisions made by another certifying agent accredited or accepted by USDA...” Further, 7 U.S.C. 6515(f) of the Organic Foods Production Act states: “Any certifying agent shall fully comply with the terms and conditions of the applicable organic certification program implemented under this title.”

- The Midwest Organic Services Association (MOSA) suspended James Penoyer’s dairy farm in Gilman, Wisconsin on July 16, 2013. Penoyer had appealed MOSA’s proposed suspension in 2012, and the NOP upheld the suspension by denying the appeal in June 2013. NICS granted certification to the farmer on May 23, 2013, and renewed his certification on October 15, 2013. Both NICS’ letters stated that the certification process was complete and that a certificate was enclosed. Neither stated that the farmer’s suspension from MOSA remained in effect until the NOP granted reinstatement, thereby overturning the decisions of MOSA and the NOP. In addition, the inspector (who is also NICS’ Executive Director) stated that MOSA and the NOP had made erroneous and conflicting statements, indicating that he did not accept either decision.

NICS corrective action: On April 25, 2014, NICS sent a Notice of Continuing Suspension to Mr. Penoyer to inform him that his operation was still suspended and therefore was not eligible to sell, label, or represent products as organic.

- Organic Crop Improvement Association (OCIA) issued a Notice of Noncompliance to the Cunningham operation in Twin Lakes, Minnesota on November 11, 2011, placing 16 acres of the producer’s operation in transition due to contamination from flooding on July 15, 2011. NICS is required to accept this certification decision and verify that the 16 acres remain in transition until July 15, 2014. The operation was subsequently suspended by OCIA on July 3, 2012, for other noncompliances. NICS included these 16 acres in the operation’s request for reinstatement and argued in an email communication to NOP staff that the 16 acres should not have been removed from certification.

NICS corrective action: On November 14, 2013 and February 6, 2014, NICS sent a letter to Mr. Cunningham stating that the 16 acres contaminated by flooding would not be eligible for certification until November 11, 2014. NICS also submitted a training memo to NICS reviewers on April 23, 2014, reminding them of the need to verify the status of all acres requested for certification.

NOP May 2014 Determination: NICS' corrective action did not address their refusal to accept the certification decisions of the NOP and other certifiers.

AIA13350BJR.NC4: Outstanding. 7 CFR §205.662 (f)(1) states: “A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.” **Further, 7 U.S.C. 6515(d) of the Organic Foods Production Act states:** “Any certifying agent shall enter into an agreement with the Secretary under which such agent shall (1) agree to carry out the provisions of this title; and (2) agree to such other terms and conditions as the Secretary determines appropriate.” **Instruction NOP 2605, Reinstating Suspended Operations, states the following in Section 3:** “Certifiers may not approve or deny certification of a suspended operation without the NOP’s written approval.”

- NICS issued a decision granting reinstatement of certification to James Penoyer on October 15, 2013. MOSA suspended Mr. Penoyer on July 8, 2013, and NICS included MOSA’s suspension notice in its request to the NOP. NICS did not submit a reinstatement request for the farmer to the NOP until October 18, 2013. Therefore, NICS granted certification to a suspended operation which was not eligible for certification.
- NICS issued a decision granting reinstatement of certification to Kyle Buchholz on December 31, 2013, prior to submitting Kyle Buchholz’s request for reinstatement on January 2, 2014. Mr. Buchholz’s operation was suspended by MOSA on July 29, 2011, and NICS included MOSA’s suspension notice in its request to the NOP. Therefore, NICS granted certification to a suspended operation which was not eligible for certification.
- NICS issued a decision granting reinstatement of certification to the Cunningham operation in Twin Lakes, Minnesota on August 22, 2013, and submitted his request for reinstatement on the same day. The operation was suspended by MOSA on May 24, 2012, and NICS included MOSA’s suspension notice in its request to the NOP. Therefore, NICS granted certification to a suspended operation which was not eligible for certification.

NICS corrective action: NICS updated its procedures manual to state the following:

“The USDA’s Secretary requires NICS to provide a letter of support for the reinstatement request, which can only be done after NICS performs an on-site inspection and conducts a review of the operation’s paperwork and supporting documentation to ensure that the operation requesting reinstatement is in compliance and is capable of ongoing compliance. This letter of support is then sent to the USDA’s Secretary for reinstatement consideration. If the USDA provides a decision to reinstate the suspended operation, then NICS will issue an organic certificate for the reinstatement operation, once notification from the USDA has been received in the NICS office. Operations who wish to request reinstatement should contact the NICS office to request information about the reinstatement process and associated fees for the process.”

On April 25, 2014, NICS issued Notices of Continuing Suspension to Mr. Bucholz and Mr. Penoyer that their prior suspensions remained in effect and that he may not sell, label, or represent his products as organic until he has been reinstated. On November 14, 2013, and February 6, 2014, NICS sent a letter to Mr. Cunningham stating that the 16 acres contaminated by flooding would not be eligible for certification until November 11, 2014. As proof of its plan to verify this corrective action, NICS submitted a copy of its request for an internal audit, which asked the auditor to emphasize a review of suspended or revoked operations. NICS' Inspection Operations Director and Certification Director will also monitor the handling of suspended operations.

NOP May 2014 Determination: NICS did not state whether these three operations sold, labeled, or represented products as organic while suspended. Certifiers must verify this information when reviewing suspended operations. There was no evidence of staff training or communication on the revised procedure. Certifiers must provide evidence to the NOP on how they will implement corrective actions throughout their organizations, and how they will monitor them to ensure that they are effective.

AIA13350BJR.NC5: Partially accepted; three out of four points outstanding. 7 CFR §205.403 (c)(1-2) states: *“The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part; [and] that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.”*

1. NICS granted two certification decisions to James Penoyer, which had outstanding noncompliances without sufficient evidence of corrective actions. NICS' inspection report did not verify full compliance by the operation, as noted below.
1. NICS did not verify the Penoyer operation's compliance with §205.105, *Allowed and prohibited substances, methods, and ingredients in organic production and handling.*
 - a. Mr. Penoyer had an outstanding noncompliance from January 5, 2012 for the use of the prohibited products Sulmet and Resorb. The NICS inspector stated that the operation did not intend to use the products on certified calves, but that it was possible that one or two calves may have been treated with these products. NICS noted that very detailed health records for 2008-2012 were present, raising questions as to why the farmer could not verify whether Sulmet or Resorb were used.

NICS corrective action: In its April 25, 2014, Notice of Continuing Suspension, NICS notified Mr. Penoyer that Sulmet is prohibited for use in organic livestock production. NICS also noted that Mr. Penoyer would need to submit additional documentation on livestock production in any future certification application.

NOP May 2014 Determination: NICS did not address the discrepancy in the inspection report.

- b. In response to the question, “§205.601: If micro-nutrients are applied, are micro-nutrient deficiencies documented through testing?” the inspector marked “not applicable.” However, the operation had a previous noncompliance for failing to provide evidence of such deficiencies through testing, and the operation provided evidence of use of synthetic micro-nutrients.

NICS corrective action: NICS’ April 25, 2014, Notice stated that Mr. Penoyer would need to submit soil or tissue tests with any future certification application. NICS also submitted a soil test for Mr. Penoyer’s operation dated May 2013.

NOP May 2014 Determination: It is not clear whether NICS had this information at the time the inspection report was marked “not applicable.” NICS did not address the discrepancy in the inspection report.

- c. The inspector noted that the farmer used dried poultry litter from an off-farm source. The report did not show sufficient evidence that the litter had not been treated with prohibited substances. Instead, the inspector commented that the farmer stated that his supplier told him that the litter was “the ‘OMRI’ one.”
- d. **NICS corrective action:** NICS’ April 25, 2014, Notice stated that Mr. Penoyer would need to submit information on all livestock and crop inputs with any future application for certification.

NOP May 2014 Determination: this response adequately addresses the noncompliance.

2. The inspector marked record-keeping requirements for crop storage and records for non-organic production as “not applicable.” However, the report stated that storage facilities were described in the OSP, and the farmer had been cited a previous noncompliance for failing to disclose his non-organic production activities.
3. **NICS corrective action:** NICS’ April 25, 2014, Notice stated that Mr. Penoyer would need to submit a complete organic system plan with any future certification application.

NOP May 2014 Determination: NICS did not mention storage facilities in the letter to Mr. Penoyer. The corrective actions did not address the discrepancy in the inspection report.

4. In response to the question, “If animals are temporarily confined, are the reasons for temporary confinement accurately and completely described?” the inspector marked “yes. However, the inspector marked the question on records for temporary confinement as “not applicable.” The inspector did not state how he was able to verify compliance with §205.239(b-c), *Livestock Living Conditions*, without viewing a record of the dates and reasons for temporary confinement.

5. **NICS corrective action:** NICS' April 25, 2014, Notice stated that Mr. Penoyer would need to submit documentation of outdoor pads, pasture, and temporary confinement with any future certification application.

NOP May 2014 Determination: Although the corrective actions appeared effective to address compliance concerns with Mr. Penoyer's operation, they did not address the discrepancies in the inspection report.

2. In submitting Joseph and Noah Miller's request for reinstatement, NICS determined that 84 acres were eligible for certification and issued a notice granting certification of this acreage on November 13, 2013. However, the NICS inspection report on the Miller operation and a statement submitted by Joseph Miller indicated 16 of the 84 acres were not eligible for certification due to the use of treated seed on the land.
3. **NICS corrective action:** NICS submitted a certificate showing that only 69 acres of the Miller's land were certified. NICS also submitted a memo to certification file reviewers instructing them to verify the organic status of all land under the management of an applicant.

NOP May 2014 Determination: NICS calculated the number of acres incorrectly, since 84 minus 16 equals 68. The certificate still shows an inaccurate number of acres.

4. In submitting Kyle Bucholz's request for reinstatement, NICS noted that Mr. Bucholz was not aware that his operation was suspended by MOSA in 2011. Mr. Bucholz continued production in 2012 and 2013. NICS's inspection report on the Bucholz operation did not verify if harvested product was sold as organic while the operation was suspended. The inspection reported noted that the organic and nonorganic sales records from 2012 – 2013 were not applicable. The inspection report also noted that the operation had not maintained records for five years, including when the operation had been certified by MOSA.
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6. **NICS corrective action:** On April 25, 2014, NICS issued a Notice of Continued Suspension to Mr. Bucholz. The Notice stated that all certification records must be kept for at least 5 years, and that all organic and nonorganic sales records from 2011 forward would need to be available at his next on-site inspection.

NOP May 2014 Determination: NICS has not investigated whether Mr. Bucholz sold, labeled, or represented products as organic since his 2011 suspension and appears to consider the reinstatement request closed. Neither the reinstatement procedure nor the inspector training addressed the need to investigate whether suspended operations continued to sell products labeled as organic.

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The Executive Director wrote all of the inspection reports which the NOP cited for noncompliances. He also supervises the two staff who will be evaluating the inspection reports and certification decisions. As stated in NC1, employees are unable to provide unbiased evaluations of their supervisor's performance. Therefore, the proposed evaluation system cannot guarantee effective monitoring and feedback.

Audit Resolution Chronology Log

Audit Identifier: AIA13350BJR

Audit Type: Noncompliance resulting from reinstatement requests & annual report review

Accredited Certifying Agent Name: Nature's International Certification Services (NICS)

Accreditation Manager: Betsy Rakola and Penny Zuck

Date	Activity
1/9/14	Betsy, Bob and Cheri met to discuss concerns regarding 4 reinstatement requests from NICS. Evidence showed failure to accept other certifiers' decisions, granting of certification prior to reinstatement, and failure to verify compliance. Betsy drafted a Notice of Noncompliance to NICS and sent it to Bob for comment.
1/10/14- 3/7/14	Bob revised the letter to be a combined notice of noncompliance/proposed suspension
1/30/14	C&E notified NICS that it must accept OCIA's decision to place 16 acres of Terry Cunningham's land in transitional status until 2014
2/6/14	NOP and OGC discussed combined notice for NICS. Betsy issued reinstatement denial to James Penoyer and NICS.
2/7/14	Bob informed NICS that Noah Miller had never been certified (associated parties of a separate, suspended operation), so it did not require reinstatement. However, the request showed evidence that land not eligible for certification would be included on the certificate.
2/6/14	Bob issued reinstatement denial to Kyle Bucholz and NICS.
3/24/14- 3/28-14	Bob on leave. Betsy assigned to complete the adverse action. Management requested a change to a NoNC only.
4/1/14	Betsy sent the NoNC to NICS via RPost email
4/29/14	NICS submitted corrective actions to the NOP
5/9/14- 5/16/14	Betsy reviewed the corrective actions. Several responses were incomplete and/or raised additional issues of concern. Betsy documented these findings in the corrective action report and scheduled a meeting with Cheri to discuss a course of action.
5/27/14	Cheri, Miles and Betsy met to discuss the evidence. All agreed that the corrective actions were insufficient, and that the response showed evidence of additional violations as well. Agreed to prepare a Notice of Proposed Suspension for the Office of the General Counsel, and to brief Mike Caceres prior to his 6/16/14 mid-term audit of NICS.
5/30/14	Betsy submitted the NoPS package to Cheri.
6/3/14	Miles edited the report. Betsy finalized the report and sent it to Miles for routing to OGC.

6/5/14	NOP met with OGC to receive guidance. OGC suggested adding citations to OFPA and explaining the reference to willful violations. Chip Kidd emailed comments to Betsy, who finalized the documents and routed them to Cheri for approval.
6/12/14	Renee Mann emailed the Notice of Proposed Suspension of Accreditation to NICS via RPost registered email. RPost confirmed Dave Engel received and opened the message the same day.
6/18/15	NICS is in the appeals process: P:\Appeals\1 CLOSED Appeals\FY 2014\14-033 NICS
7/13/15	Settlement agreement executed
9/11/15	Corrective Actions received from NICS in response to outstanding noncompliances outlined in the Administrator's Decision and required as part of the Settlement Agreement.
10/03/15	<p>PZ reviewed Corrective Actions and began the CA Report. There are two issues in need of additional information and/or revision:</p> <ol style="list-style-type: none"> 1. NICS Policy Memo (FMP #16) states that if NICS finds evidence of a noncompliance during the reinstatement inspection, a combined notice of noncompliance/proposed suspension will be issued. This is not compliant because the operation is already suspended and therefore cannot be issued a notice of proposed suspension. NOP 2605 3.4(d) states <i>"If the certifier finds evidence of a noncompliance during the application review or inspection process, then it should issue a Notice of Noncompliance to the operation. In order to be reinstated, the operation applying for reinstatement must demonstrate resolution of all noncompliances, including those that led to the suspension and any additional noncompliances identified during the reinstatement review and inspection."</i> 2. NICS response to the fourth noncompliance included an excerpt from a PowerPoint presentation that will be presented to NICS inspectors as training on conducting reinstatement inspections. Can you please provide a timeline of when NICS is planning to conduct this training for inspectors? <p>Sent CA Report and draft of email (to NICS) to RM for review prior to sending for their opportunity to correct these issues.</p>
10/15/15	Rec'd edits and comments from RM. Sent email to NICS giving them the opportunity to correct the outstanding noncompliances. Must respond by October 30, 2015.
10/23/15	Rec'd email with response and additional documentation from NICS.
11/2/15	PZ reviewed email response and documentation. NICS revised their policy in regards to issuing a noncompliance if an operation sells organic product while suspended and also submitted a timeline for completion of inspector training in March, 2016. Accepted the CAs and completed the CA report and emailed it to RM for review.
11/6/15	PZ emailed NICS to ask if the Livestock inspection report form was also updated with the new questions that pertain to reinstatement of an operation.
11/9/15	PZ Rec'd email response from NICS that they originally were not going to add the same questions to the Livestock form because typically the operations that request

	livestock certification also request crops certification, however, they went ahead and revised the Livestock form with the additional questions also. The revised form was submitted.
11/12/15	PZ Revised CA report and emailed to RM for review.
11/13/15	PZ Printed documents for CC review and approval.
11/20/15	<p>PZ revised cover letter to remove any indication that the noncompliances have been completely resolved and rather indicate that term E of the settlement agreement has been met.</p> <p>Emailed NICS for qualifications of Mary I Wilson – who conducted the evaluation of ED. Must respond with this information by 11/27/15.</p> <p>Rec'd resume for Mary I Wilson from NICS.</p>
11/24/15	Prepared file for Miles approval.

NOTICE OF NONCOMPLIANCE

APR 1 2014

Dave Engel
Nature's International Certification Services
22 East State Highway 56
Viroqua, WI 54665

Dear Mr. Engel:

On January 10, 2014, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) completed the review of four reinstatement requests submitted by Nature's International Certification Services (NICS) on behalf of four suspended organic producers. Our review revealed several repeated noncompliances in NICS inspection and certification procedures. NICS granted certification to producers who were under suspension, NICS did not accept the decisions of other accredited certifiers or the NOP, and NICS did not adequately verify the producers compliance with the regulations. In addition, findings from NOP's review of NICS's 2013 annual report determined that NICS did not conduct an annual program review of its certification activities, and the 2013 performance evaluation of NICS's Executive Director did not include a review of certification activities. These actions are noncompliances of the USDA organic regulations, as listed below.

AIA13350BJR.NC1: 7 CFR §205.501 (a)(6) states: *“Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”*

- NICS's 2013 annual report did not include staff performance evaluations of all persons involved in certification activities. The 2013 performance evaluation of NICS's Executive Director was limited to business management practices and did not evaluate certification activities performed by the Director. The evaluation did not describe measures implemented to correct any deficiencies in certification services.

AIA13350BJR.NC2: 7 CFR §205.501 (a)(7) states: *“Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation.”*

- NICS's 2013 annual report did not include an annual review of its certification activities or describe implemented measures to correct any noncompliances with the Act and its

regulations. The outside auditor's report stated that the report was limited in scope and did not include an assessment of NICS's compliance the USDA Organic Regulations.

AIA13350BJR.NC3: 7 CFR §205.505 (a)(1) states: *"A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including: Accept the certification decisions made by another certifying agent accredited or accepted by USDA..."*

- The Midwest Organic Services Association (MOSA) suspended James Penoyer's dairy farm in Gilman, Wisconsin on July 16, 2013. Penoyer had appealed MOSA's proposed suspension in 2012, and the NOP upheld the suspension by denying the appeal in June 2013. NICS granted certification to the farmer on May 23, 2013 and renewed his certification on October 15, 2013. Both NICS' letters stated that the certification process was complete and that a certificate was enclosed. Neither stated that the farmer's suspension from MOSA remained in effect until the NOP granted reinstatement, thereby overturning the decisions of MOSA and the NOP. In addition, the inspector stated that MOSA and the NOP had made erroneous and conflicting statements, indicating that he did not accept either decision.
- Organic Crop Improvement Association (OCIA) issued a Notice of Noncompliance to the Cunningham operation in Twin Lakes, Minnesota on November 11, 2011, placing 16 acres of the producer's operation in transition due to contamination from flooding on July 15, 2011. NICS is required to accept this certification decision and verify that the 16 acres remain in transition until July 15, 2014. The operation was subsequently suspended by OCIA on July 3, 2012 for other noncompliances. NICS included these 16 acres in the operation's request for reinstatement and argued in an email communication to NOP staff that the 16 acres should not have been removed from certification.

AIA13350BJR.NC4: 7 CFR §205.662 (f)(1) states: *"A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part."*

- NICS issued a decision granting reinstatement of certification to James Penoyer on October 15, 2013. MOSA suspended Mr. Penoyer on July 8, 2013, and NICS included MOSA's suspension notice in its request to the NOP. NICS did not submit a reinstatement request for the farmer to the NOP until October 18, 2013. Therefore, NICS granted certification to an operation which was not eligible for certification.
- NICS issued a decision granting reinstatement of certification to Kyle Buchholz on December 31, 2013 prior to submitting Kyle Buchholz's request for reinstatement on January 2, 2014. Mr. Buchholz's operation was suspended by MOSA on July 29, 2011

and NICS included MOSA's suspension notice in its request to the NOP. Therefore, NICS granted certification to an operation which was not eligible for certification.

- NICS issued a decision granting reinstatement of certification to the Cunningham operation in Twin Lakes, Minnesota on August 22, 2013, and submitted his request for reinstatement on the same day. The operation was suspended by MOSA on May 24, 2012, and NICS included MOSA's suspension notice in its request to the NOP. Therefore, NICS granted certification to an operation which was not eligible for certification.

AIA13350BJR.NC5: 7 CFR §205.403 (c)(1-2) states: *"The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part; [and] that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation."*

- NICS granted two certification decisions to James Penoyer, which had outstanding noncompliances without sufficient evidence of corrective actions. NICS' inspection report did not verify full compliance by the operation, as noted below.
 1. NICS did not verify the Penoyer operation's compliance with §205.105, *Allowed and prohibited substances, methods, and ingredients in organic production and handling*.
 - a. Mr. Penoyer had an outstanding noncompliance from January 5, 2012 for the use of the prohibited products Sulmet and Resorb. The NICS inspector stated that the operation did not intend to use the products on certified calves, but that it was possible that one or two calves may have been treated with these products. NICS noted that very detailed health records for 2008-2012 were present, raising questions as to why the farmer could not verify whether Sulmet or Resorb were used.
 - b. In response to the question, "§205.601: If micro-nutrients are applied, are micro-nutrient deficiencies documented through testing?" the inspector marked "not applicable." However, the operation had a previous noncompliance for failing to provide evidence of such deficiencies through testing, and the operation provided evidence of use of synthetic micro-nutrients.
 - c. The inspector noted that the farmer used dried poultry litter from an off-farm source. The report did not show sufficient evidence that the litter had not been treated with prohibited substances. Instead, the inspector commented that the farmer stated that his supplier told him that the litter was "the 'OMRI' one."
 2. The inspector marked record-keeping requirements for crop storage and records for non-organic production as "not applicable." However, the report stated that storage facilities were described in the OSP, and the farmer had been cited a previous noncompliance for failing to disclose his non-organic production activities.
 3. In response to the question, "If animals are temporarily confined, are the reasons for temporary confinement accurately and completely described?" the inspector marked "yes." However, the inspector marked the question on records for temporary confinement as

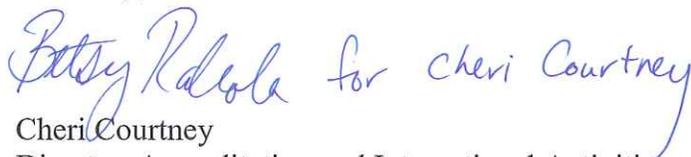
“not applicable.” The inspector did not state how he was able to verify compliance with §205.239(b-c), *Livestock Living Conditions*, without viewing a record of the dates and reasons for temporary confinement.

- In submitting Joseph and Noah Miller’s request for reinstatement, NICS determined that 84 acres were eligible for certification and issued a notice granting certification of this acreage on November 13, 2013. However, the NICS inspection report on the Miller operation and a statement submitted by Joseph Miller indicated 16 of the 84 acres were not eligible for certification due to the use of treated seed on the land.
- In submitting Kyle Buchholz’s request for reinstatement, NICS noted that Mr. Buchholz was not aware that his operation was suspended by MOSA in 2011. Mr. Buchholz continued production in 2012 and 2013. NICS’s inspection report on the Buchholz operation did not verify if harvested product was sold as organic while the operation was suspended. The inspection reported noted that the organic and nonorganic sales records from 2012 – 2013 were not applicable. The inspection report also noted that the operation had not maintained records for five years, including when the operation had been certified by MOSA.

Please submit proposed corrective actions to AIAInbox@ams.usda.gov within 30 days from the date of receipt of this letter, indicating how this noncompliance will be corrected. NICS must propose and implement measures that will correct this action. The proposed corrective actions must also indicate how the NICS management system will be modified to prevent a future noncompliance. Please refer to [NOP 2608](#), Responding to Noncompliances, for further instruction. Failure to promptly resolve this noncompliance may result in proposed adverse actions against NICS as an accredited certifying agent for the USDA.

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Pooler, at Bob.Pooler@ams.usda.gov or (202) 690-4540.

Sincerely,



Cheri Courtney
Director, Accreditation and International Activities
National Organic Program

cc: NOP Appeals

NOTICE OF PROPOSED SUSPENSION OF ACCREDITATION

Dave Engel
Executive Director
Nature's International Certification Services (NICS)
22 East State Highway 56
Viroqua, WI 54665
dave@naturesinternational.com

Dear Mr. Engel:

On April 1, 2014, the National Organic Program (NOP) issued Nature's International Certification Services (NICS) a Notice of Noncompliance regarding findings from reviews reinstatement requests and NICS' 2013 annual report, all of which were completed during the fall of 2013. Copies of the notice and audit report are enclosed for your reference. NICS submitted a corrective action proposal to the NOP on April 29, 2014. The corrective actions submitted were not sufficient to demonstrate compliance with the USDA organic regulations.

Due to the nature and extent of these noncompliances, the NOP proposes to suspend NICS's accreditation for a period of 1 year as an NOP certifying agent effective 30 days from receipt of this letter. If the NOP suspends NICS' accreditation, you will be directed to cease all certification activities and make all client files available to the NOP pursuant to § 205.665(f) of the USDA organic regulations.

Pursuant to § 205.681 of the USDA organic regulations, NICS has the right to file an appeal of this proposed action within 30 days of receipt of this letter. Appeals must be filed in writing to:

Administrator, USDA, AMS
c/o NOP Appeals Staff
1400 Independence Avenue, SW
Room 2095-S, STOP 0203
Washington, DC 20250

If you have questions regarding this proposed action, please contact your Accreditation Manager, Betsy Rakola, at Betsy.Rakola@ams.usda.gov or (202) 260-8209.

Sincerely,

Miles V. McEvoy
Deputy Administrator
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division

NOTICE OF PROPOSED SUSPENSION OF ACCREDITATION

Dave Engel
Executive Director
Nature's International Certification Services (NICS)
22 East State Highway 56
Viroqua, WI 54665
dave@naturesinternational.com

Dear Mr. Engel:

On April 1, 2014, the USDA Agricultural Marketing Service, National Organic Program (NOP) issued a Notice of Noncompliance to Nature's International Certification Services (NICS). The Notice outlined noncompliances identified during the NOP's review of four requests for reinstatement submitted by NICS between August 2013 and January 2014, as well as during the review of NICS' 2013 annual report, submitted June 20, 2013. Copies of the April 1, 2014 notice are enclosed for your reference. NICS submitted a corrective action proposal to the NOP on April 29, 2014. The corrective actions submitted did not successfully resolve the noncompliances. In addition, I have reason to believe that you have willfully violated the USDA organic regulations. Therefore, under 205.665(c) and (d) I am proposing to suspend your accreditation.

Reasons for the proposed suspension

1. Violation of 7 CFR §205.501(a)(3) which states, "*A private or governmental entity accredited as a certifying agent under this subpart must carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.*"
2. Violation of 7 CFR §205.501 (a)(6) which states: "*Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.*"
3. Violation of 7 CFR §205.505 (a)(1) which states: "*A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including: Accept the certification decisions made by another*

certifying agent accredited or accepted by USDA...”

4. Violation of 7 CFR §205.662 (f)(1) which states: *“A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.”*
5. Violation of 7 CFR §205.403 (c)(1-2) which states: *“The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part; [and] that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.”*

Detailed evidence of the violations are attached in the June 3, 2014 Corrective Action Report.

The proposed effective date

The NOP proposes to suspend NICS’s accreditation for a period of 1 year as an NOP certifying agent effective 30 days from receipt of this letter.

Impact of suspension

If the NOP suspends NICS’ accreditation, you will be directed to cease all certification activities and make all client files available to the NOP pursuant to § 205.665(f) of the USDA organic regulations.

Appeal rights

Pursuant to § 205.681 of the USDA organic regulations, NICS has the right to file an appeal of this proposed action within 30 days of receipt of this letter. Appeals must be filed in writing to:

Administrator, USDA, AMS
c/o NOP Appeals Staff
1400 Independence Avenue, SW
Room 2095-S, STOP 0203
Washington, DC 20250

Eligibility

If the NOP suspends NICS accreditation you may after the one year suspension has ended, submit a request to the Secretary for reinstatement of your accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Organic Foods Production Act and the USDA organic regulations.

If you have questions regarding this proposed action, please contact your Accreditation Manager, Betsy Rakola, at Betsy.Rakola@ams.usda.gov or (202) 260-8209.

Sincerely,

Miles V. McEvoy
Deputy Administrator
National Organic Program

Enclosure

- April 1, 2014 Notice of Noncompliance
- June 3, 2014 Corrective Action Report

cc: NOP Appeals
USDA Quality Assessment Division

12 JUN 2014

NOTICE OF PROPOSED SUSPENSION OF ACCREDITATION

Mr. Dave Engel
Executive Director
Nature's International Certification Services (NICS)
22 East State Highway 56
Viroqua, Wisconsin 54665
dave@nauresinternational.com

Dear Mr. Engel:

On April 1, 2014, the USDA Agricultural Marketing Service, National Organic Program (NOP) issued a Notice of Noncompliance to Nature's International Certification Services (NICS). The Notice outlined noncompliances identified during the NOP's review of four requests for reinstatement submitted by NICS between August 2013 and January 2014, as well as during the review of NICS' 2013 annual report, submitted June 20, 2013. A copy of the April 1, 2014, notice is enclosed for your reference. NICS submitted a corrective action proposal to the NOP on April 29, 2014. The corrective actions submitted did not successfully resolve the noncompliances. In addition, I have reason to believe that you have willfully violated the USDA organic regulations, based on the evidence summarized in the attached corrective action report, numbered AIA13350BJR. Therefore, under 7 CFR §205.665(c) and (d) of the USDA Organic Regulations, *Proposed suspension or revocation* and *Willful Violations*, I am proposing to suspend your accreditation as a certifying agent.

Reasons for the proposed suspension

1. Violation of 7 CFR §205.501(a)(3) which states, "*A private or governmental entity accredited as a certifying agent under this subpart must carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.*"
2. Violation of 7 CFR §205.501 (a)(6) which states: "*Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.*"
3. Violation of 7 CFR §205.505 (a)(1) which states: "*A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying*

agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including: Accept the certification decisions made by another certifying agent accredited or accepted by USDA...

- Further, 7 U.S.C. 6515(f) of the Organic Foods Production Act states: “Any certifying agent shall fully comply with the terms and conditions of the applicable organic certification program implemented under this title.”
4. Violation of 7 CFR §205.662 (f)(1) which states: “A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part.”
- Further, 7 U.S.C. 6515(d) of the Organic Foods Production Act states: “Any certifying agent shall enter into an agreement with the Secretary under which such agent shall (1) agree to carry out the provisions of this title; and (2) agree to such other terms and conditions as the Secretary determines appropriate.”
 - Instruction NOP 2605, *Reinstating Suspended Operations*, states the following in Section 3: “Certifiers may not approve or deny certification of a suspended operation without the NOP’s written approval.”
5. Violation of 7 CFR §205.403 (c)(1-2) which states: “The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part; [and] that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.”

Detailed evidence of the violations are attached in the June 3, 2014 Corrective Action Report.

The NOP proposes to suspend NICS’s accreditation for a period of 1 year as an NOP certifying agent effective 30 days from receipt of this letter.

If the NOP suspends NICS’ accreditation, you will be directed to cease all certification activities and make all client files available to the NOP pursuant to § 205.665(f) of the USDA organic regulations.

Pursuant to § 205.681 of the USDA organic regulations, NICS has the right to file an appeal of this proposed action within 30 days of receipt of this letter. Appeals must be filed in writing to:

Administrator, USDA, AMS
c/o NOP Appeals Staff
1400 Independence Avenue, SW
Room 2648-S, STOP 0203
Washington, DC 20250

If the NOP suspends NICS accreditation you may after the one-year suspension has ended, submit a request to the Secretary for reinstatement of your accreditation. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Organic Foods Production Act and the USDA organic regulations.

If you have questions regarding this proposed action, please contact your Accreditation Manager, Betsy Rakola, at Betsy.Rakola@ams.usda.gov or (202) 260-8209.

Sincerely,



Miles W. McEvoy
Deputy Administrator
National Organic Program

Enclosure

- April 1, 2014 Notice of Noncompliance
- June 3, 2014 Corrective Action Report
- June 4, 2013 Signed Terms of Accreditation

cc: NOP Appeals
USDA Quality Assessment Division

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Nature's International Certification Services (NICS). An onsite audit was conducted, and the audit report reviewed to determine NICS' capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Nature's International Certification Services (NICS)
Physical Address	224 State Highway 56 East, Viroqua, WI 54665
Mailing Address	224 State Highway 56 East, Viroqua, WI 54665
Contact & Title	David Engel, Executive Director
E-mail Address	dave@naturesinternational.com ; nics@naturesinternational.com
Phone Number	(608) 637-7080
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Miguel Caceres, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: September 17, 2014 Onsite audit: June 16-20, 2014
Audit Identifier	NP4167MMA
Action Required	Yes
Audit & Review Type	Mid-term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of NICS' certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	NICS' certification services in carrying out the audit criteria during the period: June 10, 2013 through June 20, 2014.

ORGANIZATIONAL STRUCTURE:

Nature's International Certification Services (NICS) is a for profit business which is wholly owned by the executive director and his spouse. NICS was initially accredited as a certifying agent on behalf of the USDA under the National Organic Program (NOP) on February 12, 2007 for crop and livestock; March 17, 2008 for wild crops; and May 26, 2010 for handling operations. At the time of the mid-term assessment, NICS had 462 certified operations, which included 301 crops, 1 wild crop, 149 livestock, and 11 handling operations certified to the NOP. All NICS clients are certified in the United States and all certification activities are conducted at their only office located in Viroqua, WI.

The NICS staff consists of an executive director, an administrative director, a quality systems

director, an inspection operations director, a certification director, three staff certification specialists, and an accounts manager. For 2013, NICS also used one contracted certification specialist and 8 contracted inspectors. The executive director, administrative director, quality systems director, inspection operations director, certification director, and one of the three staff certification specialists can also conduct inspections. The executive director and all of the staff with the exception of the accounts manager also conduct initial and final file reviews. NICS does not have a board of directors or any committees involved with the company. In addition to providing certification activities under the Final Rule, NICS is accredited to apply their NOP organic certification program and the USDA Grass (Forage) Fed Standard as a USDA ISO Guide 65 Program. Other than the issues identified in the NOP Determination portion of this report, based on the interviews conducted and a review of the personnel records, NICS demonstrated the necessary education, experience, and training to apply the scopes of certification for which they are accredited.

CERTIFICATION PROCESS:

Applicants are provided certification documents mainly through priority mail via the United States Postal Service. Information and forms are also available on the NICS website (www.naturesinternational.com) or can be provided via email. Applicants are provided a packet with a Fee Estimate Worksheet; an Organic Certification Affirmation (OCA); the appropriate OSP forms for certification; Field History Sheets (if applicable); the NICS Certification Manual; a copy of 7 CFR § 205 *Organic Regulations Final Rule*; a yearly calendar; and the *Upper Midwest Organic Resource Directory*. Once an application for certification is received, the initial review is always conducted by a NICS staff member which can also be the staff inspector assigned to inspect the operation. If the inspection is assigned to a contracted inspector, one of the NICS staff will conduct the initial review. After the inspection, the final review, including the certification decision, can be conducted by the executive director or any of the staff with the exception of the accounts manager. For the annual update process, before the annual update is due (timeframe not obtained during assessment), NICS sends the certified operations an OSP short form, a cover letter, forms applicable to the operation, the OCA if it was revised since the previous year, a printout of the material inputs list for updating, a copy of the rule, and the NICS certification manual if it has been revised. After the annual update information is received the process of initial review, inspection, and final review with a certification decision is the same as for applicants.

Materials are mainly reviewed by the quality systems director but can be reviewed by any of the final reviewers. NICS does not have a material evaluation program for liquid nitrogen fertilizers (LNF) with a nitrogen content greater than three percent. Instead, they only allow LNF with a nitrogen content greater than three percent if the product meets one of the following criteria: 1) it is approved by other accredited certifying agents that have an NOP approved material evaluation program or s) the product is listed as OMRI approved. Labels are reviewed by any of the staff reviewers, inspectors during inspections, and the final reviewers. At the time of the mid-term assessment, NICS did not have a checklist or written procedure for reviewing labels.

At the time of the mid-term assessment, NICS did not have any products requested for verification of the terms of the EU-US Organic Equivalency Arrangement and thus no import

certificates had been issued. The process for verification of the US-Canada Organic Equivalency Arrangement is not documented. However, a process is followed for verifying the terms by clients requesting it in the OSP or the OSP update short form, which are then verified by the inspector during inspections and included in the inspection report under the “*International Crop Markets*” section. NICS does not and has not provided attestation statements to any certified operations. Instead NICS places “US/Canada” as allowed marketing claims on the operation’s Profile of Organic Operations when it is requested by the client in the OSP and verified by the inspector. Since the previous assessment, NICS had not issued any TM-11 Export Certificates as none had been requested by clients. During the mid-term, the auditor of record was informed that NICS was not currently listed on the NOP 2403 as approved to issue export certificates but should be. As verification, NICS provided an email with a Notice of Export Authorization from the NOP dated March 22, 2012. The information was forwarded to NICS accreditation manager who promptly corrected the oversight on the NOP 2403 and the NOP website.

ADMINISTRATIVE RECORDS AND PROCESSES:

NICS uses the Nature’s International Certification Services Certification Manual, February 2014 to address the procedures for organic certification from application through certification. As described under “Certification Process” above, all forms from application to OPSs to recordkeeping documents are available directly from NICS or their website.

The most recent annual program review was conducted August 2013 and was reviewed by the NOP NICS accreditation manager as part of the 2014 Annual Report, which was submitted by NICS. The review of the annual program review and other issues identified by the NOP resulted in NICS being issued a notice of noncompliance dated April 1, 2014, followed by a corrective actions report dated June 3, 2014, and a notice of proposed suspension dated June 12, 2014. Because of this and NICS being in the process of conducting an internal assessment on how best to provide a response to the NOP, the annual program review was not assessed by the auditor of record. Training provided to staff and taken by contracted personnel included external training by IOIA and other entities, including the NOP.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED:

A review audit of a handling operation located in Viroqua, WI was conducted during the assessment. At the time of the assessment, the operation was not processing organic product. The certified operation does contract processing of organic apples from one specific orchard into applesauce packaged into 64, 32, and 16 ounce jars. The facility consisted of a small kitchen leased from a hotel, a small receiving dock, a cooler, and a small freezer. Applesauce is not marketed as once it is jarred/canned it is picked up by the orchard owner. Product is then transferred to the orchard where it will be labeled and the product marketed to the orchard owner’s clients. In addition to the organic applesauce, the facility also processes (as non-organic) pickled asparagus, tomatoes, wheat gluten, and grape juice. The operation would also like to process jams in the future. The auditor of record reviewed the OSP onsite with the owner of the apple orchard and the owner/manager of the handling operation. A review of the facility was conducted with the facility manager and records maintained by the orchard owner. During the review audit the operation was producing (canning) non-organic asparagus. The manager was

busy with processing operations, making it difficult to conduct the review in the limited space of the facility. Records of what was delivered (apples) and jars labeled were maintained by the orchard owner. The handler's production and processing records were not available during the audit as he stated he left them at his home office. The review audit verified the OSP was not an accurate and entire description of the actual practices on-site (See *Findings*).

A witness inspection of a crop and dairy operation in Osseo, WI was conducted. The operation consisted of 34 acres of pasture; 13 cows; two bred heifers; three heifer calves; and three steers. The milk is picked up by an organically certified operation in its own haulers. The witness inspection was an actual inspection and was an announced inspection. The witness inspection verified the inspector was knowledgeable of the operation; that it was conducted with a knowledgeable representative; that no prohibited substances were being used; that the OSP was an accurate description of the actual practices onsite; and that the operation was in compliance with the Act. The inspector was knowledgeable and conducted a closing meeting with the operations representative.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether NICS corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to NICS.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP221300A.NC1 – Outstanding – 7 CFR §205.403(c)(1) states, "The on-site inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part." **Comments (July 31, 2012):** *During the wild crop witness inspection, it was revealed that the operation had 28 types of plants that were listed as wild crop harvested. During the interview process between the inspector and the representative of the operation, it was discovered that for 7 of the 28 wild crop plants, as well as 2 others not listed, the operation bought either seeds or seedlings to rejuvenate the plant species in the wild crop area and the various plants were being harvested as wild crop. This would be considered an agricultural management practice and would not meet the definition of wild crop. This was not identified by the inspector as a potential finding during the exit meeting with the representative of the operation.* **Corrective Actions (April 23, 2013):** NICS reviewed the finding with the operation after the on-site inspection, in the inspection report, and in other correspondence. NICS also reviewed the requirements of guidance document NOP 5022, Wild Crop harvesting, of which the operation is aware and has not labeled products as wild crops. NICS issued a memorandum to all staff and inspectors reiterating its Certification manual mandate of concluding an inspection with an exit interview that includes all findings. **Outstanding (September 17, 2014):** This

noncompliance remains outstanding based on findings documented from the recent review audit of a handler conducted on June 18, 2014, which revealed that the OSP originally submitted by the applicant was incomplete. The incomplete status was documented in the initial review checklist and in the letter issued to the applicant, yet an inspection was scheduled, conducted and the subsequent inspection report indicates the OSP was updated during the inspection.

NP221300A.NC2 – Outstanding – 7 CFR §205.501 (a)(6) states, "Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services." **Comments (November 20, 2012):** *A review of the personnel files showed that performance evaluations were not conducted in 2011 or 2012 for contract inspectors employed by NICS to perform organic inspections.* **Corrective Actions (April 23, 2013):** NICS erred by not completing inspector evaluations in 2011 and 2012 because of staffing changes and the focus on other responsibilities. NICS assigned the inspector evaluation responsibility to an inspector operations director in order to guarantee completion of the evaluations on an annual basis. The 2012 evaluations of inspectors were conducted as reviews of completed work, but future evaluations will also include a personal evaluative assessment. **Outstanding (September 17, 2014):** This noncompliance remains outstanding based on a review of the personnel files at the onsite audit, which showed that the 2014 performance evaluation of the Executive Director was completed by junior employees. This approach to performance evaluation represents an inherent conflict of interest.

Noncompliances Identified during the Current Assessment

NP4167MMA.NC1 – 7 CFR §205.402(a)(1) states, "Upon acceptance of an application for certification, a certifying agent must: Review the application to ensure completeness pursuant to §205.401."

Comments: A review of one file showed the dairy OSP did not contain information concerning how the operation would identify and segregate animals treated with a prohibited material, or the subsequent exclusion of milk from the treated animal. The OSP also did not contain any information on monitoring activities required or their frequencies to ensure the milk from treated animals is excluded. This made the OSP deficient in meeting the requirements for including a description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products. A review of another file showed the handler OSP was incomplete prior to inspection. Based on a review of the original OSP submitted, the initial review checklist, and the initial review letter sent to the client it was clear the OSP was deficient in providing required information. A review of the inspection report indicated an updated OSP was included, indicating the OSP was updated during the inspection.

NP4167MMA.NC2 – 7 CFR §205.403(c) states, "The on-site inspection of an operation must verify: (1) The operation's compliance or capability to comply with the Act and the regulations of this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation."

Comments: The review audit conducted on a handling operation verified the OSP was not an accurate reflection of the actual process in place. Municipal water is used to wash apples and for equipment cleaning but filtered municipal water may be added to the product. NICS was not aware water was added to the product if needed. The OSP did not include the possibility of adding water to adjust product consistency after thawing and prior to canning. In addition, the OSP did not contain a complete description of the sediment and charcoal filter through which municipal water passes prior to adding it to the product. The OSP stated there were sediment and charcoal filters but no information was obtained by NICS to ascertain whether the filters contained any prohibited substances. In addition, there was no information in the OSP concerning the product being labeled at the orchard and not at the handling operation.

NP4176MMA.NC3 – 7 CFR §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector.”

Comments: Files reviewed and interviews conducted verified that not all operations received a receipt for the sample(s) collected for analysis. In two of five files reviewed, samples were collected but this was not indicated on the exit interview form, which serves as the record used by NICS to provide a receipt to the operation for the sample(s).

NP4167MMA.NC4 – 7 CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: In one of the six files reviewed, one handling operation was approved to use organic and non-organic dates. A review of the organic product profile (OPP) worksheet and emails verified the operation was using both organic and non-organic dates with the label indicating they were non-organic. In the same file, a review of all twelve OPP's verified the following:

- *In seven of the product OPP's, the final percentage of the ingredients included in the OPP sheets were over or under 100 percent.*
- *In nine of the OPP's, the total percentage of the organic ingredients did not match the percentage indicated under the “Indicate the total percentage of organically produced ingredients used to create this product” section of the OPP. As an example, one OPP ingredient list indicated a total of 103%. In this same OPP, the total percentage of organically produced ingredients indicated it had 99%.*
- *All OPP's had the same amounts in the “Organic % of ingredient” column and the “% in product formulation” columns.*

NP4167MMA.NC5 – 7 CFR §205.660(d) states, “Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.”

Comments: Not all notifications are sent to clients via a delivery service which provides dated return receipts. All seven of the notices of proposed suspension reviewed at the audit were sent via United States Postal Service (USPS) 2-day mail, which provides a dated return receipt. However, seven notices of noncompliance and the notices of noncompliance resolution were sent to the clients via USPS first class mail, which does not provide a dated return receipt.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Dave Engel
Nature's International Certification Services
224 State Hwy. 56 East
Viroqua, WI 54665

SEP 29 2014

Dear Mr. Engel,

On June 16-20, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Nature's International Certification Services (NICS) organic certification program as part of its USDA Mid-term Accreditation Assessment. On September 17, 2014, the NOP reviewed the results of the onsite audit to determine NICS' compliance to the USDA organic regulations. A copy of the assessment report, NP4167MMA, is enclosed for your reference.

As the report indicates, two noncompliances, AIA4140BJR.NC1 and AIA13350BJR.NC5, remain outstanding from your previous audit. Five new noncompliances, NP4167.MMA.NC1 through 5, were identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the NICS management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Lars Crail, at (202) 205-5536 or Lars.Crail@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NOTICE OF NONCOMPLIANCE AND PROPOSED SUSPENSION

Dave Engel
Nature's International Certification Services
22 East State Highway 56
Viroqua, WI 54665

Dear Mr. Engel:

On January 10, 2014, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) completed the review of four reinstatement requests submitted by Nature's International Certification Services (NICS) on behalf of four suspended organic producers. Our review revealed several repeated noncompliances in NICS' inspection and certification procedures. NICS granted certification to producers who were under suspension, NICS did not accept the decisions of other accredited certifiers or the NOP, and NICS did not adequately verify the producers' compliance with the regulations.

Due to the willful nature and extent of these noncompliances, the NOP proposes to suspend NICS's accreditation for a period of 1 year as an NOP certifying agent effective 30 days from receipt of this letter. If the NOP suspends NICS's accreditation, you will be directed to cease all certification activities and make all client files available to the NOP pursuant to § 205.665(f) of the USDA organic regulations.

The noncompliances are listed below.

AIA13350BJR.NC1. 7 CFR §205.403 (c)(1-2) states: *“The on-site inspection of an operation must verify the operation's compliance or capability to comply with the Act and the regulations in this part; [and] that the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.”*

- NICS granted two certification decisions to James Penoyer which had outstanding noncompliances without sufficient evidence of corrective actions. NICS' inspection report did not demonstrate full compliance by the operation, as noted below.
1. NICS did not verify the Penoyer operation's compliance with §205.105, *Allowed and prohibited substances, methods, and ingredients in organic production and handling.*
 - a. The operation had an outstanding noncompliance from January 5, 2012 for the use of the prohibited products Sulmet and Resorb. The inspector stated that the operation did not intend to use the products on certified calves, but that it was possible that one or two calves may have been treated with these products. NICS noted that very detailed health records for 2008-2012 were present, raising

questions as to why the farmer could not verify whether Sulmet or Resorb were used.

- b. In response to the question, “§205.601: If micro-nutrients are applied, are micro-nutrient deficiencies documented through testing?” the inspector marked “not applicable.” However, the operation had a previous noncompliance for failing to provide evidence of such deficiencies through testing, and the operation provided evidence of use of synthetic micro-nutrients.
 - c. The inspector noted that the farmer used dried poultry litter from an off-farm source. The report did not show sufficient evidence that the litter had not been treated with prohibited substances. Instead, the inspector commented that the farmer stated that his supplier told him that the litter was “the ‘OMRI’ one.”
2. The inspector marked record-keeping requirements for crop storage and records for non-organic production as “not applicable.” However, the report stated that storage facilities were described in the OSP, and the farmer had been cited a previous noncompliance for failing to disclose his non-organic production activities.
 3. In response to the question, “If animals are temporarily confined, are the reasons for temporary confinement accurately and completely described?” the inspector marked “yes. However, the inspector marked the question on records for temporary confinement as “not applicable.” The inspector did not state how he was able to verify compliance with §205.239(b-c), *Livestock Living Conditions*, without viewing a record of the dates and reasons for temporary confinement.
- In submitting Joseph and Noah Miller’s request for reinstatement, NICS determined that 84 acres were eligible for certification and issued a notice granting certification of this acreage on November 13, 2013. However, the NICS inspection report on the Miller operation and a statement submitted by Joseph Miller indicated 16 of the 84 acres were not eligible for certification due to the use of treated seed on the land.
 - In submitting Kyle Buchholz’s request for reinstatement, NICS noted that Mr. Buchholz was not aware that his operation was suspended by MOSA in 2011. Mr. Buchholz continued production in 2012 and 2013. NICS’s inspection report on the Buchholz operation did not verify if harvested product was sold as organic while the operation was suspended. The inspection report noted that the organic and nonorganic sales records from 2012 – 2013 were not applicable. The inspection report also noted that the operation had not maintained records for five years, including when the operation had been certified by MOSA.

AIA13350BJR.NC2. 7 CFR §205.505 (a)(1) states: “A private or governmental entity seeking accreditation under this subpart must sign and return a statement of agreement prepared by the Administrator which affirms that, if granted accreditation as a certifying agent under this subpart, the applicant will carry out the provisions of the Act and the regulations in this part, including: Accept the certification decisions made by another certifying agent accredited or accepted by USDA...”

- The Midwest Organic Services Association (MOSA) suspended James Penoyer's dairy farm in Gilman, Wisconsin on July 16, 2013. Penoyer had appealed MOSA's proposed suspension in 2012, and the NOP upheld the suspension by denying the appeal in June 2013. NICS granted certification to the farmer on May 23, 2013 and renewed his certification on October 15, 2013. Both NICS' letters stated that the certification process was complete and that a certificate was enclosed. Neither stated that the farmer's suspension from MOSA remained in effect until the NOP granted reinstatement, thereby overturning the decisions of MOSA and the NOP. In addition, the inspector stated that MOSA and the NOP had made erroneous and conflicting statements, indicating that he did not accept either decision.
- Organic Crop Improvement Association (OCIA) issued a Notice of Noncompliance to the Cunningham operation in Twin Lakes, Minnesota on November 11, 2011, placing 16 acres of the producer's operation in transition due to contamination from flooding on July 15, 2011. NICS is required to accept this certification decision and verify that the 16 acres remain in transition until July 15, 2014. The operation was subsequently suspended by OCIA on July 3, 2012 for other noncompliances. NICS included these 16 acres in the operation's request for reinstatement and argued in an email communication to NOP staff that the 16 acres should not have been removed from certification.

AIA13350BJR.NC3. 7 CFR §205.662 (f)(1) states: *"A certified operation whose certification has been suspended under this section may at any time, unless otherwise stated in the notification of suspension, submit a request to the Secretary for reinstatement of its certification. The request must be accompanied by evidence demonstrating correction of each noncompliance and corrective actions taken to comply with and remain in compliance with the Act and the regulations in this part."*

- NICS issued a decision granting reinstatement to James Penoyer certification on October 15, 2013. MOSA suspended Mr. Penoyer on July 8, 2013, and NICS included MOSA's suspension notice in its request to the NOP. NICS did not submit a reinstatement request for the farmer to the NOP until October 18, 2013. Therefore, NICS knowingly granted certification to renewal to an operation which was not eligible for certification.
- NICS issued a decision granting reinstatement of certification to Kyle Buchholz on December 31, 2013 prior to submitting Kyle Buchholz's request for reinstatement on January 2, 2014. Mr. Buchholz's operation was suspended by MOSA on July 29, 2011 and NICS included MOSA's suspension notice in its request to the NOP. Therefore, NICS knowingly granted certification to an operation which was not eligible for certification.
- NICS issued a decision granting reinstatement of certification to the Cunningham operation in Twin Lakes, Minnesota on August 22, 2013, and submitted his request for reinstatement on the same day. The operation was suspended by MOSA on May 24, 2012, and NICS included MOSA's suspension notice in its request to the NOP. Therefore, NICS knowingly granted certification to an operation which was not eligible for certification.

Pursuant to § 205.681 of the USDA organic regulations, NICS has the right to file an appeal of this proposed action within 30 days of receipt of this letter. Appeals must be filed in writing to:

Administrator, USDA, AMS
c/o NOP Appeals Staff
1400 Independence Avenue, SW
Room 2095-S, STOP 0203
Washington, DC 20250

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Pooler, at Bob.Pooler@ams.usda.gov or (202) 690-4540.

Sincerely,

Miles McEvoy
Deputy Administrator
National Organic Program

cc: NOP Appeals
USDA Grading and Verification Division

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a two-day onsite compliance audit of the USDA accredited certifying agent New Jersey Department of Agriculture (NJDA). The NOP reviewed the auditor's report to assess NJDA's conformance to the terms of a 2013 Settlement Agreement and compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name:	New Jersey Department of Agriculture
Physical Address:	369 South Warren Street, Trenton, NJ 08625
Mailing Address:	P.O. Box 330, Trenton, NJ 08625
Contact & Title:	Erich Bremer, Supervisor, Organic Certification Program
E-mail Address:	Erich.bremer@ag.state.nj.us
Phone Number:	609-984-2225
Auditor(s) and Reviewer (s):	Lars Crail, NOP Auditor.
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	An onsite audit was conducted May 1 – 2, 2014.
Audit Identifier:	AIA14121LMC
Action Required:	Yes
Audit and Review Type:	Compliance Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to the accuracy and implementation of the NJDA's corrective actions accepted as stated in the 2013 Settlement Agreement.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	NJDA's certification activities.

NJDA is a state government agency that was accredited as an USDA organic certifying agent on April 12, 2007. NJDA is approved to certify operations to the following scopes: crops, wild crops, livestock, and handling. The NJDA Organic Certification Program currently certifies 86 operations, consisting of 63 crops, 2 wild crops, 5 livestock, and 23 handlers (22 processors and 1 distributor). All certified operations are located in the states of New Jersey and Pennsylvania.

The NJDA organic certification staff consists of the Secretary of Agriculture, a supervisor, a program manager, an administrative assistant, two NJDA consultants, and six contract (independent) inspectors. As part of the onsite audit of NJDA, one witness audit was conducted of NJDA's unannounced inspection of an on-going certified handler operation.

On September 25, 2013, the NOP and NJDA entered a settlement agreement to resolve a proposed adverse action issued to NJDA. The proposed adverse action resulted from outstanding noncompliances issued during NJDA's 2012 accreditation renewal assessment. The settlement agreement allows NOP to conduct an additional onsite audit to verify NJDA's compliance to USDA organic regulations.

NOP DETERMINATION

NOP reviewed the onsite compliance audit report and determined the status of NJDA's correction actions to adequately address outstanding noncompliances. Any noncompliance labeled as "Cleared," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "Outstanding" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

During the onsite audit, new findings were identified and as a result, NOP is issuing noncompliances.

Noncompliances from Prior Assessments

NP8217OOA.NC3 – Outstanding. NOP §205.501(a)(6) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services." *Annual performance evaluations have not been conducted within the last year for the inspectors.* **Corrective Actions (2009):** NJDA has conducted the annual performance evaluations for 2007 for the inspectors. These were submitted for review and it was verified that all were satisfactorily performing their duties. **Verification of Corrective Action (May 2012):** Records reviewed indicated that seven of eleven personnel had no current performance evaluations on file. **Corrective Action (January 2013):** NJDA has added an additional part-time staff person to assist with the workload. The Supervisor has completed evaluations for all inspectors used during 2011; NJDA provided copies of the evaluations to the NOP. NJDA plans to complete inspector evaluations in January/February going forward. In order to ensure the completion of evaluations, NJDA updated its General Procedures to state that contractors will be evaluated at least once annually. Evaluations shall include notes made during inspection report compliance reviews, evaluation survey cards given to clients during inspection, and any communication received from clients. The Program Manager has established reminders in his calendar system to ensure that the task is completed by the end of February annually. **Verification of Corrective Action (May 2014):** The auditor reviewed contract inspector performance evaluations that were completed in 2013.

Those evaluations are based on inspected operation feedback and NJDA evaluator comments (e.g. timeliness of reporting, report completeness, and report writing ability, etc...). However, no field evaluations of inspectors were conducted as recommended in NOP 2027, *Personnel Performance Evaluations*. When the auditor requested to review the state employed NJDA certification staff performance evaluations, his request was denied due to NJDA's restrictive access policy. The NJDA Human Resource Manager did provide the auditor a letter stating that three of the four certification staff had received satisfactory evaluation ratings. The missing staff evaluation result was that of the New Jersey Secretary of Agriculture, the final certification decision maker. Since the auditor was unable to verify that the performance evaluations of state employed NJDA certification staff was based on USDA organic certification activities and since inspector field reviews were not conducted in 2013, this corrective measure cannot be cleared.

NP821700A.NC4 – Cleared. NOP §205.501(a)(7) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any non-compliances with the Act and the regulations in this part that are identified in the evaluation.” *There is no procedure for conducting a program review. An annual program review has not been conducted.* **Corrective Action (2009):** NJDA General Procedures for Organic Certification has been revised to include an annual program review procedure. The program review may be performed by NJDA staff or a contracted auditor. Currently, NJDA is in the process of acquiring the services of a third party to complete the first internal program review. NJDA has been provided with a cost estimate and plans from the third party and plans to have the audit in August of 2009. **Verification of Corrective Action (May 2012):** *An annual program review was conducted by an outside party during 2009; however, no annual program review has been conducted since.* **Corrective Action (January 2013):** NJDA updated its procedures to state that an annual internal audit shall be conducted in accordance with USDA organic regulations. In August 2012, NJDA solicited quotes from three qualified parties for internal auditing services. NJDA subsequently identified the contractor to be used for the upcoming internal audit; however, the date of the audit has yet to be determined. NJDA staff will shadow the contractor during the process in order to learn how to perform annual program reviews, with the intent of using internal staff to complete this task in future years. At present, NJDA has not conducted internal program reviews for 2010, 2011 or 2012. **Corrective Action (April 2013):** NJDA started the process of an internal program review using an outside auditor who conducted a desk review of documents. An on-site internal program review audit was conducted in May 2013. NJDA is training a staff member to conduct future internal program reviews. **Verification of Corrective Action (May 2014):** The auditor reviewed the detailed 2013 internal review report conducted by a contractor and found it comprehensive and well done. The auditor also interviewed the NJDA employee that will conduct the 2014 internal review. The NJDA employee is not involved in organic certification activities.

NP821700A.NC5 – Cleared. NOP §205.501(a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations

concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.” *There are no current conflict of interest disclosure reports signed by inspectors involved in the certification process except for the newest inspector.* **Corrective Action (2009):** Current conflict of interest disclosure reports were submitted for review. The NJDA Conflict of Interest procedure has been revised to have all conflict of interest disclosure reports completed each year by January 1. **Verification of Corrective Action (May 2012) :** Records reviewed indicated that all certification personnel had a completed annual conflict of interest disclosure report, except for the Secretary of Agriculture who makes the final certification decision. **Corrective Action (April 2013):** NJDA now has current, signed confidentiality and conflict of interest forms on file for the Secretary. **Verification of Corrective Action (May 2014):** All NJDA certification staff confidentiality and conflict of interest forms were reviewed by the auditor and are current as of January 2014.

NP2142ACA.NC1 – Cleared. NOP §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.” *In two files reviewed, NJDA issued a certification decision letter with a notice of concern instead of noncompliances. One letter was issued to an operation that failed to conduct an organic seed search, and another was issued to an operation that did not keep records of manure spreading or harvest dates. The letters stated that the information would be reviewed at the next annual inspection, but did not give a date by which the issues must be corrected. Three other files reviewed and two witness audits observed showed evidence of purchases of non-organic seed and/or planting stock. There was no documentation of commercial unavailability of organic seeds or planting stock. None of the operations received a noncompliance from NJDA for failure to comply with §205.204.*

Corrective Action (October 2012): NJDA previously issued “qualifications” letters to organic producers who did not conduct organic seed searches. Going forward, NJDA will issue Notices of Noncompliance to any producer who utilized non-organic seed and failed to show documentation of a seed search. NJDA provided an example of a Notice of Noncompliance issued to a producer who had recurring recordkeeping issues, which were previously issued as qualifications. NJDA plans to issue Notices of Noncompliance for clear violations of the USDA organic regulations rather than discussing qualifications in “update letters.” In September 2012, NJDA began using the NOP penalty matrix as a guide to properly classify noncompliances versus minor issues/conditions for certification. **Verification of Corrective Action (May 2014):** The auditor conducted a review of several client files where noncompliances were issued and found that NJDA was issuing the noncompliances according to USDA organic regulations and policy.

NP2142ACA.NC2 – Cleared. NOP §205.504(b)(5) states, “A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request: Certification certificates issued during the current and 3 preceding calendar years;... The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years...” *Interviews with staff revealed that NJDA will not provide copies of certificates to members of*

*the public via email or postal mail. Members of the public may only view copies of certificates and results of laboratory analyses for residues of pesticides and other prohibited substances by visiting the NJDA office in Trenton and reviewing hard copies that are on file with the organic certification program. **Corrective Action (October 2012):** NJDA has changed its policy to state that copies of organic certificates will be made available to members of the public upon written request. The modified procedure has been incorporated into the “General Procedures for NJDA Organic Certification.” **Verification of Corrective Action (May 2014):** NJDA indicated that one request for information was received since NJDA’s policy was implemented. The auditor reviewed the policy regarding the release of information to the public and determined that it aligns with the instructions in NOP 2607, *Disclosure of Information Concerning Operations Certified under the National Organic Program.**

NP2142ACA.NC3 – Cleared. NOP §205.662(c)(1)(2) and (4) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension...of certification of the entire operation or a portion of the operation, as applicable to the noncompliance... The notification of proposed suspension...of certification shall state: (1) The reasons for the proposed suspension... (2) The proposed effective date of such suspension...; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.” *Two Notices of Proposed Suspension reviewed did not clearly state the right to request mediation or to file an appeal. The explanation of mediation and appeal rights in both letters implied that an appeal could only occur after a request for mediation had been rejected by the certifying agent. One letter did not give the reasons for the proposed action. One letter did not give a timeframe for the length of the proposed suspension. **Corrective Action (October 2012):** NJDA reviewed all Notices of Proposed Suspension issued in 2011-12. NJDA determined that, as of April 2011, staff had implemented a new template which corrected the errors mentioned in the noncompliance. NJDA provided examples of the corrected letters to the NOP. In addition, NJDA provided its revised template for Notices of Proposed Suspension, which includes clear and separate references to §205.663 and §205.681. **Verification of Corrective Action (May 2014):** A review of several Notices of Proposed Suspensions issued and the template used to create notices of proposed suspension indicate that the option to request mediation or file an appeal is clearly and correctly described.*

NP2142ACA.NC4 – Cleared. NOP §205.501(a)(11)(iv) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification.” *During two witness audits, the inspector advised farmers on methods and documentation required to demonstrate compliance with the USDA organic regulations for organic seed searches, use of municipal compost, use of manure, planting stock, and organic feed suppliers. The inspector also instructed the farmers to submit written corrective actions to the NJDA and set a date by which the corrective actions were required. **Corrective Action (October 2012):** NJDA has added information to its inspector job descriptions, its cover letters for annual conflict of interest forms, and its nondisclosure report forms. This information highlights the importance of inspector’s neutrality and reminds them that they 1) are not final certification decision-makers, 2) may not offer*

advice on how operations may overcome barriers to certification, and 3) must identify potential noncompliances without discussing possible corrections. NJDA has also modified its Special Instruction letters, which are sent to inspectors pre-inspection, to note that information should not be shared with the operation being inspected, if that information could result in advice on how to overcome barriers to certification. NJDA submitted a copy of its letter to the inspector mentioned in the NC and its revised job descriptions as evidence. **Verification of Corrective Action (May 2014):** The auditor's review of several certified operation files, interviews with NJDA personnel, and an observation of an unannounced inspection did not reveal any evidence that consulting was occurring or had occurred.

NP2142ACA.NC5 – Cleared. NOP §205.402(a)(2) states, "Upon acceptance of an application for certification, a certifying agent must: Determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part." *Two of four labels reviewed did not comply with regulatory requirements:*

- a) *A single ingredient product was incorrectly labeled as "95% organic," which is not in compliance with §205.303(a)(2). This percentage is not possible as it listed only a single ingredient.*
- b) *An "organic" product label had the "Certified organic by * * *" statement to the left of the distributor name, which is not in compliance with §205.303(b)(2).*

In addition, the files did not record whether the labels had been approved by NJDA. **Corrective Actions (January 2013):**

- a) NJDA stated that the document in question was not a label but rather a shipping insert. Because of this, NJDA did not consider the document a formal label for approval and did not record the process used to evaluate or approve it. The program supervisor could not verify the information submitted by the client or explain the process used to evaluate the product composition and labeling category. In January 2013, NJDA told the client that the 95% label was not accurate and could not be used any longer, stating that "there is no label claim in the Rule for '95% organic.'" However, this statement contradicts § 205.303 (a)(1).
- b) NJDA has reviewed NOP *Policy Memo 12-2, "Placement of the Certified Organic By ***" Statement.* This policy was forwarded to NJDA certified clients via e-mail on September 27, 2012 with the following instructions: "Please pay extra attention to the notice on the 'certified organic by ***' statement.' This [memo] changes previous determinations, and many NJDA clients will have to make changes to and re-submit their labels by 2014 to be in compliance with the labeling requirements." NJDA will address labels with individual clients during the completion of the 2012 and 2013 updates to ensure all clients' labels are properly revised before the deadline date of January 1, 2014.

Corrective Action (June and July 2013):

- a) As NJDA stated that the document in question was a shipping insert, NJDA reviewed the document under § 205.307 as a label for nonretail containers used for shipping and

submitted it as evidence to show that the product was listed only as “organic.” To facilitate the label review process, NJDA developed a new form to document the review process for each label and a template to track all labels submitted by producers; and revised its “General Procedures for NJDA Organic Certification” to indicate the implementation of the new documents. NJDA also submitted agendas and certificates, and noted several training modules or meetings which staff attended as evidence of completion of organic labeling regulation reviews in order to prevent a reoccurrence of the noncompliance.

Verification of Corrective Action (May 2014): The auditor reviewed several certified operation files that included approved labels. The NJDA Label Review Form is used and the NJDA reviewer notes are clear and correspond accurately with a decision as to whether the label is compliant. The auditor did recommend that NJDA modify their label review form to include a checklist with components similar to that of NOP 2005, Table 6a, to ensure all label requirements are reviewed for compliance.

NP2142ACA.NC6 – Outstanding. NOP §205.510(a)(4) states, “An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports...: The results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent’s operation and procedures implemented or to be implemented in response to the performance evaluations and program review.” *Records reviewed indicated that seven of eleven personnel had no current performance evaluations on file. None of the results of performance evaluations were recorded as submitted to the Administrator as part of an Annual report. An annual program review was conducted by an outside party during 2009; however, no annual program review has been conducted since and submitted to the Administrator as part of an Annual report.* **Corrective Action (October 2012):** Performance evaluations for all inspectors used during the 2011 season as explained in NP8217OOA.NC3. Corrective actions concerning conducting the annual program review are addressed in NP8217OOA.NC4. **Verification of Corrective Action (May 2014):** This noncompliance remains outstanding since NJDA provided a letter indicating the performance evaluation results for three of the four certification staff. The New Jersey Secretary of Agriculture, the certification decision maker, performance evaluation results were not listed and thus does not constitute a listing of all certification staff performance results. The auditor reviewed the detailed 2013 internal review report conducted by a contractor and found it comprehensive and well done. The auditor also interviewed the NJDA employee that will conduct the 2014 internal review.

Noncompliances Identified during the Current Assessment

AIA14121LMC.NC1 NOP §205.501(a)(9) states that certifiers must “maintain all records pursuant to § 205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official;..” *When the NOP auditor asked to review the performance evaluations for NJDA staff involved in certification activities, his request was*

denied due to NJDA's access policy and on the basis of confidentiality. The NJDA Human Resource manager did provide the auditor a letter stating that three of the four certification staff (NJDA employees) had received satisfactory evaluation ratings. The letter was not sufficient for the auditor to verify that performance reviews of NJDA certification staff are evaluated on their organic certification responsibilities and activities.

AIA14121LMC.NC2 NOP §205.670(d) states that “a certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number.” *NJDA did not conduct pesticide residue sampling or testing of operations during 2013. The NJDA program manager stated that for 2014, NJDA would conduct sampling and testing of 10% of the total number of certified operations to make up for the lack of 2013 sampling and testing.*

AIA14121LMC.NC3 NOP §205.642 states that “fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator.” Furthermore, NOP 2609, Unannounced Inspections, section 4.1.12, states that “certifying agents may charge an operation for unannounced inspections as long as the fees are clearly disclosed to all certified operations. Fees charged must be filed with the Administrator in accordance with § 205.642.” *NJDA indicated that they charge operations for unannounced inspections; however, NJDA's fee schedule does not clearly indicate this policy and charge to operations.*

AIA14121LMC.NC4 NOP §205.662 (c) states that “the notification of proposed suspension or revocation of certification shall state:

- (1) The reasons for the proposed suspension or revocation;
- (2) The proposed effective date of such suspension or revocation;
- (3) The impact of a suspension or revocation on future eligibility for certification; and
- (4) The right to request mediation pursuant to § 205.663 or to file an appeal pursuant to §205.681.”

NJDA is issuing notices of proposed suspension indicating that operations have the option of submitting corrective actions or rebuttals for issued noncompliances which is not an option according to §205.662 (c).

AIA14121LMC.NC5 NOP §205.504 (b) (1) states that “a copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates;..” *NJDA does not have written procedures in their program manual describing its material review process and the forms used.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

JUN 26 2014

Erich Bremer
New Jersey Department of Agriculture
P.O. Box 330
Trenton, NJ 08625

Dear Mr. Bremer:

On May 1 - 2, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a Compliance Assessment of the New Jersey Department of Agriculture (NJDA) organic certification program. The objective of the assessment was to determine NJDA's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, AIA14121LMC, is enclosed for your reference.

As the report indicates, five noncompliances (AIA14121LMC.NC1 through NC5) were identified during the assessment. Two noncompliances (NP8217OOA.NC3 and NP2142ACA.NC6), remain outstanding from your previous assessments. Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the NJDA's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Ms. Renee Mann, at (202) 260-8635 or Renee.Mann@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received New Jersey Department of Agriculture's (NJDA) accreditation renewal application to become a U.S. Department of Agriculture (USDA) accredited certifier on December 13, 2016. The NOP has reviewed NJDA's application, conducted an onsite audit, and reviewed the audit report to determine NJDA's capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	New Jersey Department of Agriculture (NJDA)
Physical Address	369 S. Warren Street, P.O. Box 330 Trenton, NJ 08625-0330
Mailing Address	369 S. Warren Street, P.O. Box 330 Trenton, NJ 08625-0330
Contact & Title	Erich V. Bremer, Supervisor, Organic Certification
E-mail Address	erich.bremer@ag.state.nj.us
Phone Number	609-633-1738
Reviewer & Auditors	Graham Davis, NOP Reviewer; Penny Zuck and Graham Davis, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: July 5, 2017 Onsite audit: May 15-19, 2017
Audit Identifier	NP7135PZA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of NJDA's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	NJDA's certification services in carrying out the audit criteria during the period: October 26, 2015 through May 15, 2017

The New Jersey Department of Agriculture (NJDA) is a state agency that was accredited as a certifying agent on April 12, 2007 by the National Organic Program (NOP) for the scopes of crops, wild crops, livestock, and handling/processing. The NJDA Organic Certification Program currently certifies a total of 103 to the following certification scopes: 73 crops, 2 wild crops, 6 livestock, and 30 handler/processor. All certified operations are located in the United States. The NJDA only accepts applications for new certifications in the state of New Jersey, however, there are a few operations certified in Pennsylvania since the program was first accredited.

The organic program is overseen by the Program Manager. There is one full-time staff member dedicated to the organic program, The Organic Certification Program Supervisor, who performs

all certification activities and who is assisted part-time by the Ag Resource Specialist and the Agricultural Products Agent 1. NJDA contracts with three independent organic inspectors.

The NJDA renewal audit included two witness audits. One of a crops and livestock operation, and one of a processor/handler operation. One review audit was conducted of a processor/handler operation.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether NJDA corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to NJDA.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP5299JZA.NC1 – Cleared. 7 CFR §205.642 states that, “The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable.”

Comments: *The statement describing the refund of fees for initial applicants on the NJDA Fee Schedules (Producer and Handler) is unclear: Application fees are remitted before a “content assessment” is conducted. The term “content assessment” is not defined and requires clarification for certification applicants to understand when fees are refundable.*

2016 Corrective Action: The NJDA Certification Program fee schedules (Handler and Producer) were revised to include which part of the fees are nonrefundable and at what stage during the certification process the fees become nonrefundable. The revised fee schedules were submitted to the NOP. By updating the document control log with the revised fee schedules, the NJDA staff have been informed of the changes.

Verification of Corrective Action: Auditor reviewed the revised handler and producer fee schedules that are currently being mailed with applications and annual update packets. The following statement is on both fee schedules: “Applicants who withdraw their application BEFORE the application has been initially reviewed will be remitted their certification fees, minus the application order fee. Once a review of the application has taken place applicants are not eligible for a refund of fees. Withdraw requests must be made in writing to the NJDA Organic Certification Program.”

NP5299JZA.NC2 – Cleared. 7 CFR §205.642 states that, “...the certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification.”

Comments: *NJDA is providing operations fee estimates for initial and continuing certification; however, those estimates are incomplete. The Handler Application/Update Acknowledgement Form does not provide an inspection fee estimate. Statements in the Producer Application/Update Acknowledgement Form imply that the fee estimate is for initial applicants only.*

2016 Corrective Action: NJDA revised the Handler Application/Update Acknowledgement Form to include an estimate of inspection cost and the Producer Application/Update Acknowledgement Form to indicate the estimate is for new applicants and updates. The revised acknowledgement forms were submitted to the NOP. By updating the document control log with the revised forms, the NJDA staff have been informed of the changes.

Verification of Corrective Action: Auditor reviewed a recent Producer Application/Update Acknowledgement Form sent to a producer in March 2017 and it included the revised language indicating the certification cost estimate is for new applicants and updates. Auditor reviewed a recent Handler Application/Update Acknowledgement Form sent to a handler in November 2016 and it included the certification cost estimate including inspection costs.

NP5299JZA.NC3 – Outstanding. 7 CFR §205.404(b) states, “The certifying agent must issue a certificate of organic operation which specifies the: (1) Name and address of the certified operation; (2) Effective date of certification; (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.” NOP 2603, Organic Certificates, Section 3.1 states, “Organic certificates should be issued in English and include the following (* identifies elements required by 7 CFR § 205.404 of the USDA organic regulations): 1. Certified operation’s name (all legal names) and address(es), including a physical address if the mailing or legal address is not the physical location of the operation*; 2. Certifying agent’s name, address, web site, and phone number*; 5. Anniversary date (when the certified operation must submit its annual update); and 6. Categories of organic operation (crops, wild crops, livestock, and handling/processing)*.”

Comments: *Organic certificates issued by NJDA do not contain the following information or terms:*

- *NJDA’s website;*
- *Anniversary date (certificates do state the most recent and next updates; however, the term “anniversary date” is not used);*
- *Issue date;*
- *The certification category of “wild crops.” NJDA certificates use the term “Wild Crafting.”*
- *All physical location(s) of the handler and production sites are not identified. In some cases, only the mailing address is listed which may be a post office box, not the operation’s physical address(es).*

2016 Corrective Action: NJDA revised the category of certification field on the certificate to include “Wild Crops” instead of “Wild Crafting” and added the website address. The Organic Certificate Addendum was revised to include Anniversary Date, and Issue Date, The revised

template also notes that a physical address must be provided on the organic certificate, and cannot be a PO Box address. Email notification was sent to the staff about this change. The revised documents and copy of the email notification were submitted to the NOP.

Verification of Corrective Action: The current certificate template indicates “wild crops” instead of “wild crafting”, however, no new certificates with this change have been issued yet. Auditor reviewed various certificates that were recently issued and they do not consistently include the NJDA’s website address and/or physical address of the operation when a mailing address is on the certificate.

NP5299JZA.NC4 – Cleared. 7 CFR §205.406(c) states that, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.

2015 Comments: *The Producer Application/Update Acknowledgement Form states that “Additional fees must be received before certification decisions can be released or updates completed.” Auditor interviews with NJDA certification staff indicated that in at least one incident, an operation’s Update Completion Letter was not issued until the operation paid an outstanding fee balance. A Notification of Noncompliance was not issued to this operation for non-payment of fees (§205.400).*

2016 Corrective Action: NJDA revised the Producer Application/Update Acknowledgement Form by removing the statement requiring fees to be paid prior to certification decisions can be released or updates can be completed. The revised form was submitted to the NOP. By updating the document control log with the revised form, the NJDA staff have been informed of the changes.

Verification of Corrective Action: Auditor reviewed a Producer Application/Update Acknowledgement form that was recently sent to a producer in March 2017 and the language requiring fees has been removed from the form. Updated certifications are being issued to some producers prior to inspections. New applicants will be issued a Notice of Noncompliance if fees are not received prior to the final review of the certification process, however, this situation has not occurred since the last audit.

NP5299JZA.NC5 – Cleared. 7 CFR §205.403(c)(1-3) states that, “The on-site inspection of an operation must verify:

- 1) The operation's compliance or capability to comply with the Act and the regulations in this part;
- 2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;
- 3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.”

Comments: *During the review and witness audits conducted by the NOP Auditor, the following observations were made:*

- 1. An inspection report indicated that the crop operation had completed an “on-farm” processing form for a new processed product and that the processing was occurring at an off-farm facility. The auditor’s interview of the certified crop operators revealed that the off-site facility was not inspected by the NJDA inspector during the inspection.*
- 2. Several input materials either used by the crop operator and/or located at a crop operation location were not listed on the verified list of materials. These materials were either not identified during the last inspection or not reported in the inspection report.*
- 3. NJDA inspection checklist templates do not request or prompt inspectors to verify compliance to all international trade agreement terms for exported and imported products and ingredients.*
- 4. At the handler facility the inspection report reviewed by the NOP auditor did not verify label compliance. The inspection report indicated that there was no change to the label; however, the label indicated that the “Certified organic by NJDA” statement was not placed below the manufacturer or the distributor name and therefore not compliant.*
- 5. During a crop witness audit, there was significant soil erosion from recent rains. Although the operator and the inspector briefly discussed the erosion, this observation was not addressed as an issue of concern during the exit interview by the inspector.*
- 6. During a crop review audit, the NOP auditor found that the operation does not maintain an activity log to record applied inputs and other cultural activities despite the operation’s OSP indicating that such record exists and maintained. This discrepancy was not noted as an issue of concern during the last on-site inspection. Without a farm activity record it is unclear how the inspector verified the application of inputs.*
- 7. During the review audit, the NOP auditor learned that the operation was selling a new processed product not listed on its certificate. The operation had partially disclosed the handling of this new product in their annual update and special inspector instructions were issued by NJDA to obtain additional information about the processing of this new product. The new product was incompletely verified during the on-site inspection (August 2015) and the inspector did not provide NJDA information to issue a certification decision.*

2016 Corrective Action:

- 1. NJDA included this noncompliance in the inspector’s evaluation to address that the handling site should have been inspected per the inspector job description form signed by the inspector. The NJDA inspector job description form includes the requirement of inspecting all production areas. As part of the inspector evaluation process, all NJDA inspectors were notified of this noncompliance and the inspection requirement.*
- 2. NJDA included this noncompliance in the inspector’s evaluation to address that locations where the operation stores materials for use in organic production must be inspected. To prevent reoccurrence, the NJDA Producer Inspection Checklist was revised to include a statement instructing the inspector to inspect the location where the operation stores materials for use in organic production. NJDA contacted the operation regarding this noncompliance and requested documentation as to whether these additional materials in storage are intended to be used in organic production or not. As part of the inspector evaluation process, all NJDA inspectors were notified of this noncompliance.*

3. NJDA revised the Inspection Checklists for Handling, Crops, and Livestock Operations to prompt the inspectors to check for import and export documentation, as applicable. As part of the inspector evaluation process, all NJDA inspectors were notified of this noncompliance.
4. NJDA received the operation's annual update and resubmission of labels following the audit. NJDA indicated the labels were not compliant and not approved for use. The noncompliant labels were never used since the operation has yet to handle or sell any organic products. The NJDA inspector checklist for handling operations asks inspectors to verify whether all labels used on organic products were submitted and reviewed by NJDA. As part of the inspector evaluation process, all NJDA inspectors were notified of this noncompliance.
5. NJDA included this noncompliance in the inspector's evaluation to address that the soil erosion issue should have been included in the exit interview as a concern even though it was described in the inspector's report. NJDA issued a notice of noncompliance to the operation and corrective actions were received. As part of the inspector evaluation process, all NJDA inspectors were notified of this noncompliance.
6. NJDA issued a minor noncompliance to the operation for not maintaining an activity log to record applied inputs and other cultural activities despite the operation's OSP indicated that such records exist and are maintained. NJDA will follow up by monitoring this client's record keeping system during the 2016 update process. As part of the inspector evaluation process, all NJDA inspectors were notified of this noncompliance.
7. NJDA included this noncompliance in the inspector's evaluation to address that the handling site should have been inspected per the inspector job description form signed by the inspector. The NJDA inspector job description form includes the requirement of inspecting all production areas. As part of the inspector evaluation process, all NJDA inspectors were notified of this noncompliance and the inspection requirement.

Verification of Corrective Action:

1. This particular inspector is no longer contracted to conduct inspections for the NJDA. An email was sent to all inspectors with the reminder that all production areas must be inspected. The additional processing facility was inspected in August 2016.
2. This particular inspector is no longer contracted to conduct inspections for the NJDA. Auditor verified the revised inspection report is being used, which includes the statement "Materials Verification – the location where the operation stores materials for use in organic production must be inspected." All inspectors were notified of this requirement via email.
3. The inspection checklists were reviewed and the revisions were verified. All checklists now include an area for the inspector to verify exporting of any products/ingredients according to international arrangements. The Handler checklist also includes a section to verify import documentation for importing of ingredients.
4. This was an isolated situation. The label in question was not submitted to NJDA for approval. Inspectors were notified with a reminder to verify approved labels on-site.
5. Auditor reviewed this operation's file and verified the notice of noncompliance was issued to the operation and corrective actions were received and accepted by the NJDA. Inspectors were notified with a reminder to report issues of concern during the exit interview.

6. Auditor reviewed the operation's file and verified the letter with minor noncompliance was issued to the operation. The inspector special instructions asked the inspector to check records (August 2016) at the next inspection and the inspector noted that sufficient records were on file. Inspectors were notified and reminded.
7. The NJDA collected the information from the operation for the addition of this new product and conducted an on-site inspection to determine compliance. The product was then approved and added to their certification. The inspector who conducted the original inspection is no longer contracted to conduct inspections for the NJDA.

NP5299JZA.NC6 – Cleared. 7 CFR §205.662(c) states that, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state:

- 1) The reasons for the proposed suspension or revocation;
- 2) The proposed effective date of such suspension or revocation;
- 3) The impact of a suspension or revocation on future eligibility for certification; and
- 4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *One proposed suspension notification reviewed by the NOP auditor stated that the operation was allowed the option of surrendering their certification. The USDA organic regulations state that a proposed suspension notice allows for an operation to either request mediation with the certifier or file an appeal with the USDA AMS Administrator.*

2016 Corrective Action: NJDA clarified that the NJDA Notice of Proposed Suspension template does not include language with the option to surrender in order to stay the proposed suspension, but the option to surrender was added to this particular notice because the only noncompliance for the operation was not submitting the annual update paperwork. The NJDA General Procedures for Certification was amended to state, “An operation wishing to surrender certification that has an outstanding Notice of Noncompliance or Proposed Suspension may do so. The NJDA will accept the surrender of certification. For operations with an outstanding Notice of Proposed Suspension, surrender of certification must not stop the adverse action proceedings as outlined in §205.662 of the Rule, and the Proposed Suspension must be successfully mediated or appealed by the client to stop the issuance of Suspension.”

Verification of Corrective Action: Auditor reviewed two files with notices of proposed suspension (dated 5/9/17 and 5/11/17). The option to surrender is no longer included in the notices. The auditor verified the current NJDA General Procedures for Certification was amended in the Cessation of Certification Activities section to include, “An operation wishing to surrender certification that has an outstanding Notice of Noncompliance or Proposed Suspension may do so. The NJDA will accept the surrender of certification. For operations with an outstanding Notice of Proposed Suspension, surrender of certification must not stop the adverse action proceedings as outlined in §205.662 of the Rule, and the Proposed Suspension must be successfully mediated or appealed by the client to stop the issuance of Suspension.”

NP5299JZA.NC7 – Cleared. 7 CFR §205.501(a)(8) states that certifiers must “Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;”

Comments: *The following items are not in compliance with the regulations:*

1. *NJDA Organic System Plan (OSP) templates do not have adequate information allowing an operation to disclose product or ingredient export and import activities to demonstrate compliance to established international trade agreement terms. There is no reference (e.g. NOP website or fact sheet) to allow operators to obtain information and the requirements for trading organic products under the existing international trade agreements.*
2. *The NJDA Producer OSP templates do not allow the operator to indicate the legal status of the entity requesting certification.*

2016 Corrective Action: NJDA revised the Organic System Plan templates (Organic Farm Plan, Organic Livestock Plan, and Organic Handling Plan) to ask applicants additional information on importing and exporting organic ingredients and products. NJDA revised the Operation Information Cover Sheet template, which is completed by each operation with initial application and annual updates, asking for the legal status of the operation. The revised templates were submitted to the NOP and by updating the document control log with the revised templates, the NJDA staff have been informed of the changes.

Verification of Corrective Action: Auditor reviewed a handling operation file with current handling plan dated September 2016 and section 3 of the Organic System Plan includes the information on trade arrangements and requires information on exporting and importing organic ingredients and products. Auditor reviewed a crops operation file with the current Organic System Plan dated February 2017 and there is a section on “International Sales” which includes the information regarding international arrangements and directs the operator to the NOP webpages for additional information. It also asks whether products are being exported to other countries. Auditor reviewed the current livestock Organic System Plan (no new livestock operations are in the certification process at this time) and it was revised with sections on Imported Ingredients or Products and International Sales to request information regarding any importing and exporting of products or livestock feed.

NP5299JZA.NC8 – Cleared. 7 CFR §205.504(b)(1) states that certifiers must establish, “...procedures to be used to evaluate certification applicants, make certification decisions, and issue certification decisions, and issue certification certificates.”

Comments: *NJDA’s Program Manual does not include procedures describing its activities for complying with the terms of international trade agreements and to ensure that certified operations are complying.*

2016 Corrective Action: NJDA clarified that the Program Manual does not include specific procedures for each compliance requirement found in the USDA organic regulations, it instead includes general procedures for organic certification. NJDA revised the Compliance Review Checklist for Producer Applications and Updates and the Compliance Review Checklist for Handler Applications and Updates to review and verify whether operations are importing or exporting according to international trade arrangements. The revised templates were submitted to the NOP. By updating the document control log with the revised templates, the NJDA staff have been informed of the changes.

Verification of Corrective Action: Auditor reviewed the current Handler and Producer Compliance Review Checklists and verified the documents were revised with an International Trade section to verify whether operations are importing or exporting according to international trade arrangements.

NP5299JZA.NC9 – Outstanding. 7 CFR §205.501(a)(4) states that a certifier must “Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;”

Comments: *The NOP auditor reviewed three of eight operation files where the annual update cycle from date the update report was received by NJDA to certification decision was not or has not been completed in a reasonable length of time:*

- *A 2014 update report received in October 2014, inspection occurred in January 2015, and the update review and decision remains pending (October 2015).*
- *2014 update report received May 2014, inspection occurred July 2014, and the update decision issued in September 2015.*
- *2015 update report received February 2015, inspection occurred in August 2015, and the update decision remains pending (October 2015).*

NJDA is not conducting accreditation activities in a reasonable amount of time due to the lack of adequate staffing. Currently there is one NJDA staff official (Organic Supervisor) dedicated full-time to the organic program. There are three additional NJDA organic certification staff officials (including the Organic Program Manager) that are part-time and have other work responsibilities within the State’s agricultural and marketing programs. Although the one full-time NJDA organic program staff official is experienced and knowledgeable; and the other part-time NJDA staff officials are competent, the workload for a program containing approximately 100 certified operations and growing appears to be unsustainable.

2016 Corrective Action: NJDA has restructured the job duties of those involved with the certification program to maximize time management and to provide the additional resources needed to maintain and expand the program. As part of this restructure, one of the part-time staff is now dedicating 90% of his time to certification program duties.

Verification of Corrective Action: Auditor verified the part-time staff member has been assigned the responsibility of reviewing all handler files and continues training with the Supervisor to take on additional certification activities. One witness inspection that took place during the audit had not yet received their certification decision letter from the previous year. The annual update was received in January 2016. Two other files reviewed show dates of completion (findings issued) one year after the date of receiving the annual update paperwork.

NP5299JZA.NC10 – Outstanding. 7 CFR §205.406(c) states that, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.”

Comments: *The NOP Auditor reviewed several operation files with labels that were not compliant with the regulations as follows:*

1. A “Made with Organic...” essential oil product contained additional language on the principal label panel making an “Organic” category claim. §205.304(a)(1).
2. During a review audit, the operation’s retail label’s “Certified Organic By ...” statement was not located below the name of the manufacturer or distributor. §205.303(b)(2).
3. In both of the above cases, the labels were not identified as noncompliant by the NJDA reviewers or inspectors. In the case of the incorrect placement of the “Certified Organic By...” statement, the most recent inspection report stated that there was no change in the label. There was no mention in the inspection report as to whether the inspector had conducted a label verification during the inspection or why this label issue of concern was not identified.

2016 Corrective Action:

- The operation identified with the noncompliant product label is no longer certified by NJDA. NJDA re-reviewed all “Made with Organic...” labels and verified they were in compliance with the USDA organic regulations. NJDA staff members were notified of the noncompliance and instructed on the USDA organic regulations at §205.304(a)(1). This notification included NOP 5032 and NOP 5032-1.
- NJDA received the operation’s annual update and resubmission of labels following the audit. NJDA indicated the labels were not compliant and not approved for use. The noncompliant labels were never used since the operation has yet to handle or sell any organic products. The NJDA inspector checklist for handling operations ask inspectors to verify whether all labels used on organic products were submitted and reviewed by NJDA. As part of the inspector evaluation process, all NJDA inspectors were notified of this noncompliance.

Verification of Corrective Action:

1. A “Made with organic...” product label that was approved by the NJDA included the USDA seal and “organic” in the brand name.
2. This was an isolated incident. The label in question was not submitted to the NJDA by the operation for approval and the label was never used.

NP5299JZA.NC11 – Cleared. 7 CFR § 205.501(a)(6) states that “A private or governmental entity accredited as a certifying agent under this subpart must: ... Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.” NOP 2027, Performance Evaluations, Section 3.2 (b), states that “Inspectors should be evaluated during an onsite inspection by a supervisor or peer (another inspector) at least annually. This field evaluation should be conducted at the certifying agent’s expense.”

Comments: *Annual field performance evaluations of inspectors was not conducted during 2014 and 2015. Desk evaluations of inspectors are conducted based upon the inspection report and a postcard evaluation submitted by inspected operations.*

2016 Corrective Action: NJDA developed a checklist form to use for inspector field evaluations and has begun conducting the evaluations for 2016. One evaluation was completed and submitted to the NOP. The other evaluations have been scheduled and NJDA plans to complete field evaluations for all independent organic inspectors for 2016 by the end of the

calendar year. The NJDA General Procedures was revised to indicate the NJDA Organic Certification Program will perform annual field evaluations of all independent organic inspectors. The revised NJDA General Procedures document was submitted to the NOP.

Verification of Corrective Action: The NJDA conducted field evaluations of all inspectors in 2016 and are planning to continue field evaluations each year for all inspectors. Auditor reviewed all field evaluations conducted in 2016.

NP5299JZA.NC12 – Cleared. 7 CFR §205.501(a)(21), states that certifiers must “Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2609, Instruction Unannounced Inspections, Section 4.1.1 instructs certifying agents to “conduct unannounced inspections of 5 percent of their total certified operations per year...”

Comments: *NJDA is not conducting unannounced inspections to attain the minimum of 5 percent of their total certified operations.*

2016 Corrective Action: NJDA plans to conduct unannounced inspections of at least 5% of their total certified operations in 2016 and this is included in the NJDA General Procedures. NJDA submitted the inspection report for one unannounced inspection that took place in July 2016; one is scheduled to take place October 23, 2016; and three others have been assigned to a staff inspector to be conducted by the end of the 2016 calendar year. This would total 5 unannounced inspections in 2016 and will meet the required 5%. Copies of the inspector notifications/assignments were submitted to the NOP.

Verification of Corrective Action: Auditor reviewed inspection reports for the last four unannounced inspections, which took place 10/25/16, 11/16/16, 11/9/16, and 11/18/16. A total of five unannounced inspections took place in 2016.

NP5299JZA.NC14 – Cleared. 7 CFR §205.403(e)(2) states that “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.” NOP 2613, Responding to Residue Results, Section 5.1.a, states that the certifier, “Notify the certified operation of the test results and indicate that the product may be sold as organic.”

Comments: *NJDA issued an operation a notice, “Results of Testing from Samples Taken,” where there was no detection of residues; however, the notice did not “indicate that the product may be sold as organic.”*

2016 Corrective Action: NJDA revised the General Procedures for Certification to include indication whether or not the product can be sold as organic with reporting of test results to clients. The revised NJDA General Procedures document was submitted to the NOP.

Verification of Corrective Action: During the review of all sampling results that took place in 2016, all test results of no detection were mailed to the operations with notification including the product may be sold as organic.

NP5299JZA.NC15 – Outstanding. 7 CFR §205.403(e)(2) states that “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.”

Comments: *The NOP auditor reviewed one unannounced inspection where a sample for pesticide residues was collected and where NJDA conducted an inspection of the production and handling sites. NJDA did not complete and issue an inspection report to the operation.*

2016 Corrective Action: NJDA revised the “Unannounced Inspections” section of the General Procedures for Certification to include a report must be generated for all unannounced inspections and a copy of the report and review findings must be sent to the client. The revised NJDA General Procedures document was submitted to the NOP.

Verification of Corrective Action: Auditor reviewed the unannounced inspection files from 2016. The unannounced inspection reports have not yet been sent to the operations since the final reviews have not been completed. Copies of inspection reports will be sent to the operation with the final decision letter following final review.

NP5299JZA.NC16 – Cleared. 7CFR §205.404(c) states that “Once certified, a production or handling operation's organic certification continues in effect until surrendered by the organic operation...”

Comments: *The NJDA Program Manual, p. 9, states, “An operation who has an outstanding noncompliance for any concern other than a late update must address the noncompliance prior to surrender being accepted.” The regulations do not require noncompliances to be corrected prior to surrendering certification.*

2016 Corrective Action: NJDA revised the General Procedures for Certification which now states, “An operation wishing to surrender certification that has an outstanding Notice of Noncompliance or Proposed Suspension may do so. The NJDA will accept the surrender of certification. For operations with an outstanding Notice of Proposed Suspension, surrender of certification must not stop the adverse action proceedings as outlined in §205.662 of the Rule, and the Proposed Suspension must be successfully mediated or appealed by the client to stop the issuance of Suspension.”

Verification of Corrective Action: The General Procedures for Certification has been revised as indicated. There have not been any other operations with outstanding noncompliances at the time of surrender to review whether the new procedure has been followed.

Non-compliances Identified during the Current Assessment

NP7135PZA.NC1 – 7 C.F.R. §205.501(a)(9) states, “A private or governmental entity accredited as a certifying agent under this subpart must:... Maintain all records pursuant to §205.510(b) and make all such records available for inspection and copying during normal business hours by authorized representatives of the Secretary and the applicable State organic program's governing State official;...”

Comments: *Product labels approved by the NJDA are not easily accessible. The auditor could not determine the most recent labels approved as part of the organic system plans for operation files reviewed in the NJDA filing system.*

NP7135PZA.NC2 - 7 C.F.R. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart; Comply with, implement, and

carry out any other terms and conditions determined by the Administrator to be necessary.” The NOP website provides instructions and the terms of international trade arrangements.

Comments: *Product labels for exported products to Korea were not requested or reviewed by NJDA for compliance to the US-Korea Equivalency Arrangement terms.*

NP7135PZA.NC3 – 7 C.F.R. §205.662(c)(1-4) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance...The notification of proposed suspension or revocation of certification shall state:...The proposed effective date of such suspension or revocation;...and...The right to request mediation pursuant to §05.663 or to file an appeal pursuant to §205.681.”

Comments: *The NJDA Notice of Proposed Suspension indicates the operation has 30 days, from the issue date of the notice, to file an appeal. The review of two Notices of Proposed Suspension issued to operations in May 2017 indicate the proposed effective dates of Suspension, which are less than 30 days from the date of the notices. This does not allow the operation 30 days to file an appeal.*

NP7135PZA.NC4 – 7 C.F.R. §205.663 states, “Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent.”

Comments: *NJDA is accepting certification surrender from operations resolving a notice of proposed suspension without engaging in mediation.*

NP7135PZA.NC5 - 7 CFR §205.403(c)(1-3) states, “The on-site inspection of an operation must verify:

- 1) The operation's compliance or capability to comply with the Act and the regulations in this part;
- 2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;
- 3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.”

Comments: *During one witness audit, the following auditor observations were made:*

1. *The inspector did not verify labels being used by the operation and approved by NJDA as part of the Organic System Plan.*
2. *The operation provided the inspector with the numbers/quantity to perform two in/out mass balances. The inspector did not verify the numbers with actual documents such as purchase invoices, inventory records, and sales records.*

3. *The inspector asked the operation to review the input list in the organic system plan and make changes to it (additions, deletions, etc.), however, the inspector did not verify the inputs during the inspection (including cleaning materials, sanitation materials, and flavor ingredients).*
4. *The inspector did not verify the varieties of coffee and tea onsite and those listed on the organic system plan and certificate.*
5. *The inspector did not verify supplier certificates along with the approved organic product profiles or list of approved ingredient suppliers.*
6. *The inspector did not verify cleaning/purging procedures by reviewing cleaning/purging documentation/logs and/or interviewing staff in the production area.*

NP7135PZA.NC6 - 7 C.F.R. §205.402(b)(3), “The certifying agent shall within a reasonable time: provide the applicant with a copy of the test results for any samples taken by an inspector.”

Comments: *NJDA provided a copy of residue test results in May 2017 to the operations from which samples were collected in November, September, July, and May of 2016.*

NP7135PZA.NC7 - 7 C.F.R. §205.670(d) “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.”

Comments: *The percentage of prohibited substance testing (3.7%) conducted in 2016 did not achieve the 5% requirement.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Eric Bremer
New Jersey Department of Agriculture
369 S. Warren Street
Trenton, NJ 08625

Dear Mr. Bremer:

On May 15-19, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the New Jersey Department of Agriculture (NJDA) organic certification program as part of its USDA Renewal Accreditation Assessment. On July 5, 2017, the NOP reviewed the results of the onsite audit to determine NJDA's compliance to the USDA organic regulations. A copy of the assessment report, NP7135PZA, is enclosed for your reference.

As the report indicates, four (4) noncompliances, (NP5299JZA, NC3, NC9, NC10, and NC.15), remain outstanding from a previous audit. Seven new noncompliances (NP7135PZA, NC1-NC7), were identified during the onsite audit. Please submit corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All corrective actions must indicate how the noncompliances will be corrected and how the NJDA management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of NJDA's USDA accreditation.

If you have questions regarding this notice, please contact, Jason Lopez, Accreditation Manager, at JasonJ.Lopez@ams.usda.gov or (202) 260-9445.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report NP7135PZA

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

JUL 21 2017

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If you have questions regarding this notice, please contact, Jason Lopez, Accreditation Manager, at JasonJ.Lopez@ams.usda.gov or (202) 260-9445.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report NP7135PZA

cc: AIA Inbox

NMDA Mid-term Assessment

Chronology Log

Audit Identifier (if any): NP4209ACA

Audit Type: Mid-Term Assessment

Accredited Certifying Agent Name: NMDA

Accreditation Manager: Robert Yang

Date	Activity
9/15/14	Assigned to RY
10/27/14	Discussed audit report findings with NMDA (Brett Baker); Brett stated that the function of the Organic Advisor is to provide advice for certification.
10/29/14	RY drafted NC Rpt
10/30/14	RY received organizational structure from Brett Baker <ul style="list-style-type: none">NMDA Marketing & Development Division organization structure shows that Stacey Gerk, NMDA Marketing Specialist/Coordinator supervises both the Organic Advisor (Joan Quinn) and Certifier (Brett Baker)
11/4/14	RY followed-up with David to receive additional details, clarified that Steve Ross was the auditor who questioned the organic advisor and determined the finding.
11/19/14	RY discussed with Renee possibility of issue with organization structure, decided to contact Steve for additional information
11/20/14	RY contacted Steve Ross; Steve clarified that the structure is not new, confirmed from the supervisor that the Organic Advisor should not be providing advice.
12/1/14	Further discussed with RM, decided to request job descriptions via email for NMDA Marketing Specialist; Certifier; and Organic Advisor in order to verify responsibilities, who makes final decisions
12/2/14	Received NMDS inspector, Organic Commodity Advisor job descriptions; NMDA QM 2014 manual. <ul style="list-style-type: none">QM states that the NMDA Organic Program is an activity of the NMDA Marketing & Development Division, under New Mexico State University (NMSU); 1) The Coordinator facilitates overall management of the Organic Program and personnel, may provide feedback, guidance and recommendations but shall have no authority or influence over certification decisions, final decision making is by the Chief Inspector and the Deputy Inspector; annually reviews the functions of the certification unitOrganic Commodity Advisor job description states, “educates and assists farmers in maintaining eligibility standards and program procedures, provides advice regarding organic certification; serves as the state representative for the solicitation of organic certification of organic certification, interprets policies

	and procedures of certification programs for industry.
12/11/14	<p>RY sent email to NMDA; Brett confirmed that Stacy supervises both the Organic Advisor and the Certifier, classified as a higher grade Inspector. The organic program is under the Marketing & Development Division, with Marketing & Education as two separate components, both under supervision of Gerke and Lucero.</p> <p>RY discussed with Cheri the potential for (b) (5)</p> <p>RY further discussed with Cheri, advised to set up meeting with Miles to discuss.</p>
12/14/14	RY revised NC report, drafted NoNC.
12/15/14	RY submitted to Cheri for review.
12/18/14	RY issued NoNC, NCRpt
1/15/15	NOP received CA submission from NMDA
1/23/15	RY reviewed CA submission
1/26/15	RY submitted CARpt, No ConAccred to RM for review



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

DEC 18 2014

Brett Bakker
Chief Organic Certifier/Inspector
New Mexico Department of Agriculture (NMDA)
2604 Aztec NE
Albuquerque, NM 87107

Dear Mr. Bakker

On July 28 – 31, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the New Mexico Department of Agriculture's organic certification program as part of its USDA Mid-Term Accreditation Assessment. On October 29, 2014, the NOP reviewed the results of the onsite audit to determine NMDA's compliance to the USDA organic regulations. A copy of the assessment report, NP4209ACA, is enclosed for your reference.

As the report indicates, three corrective actions for prior noncompliances, NP2232AKA.NC1, NC2, and NC4, were cleared and determined to be implemented and effective. NP2232AKA.NC3 remains outstanding from your previous audit. One finding, NP4209ACA.NC1, was identified during the onsite audit and determined to be a noncompliance. Please submit proposed corrective actions for the noncompliance to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the NMDA's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 690-4540 or RobertH.Yang@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of the New Mexico Department of Agriculture (NMDA). An onsite audit was conducted, and the audit report reviewed to determine NMDA's capability to continue operating as a USDA accredited certifying agent. This report provides the results of the mid-term assessment and review of NMDA's corrective actions.

GENERAL INFORMATION

Applicant Name	New Mexico Department of Agriculture (NMDA)
Physical Address	2604 Aztec NE, Albuquerque, NM 87107
Mailing Address	2604 Aztec NE, Albuquerque, NM 87107
Contact & Title	Brett Bakker, Chief Organic Certifier/Inspector
E-mail Address	bbakker@nmda.nmsu.edu
Phone Number	(505) 841-9422
Reviewer(s) & Auditor(s)	Robert Yang, NOP Reviewer; David J. Hildreth, Onsite Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Review of corrective actions date: January 23, 2015 Onsite assessment date: July 28 – 31, 2014
Audit Identifier	NP4209ACA
Action Required	None
Audit & Review Type	Mid-term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of NMDA's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	Review of corrective actions submitted on January 15, 2015 for noncompliance resulting from the mid-term assessment.

The New Mexico Department of Agriculture (NMDA) was originally accredited by the National Organic Program (NOP) on April 29, 2002 as the New Mexico Organic Commodity Commission (NMOCC), an independent agency of the State of New Mexico. On July 1, 2011, NMOCC was dissolved as an independent agency, and the organic program and staff were transferred to the New Mexico Department of Agriculture, which is under the authority of New Mexico State University. The NMDA Organic Program is an activity of the NMDA Marketing & Development Division, under the New Mexico State University.

NMDA is currently accredited for the scopes of crops, wild crops, livestock, and handling. As of July 29, 2014, the NMDA client list consisted of 142 operations, which included 98 crop, 37 handler/processor, and 7 livestock operations. NMDA also certifies one crop grower group. The majority of NMDA's certified operations are located in New Mexico. Only two are located in Texas.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether NMDA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP2232AKA.NC1 – Cleared

NP2232AKA.NC2 – Cleared

NP2232AKA.NC3 - Accepted – 7CFR §205.406(b) states, "Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to §205.403..." and §205.403(a)(1) states, "...An on-site inspection shall be conducted annually... for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue." Of the 12 certification files reviewed, one operation was not inspected in 2011. On-site inspections for this operation were conducted on June 10, 2010 and Aug 21, 2012.

Corrective action (2012): NMDA's revised its program instruction for Management Review to indicate how an annual internal audit would be used to ensure that all operations have been reviewed and inspected, and each operations file would be completed by January 30 of the following year. To achieve this objective, NMDA revised its management review instructions to indicate that a quarterly audit will be conducted to verify which files have been completed and which files require further action. The third calendar year quarter will be the final check to ensure farms have been inspected, and a check on handler/processor inspections will be performed during the fourth quarter. NMDA provided a copy of the revised management review instructions.

Verification of Corrective Action (July 2014): NMDA has conducted quarterly audits. However, of the 9 files reviewed, one annual onsite inspection was not arranged and conducted

within a reasonable time. The operation's application for continuation of certification was reviewed in May 2013, and the onsite inspection was conducted in March 2014.

Corrective Action: In order to improve the timeliness of its certification process, NMDA added one more person to the organic program's staff, thereby increasing the number of certification staff to three persons and the inspector pool to five. NMDA will continue conducting quarterly audits as part of its internal Management Review to verify which certification files need further action. NMDA is also currently developing a database that will alert certification staff of inspection, review, and certification deadlines, and an online certification program in order to streamline turnaround time. The database will be implemented by June 1, 2015, and the online program by 2017.

NP2232AKA.NC4 - Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4209ACA.NC1 – Accepted – 7 CFR §205.501 (a)(11)(iv) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification."

Comments: *During an interview with NMDA Marketing & Development division staff, the Organic Commodity Advisor, who is responsible for Marketing and Education, indicated that she provides clients with advice on how to correct a noncompliance resulting from an onsite inspection. Additionally, the current job description of the Organic Commodity Advisor includes providing advice regarding organic certification. Although the Organic Commodity Advisor functions independently of the Organic Program, the position's activities fall within the same division. Also, oversight of the Organic Program and Marketing and Education is conducted by the same person.*

Corrective Action: NMDA removed the Organic Commodity Advisor position from the program. NMDA updated its Quality Manual (effective date 1/15/15 Version F) to reflect the new organizational structure.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the New Mexico Department of Agriculture (NMDA) organic program was conducted on July 28 – 31, 2014. The National Organic Program (NOP) reviewed the auditor's report to determine NMDA's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	New Mexico Department of Agriculture (NMDA)
Physical Address	2604 Aztec NE, Albuquerque, NM 87107
Mailing Address	2604 Aztec NE, Albuquerque, NM 87107
Contact & Title	Brett Bakker, Chief Organic Certifier/Inspector
E-mail Address	bbakker@nmda.nmsu.edu
Phone Number	505-841-9422
Reviewer(s) & Auditor(s)	Robert Yang, NOP Reviewer; David J. Hildreth, Onsite Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: October 29, 2014 Onsite audit: July 28 – 31, 2014
Audit Identifier	NP4209ACA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of NMDA's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	NMDA's certification services in carrying out the audit criteria during the period: August 24, 2012 through July 31, 2014

ORGANIZATION STRUCTURE:

The New Mexico Department of Agriculture (NMDA) was originally accredited by the National Organic Program (NOP) on April 29, 2002 as the New Mexico Organic Commodity Commission (NMOCC), an independent agency of the State of New Mexico. On July 1, 2011, NMOCC was dissolved as an independent agency, and the organic program and staff were transferred to the New Mexico Department of Agriculture, which is under the authority of New Mexico State University. The NMDA Organic Program is an activity of the NMDA Marketing & Development Division, under the New Mexico State University.

NMDA is currently accredited for the scopes of crops, wild crops, livestock, and handling. As of July 29, 2014, the NMDA client list consisted of 142 operations, which included 98 crop, 37 handler/processor, and 7 livestock operations. NMDA also certifies one crop grower group. The majority of NMDA's certified operations are located in New Mexico. Only two are located in Texas.

NMDA's one office is located in Albuquerque, New Mexico. NMDA staff consists of the Organic Program Manager (Coordinator), Chief Certifier/Inspector, Deputy Certifier/Inspector, Information Specialist, and two subcontracted inspectors. The Organic Program Manager oversees the program, but is not involved in the certification process.

CERTIFICATION PROCESS:

Certification information and application materials may be requested by phone, email, or fax. New applicants are usually directed to the NMDA website, which contains all the forms and documents needed to apply for certification, including a link to the USDA organic regulations. NMDA also sends application packets via mail upon request. Upon receipt of an application for certification, the Chief Certifier/Inspector or Deputy Certifier/Inspector conducts the initial review. Inspections are assigned by the Chief Inspector and are mainly conducted by two subcontracted inspectors. The final review is typically conducted by the Chief Certifier/Inspector, who also makes the certification decision. The Deputy Certifier/Inspector may conduct the final review and make the certification decision. For annual updates, NMDA sends out a notification to all its certified clients in March with a request for the client to submit updates to their Organic System Plan. Once the annual update information is received, the process of initial review, inspection, final review, and certification decision for continuation of certification is the same as that for application for certification.

NMDA has a material review contract and recognition agreement with the Organic Materials Review Institute (OMRI) and Pennsylvania Certified Organic (PCO). NMDA also has a materials review procedure for reviewing materials that are not approved by OMRI or PCO.

Labels and inputs are reviewed and approved for use by the Chief Certifier and/or Deputy Certifier, and subsequently verified by the inspector during the onsite inspection.

NMDA has procedures for handling international exports and import activities. NMDA has not issued any export certificates since the last assessment.

ADMINISTRATIVE RECORDS AND PROCESSES:

NMDA's NOP certification program procedures can be found in the NMDA Organic Program Quality Manual. NMDA conducts internal audits and NOP-specific annual program reviews. Non-conformances are identified and corrective actions are implemented as needed. Records of both internal and external training are maintained. In-house training is conducted for all staff and contract inspectors annually. Additional training is conducted as needed.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED:

A witness audit of a crop/livestock inspection was conducted. The operation included mixed vegetable and egg production. An exit interview was conducted with the operation representative at the end of the inspection, and issues of concern were relayed by the inspector.

A review audit of a handler operation was conducted. The review audit confirmed that NMDA is reviewing and verifying updated changes to the OSP. The results of the previous inspection were also confirmed by the inspector during the onsite inspection.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether NMDA corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to NMDA.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2232AKA.NC1 – Cleared

NP2232AKA.NC2 – Cleared

NP2232AKA.NC3 - Outstanding - NOP §205.406(b) states, “Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to §205.403...” and §205.403(a)(1) states, “...An on-site inspection shall be conducted annually... for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.” Of the 12 certification files reviewed, one operation was not inspected in 2011. On-site inspections for this operation were conducted on June 10, 2010 and Aug 21, 2012.

Corrective action: NMDA’s revised its program instruction for Management Review to indicate how an annual internal audit would be used to ensure that all operations have been reviewed and inspected, and each operations file would be completed by January 30 of the following year. To achieve this objective, NMDA revised its management review instructions to indicate that a quarterly audit will be conducted to verify which files have been completed and which files require further action. The third calendar year quarter will be the final check to ensure farms have been inspected, and a check on handler/processor inspections will be performed during the fourth quarter. NMDA provided a copy of the revised management review instructions.

Verification of Corrective Action: NMDA has conducted quarterly audits. However, of the 9 files reviewed, one annual onsite inspection was not arranged and conducted within a reasonable time. The operation's application for continuation of certification was reviewed in May 2013, and the onsite inspection was conducted in March 2014.

NP2232AKA.NC4 - Cleared

Noncompliances Identified during the Current Assessment

NP4209ACA.NC1 – 7 CFR §205.501 (a)(11)(iv) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification.”

Comments: *During an interview with NMDA Marketing & Development division staff, the Organic Commodity Advisor, who is responsible for Marketing and Education, indicated that she provides clients with advice on how to correct a noncompliance resulting from an onsite inspection. Additionally, the current job description of the Organic Commodity Advisor includes providing advice regarding organic certification. Though the Organic Commodity Advisor functions independently of the Organic Program, the position's activities fall within the same division. Also, oversight of the Organic Program and Marketing and Education is conducted by the same person.*

Mid-Term Audit Resolution Chronology Log

Audit Identifier (if any): NP4237NNA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: NOFA-NY
Accreditation Manager: Janna Howley

Date	Activity
08/25/14-08/27/14	Onsite Mid-Term Audit conducted by Patricia Heckart & Jamie Schoop. Audit docs sent to AIA on 09/16/14.
10/23/14	JH began reviewing audit report docs. Reviewed 2012 audit because mid-term audit report indicated that two 2012 NCs were 1) Rebuttal Submitted and Accepted, and 2) Submitted and No Longer Applicable. Indicated this on NC report.
10/27/14	JH completed audit review and drafted NC report and letter.
10/28/14	JH emailed draft letter and report to RM for review.
11/19/14	Edited report per RM changes. Updated version and saved as new file.
11/25/14	Per RM, sent to CC for review.
12/02/14	Rcvd edit from CC. Updated and printed hard copy for signature.
12/03/14	RM and CC approved hard copy.
12/04/14	MM approved hard copy.
12/08/14	JH emailed letter and report to NOFA-NY.
12/18/14	Rcvd CAs from NOFA-NY. Added to WTL.
01/06/15	Reviewed CA documents and response sent by NOFA-NY. Drafted CA report and Cont Accred letter.
01/07/15	Emailed docs to RM for review.
01/08/15	Rcvd approval from RM to forward electronically to CC for review. Emailed to CC.
01/21/15	Email to CC to determine status of document review.
01/23/15	OK from CC to print hard copy documents for review. Printed and gave to CC.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of NOFA-NY Certified Organic, LLC (NOFA-NY). An onsite audit was conducted, and the audit report reviewed to determine NOFA-NY's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	NOFA-NY Certified Organic, LLC (NOFA-NY)
Physical Address	840 Upper Front Street, Binghamton, NY 13905
Mailing Address	Same
Contact & Title	Lisa Engelbert, Certification Program Administrator
E-mail Address	lisaengelbert@NOFA-NYny.org
Phone Number	607.724.9851
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer Patricia Heckart & Jamie Schoop, On-site Auditors
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: October 27, 2014 Onsite audit: August 25-27, 2014
Audit Identifier	NP4237NNA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of NOFA-NY's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	NOFA-NY's certification services in carrying out the audit criteria during the period: June 2012 through August 2014.

Organizational Structure

NOFA-NY Certified Organic (NOFA-NY) is a Limited Liability Company (LLC) conducting third party verification activities for agricultural producers and handlers of organic products. NOFA-NY is a wholly owned subsidiary of Northeast Organic Farming Association of New York, Inc. NOFA-NY is a non-profit, tax-exempt educational organization. NOFA-NY is operated in the same non-profit manner as Northeast Organic Farming Association of New York, Inc. under the 501(c)(3) requirements.

NOFA-NY has been accredited as a certifying agent since April 29, 2002 to the National Organic Program (NOP) for the scopes of crop, wild crop, livestock, and handling. NOFA-NY currently has approximately 666 certified clients, which include 311 crops, 299 livestock, 30 wild crops, and 56 handling operations certified to the NOP. The clients are certified in the United States,

and all certification activities are conducted at the Binghamton office.

The NOFA-NY certification program staff consists of an Interim Certification Director, two Certification Program Administrators (final review and administration), four Certification Specialists (final review), and three Certification Coordinators (file review and follow-up). There are 12 inspectors; four are staff and eight are contracted.

A Management Committee, appointed by the Board of the Northeast Organic Farming Association of New York, Inc., has all powers to control and manage NOFA-NY as stated in the operating Agreement between the Northeast Organic Farming Association of New York, Inc. and NOFA-NY. The Management Committee sets policies for NOFA-NY based on NOP Regulations and recommendations from certification staff, contract reviewers and inspectors. Management Committee members do not review any client files and are not engaged in organic production.

There were current conflict of interest disclosure reports, which included a confidentiality agreement, for all staff members. The management committee members had signed confidentiality statements. A review of the files and interviews conducted verified that the organic certification staff had sufficient experience, training, and education (or a combination thereof) in agriculture, organic production, and organic handling. A review of the personnel files confirmed that annual performance evaluations had been conducted as required.

Certification Process

Operations requesting certification are provided with an application package that includes a fee determination form; Certification Application guides describing the types of records that need to be kept; the appropriate Organic System Plan (OSP) and supporting documents; and NOFA-NY's policy manual, including the NOP standards. All documents can be provided to applicants in paper or electronic form.

Once completed applications and organic system plans are submitted, a NOFA-NY reviewer reviews the information for completeness and ability to comply with the NOP Standard. When the initial review is completed, an inspector is assigned according to geographical area and expertise. Inspections are conducted to verify the information submitted by the operation. After completion of the inspection, the inspection report and OSP are checked for completeness and given to a final reviewer for a recommendation. The final certification decision is made by someone other than one of the initial reviewers.

For continuation of certification, NOFA-NY sends out annual update information to certified operations in December, with the exception of handling operations. The OSP forms that the operations receive have all the current information that NOFA-NY has to date. The operator is to update the OSP to include any changes anticipated for the upcoming year. Annual update information is due by the end of February. Handling operations receive the update documents prior to their anniversary date. All update information received is reviewed for compliance. The procedures for the review of renewal applications are the same as those for new applicants.

During the assessment, OSPs were reviewed and appear to be adequately completed. NOFA-NY

relies on inspectors to gather documents and obtain information during inspections that clarifies or completes the OSP.

NOFA-NY conducts unannounced inspections throughout the year. Operations for unannounced inspections are selected based on risk or through random selection.

NOFA-NY has a process in place for material reviews. The Certification Program Administrators receive input/materials information from the client requesting approval. All ingredients in a product are researched through use of the National List, GRAS list and available information from OMRI. NOFA-NY will request ingredient lists from manufacturers to determine compliance of a material. If any information cannot be obtained through these means the material is not allowed. NOFA-NY maintains a database of all materials reviewed. Operations that are using a particular material are also noted in this database. NOFA-NY does not have a material evaluation program for liquid nitrogen fertilizers with nitrogen content greater than 3%.

Label reviews are conducted by the reviewers. All reviewers can make approvals for retail organic product labels. NOFA-NY reviewers utilize a “review checklist” similar to the NOP checklist for label approval.

NOFA-NY has completed export documents for shipments made to Canada and the European Union. Product information provided by the operation is reviewed for compliance to the particular regime. There have been no shipments to Japan or Taiwan.

Administrative Records and Processes

NOFA-NY maintains a policy manual describing procedures for the certification process. The policy manual covers the process for certification for all applicants and renewals, and also compliance and adverse actions. NOFA-NY has detailed OSP templates and forms for supporting information.

NOFA-NY contracts with a third party to conduct their internal audit. The findings of the internal audit were the basis of a revision of the policy manual. Annual reports have been submitted to the Administrator as required.

Training records were available for staff members. NOFA-NY conducts internal training for its staff members and inspectors. Records of outside training sessions attended by staff were also available for review.

Summary of Witness Inspections and Review Audits Conducted

The mid-term assessment included one witness inspection and a review audit. The witness inspection was conducted at a seed handling operation in Greene, NY. This operation handles mostly conventional seed with only 5% organic handled. The company co-packs for four other companies. The inspection was conducted by a NOFA-NY staff inspector who was very well prepared and very thorough in the inspection. NOFA-NY had provided the client file to the inspector with the updated information, previous inspection report and letter of review that detailed additional information that the operation must provide during the inspection. An exit

interview was conducted at the conclusion of the inspection.

The review audit was conducted at a dairy/crop farm near Owego, NY. The operation, which had been certified organic since 2006, was approved for hay and pasture, as well as dairy cows producing beef, milk and replacement animals. The review audit confirmed the results of the previous inspection and that NOFA-NY was completing the organic certification and renewal process as required by the NOP Regulations.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether NOFA-NY corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to NOFA-NY.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2135MMA.NC1 – Cleared: NOP §205.405 (a) states, “When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification.”

Comments: NOFA-NY, LLC did not issue a notification of noncompliance, a denial of certification, or a combined notice to an applicant which had used a prohibited substance on all but one field prior to applying for certification. Instead, the operation was issued a Certification Notification for the one field which was certified; a notice of non-compliance and/or denial of certification were not issued for the fields treated with prohibited substances.

Corrective Action: NOFA-NY held staff training on May 21, 2012 addressing the requirement to issue Notices of Non-compliance or Notices of Denial to operations in violation; for non-correctable issues, NOFA-NY’s response notes that staff was informed these could be combined notices. NOFA-NY also updated the Review Checklist that requires notation in two places in the event prohibited substances are used so the final decision maker can ensure proper action. If effectively implemented, NOFA-NY’s response demonstrates capability to comply with NOP accreditation requirements.

Verification of Corrective Action (2014): The audit confirmed that the corrective actions were implemented. The auditor reviewed denials from 2013 that were conducted in the correct manner. There was one denial for a willful violation.

NP2135MMA.NC2 – Cleared: NOP §205.501 (a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of

the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: *A review of the file and interviews conducted during the wild crop witness inspection found that NOFA-NY, LLC granted certification to the scope of wild crop when some of the crops were actually harvested from cultivated fields. In addition, one crop had been planted for at least the two previous years on the operation.*

Corrective Action: Staff was trained on wild crop requirements. Inspectors were informed of wild crop requirements, including receipt of NOP 5022; NOFA-NY also covered this topic during its 2013 Inspector Training in April, 2013. The Final Reviewer used NOP 5022 for the remainder of wild crop files coming through for 2012. To review renewing clients, NOFA-NY revised the wild crop addendum (part of the OSP application form for new and renewing clients) to reflect NOP 5022; this revised wild crop addendum was used to capture information from renewing clients. If effectively implemented, NOFA-NY’s response demonstrates capability to comply with NOP accreditation requirements.

Verification of Corrective Action (2014): The audit verified that NOFA-NY added additional questions to the inspection report, added questions to the wild crop OSP, and conducted staff training on these items.

NP2135MMA.NC3 – Cleared: NOP §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”

Comments: *Eight of the 23 annual performance evaluations were not conducted by NOFA-NY, LLC as required. Specifically, there were no current performance evaluations for six staff members and two inspectors.*

Corrective Action: NOFA-NY has updated its Program Manual to require a timeframe for annual performance reviews for all staff, scheduled for November of each year. Missing performance reviews were conducted first in 2012, in October and November. Calendar reminders have been set up for Cert Director and management as a prompt to start and complete the process in accordance with the Program Manual. If effectively implemented, NOFA-NY’s response demonstrates compliance with NOP accreditation requirements.

Verification of Corrective Action (2014): The audit verified that NOFA-NY conducted annual evaluations for all staff. These were included in the annual update for 2014.

NP2135MMA.NC4 – Cleared: NOP §205.501(a)(10) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in §205.504(b)(5)” and the NOFA-NY Annual Update for Handling Operations states, “I

understand that the following information which is not considered confidential and may be released upon request by members of the public includes: name, farm name, address, telephone number, Organic Certificate, Inputs materials, livestock medications, and results of any sampling residue testing. Any other information may be released only upon written permission by an authorized person listed below.”

Comments: *The NOFA-NY Certification Standards Manual and affirmations signed by applicants and certified operations state that the general public may request in writing specific information regarding what was applied to a farmer’s fields in the previous year and type of health care materials used to treat specific animals in the previous year. Requiring the operations address, telephone number, and inputs used to be disclosed to the general public is not supported by NOP §205.504(b)(5) and the affirmations do not give the operation the option of disclosing the information by their own choosing.*

Corrective Action: NOFA-NY has updated its waiver form to clients and the Program Manual to cite the language from the regulation cited above. If effectively implemented, NOFA-NY’s response demonstrates capability to comply with NOP accreditation requirements.

Verification of Corrective Action (2014): The audit verified that clients now sign an affirmation that states that only information as outlined in NOP §205.504(b)(5) is available to the public.

NP2135MMA.NC5 – Rebuttal Submitted and Accepted

NP2135MMA.NC6 – Cleared: NOP §205.501 (a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform on-site inspections, review certification documents...and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.”

Comments: *None of the six members on the NOFA-NY, LLC Management Committee had a current conflict of interest disclosure report on file.*

Corrective Action: NOFA-NY obtained and provided in its response copies of signed COI disclosure statements for all Management Committee members. NOFA-NY has also set up a timeframe for annual completion of disclosure forms for all staff and MC members, requiring full completion by January of each year. The NOFA-NY Manuals were revised to include this timeframe in its policies. If effectively implemented, NOFA-NY’s response demonstrates capability to comply with NOP accreditation requirements.

Verification of Corrective Action (2014): The audit confirmed that 2014 conflict of interest disclosure reports were submitted for all members of the management committee.

NP2135MMA.NC7 – Cleared: NOP §205.504 (a)(2) states, “A private or governmental entity seeking accreditation as a certifying agent must submit the following documents and information to demonstrate its expertise in organic production or handling techniques... The name and position description of all personnel to be used in the certification operation...”

Comments: *The NOFA-NY, LLC Administrative Procedures Manual (APM) contains qualification for final reviewer but does not include the qualifications required for each scope of certification. The APM also does not define the qualifications of certification specialists and certification coordinator except in an administrative capacity, and does not address specifics to the scopes of certification.*

Corrective Action: Job titles have been revised to clarify job functions. The Management Committee in August 2012 approved these titles (Certification Specialists and Certification Coordinators) and accompanying job responsibilities. Additionally, the NOFA-NY APM/PM manuals were revised to include specified qualifications for application and final reviewers in order to address the APM's lack of definition of these jobs. Sample text of the changes was provided as objective evidence. If effectively implemented, NOFA-NY's response demonstrates capability to comply with NOP accreditation requirements.

Verification of Corrective Action (2014): The audit confirmed that job descriptions were created, with qualifications for each position.

NP2135MMA.NC8 – Cleared: NOP §205.504 (b)(5) states, “A private or governmental entity seeking accreditation as a certifying agent must submit... A copy of the procedures to be used, including fees to be assessed, for making the following information available to any member of the public upon request: (i) Certification certificates issued during the current and 3 preceding calendar years; (ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years; (iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years.”

Comments: *The NOFA-NY Administrative Procedures Manual (APM) does not address the requirement that the list of certified operations should contain the effective date of certification and a review of the list of certified operations on the NOFA-NY website verified the effective date of certification is not included. Additionally, the APM does not address the availability of certificates and results of analysis for the preceding 3 years.*

Corrective Action: NOFA-NY has updated the PM to cite the exact requirements from the NOP regulation above. The certified operations listing on NOFA-NY's website has been updated to include the effective date. NOFA-NY conducted a training with staff on May 21, 2012 and addressed this topic to ensure all staff are aware of the 504(b)(5) requirements. If effectively implemented, NOFA-NY's response demonstrates capability to comply with NOP accreditation requirements.

Verification of Corrective Action (2014): The auditor verified that the list provided to NOP, and on the NOFA-NY website, meets the requirements that the list of certified operations contain the effective date of certification.

NP2135MMA.NC9 – Cleared: NOP §205.662 (a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certification operation.”

Comments: *One label reviewed and approved by NOFA-NY, LLC for a mixed ingredient product did not identify the organic ingredients as organic as required by NOP §205.303 (b)(1). Additionally, the product profile sheet included one ingredient not identified on the label (oregano) and the label contained one ingredient which was not listed on the product profile sheet (fennel). There was no notice of noncompliance issued to the operation for the labeling discrepancies.*

In another file reviewed, a crop operation planted treated seed and NOFA-NY, LLC requested a temporary variance from the NOP in 2011 which was denied. There was no notice of noncompliance issued to the operation which eventually surrendered certification in April 2012.

Corrective Action: NOFA-NY's response demonstrates changes to the file review checklist (in response to bullet 2 above) and implementation of a label review checklist (*preventive action response* to bullet 1 above). The file review checklist changes include notation of inputs used and citing non-compliant materials in two separate areas so the final decision maker can ensure proper action. For the label checklist, all labels approved must be documented with a reviewer's initials and dates; the checklist itself follows requirements in the NOP regulation. The NOFA-NY staff was trained on this topic on May 21, 2012. The NOFA-NY Manuals (APM/PM) were revised at the end of 2012, for implementation at the beginning of the 2013 certification year. In response to the first bullet, NOFA-NY provided a response to this specific issue, showing that a NoNC was sent to the client requiring correction of the labeling issue. The client changed the label, NOFA-NY showed the new label checklist was used to review and approve, and NOFA-NY issued a NoNC resolution. If effectively implemented, NOFA-NY's response demonstrates capability to comply with NOP accreditation requirements in the future.

Verification of Corrective Action (2014): The audit verified that NOFA-NY now utilizes the revised checklists for file review and label review.

NP2135MMA.NC10 – Submitted and No Longer Applicable: NOP §205.670 (d)(1) states, "Results of all analyses and tests performed under this section: (1) Must be promptly provided to the Administrator."

Comments: *The test results for the only samples collected since the previous assessment were not submitted to the NOP.*

Corrective Actions submitted by NOFA-NY in 2012: NOFA-NY established and implemented a tracking form for all samples performed that prompts staff to send results to the NOP. The NOFA-NY manuals (APM/PM) were updated to reflect this change to the system for implementation by Jan 2013.

November, 2013 Update from the NOP: Due to a change to the USDA organic regulations that occurred after this noncompliance was issued to NOFA-NY, 7 CFR §205.670 no longer requires certifiers to submit the results of all analyses and tests to the USDA. This is no longer a noncompliance and NOFA-NY does not need to implement the proposed corrective actions in reference to NP2135MMA.NC10.

Noncompliances Identified during the Current Assessment

NP4237NNA.NC1 – NOP §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2609, section 4.1.1 states, “We recommend that certifying agents conduct unannounced inspections of 5 percent of their total certified operations per year as a tool in ensuring compliance with the regulations.”

Comments: *NOFA-NY conducted 29 unannounced inspections in 2013. The total number of certified operations on January 1, 2013 was 630; five percent of this amount would have been 32. NOFA-NY does have procedures describing unannounced inspections and conducts these inspections based on risk, and also by random selection.*

NP4237NNA.NC2 – NOP §205.510(b) states, “Certifying agents must maintain records according to the following schedule: (2) Records created by the certifying agent regarding applicants for certification and certified operations must be maintained for not less than 10 years beyond their creation.”

Comments: *In review of eight records for sampling results, two receipts for sample collection were missing and four notification letters for sampling results were missing. NOFA-NY was unable to locate these records. NOFA-NY does have procedures for sampling and chain of custody for samples collected. In all cases, a receipt had been issued to the operator; however, the records of sample receipts were not retained as required.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

DEC 08 2014

Lisa Engelbert
NOFA-NY Certified Organic, LLC
840 Upper Front Street
Binghamton, NY 13905

Dear Ms. Engelbert:

On August 25-27, 2014 representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the NOFA-NY Certified Organic, LLC (NOFA-NY) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On October 27, 2014, the NOP reviewed the results of the onsite audit to determine NOFA-NY's compliance to the USDA organic regulations. A copy of the assessment report, **NP4237NNA**, is enclosed for your reference.

As the report indicates, eight corrective actions for prior noncompliances (**NP2135MMA.NC1-.NC4 and NP2135MMA.NC6-.NC9**), were cleared and determined to be implemented and effective. Two new noncompliances (**NP4237NNA.NC1-.NC2**) were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the NOFA management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Janna Howley, at (202) 692-0047 or JannaB.Howley@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM REPORT: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An on-site compliance audit of the Organic Crop Improvement Association (OCIA) organic program was conducted from August 12 – 15, 2014. The audit was conducted to review OCIA’s corrective actions in response to a July 2013 settlement agreement between the USDA and OCIA. The National Organic Program (NOP) reviewed the auditor’s report to assess OCIA’s compliance to the USDA organic regulations. This report provides the results of NOP’s assessment.

GENERAL INFORMATION

Applicant Name:	Organic Crop Improvement Association International (OCIA)
Physical Address:	1340 North Cotner Boulevard, Lincoln, NE 68505
Mailing Address:	1340 North Cotner Boulevard, Lincoln, NE 68505
Contact & Title:	Cindy Elder, Inspection Services Coordinator
E-mail Address:	CElder@ocia.org
Phone Number:	402-477-2323
Reviewer (s) and Auditor(s):	Robert Yang, NOP Reviewer; Rick Skinner, Onsite Auditor
Program:	USDA National Organic Program (NOP)
Review and Audit Date(s):	NOP Review date: May 1, 2015 Onsite audit date: August 12 – 15, 2014
Audit Identifier:	NP4224EEA
Action Required:	Yes
Audit and Review Type:	Compliance Assessment
Audit Objective:	To evaluate the conformance to the settlement agreement and to verify the implementation and effectiveness of OCIA’s corrective actions in response to the settlement agreement.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	Assessment of OCIA’s certification services in carrying out the audit criteria during the period August 30, 2012 to August 15, 2014

ORGANIZATIONAL STRUCTURE:

Organic Crop Improvement Association International (OCIA) operates out of its main office in Lincoln, Nebraska. OCIA has six additional regional offices in Ontario and Quebec, Canada; Mexico; Japan; Peru; and Nicaragua.

OCIA has been accredited by the National Organic Program (NOP) since April 29, 2002 to certify crop, livestock, wild crop, and handling operations under the USDA organic regulations. OCIA's 2012 list of certified operations included 1,158 certified operations, consisting of 870 crop, 7 wild crop, 79 livestock, 249 handling operations (204 processors, 35 distributors, and 10 warehouses) and 39 grower groups.

Certification program staff consists of the Executive Director, one certification specialist (lead), certification specialists, regional managers, regional coordinators, 2 staff inspectors, and various administrative staff. OCIA also uses contracted inspectors.

CERTIFICATION PROCESS:

OCIA responds to requests for certification by emailing or mailing a certification packet that includes the OCIA Fee Schedule, a copy of the USDA organic regulations, an appropriate Organic System Plan template based on the certification requested, and an Operator License Agreement. Upon receipt of the completed application by a regional office or the main office, a certification specialist conducts a pre-inspection review in order to verify the operator's ability to comply. If the information provided is adequate, the file is then assigned to an inspector.

Upon receipt of the inspection report, a certification specialist other than the person who conducted the pre-inspection review reviews the file and makes the certification decision. If the certification specialist identifies a non-compliance that results in an adverse action, the file is forwarded to the Quality Control Committee for review and certification decision.

For continuation of certification, a notification is sent to the certified operator 120, 90, 60 and 30 days prior to the previous year's inspection date. At 30 days, OCIA sends a notice of noncompliance to the operation for not submitting the updated organic system plan as required by the License Agreement. The annual update certification process is the same as that of initial application, and includes a technical review of the completed update prior to inspection.

Labels and material inputs are reviewed by the certification specialists. OCIA does not have a material evaluation program for liquid nitrogen fertilizers with a nitrogen content greater than 3%. Only products approved by OMRI or an accredited materials review program are allowed for use.

SUMMARY OF WITNESS AND REVIEW AUDITS CONDUCTED:

The assessment included one witness inspection and one review audit. The witness inspection was conducted at a crop operation in Sherburn, Minnesota. The operation was a 117-acre farm with 108 acres under organic management. The review audit was conducted at a crop operation in Abie, Nebraska. The operation was a 51.49-acre farm with one 24.49 acre field under organic management. Both inspectors demonstrated a thorough understanding of the USDA organic regulations, and all aspects of organic production were verified.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether OCIA's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to OCIA.

Noncompliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP0224BBA.NC4 – Cleared. 7CFR §205.510 (a)(1-4) states, "An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports ...: a complete and accurate update of information submitted pursuant to §§ 205.503 and 205.504; information supporting any changes being requested in the areas of accreditation described in § 205.500; a description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation; and the results of the most recent performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review."

***Comments:** OCIA submitted annual updates through 2009 but did not send the annual update in 2010, which was required on or before their anniversary date of the issuance of the notification of accreditation.*

Corrective Action (November 2010): OCIA was late in submitting the 2010 Annual Update because of company issues – OCIA was considering splitting the company in two, with a new branch called "OCIA Certification Services (OCS)." OCIA did not think the Annual Update was necessary with this type of division; however, the 2010 Annual Update was submitted to the NOP as part of this Mid-Term Assessment noncompliance response, confirmed via email (objective evidence) showing the update was received at the NOP. OCIA understands Annual Updates are required annually – audit or no audit. If OCIA maintains this implementation of submitting Annual Updates annually, OCIA's response demonstrates capability to comply with NOP accreditation requirements.

Verification of Corrective Actions (August 2012): OCIA did not submit an annual report to the NOP in 2011. OCIA staff were not immediately aware of the requirement. The original noncompliance was incorrectly cited to §205.501(a)(21), which refers to other terms and conditions required by the Administrator. The NOP has changed the citation to §205.510(a)(1-4) to reference the requirements for annual reports.

Corrective action (April 2013): OCIA’s management team completed training on annual report requirements in April 2013, including instruction document NOP 2024, Information Submission Requirements for Certifying Agents. OCIA submitted a training log as evidence. OCIA submitted its annual report on April 23, 2013, prior to the deadline of April 29, 2013.

Verification of Corrective Action (August 2014): OCIA’s submitted 2014 annual report was reviewed and verified to include all the required information.

NP2143MMA.NC1 – Cleared. 7CFR §205.402 (a)(1) states, “Upon acceptance of an application for certification, a certifying agent must review the application to ensure completeness pursuant to §205.401.”

Comments: Three of 7 files reviewed showed that OCIA was not properly identifying or taking action on incomplete organic system plans (OSP). The OSP for a livestock operation did not include information on what monitoring activities were conducted or the frequencies at which they would be conducted to verify the plan was effectively implemented, per §205.201(a)(3). The OSP for a handling operation did not include sufficient information to know what the operation’s activities were and what monitoring activities would be conducted. The handler OSP for the witness inspection did not contain a complete list of products to be certified and did not identify how organic products would be separated from conventional products.

Corrective action (April 2013): OCIA modified its OSP templates to include questions on monitoring practices and procedures. OCIA submitted a revised handler OSP template. OCIA noted that the handling OSP already required the submission of current supplier lists, but this information was not verified by certification staff for the handling operation reviewed during the witness inspection. OCIA conducted training with review staff in March 2013 to ensure that staff conduct file completeness reviews on all applications and submitted a training log as evidence. In addition, OCIA found that the handling operation in question was not implementing their OSP and had not fully disclosed its activities. Therefore, OCIA addressed the issue through a Notice of Noncompliance and an unannounced inspection of the handling operation in March 2013.

Verification of Corrective Action (August 2014): A review of eight certification files indicated that OCIA applications were reviewed for completeness.

NP2143MMA.NC2 – Cleared. 7CFR §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.”

Comments:

- 1) *The handler OSP for the witness inspection did not contain a complete list of products to be certified. The operation was producing emulsified meats and multi-product slurries, as shown on the inspection report. However, the certificate only listed single-ingredient products. The operation’s supplier list contained in the OSP did not include potatoes, tomatoes, cranberries, or pork, despite the fact that they were used as ingredients for organic slurries. There were no organic certificates on file for these products, and the*

quality manager stated that she would accept a supplier's verbal assurance of organic status as sufficient proof for organic ingredients. The operation had no evidence of documentation or procedures to prevent contamination or commingling of organic products, and an open tote bin of organic apples sat on the bottom of 3 shelves with no label. OCIA only cited one of these three issues, the lack of supplier certificates, in its 2012 Notice of Noncompliance.

- 2) *One file reviewed showed that the operation was using nonorganic kelp, but neither the inspector nor the reviewer noted this as a noncompliance. The label provided as a part of the OSP showed that the kelp was not organic.*
- 3) *2 of 8 labels reviewed showed an incorrect use of the USDA organic seal. OCIA did not issue a Notice of Noncompliance to these operations.*

Corrective action (April 2013):

- 1) OCIA issued a Notice of Noncompliance to the handling operation regarding their incomplete supplier list, lack of proof of organic certification for their ingredients, and labels. The deadline for a response was March 5, 2013. OCIA conducted an unannounced inspection of this operation in March 2013 to investigate issues of concern and issued a Notice of Noncompliance in April 2013.
- 2) NOP guidance 5027, The Use of Kelp in Organic Livestock Feed, requires that all kelp used in organic livestock feed be certified organic by March 4, 2014. OCIA will implement this policy by that date.
- 3) OCIA submitted revised labels showing correctly reproduced USDA organic seals. OCIA will implement NOP Policy Memo 12-2 for the revised placement of all "Certified Organic By ***" statements on existing labels by January 1, 2016.

Verification of Corrective Action (August 2014): A review of the handling operation's Certification Determination Team review checklists indicated that all noncompliances were resolved. OCIA informed its certified operations of the requirements of NOP 5027 through its newsletter. The review of a livestock certification file indicated that the operation was using organic kelp. The review of two files in which the "Certified Organic By OCIA" statement on the operation's label was noncompliant indicated that both operations were notified that the labels must be used up by the end of 2014.

NP2143MMA.NC3 – Cleared. 7CFR §205.403 (a)(1) states, "A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue."

Comments:

- 1) *During the crop witness inspection, the inspector did not inspect all fields. He stated that he did not need to inspect all fields, only a random sampling. An interview with the farm manager verified that previous OCIA inspectors had inspected only half of the fields on the certified operation.*

- 2) *One file review showed that OCIA did not conduct an annual inspection within 16 months of the previous inspection. After 16 months, OCIA issued a notification of noncompliance for not submitting the annual updated organic system plan.*

Corrective action (April 2013):

- 1) OCIA states that the NOP's evidence is incorrect; after the NOP auditor told the inspector to complete the inspection of all fields, the auditor did so. Therefore, the auditor did not observe an actual violation of 403(a)(1), but rather an intention to do so. OCIA submitted inspection reports for the operation in question for 2012 and 2011, which demonstrated that all fields were inspected. OCIA also submitted a 2009 inspection report showing that a sampling of fields was visited by the inspector. OCIA submitted a revised inspection policy, A-6, to add clarity regarding acceptable reasons when an inspector may not be able to visit all production units, facilities, and sites. This section clarifies that all exceptional circumstances must be reported by the inspector, and reviewed and approved by OCIA. OCIA submitted the attendee list and presentation slides for a training it conducted with inspectors in May 2013, which reviewed these policies. OCIA explained its continuous evaluation program for contracted inspectors to demonstrate how deficiencies in inspections are identified immediately. OCIA referenced its Procedure for Review and Evaluation of Inspectors (D-2) and submitted two example database screen captures showing how Certification Specialists are prompted by the database to review inspectors after each inspection.
- 2) OCIA investigated the matter and found this to be an isolated staff error. OCIA's database system includes reminders and reports which allow staff to send timely renewal application materials. OCIA has purchased new database software which will allow better tracking of operations through the certification cycle and to prevent this noncompliance from recurring in the future.

Verification of Corrective Action (August 2014): During the witness audit of a crops operation, the inspector inspected all fields. Additionally, a review of training logs indicated that all certification staff and inspectors attended the training. The review of certification files indicated that inspectors have adhered to the revised inspection policy (A-6), and that both annual reviews and inspections were conducted in a reasonable amount of time.

NP2143MMA.NC4 – Cleared. 7CFR §205.501 (a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: *A review of the file and observations during the handling witness audit verified that OCIA issued a Notice of Noncompliance to the operation based on the use of a sanitizer whose label listed peracetic acid, hydrogen peroxide, and acetic acid as components. The Notice of Noncompliance stated that the product contained “products that are not allowed under the NOP.” The file showed that an OCIA reviewer determined that acetic acid was a prohibited material. However, acetic acid and hydrogen peroxide are the components of peracetic acid, which is allowed with restrictions under §205.605(b).*

Corrective action (April 2013): In August 2012, OCIA notified the operator that hydrogen peroxide and peracetic acid are allowed per §205.605(b), but that acetic acid is not specifically

listed and therefore required a documented removal or rinse prior to contact with organic product. OCIA submitted OMRI's listing for acetic acid as evidence to support their decision. OCIA provided training to staff reviewers on the National List and material reviews in March 2013 and plans to provide training to inspectors on the same topic later in the spring of 2013. OCIA reviews all materials against the National List and uses OMRI's generic materials list as a reference. OCIA submitted their Materials Review Procedure, C-7, as evidence of compliance. OCIA also noted that the operator stopped using the peracetic acid product and switched to a different sanitizer, which OCIA approved for use.

Verification of Corrective Action (August 2014): All new material reviews were being conducted by certification specialists who were trained specifically on material review. OCIA also has a contract with OMRI to provide assistance with material reviews where a determination cannot be made in-house. The review of certification files indicated that material review decisions were being made in accordance with OCIA's material review procedures and the requirements of the USDA organic regulations.

NP2143MMA.NC5 – Cleared. 7CFR §205.501 (a)(11)(iv) states, "A private or governmental entity accredited as a certifying agent under this subpart must prevent conflicts of interest by not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification."

Comments:

- 1) *During the handling witness inspection, the inspector engaged in an in-depth discussion on the regulations on cleansers and sanitizers on the National List. He stated that he disagreed with OCIA's decision on the prohibition of a sanitizer listed on the organic system plan, explained the National List in detail, and suggested that the operation petition the NOP if they felt that a new substance should be allowed for use in organic handling.*
- 2) *Regional Chapter personnel provide technical assistance and support services to OCIA chapter members. Regional Chapters also conduct initial application reviews for completeness and return any incomplete applications to the applicants for further information. Letters sent to applicants by the staff of WI Chapter 1 included specific instructions to the applicants on how to correct their applications in order to comply with the USDA organic regulations.*

Corrective action (April 2013):

- 1) OCIA reviewed its inspection policy and amended it to provide examples of conduct that would violate this regulation, such as explaining how the regulations apply to a particular operation, what materials the operation may use, and advice on how operations could respond to adverse actions. OCIA sent this new policy to all inspectors in September, 2012. OCIA submitted an attendee list and presentation slides for its May, 2013 inspector training demonstrating that the revised policy was explained to its inspectors. OCIA incorporated NOP 2614, Technical Assistance, into its conflict of interest procedures and will use this as a basis for inspector training, as evidenced by draft training slides.
- 2) OCIA removed chapter offices from its certification and file handling procedures, since these chapters are separate legal entities and chapter staff members are not paid or

overseen by OCIA International. OCIA removed all references to chapters in its file handling procedures and certification specialist work instructions, including file completeness reviews, inspections, and non-compliances.

Verification of Corrective Action (August 2014): During the witness audit conducted at a crops operation, the inspector did not provide the operator with advice or consultancy services. Chapter personnel were verified to no longer be involved in the certification process.

NP2143MMA.NC6 – Cleared. 7CFR §205.501 (a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”

Comments: Performance evaluations are not conducted for staff in the Mexico, Peru, or Nicaragua offices. Since these are contracted staff, OCIA stated that if they are not performing satisfactorily, their contract would not be renewed. However, these staff members perform initial application reviews for completeness and then return the applications to the operators if they are incomplete. OCIA headquarters staff did not know whether the regional offices issued a Notice of Noncompliance or Notice of Denial of Certification to these applicants.

Corrective action (April 2013): OCIA submitted evidence of performance reviews of its contracted staff members. OCIA clarified that regional offices will only issue Notices of Noncompliance for operations which fail to submit annual updates and pay certification fees. All other Notices of Noncompliance and/or Denials of Certification will be issued by Certification Specialists out of the OCIA headquarters office.

Verification of Corrective Action (August 2014): A review of 2013/2014 performance evaluation records indicated that OCIA conducted performance reviews of all regional office staff. The review of certification files indicated that notices of noncompliance were issued by the OCIA headquarters staff.

NP2143MMA.NC7 – Cleared. 7CFR §205.662 (c) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.”

Comments: If a rebuttal or correction of the noncompliance is unsuccessful, OCIA's procedure allows for the issuance of a Notice of Continuing Noncompliance as an additional step prior to issuing a Notice of Proposed Suspension or Revocation. The OCIA Operation Manual EN-QS-P-083 Revision D, Certification Specialist Work Instructions, states, “Notice of Continuing Noncompliance letters are written if the operation submits a response to a Notice of Noncompliance and does not address all noted noncompliance's, or otherwise indicates the member does not clearly understand the noncompliance. Within the Checklist, the Specialist is to clearly indicate the reason for issuing a Notice of Continuing Noncompliance. The letter must also contain the elements identified in the Notice of Noncompliance listed above.”

Corrective action (April 2013): OCIA has removed references to Continuing Notices of Noncompliance in its quality manual. However, OCIA may still grant an extension for the submission of corrective actions on a case-by-case basis.

Verification of Corrective Action (August 2014): The review of certification files indicated that OCIA no longer issues Continuing Notices of Noncompliance.

NP2143MMA.NC8 – Cleared. 7CFR §205.405 (a) states, “When the certifying agent has reason to believe, based on a review of the information specified in § 205.402 or § 205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. When correction of a noncompliance is not possible, a notification of noncompliance and a notification of denial of certification may be combined in one notification.”

Comments:

- 1) *Regional and chapter offices often return incomplete applications to applicants for initial and continuing certification. These operations are not provided with a Notice of Noncompliance or Notice of Denial of Certification. If the operation does not respond to the request for additional information, the regional or chapter office takes no further action. OCIA headquarters has no way of tracking such applications.*
- 2) *In December 2011, OCIA sent a suspended operation a combined Notice of Noncompliance and Notice of Denial of Certification because the operation had not submitted a letter requesting reinstatement to the NOP Administrator. However, correction of this noncompliance was possible.*

Corrective Action (April 2013): Chapter offices will no longer conduct file reviews for OCIA International. Instead, certification specialists in the OCIA headquarters or regional offices will now conduct all file completeness and compliance review. The certification specialist work instructions clearly outline procedures for issuing Notices of Noncompliance and/or Denials of Certification.

- 1) OCIA submitted revised file review procedures as evidence.
- 2) OCIA conducted training on March 4th, 2013 to clarify the definitions of “correctable” versus “non-correctable” non-compliances and cases where a combined adverse action notice would be allowed.

Verification of Corrective Action (August 2014): Chapter personnel were verified to no longer be involved in the certification process. The review of certification files indicated that applications for initial and continuing certification were complete. OCIA has not issued any combined Notice of Noncompliance and Notice of Denial of Certification since the 2012 assessment. Interviews conducted indicated staff were aware that a combined notice of noncompliance and notification of denial of certification should be issued when the correction of a noncompliance is not possible.

NP2143MMA.NC9 – Cleared. 7CFR §205.501 (a)(8) states, “A private or governmental entity accredited as a certifying agent under this subpart must provide sufficient information to

persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part.”

Comments: *OCIA suspended a crop operation in June 2009, and the operation reapplied for certification in October 2010. OCIA did not inform the operation they had to request reinstatement through the USDA. OCIA conducted an initial review and inspection in October 2010. In December 2011, OCIA sent the operation a combined Notice of Noncompliance and Notice of Denial of Certification because the operation had not submitted a letter requesting reinstatement to the NOP Administrator.*

Corrective action (April 2013): OCIA revised its reinstatement procedures to require Regional Coordinators to inform suspended operations that they must submit a request for reinstatement to the USDA in order to be reinstated. The procedure further states that the operator must include a copy of this letter with their request for reinstatement. OCIA will provide sample letters to operators in order to assist them in preparing reinstatement requests.

Verification of Corrective Action (August 2014): OCIA has not processed any reinstatement requests since the 2013 assessment. However, OCIA’s Operation Manual was verified to include procedures for coordinators to inform a suspended operation that the request for reinstatement must be submitted to the USDA and provide the operator with a letter template.

NP2143MMA.NC10 – Cleared. 7CFR §205.501 (a)(11)(i) states, “A private or governmental entity accredited as a certifying agent under this subpart must prevent conflicts of interest by not certifying a production or handling operation if the certifying agent or a responsibly connected party of such certifying agent has or has held a commercial interest in the production or handling operation, including an immediate family interest or the provision of consulting services, within the 12-month period prior to the application for certification.”

Comments:

- 1) *A member of the OCIA board of directors provided consulting services during inspections of 19 operations which were certified by OCIA. This conflict of interest was identified by OCIA through comments on inspection reports. The Executive Director informed the board of this issue in early July 2012, and the member in question agreed to end her consulting services for OCIA members as of July 15, 2012. She remains a member of the board.*
- 2) *Several members of the OCIA board have organic operations which are certified by OCIA. In April 2004, the NOP accepted OCIA’s proposal to correct this conflict of interest by requiring all board members who were certified by OCIA to obtain a second organic certification from another USDA-accredited certifying agent. At the time of the renewal assessment, one board member whose operation was certified by OCIA had not obtained certification with a second certifying agent.*

Corrective action (April 2013):

- 1) As of February 2013, the board member who provided consulting services no longer serves on the OCIA International Board of Directors. On October 9, 2012, OCIA sent a letter to the 19 operations who had received consulting services from an OCIA Board member, informing them of the conflict of interest and the provisions of §205.501(a)(12)(ii), and referring the operations to another certifying agent. 16

requested to continue certification with OCIA, and 3 indicated that they will apply for certification elsewhere.

- 2) During the review of the corrective action, the NOP determined that dual certification still presented a conflict of interest according to §205.501(a)(11)(i). Therefore, OCIA was instructed to cease certifying any of its Board members. OCIA agreed to stop certifying its Board members. Most current OCIA Board members have surrendered their certification with OCIA and are now certified only through a different certifying agent. Three of nine board members remain certified by OCIA, but are in the process of seeking certification through other accredited certifying agents or dropping their certification with OCIA and having no certification. OCIA noted that one Board member is certified by OCIA under the Canadian Organic Regime, which is acceptable because on April 4, 2013, the NOP approved this in an email to OCIA. The NOP informed OCIA that the Board member certified to the Canadian standards did not present a conflict of interest. OCIA provided a list of Board members and their progress toward certification from another certification agency as of 5/29/2013 to demonstrate the corrective action.

Verification of Corrective Action (August 2014): A review of the certification status of the current Board of Directors indicated that none are certified to the USDA National Organic Program by OCIA.

NP2143MMA.NC11 – Cleared. 7CFR §205.501 (a)(12)(ii) states, “A private or governmental entity accredited as a certifying agent under this subpart must refer a certified operation to a different accredited certifying agent for recertification and reimburse the operation for the cost of the recertification when it is determined that any person covered under §205.501(a)(11)(i) at the time of certification of the applicant had a conflict of interest involving the applicant.”

Comments: OCIA identified 19 operations for which an OCIA board member provided consultation services during OCIA inspections. At the time of the renewal assessment, OCIA had not yet referred the operations to a different ACA for recertification.

Corrective action (April 2013): On October 9, 2012, OCIA sent a letter to all of the certified operations who had received consulting services from its board member. This letter informed the operations of their ability to seek certification services from another certifying agent. On March 1, 2013, OCIA contacted the 3 operators who elected to pursue certification elsewhere and offered them reimbursement for their certification costs.

Verification of Corrective Action (August 2014): Of the three operators who elected to pursue certification elsewhere, two have surrendered certification while one has been suspended for not re-applying for certification with another certifier. The review of certification files did not indicate any issues with conflict of interest.

NP2143MMA.NC12 – Cleared. 7CFR §205.501 (a)(11)(iii) states, “A private or governmental entity accredited as a certifying agent under this subpart must prevent conflicts of interest by not permitting any employee, inspector, contractor, or other personnel to accept payment, gifts, or favors of any kind, other than prescribed fees, from any business inspected.”

Comments: *The OCIA Operation Manual states that OCIA staff, contracted employees, board of directors, committee members, chapter administrators, and contracted inspectors shall not accept substantial gifts/favors from any person(s) or business associates of any person(s) that are certified or are applying for certification through OCIA. However, the Operation Manual also states that OCIA staff, contracted employees, board of directors, committee members, chapter administrators, and contracted inspectors may accept nominal gifts/favors (defined as anything valued under \$100), from any person(s) or business associates of any person(s) that are certified or are applying for certification through OCIA, provided that the gift is not intended to affect the certification decision. Furthermore, the manual states that “this policy does not include voluntary committee involvement,” allowing OCIA volunteers serving on committees to accept gifts.*

Corrective action (April 2013): OCIA submitted a revised “OCIA Policy on Gifts” (part of the OCIA Operations Manual) that states that staff, contract employees, board members, committee members, and contract inspectors will not accept gifts or favors of any kind. The policy on voluntary committee involvement has been clarified to indicate that, as a non-profit entity, OCIA may accept voluntary labor from certified operations.

Verification of Corrective Action (August 2014): OCIA’s current Operations Manual does not allow the acceptance of gifts. There was no indication that gifts of any kind were received by OCIA staff.

NP2143MMA.NC13 – Cleared. 7CFR §205.501 (a)(16) states, “A private or governmental entity accredited as a certifying agent under this subpart must charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator.”

Comments:

- 1) *A review of the fee schedule submitted to applicants by WI Chapter 1 and interviews with regional staff verified that the fee schedule submitted to the Administrator differs from the fees charged to certified operations who are also members of the OCIA chapters. The chapters each set their own fee schedules, which are usually higher than the certification fee schedule which OCIA submitted to the NOP. The chapters bill OCIA Chapter Associates for both membership and certification fees. OCIA International then bills the chapters for the amount of the certification fees that correspond to the headquarters fee schedule (the schedule submitted to the NOP). Only direct applicants to OCIA headquarters (those who do not apply through the chapter offices) are charged fees according to the schedule submitted to the NOP.*
- 2) *A review of the fee schedule showed that OCIA had changed the schedule six times since January 2012; however, only one of these changes was submitted to the NOP.*

Corrective action (April 2013):

- 1) OCIA is in the process of implementing a new system to bill all certified operations directly, regardless of whether they are chapter members. This will allow OCIA to bill all operations in accordance with the fee structure submitted to the Administrator. The system should be in place by July 2013 and fully implemented by the Fall of 2013.

- 2) OCIA noted that its Fee Schedule contains both fees and policies that are connected to fees. Therefore, although the fee schedule had changed many times, all changes were associated with wording changes to fee policies independent of the actual fees. OCIA stated that through discussion with the NOP auditors, it understands that even though changes were to policy, rather than fees, all changes to the 'Fee Schedule' must be submitted to the Administrator. OCIA indicated that all revised fee schedules, including only text edits, will be submitted to the Administrator in the future.

Verification of Corrective Action (August 2014): The current fee schedule was verified to have been submitted to the Administrator on December 18, 2013.

Noncompliances Identified during the Current Assessment:

NP4224EEA.NC1- 7CFR §205.501(a)(21) states, "A private or governmental entity accredited as a certifying agent under this subpart must: ... implement, and carry out any other terms and conditions determined by the Administrator to be necessary." Furthermore, NOP 2603 Instruction Organic Certificates states, "Organic certificates should ... include the following ... Effective date (when the current or initial certifying agent first certified the operation to the USDA organic regulations)*"

Comments: *The effective date on OCIA's organic certificate template is the date of the last inspection.*

OCIA Compliance Audit Chronology Log

Audit Identifier (if any): NP4224EEA

Audit Type: On-site Compliance

Accredited Certifying Agent Name: OCIA

Accreditation Manager (who is working on the project): Robert Yang

Date	Activity
11/21/14	RY reviewed audit report; discussed findings reported by auditor with RM
11/24/14	RY sent auditor electronic audit report with comments, requested response
12/12/14	RY sent reminder to auditor
12/22/14	RY confirmed with auditor that he is working on the response
1/12/15	RY received from auditor response to comments
1/15/15	RY reviewed responses
1/20/14	RY discussed with RM findings; RM advised to contact auditor for additional clarification; RY sent email to auditor requesting call
1/22/15	RY discussed with auditor via phone
3/6/15	Requested additional information from OCIA (Lisa) via phone
5/1/15	Drafted NC Report, NoNC
5/4/15	Submitted to RM for review
5/5/15	Requested additional from OCIA (Cindy); received additional information
5/7/15	Submitted revised NC Report, NoNC to RM for review
5/12/15	RY issued NC Report, NoNC to OCIA
5/14/15	NOP received CA submission from OCIA
6/15/15	Assigned to RY
6/17/15	<p>RY reviewed CA submission; requested clarification from OCIA (Cindy) whether effective date is date operation was first certified (by initial certifier), or date first certified by OCIA, along with the documented policy/procedure</p> <p>Cindy responded that the effective date is the date operator was first certified by NOP by the initial certifier, if not by OCIA; the policy is not documented</p> <p>RY requested documented policy.</p>
6/19/15	<p>Cindy informed RY via email that after discussion with staff, they determined that it is difficult to obtain the initial date of certification to NOP when the operation was initially certified by another certifier so will use date first certified by OCIA. Will updated Operational Manual accordingly and submit next week.</p>

6/25/15	<p>Cindy informed RY via email of their plan to add in the OCIA Operation Manual a statement that clarifies that the effective date will be the date the operation was first certified by OCIA.</p> <p>RY requested that OCIA submit the approved, revised Operational Manual.</p> <p>Cindy responded that the manual has been submitted for approval, will be able to submit approved version on July 2.</p>
7/2/15	<p>Cindy submitted via email approved updated manual. (RY was out of office conducting certifier audit -- 6/28 ~ 7/3)</p>
7/6/15	<p>RY reviewed updated manual, drafted CA Report, NoNC Resolution; submitted to RM for review</p>



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Ms. Cindy Elder
Organic Crop Improvement Association
1340 North Cotner Blvd.
Lincoln, Nebraska

Dear Ms. Elder:

On August 12 – 15, 2014, a representative of the United States Department of Agriculture (USDA), National Organic Program (NOP), completed an onsite audit of the Organic Crop Improvement Association (OCIA) organic certification program. The audit was conducted to review OCIA's corrective actions in response to a July 2013 settlement agreement between the USDA and OCIA. On May 1, 2015 the NOP reviewed the results of the onsite audit to determine OCIA's compliance to the USDA organic regulations. A copy of the assessment report, NP4224EEA, is enclosed for your reference.

As the report indicates, fourteen corrective actions for prior noncompliances NP0224BBA.NC4; NP2143MMA.NC1 through NC13 were cleared and determined to be implemented and effective. One new noncompliance, NP4224EEA.NC1, was a finding identified during the onsite audit and determined to be a noncompliance. Please submit proposed corrective actions for the noncompliance to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective action must also indicate how the OCIA management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 748-4858 or RobertH.Yang@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Report

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

MAY 12 2015

Ms. Cindy Elder
Organic Crop Improvement Association
1340 North Cotner Blvd.
Lincoln, Nebraska

Dear Ms. Elder:

On August 12 – 15, 2014, a representative of the United States Department of Agriculture (USDA), National Organic Program (NOP), completed an onsite audit of the Organic Crop Improvement Association (OCIA) organic certification program. The audit was conducted to review OCIA's corrective actions in response to a July 2013 settlement agreement between the USDA and OCIA. On May 1, 2015 the NOP reviewed the results of the onsite audit to determine OCIA's compliance to the USDA organic regulations. A copy of the assessment report, NP4224EEA, is enclosed for your reference.

As the report indicates, fourteen corrective actions for prior noncompliances NP0224BBA.NC4; NP2143MMA.NC1 through NC13 were cleared and determined to be implemented and effective. One new noncompliance, NP4224EEA.NC1, was a finding identified during the onsite audit and determined to be a noncompliance. Please submit proposed corrective actions for the noncompliance to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective action must also indicate how the OCIA management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 748-4858 or RobertH.Yang@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Report

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a renewal assessment of the Oregon Department of Agriculture (ODA). An onsite audit was conducted and the audit report reviewed to determine ODA's capability to continue operating as a USDA accredited certifying agent. This report provides the results of the renewal assessment and review of ODA's corrective actions.

GENERAL INFORMATION

Applicant Name	Oregon Department of Agriculture (ODA)
Physical Address	635 Capital Street NE, Room 247, Salem, OR 97301
Mailing Address	635 Capital Street NE, Room 247, Salem, OR 97301
Contact & Title	Kate Allen, Certification Development and Programs Manager
E-mail Address	kallen@oda.state.or.us
Phone Number	(503) 576-9176
Reviewer(s) & Auditor(s)	Robert Yang, NOP Reviewer; Mike Lopez, Onsite Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Review of corrective actions date: January 16, 2015 Onsite assessment date: August 18 – 22, 2014
Audit Identifier	NP4230AKA
Action Required	None
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of ODA's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	Review of corrective actions submitted on December 23, 2014 for noncompliance resulting from the renewal assessment.

The Oregon Department of Agriculture (ODA) is a state government entity which was initially accredited on August 10, 2009 for the scopes of crops and processing/handling. ODA currently certifies a total of 89 operations (43 crops, 46 processors), all of which are located in Oregon. All key activities are performed in ODA's office in Salem, Oregon.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether ODA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP0306OOA.NC1 – Cleared

NP0306OOA.NC2 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4230AKA.NC1- Accepted. 7CFR §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through 205.406 and §205.670." Furthermore, 7CFR §205.304(a)(1)(iii) states, "Agricultural products in packages described in §205.301(c) may display on the principal display panel, information panel, and any other panel ... the statement: "Made with organic ..." which appears in letters that do not exceed one-half the size of the largest type size on the panel..."

Comments: The "Made with Organic" statement on a label approved by ODA was the largest type size on the panel.

Corrective Action: ODA issued a notice of noncompliance to the operation for the noncompliant label. The operation submitted a revised label, which was verified by ODA to be compliant. ODA also updated its Label Review Procedures (revision 2.3) and Organic Product and Label Review checklist (revision 2.0) to include verification of the type size of a "Made with Organic" statement. Certification review staff has been trained on the updated procedure and checklist.

NATIONAL ORGANIC PROGRAM REPORT: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of the Oregon Department of Agriculture (ODA) organic program was conducted on August 18 – 22, 2014. The National Organic Program (NOP) reviewed the auditor’s report to assess ODA’s compliance to the USDA organic regulations. This report provides the results of NOP’s assessment.

GENERAL INFORMATION

Applicant Name:	Oregon Department of Agriculture (ODA)
Physical Address:	635 Capital Street NE, Room 247, Salem, OR 97301
Mailing Address:	635 Capital Street NE, Room 247, Salem, OR 97301
Contact & Title:	Kate Allen, Certification Development and Programs Manager
E-mail Address:	kallen@oda.state.or.us
Phone Number:	(503) 576-9176
Reviewer (s) and Auditor(s):	Robert Yang, NOP Reviewer; Mike Lopez, Onsite Auditor
Program:	USDA National Organic Program (NOP)
Review and Audit Date(s):	NOP Review date: November 17, 2014 Onsite assessment date: August 18 – 22, 2014
Audit Identifier:	NP4230AKA
Action Required:	Yes
Audit and Review Type:	Renewal Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of ODA’s certification system.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	Assessment of ODA’s certification services in carrying out the audit criteria during the period November 4, 2010 to August 22, 2014.

ORGANIZATIONAL STRUCTURE:

The Oregon Department of Agriculture (ODA) is a state government entity which was initially accredited on August 10, 2009 for the scopes of crops and processing/handling. ODA currently certifies a total of 89 operations (43 crops, 46 processors). All certified operations are located in Oregon.

All key activities are performed in the office in Salem, Oregon. ODA certification staff consists of a Program manager, two Certification Specialists/Lead Auditors (inspectors), three Auditors (inspectors), and three administrative staff. One certification specialist and three auditors work from other offices within the state.

CERTIFICATION PROCESS:

ODA provides applicants for certification with an initial application packet that includes general information about the organic certification program, a fee schedule, an application form, an agreement (contract), and applicable OSP(s). Information and forms are also available on the ODA website. Upon receipt of the completed forms and application fee, the application is assigned to a certification specialist who reviews the submitted documents for completeness and compliance. If the applicant appears to comply, an inspector is assigned to conduct the onsite inspection. The inspector is responsible for sending the applicant a letter that provides the date of the onsite inspection and an estimate of the cost of certification. After conducting the onsite inspection, the inspector submits an inspection report, along with any documentation collected at the time of the inspection. Certification specialists review the report and provide the program manager with a recommendation to make the final certification decision.

The annual certification update/renewal process is similar to that of initial applicants. ODA sends out an application/OSP update form to its certified operators in January. Operators return the form completed with their intent to continue certification and any changes to their OSP. Renewals are due to ODA by the first of April.

ODA conducts unannounced inspections of 5% of their total certified operations per year. In 2013, ODA conducted 5 unannounced inspections, which was 6.1% of their 81 certified operations. Generally, operations for unannounced inspections are chosen randomly. Operations may also be chosen based on risk or due to a complaint.

ODA has a material review process in place. Certification specialists are mainly responsible for conducting material reviews. Procedures are in place for obtaining full product formulations and checking ingredients against the National List.

Both certification specialists and auditors conduct final product label reviews. ODA uses label review checklists to aid reviewers in determining whether submitted labels comply with NOP requirements. Approved labels are maintained in the operator's file and a master list of approved labels is maintained per operator.

ODA provides attestations for organic products exported to Canada by either including the attestation statement on the operation's organic certificate or providing the operation with an attestation letter.

ADMINISTRATIVE RECORDS AND PROCESSES:

ODA's policies, procedures, and work instructions are maintained electronically.

An auditor within ODA who is not involved in the organic certification program conducts annual reviews of the program. Additionally, certification specialists periodically conduct peer reviews to ensure new employees are provided with continuous training and there is uniformity in decision-making.

All employees involved in the certification process are provided annual refresher training. Staff is also required to take three hours of continuing education from external sources such as IOIA.

Inspectors undergo ISO auditor training annually.

SUMMARY OF WITNESS AND REVIEW AUDITS CONDUCTED:

Two witness audits were conducted for the scopes of crops and handling/processing. The first witness audit was conducted at a crops operation in Dayton, Oregon that produces organic grapes. Nine varieties of organic grapes were being grown on a total of 56 acres. Buffer zones were verified to be adequate. All inputs were verified to be approved for use and used in accordance with the National List restrictions. Upon completion of the inspection, the inspector conducted an exit interview, which included a request for additional information.

The second witness audit was conducted at a handling/processing operation in Eugene, Oregon that processes organic hummus, salsa, and a made with organic black bean dip product. All production and storage areas were inspected. The use of approved cleaners and sanitizers on equipment and utensils was verified. The inspector conducted a review of product formulations and a traceback audit. An exit interview was conducted at the end of the inspection, which resulted in no issues of concern.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether ODA's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to ODA.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP0306OOA.NC1 – Cleared. 7CFR §205.510(a) states, "*Annual report and fees.* An accredited certifying agent must submit annually to the Administrator, on or before the anniversary date of the issuance of the notification of accreditation, the following reports and fees: (1) A complete and accurate update of information submitted pursuant to §§205.503 and 205.504; (2) Information supporting any changes being requested in the areas of accreditation described in §205.500; (3) A description of the measures implemented in the previous year and any measures to be implemented in the coming year to satisfy any terms and conditions determined by the Administrator to be necessary, as specified in the most recent notification of accreditation or notice of renewal of accreditation; (4) The results of the most recent

performance evaluations and annual program review and a description of adjustments to the certifying agent's operation and procedures implemented or to be implemented in response to the performance evaluations and program review." *Interviews with the Program Manager indicated that an annual report had not been submitted to the Administrator in 2010.*

Corrective Action: On November 15, 2010, prior to completion of the ARC Audit Report NO0306OOA NC, ODA staff submitted their annual report to NOP. On December 8, 2010, ODA staff submitted an updated program manual procedure (CID.OCP.DP.8) covering the annual report and fee submission requirements. All documents were reviewed for compliance and found to adequately address the noncompliance.

Verification of Corrective Action (August 2014): Annual reports generated since the previous assessment were reviewed and verified to have been sent to the Administrator as required.

NP0306OOA.NC2 – Cleared. 7CFR § 205.662(a) states, "*Notification.* When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation." *The decision letter of one of the files reviewed had items that were identified as recommendations which were noncompliant to the NOP Rule. Any issues found that are noncompliant to the NOP Rule must be identified as a non-compliance.*

Corrective Action: On January 12, 2011 and March 14, 2011 ODA staff submitted materials to address the noncompliance. ODA staff issued a Notice of Noncompliance to the operator on November 17, 2010. On January 12 and March 16, 2011, ODA staff submitted an updated program manual procedure (CID.OCP.DP.11) addressing and clarifying procedures for the issuance of noncompliances. All documents were reviewed for compliance and found to adequately address the noncompliance.

Verification of Corrective Action (August 2014): The review of eight certification files confirmed that ODA is issuing a Notice of Noncompliance when an issue of concern identified during the inspection is determined to be a noncompliance.

Non-compliances Identified during the Current Assessment

NP4230AKA.NC1- 7CFR §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through 205.406 and §205.670." Furthermore, 7CFR §205.304(a)(1)(iii) states, "Agricultural products in packages described in §205.301(c) may display on the principal display panel, information panel, and any other panel ... the statement: "Made with organic ..." which appears in letters that do not exceed one-half the size of the largest type size on the panel..."

Comments: *The "Made with Organic" statement on a label approved by ODA was the largest type size on the panel.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Kate Allen
Certification Development and Programs Manager
Oregon Department of Agriculture (ODA)
635 Capital Street NE, Room 247
Salem, OR 97301

Dear Ms. Allen:

On August 18 – 22, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), conducted an onsite audit of the Oregon Department of Agriculture's organic certification program as part of its USDA Renewal Accreditation Assessment. On November 17, 2014, the NOP reviewed the results of the onsite audit to determine ODA's compliance to the USDA organic regulations. A copy of the assessment report, NP4230AKA, is enclosed for your reference.

As the report indicates, two corrective actions for prior noncompliances, NP0306OOA.NC1 and NC2, were cleared and determined to be implemented and effective. One new noncompliance, NP4230AKA.NC1, was a finding identified during the onsite audit and determined to be a noncompliance. Please submit proposed corrective actions for the noncompliance to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how ODA's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 690-4540 or RobertH.Yang@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

DEC 01 2014

Kate Allen
Certification Development and Programs Manager
Oregon Department of Agriculture (ODA)
635 Capital Street NE, Room 247
Salem, OR 97301

Dear Ms. Allen:

On August 18 – 22, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), conducted an onsite audit of the Oregon Department of Agriculture's organic certification program as part of its USDA Renewal Accreditation Assessment. On November 17, 2014, the NOP reviewed the results of the onsite audit to determine ODA's compliance to the USDA organic regulations. A copy of the assessment report, NP4230AKA, is enclosed for your reference.

As the report indicates, two corrective actions for prior noncompliances, NP0306OOA.NC1 and NC2, were cleared and determined to be implemented and effective. One new noncompliance, NP4230AKA.NC1, was a finding identified during the onsite audit and determined to be a noncompliance. Please submit proposed corrective actions for the noncompliance to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how ODA's management system will be modified to prevent future noncompliances.

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If you have questions regarding this notice, please contact your Accreditation Manager, Robert Yang, at (202) 690-4540 or RobertH.Yang@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Ohio Ecological Food and Farm Association (OEFFA). An onsite audit was conducted, and the audit report reviewed to determine OEFFA's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Ohio Ecological Food and Farm Association (OEFFA)
Physical Address	41 Crosswell Road; Columbus, OH 43214
Mailing Address	41 Crosswell Road; Columbus, OH 43214
Contact & Title	Kate Schmidt Blake, Certification Program Manager
E-mail Address	kate@oeffa.org
Phone Number	614-262-2022
Reviewer(s) & Auditor(s)	Robert Yang, NOP Reviewer; David Hildreth, Onsite Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: November 14, 2014 Onsite audit: August 11-14, 2014
Audit Identifier	NP4223ACA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of OEFFA's certification
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	OEFFA's certification services in carrying out the audit criteria during the period: June 21, 2012 through August 14, 2014.

ORGANIZATIONAL STRUCTURE:

The Ohio Ecological Food and Farm Association (OEFFA) is a not-for-profit 501(c)(5) corporation that was accredited by the National Organic Program (NOP) on April 29, 2002 for the scopes of crop, wild crop, livestock, and handling. OEFFA currently has 775 NOP-certified clients, which include 339 crops, 347 livestock, 17 wild crops, and 96 handling operations. OEFFA's certified operations are mostly located in the Midwest. All certification activities are conducted at the Columbus, Ohio office.

OEFFA organic certification program staff consists of the Executive Director, Certification Program Manager, Program Associate, Certification Operations Coordinator/Specialist, Certification Specialist/Materials Reviewer, Certification Specialist/Livestock Coordinator, 10

Certification Specialists, 2 Certification Program Assistants, and 30 contracted inspectors. The Certification Program Manager, Program Associate, Materials Reviewer, and Certification Operations Coordinator are also staff inspectors.

CERTIFICATION PROCESS:

Parties seeking organic certification are provided with a packet that includes a fee sheet, applicable OSP, NOP regulations, OEFFA's Certification Policies and Procedures, OEFFA's Approved Product List, and a current certification bulletin. Once the application is received, it is assigned to a certification specialist who reviews the application for completeness and compliance with the NOP regulations. If the operation appears to comply, the certification operations coordinator assigns a qualified inspector. Inspector selection is based on experience, scope and geographical location. Upon completion of the inspection, the inspector submits a report to OEFFA. The certification specialist reviews the report and any submitted documentation. The certification final decision is made by the certification program manager. In the absence of the certification program manager, a certification specialist who has not been involved in the certification review or inspection will make the final decision for certification.

For continuation of certification, OEFFA sends letters annually to all its certified clients as a reminder to submit updated OSP's. A copy of the applicable OSP template is included in the mailing. The procedures for the review of renewal applications are the same as those for new applicants.

OEFFA allows the use of materials that have been approved by OMRI or WSDA. OEFFA also has an internal material review program in place. Materials approved by OEFFA are listed on the Approved Product List, which is compiled and sent out as a publication to OEFFA's certified operators annually. OEFFA does not review liquid nitrogen fertilizers with a nitrogen analysis greater than 3%, and only allows products that have been approved by OMRI.

Labels and inputs are reviewed by the certification specialist/materials reviewer, and then verified by the inspector during the on-site inspection.

OEFFA is approved to issue TM-11 export certificates to Taiwan, and has received requests to do so.

ADMINISTRATIVE RECORDS AND PROCESSES:

The OEFFA Quality Manual includes the procedures and forms OEFFA uses for its NOP certification activities. OEFFA conducts internal audits and has an annual program review relating to NOP-specific requirements. Non-conformances are identified and corrective actions are implemented as needed. Both internal and external training is conducted. Refresher and additional training is conducted as needed.

SUMMARY OF WITNESS AND REVIEW AUDITS CONDUCTED:

One witness audit of an inspection covering two scopes of accreditation, livestock and crops, was

conducted. Pasture on the dairy operation was used only for the dairy cattle, and all other feed was verified to be organic and purchased by the owner. An exit interview that included the identification of issues of concern was conducted with the operation representative at the end of the inspection.

Also, one review audit of a handling operation was conducted. All areas of the operation, including the results of the previous inspection, were reviewed and verified during the review audit. The review audit confirmed that OEFFA is reviewing and verifying updated changes to the OSP.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether OEFFA's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the results of the onsite audit to determine whether noncompliances should be issued to OEFFA.

Noncompliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP215800A.NC1 – Cleared. 7 CFR §205.403(c)(1) states, "The on-site inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part." *During the wild crop witness audit, the inspector did not verify compliance with §205.207(b) regarding harvesting practices and ensuring that "such harvesting or gathering will not be destructive to the environment and will sustain the growth and production of the wild crop". The inspector did review some of the area where wild crop trees grow, but harvesting was not occurring at the time of inspection and further information regarding specific harvest and gathering procedures were not discussed or reviewed.*

Corrective Action: OEFFA submitted a response indicating OEFFA has updated the Inspection Form for wild crop operations requiring the inspector to verify a plan for compliance with the wild crop standards is in place; that the plan for compliance has been verified through on-site inspection during a time of wild crop harvesting; and, should wild crop harvesting not occur at the time of inspection, how the inspector verified the operation was in compliance, provided in the inspection report in a narrative format. OEFFA also indicated they revised the Quality Manual and would provide training to inspectors at 2013 annual training. The revisions and training would address OEFFA's expectation of the inspectors and that "they will fully understand what they are expected to verify about these operations and how they are supposed to do so." A copy of the revised inspection form and Quality Manual were submitted as objective evidence; further, a copy of the training agenda for 2013 annual training was submitted as supporting documentation to the written response.

Verification of Corrective Action (August 2014): A review of copies of three inspection reports for wild crops indicated that the inspectors verified the client's plan for compliance. OEFFA conducted training on the revised inspection form and Quality Manual at its 2013 inspector training.

NP215800A.NC2 – Cleared. 7CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

- *Section 4.2b of the OEFFA Quality Manual requires that approved materials be re-reviewed every 3 years. During an interview with the Materials Reviewer, it was determined that materials are not being re-reviewed in accordance with the requirements set forth in the quality manual.*

Corrective Action: OEFFA identified a lack of staff support available to the Materials Review Manager as a reason for the breakdown of this particular system. OEFFA hired a Certification Program Assistant for direct support to the Materials Review Manager, who began on July 30, 2012. The Certification Program Assistant has begun the work of updating material information, such as supporting documents from material manufacturers, review documentation and/or approval from OMRI or other accredited certifying agents, material labels, etc. After this first round of materials on OEFFA's “approved” list with more than 3 years passed since the last review is completed, the Certification Program Assistant will be tasked with reviewing the materials log quarterly to ensure OEFFA maintains its timeliness and this non-compliance does not reoccur.

Verification of Corrective Action (August 2014): The Certification Program Assistant has been helping the Materials Review Manager. Materials are being re-reviewed in accordance with requirements set forth in the OEFFA Quality Manual.

- *OEFFA policy regarding the approval and use of quaternary ammonia sanitizers, prohibited under §205.272 (i.e., not listed for use under §205.605) states, “cleaners containing quaternary ammonium compounds or “quats” must be followed by a test documenting less than 6ppm remains on the surface before contact with organic products”. Since the “quats” are not listed on §205.605, then these materials are prohibited without exception and the operation must demonstrate adequate protection measures that are in place to prevent contamination of organic products.*

Corrective Action: OEFFA's response indicates the Cleaners and Sanitizers policy represented in the Approved Materials List has been revised to indicate, “for quaternary ammonium cleaners, a zero test strip reading on all contact surfaces or a documented standard operating procedure that is proven to reliably produce a zero reading is required before contact with organic products.” A copy of this change was included in the supporting documents submitted with the written response. Clients were notified of this change in the OEFFA Certification Bulletin, sent to all clients in August 2012. This revised policy will also be given to all clients in January 2013, when OEFFA annually releases the “OEFFA Certification Policies and Procedures Manual.” Lastly, OEFFA

updated the inspection form all inspectors are required to use to that explains the new policy.

Verification of Corrective Action (August 2014): The auditor verified that the inspection form was updated and is in use. Also, the revised policy was given to clients in 2013.

NP215800A.NC3 – Cleared. 7CFR §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.” *On 8 of the 10 files reviewed it was found that the certification process was not being done in a timely manner (some were over a year in process). Interviews with the certification program manager verified that they did not have enough personnel to be able to get all of the update clients done as needed in a timely manner.*

Corrective Action: OEFFA’s response indicated a change of responsibilities of current staff to better align with certification activities and priority. OEFFA has also hired one Certification Program Assistant to help out not only with the Materials Review Program, as noted under NC2 bullet 1 above; but also to assist generally with certification needs. Additionally, OEFFA has been approved to post a position for a processing certification file reviewer, an area of certification where OEFFA has identified a need, as the organization has few staff members that meet qualification criteria.

Verification of Corrective Action (August 2014): OEFFA hired one processing certification file reviewer and realigned staff responsibilities. It appears that OEFFA has a sufficient number of personnel to handle all certification duties and responsibilities.

Noncompliances Identified during the Current Assessment

No noncompliances were issued as a result of the recent onsite audit.

Audit Resolution Chronology Log

Audit Identifier (if any): NP6217ADA

Audit Type: Renewal Assessment

Accredited Certifying Agent Name: Oregon Tilth Certified Organic (OTCO)

Accreditation Manager (who is working on the project): Graham Davis (GD)

Date	Activity
12/2/2016	RM assigned NC Report to GD
12/14/2016	GD reviewed the documents and started the NC Report draft
12/15/2016	GD drafted a NoNC. GD submitted NoNC and NC Report to RM for approval.
12/16/2016	GD accepted CC edits and printed documents for final approval.
12/16/2016	GD emailed NoNC and NC Report via RPost.
1/18/2017	Rebecca Claypool (RC) was assigned the corrective action report.
1/20/2017	RC reviewed the CAs and found the response acceptable. CA Report and Notice of Accreditation Renewal were drafted. An updated copy of the certifier's certificate was updated, and all the materials were submitted to RM and CC for review (via email DocRouter) to be passed on the Accreditation Committee.
1/30/2017	JR processed and issued NoAccred Renewal to Certifier via Rpost. Awaiting the return of the signed 'Terms of Accreditation'.
2/8/2017	Received Terms of Accred. And Sent Accred Certificate Certifier.

NC Report Chronology Log

Audit Identifier : NP4237AKA
Audit Type: Mid-term
Accredited Certifying Agent Name: OTCO
Accreditation Manager: Renée Gebault King (RGK).

Date	Activity
10/22/14	Assigned to RGK.
11/17/14	RGK initiated review of audit documents.
11/18/14	RGK prepared NC Report and NoNC letter; submitted electronically to R Mann (RM) for review.
11/20/14	Received edits from RM.
11/28/14	RGK edited and resubmitted to RM for review.
12/03/14	RGK received review approval from RM.
12/04/14	RGK submitted to C Courtney (CC) for approval.
12/11/14	RGK received edits from CC, updated report, and submitted hard copies to CC for final review.
12/12/14	RGK met with RM and CC to clarify NoNC and letter to reflect 2 NCs based on M McEvoy review.
12/15/14	Updated NC Report and NoNC letter to reflect 2 NCs.
4/20/15	RM assigned Corrective Action review to PZ
5/6/15	PZ reviewed CA and processed CA report – emailed to RM for review Note: OTCO’s response to not conducting at least 5% unannounced inspections in 2013 is because the NOP 2609 instruction only recommends 5% be performed, but this is not a regulation. However, they performed more than 5% unannounced inspections in 2014 and plan to perform more than 5% in 2015 also.
5/18/15	PZ Received additional requested information and documentation from OTCO. Reviewed and made changes to the CA report.
5/19/15	Emailed CA Report and Resolution letter to RM for review.
5/20/15	Printed CA Report and Resolution letter for signature.
5/22/15	Sent to OTCO

NATIONAL ORGANIC PROGRAM REPORT: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Oregon Tilth Certified Organic (OTCO) organic program was conducted on August 25-29, 2014. The National Organic Program (NOP) reviewed the auditor's report to assess OTCO's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

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Physical Address:	2525 SE 3rd Street, Corvallis, OR 97333
Mailing Address:	2525 SE 3rd Street, Corvallis, OR 97333
Contact & Title:	Connie Karr, Certification Director
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Phone Number:	503-566-3022
Reviewer (s) and Auditor(s):	Renée Gebault King, NOP Reviewer; Mike Lopez, Lead Auditor.
Program:	USDA National Organic Program (NOP)
Review and Audit Date(s):	NOP Review date: November 17, 2014 Onsite assessment date: August 25-29, 2014 Witness inspections: July 15 and August 27, 2014
Audit Identifier:	NP4237AKA
Action Required:	Yes
Audit and Review Type:	Mid-term (12.5 year) Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of OTCO's certification system.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	Assessment of OTCO's certification services in carrying out the audit criteria

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Oregon Tilth Certified Organic (OTCO) is a non-profit organization whose mission is to support and promote sustainable agriculture through education, research, advocacy, and certification. OTCO provides certification services for agricultural producers, product manufacturers, and other handlers of organic products. Initial accreditation by the NOP was granted on April 29, 2002 in the scopes of crops, wild crops, livestock, and handling. OTCO also maintains accreditation for the Global Organic Textile Standard (GOTS). OTCO certifies operations in the United States, Canada, Chile, China, Costa Rica, Guatemala, and Mexico. The current client list identifies 1,334 NOP certified operations (737 crop, 16 wild crop, 262 livestock, and 756 handlers).

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Both witness inspections were conducted in an adequate manner and in such a way as to confidently certify the operations to their respective scopes as organic.

NOP DETERMINATION

NOP reviewed the onsite audit report and determined the status of OTCO's correction actions to adequately address previous noncompliances.

During the onsite audit, one new finding was identified and as a result, NOP is issuing a noncompliance.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

There are no **Outstanding** or **Cleared** noncompliances from previous audits.

Non-compliances Identified during the Current Assessment

NP4155ADA.NC1 – 7 CFR §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through 205.406 and 205.670." *Two cosmetic product labels approved by OTCO were found to be non-compliant. One "Made with organic (specified ingredients)" label was not compliant with §205.304(a)(1)(iii) because the percentage statement on the panel was highlighted with bold type. For the other product label, the percentage statement did not comply with §205.304(a)(2) because the "Made with" statement was 56% of the largest type on the panel when it should not exceed more than one-half the largest type size.*

NP4155ADA.NC2 – 7 CFR §205.403(a)(2)(ii) states, "The Administrator...may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part." *The unannounced inspections conducted in 2013 did not achieve the 5% benchmark described in the regulations and NOP 2609 instruction.*

NATIONAL ORGANIC PROGRAM REPORT: NONCOMPLIANCE REPORT

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SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED:

In conjunction with this onsite assessment, two witness inspections were conducted in the scopes of crops, livestock, and handling/processing. Both were annual renewal inspections and were announced, and both a staff inspector and a contracted inspector were observed.

The first witness inspection was conducted at an egg production operation in central Kansas. This operation is certified in the scopes of crops, livestock, and handling. For the scope of crops, the land where this facility is located is certified organic solely for the purpose of providing outdoor access areas for the chickens; there is no crop production on this land. For the scope of livestock, approximately 350,000 laying hens (housed in structures with porches) and 50,000 pullets are certified organic for the production of organic shell eggs. And finally, for the scope of handling, this operation is certified to package the organic shell eggs into various packages for retail sale.

The contract inspector was thorough and covered all areas for all scopes of the operation. A product trace-back audit was performed with satisfactory results. All materials observed were either OMRI approved or in direct compliance to the National List; there are no additional inputs. The inspector conducted an exit interview. Overall, the inspector conducted herself in a professional manner and displayed excellent knowledge of the NOP standards.

The second witness inspection was conducted at a brewery in western Oregon. This operation is certified in the scope of handling/processing and produces organic beer. This facility includes the brewery, a walk-in cooler for storage of raw ingredients and finished products, a warehouse/storage area, a loading dock, and an attached brew pub with restaurant.

An OTCO staff inspector performed this inspection; he reviewed all inputs and materials used for cleaning/sanitizing, reviewed all labels and formulations, and conducted an ingredient trace-back audit. An exit interview was conducted. This inspector was very knowledgeable of the subject matter and conducted himself in a professional manner.

Both witness inspections were conducted in an adequate manner and in such a way as to confidently certify the operations to their respective scopes as organic.

NOP DETERMINATION

NOP reviewed the onsite audit report and determined the status of OTCO's correction actions to adequately address previous noncompliances.

During the onsite audit, one new finding was identified and as a result, NOP is issuing a noncompliance.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

There are no **Outstanding** or **Cleared** noncompliances from previous audits.

Non-compliances Identified during the Current Assessment

NP4155ADA.NC1 – 7 CFR §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through 205.406 and 205.670." *Two cosmetic product labels approved by OTCO were found to be non-compliant. One "Made with organic (specified ingredients)" label was not compliant with §205.304(a)(1)(iii) because the percentage statement on the panel was highlighted with bold type. For the other product label, the percentage statement did not comply with §205.304(a)(2) because the "Made with" statement was 56% of the largest type on the panel when it should not exceed more than one-half the largest type size.*

NP4155ADA.NC2 – 7 CFR §205.403(a)(2)(ii) states, "The Administrator...may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part." *The percentage of unannounced inspections (4.5%) conducted in 2013 did not achieve the 5% benchmark described in the NOP 2609 instruction.*

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Oregon Tilth Certified Organic (OTCO) organic program was conducted on August 25-29, 2014. On December 18, 2014, the National Organic Program (NOP) issued a Noncompliance Report to OTCO. This report provides the results of NOP's review of the corrective actions submitted by OTCO in response to the Noncompliance Report.

GENERAL INFORMATION

Applicant Name	Oregon Tilth Certified Organic (OTCO)
Physical Address	2525 SE 3 rd Street, Corvallis, OR 97333
Mailing Address	2525 SE 3 rd Street, Corvallis, OR 97333
Contact & Title	Connie Karr, Certification Director
E-mail Address	connie@tilth.org
Phone Number	503-566-3022
Reviewer(s) & Auditor(s)	Penny Zuck, NOP Reviewer Mike Lopez, Lead Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action Review Date: May 20, 2015 Audit Review Date: November 17, 2014 Onsite Assessment date: August 25-29, 2014 Witness Inspections: July 15, and August 27, 2014
Audit Identifier	NP4237AKA
Action Required	None
Audit & Review Type	Mid-term (12.5 year) Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of OTCO's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	Assessment of OTCO's certification services in carrying out the audit criteria.

Oregon Tilth Certified Organic (OTCO) is a non-profit organization whose mission is to support and promote sustainable agriculture through education, research, advocacy, and certification. OTCO provides certification services for agricultural producers, product manufacturers, and other handlers of organic products. OTCO is accreditation by the NOP in the scopes of crops, wild crops, livestock, and handling. OTCO provides export certification for Canada, the European Union, Japan, and Taiwan. OTCO also maintains accreditation for the Global Organic Textile Standard (GOTS). OTCO certifies operations in the United States, Canada, Chile, China,

Costa Rica, Guatemala, and Mexico. The current client list identifies 1,334 NOP certified operations (737 crop, 16 wild crop, 262 livestock, and 756 handlers). OTCO certifies eleven grower groups in Chile, Guatemala, and Mexico.

OTCO has recently opened an office in Mexico, which oversees inspection assignments in Latin America. All certification activities, however, take place in the main office in Corvallis, Oregon. OTCO currently has a staff of 39 individuals, of which 22 are involved in certification, 12 are administrative, and 5 conduct research and education activities. There is also a Board of Directors to govern the business side of the organization. OTCO uses 39 contract and 17 staff inspectors.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether OTCO's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

There are no **Outstanding** or **Cleared** noncompliances from previous audits.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4155ADA.NC1 – Accepted - 7 CFR §205.501(a)(3) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through 205.406 and 205.670."

Comments: *Two cosmetic product labels approved by OTCO were found to be non-compliant. One "Made with organic (specified ingredients)" label was not compliant with §205.304(a)(1)(iii) because the percentage statement on the panel was highlighted with bold type. For the other product label, the percentage statement did not comply with §205.304(a)(2) because the "Made with" statement was 56% of the largest type on the panel when it should not exceed more than one-half the largest type size.*

Corrective Action: OTCO submitted a revised and approved label for the product that was noncompliant because the percentage statement was highlighted. The percentage statement has been removed from the new product label. OTCO plans to address and request correction of the

other labeling issue at the client's next renewal/update for the product with the "made with" statement at 56% of the largest type on the panel. OTCO has documented this in a memo that will notify the inspector through the Inspection Work Order (IWO) and the reviewer through their workflow of the issue and the need to address it with the client during their 2015 audit. OTCO staff underwent training on the made with label reviews in December 2014. In 2015 OTCO plans to conduct random internal audits with a focus on made with labels and their compliance with the regulations.

NP4155ADA.NC2 – Accepted - 7 CFR §205.403(a)(2)(ii) states, "The Administrator...may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part."

Comments: *The percentage of unannounced inspections (4.5%) conducted in 2013 did not achieve the 5% benchmark described in the NOP 2609 instruction.*

Corrective Action: OTCO performed 5.7% unannounced inspections in 2014 and plans to conduct unannounced inspections of more than 5% of their certified operations in 2015. OTCO submitted their unannounced inspection plan for 2015, which documents the requirement for unannounced inspection of NOP certified operations at 5%.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Connie Karr
Oregon Tilth Certified Organic
2525 SE 3rd Street
Corvallis, OR 97333

Dear Ms. Karr,

On August 25-29, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Oregon Tilth Certified Organic (OTCO) organic certification program as part of its USDA Mid-term Accreditation Assessment. On November 17, 2014, the NOP reviewed the results of the onsite audit to determine OTCO's compliance to the USDA organic regulations. A copy of the assessment report, NP4237AKA, is enclosed for your reference.

As the report indicates, there were no prior noncompliances from your previous audit. One new noncompliance, NP4237AKA.NC1, was identified during the onsite audit. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the OTCO management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renée Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Connie Karr
Oregon Tilth Certified Organic
2525 SE 3rd Street
Corvallis, OR 97333

Dear Ms. Karr,

On August 25-29, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Oregon Tilth Certified Organic (OTCO) organic certification program as part of its USDA Mid-term Accreditation Assessment. On November 17, 2014, the NOP reviewed the results of the onsite audit to determine OTCO's compliance to the USDA organic regulations. A copy of the assessment report, NP4237AKA, is enclosed for your reference.

As the report indicates, there were no prior noncompliances from your previous audit. Two new noncompliances, NP4237AKA.NC1 and NC2, were identified during the onsite audit. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the OTCO management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renée Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

DEC 18 2014

Connie Karr
Oregon Tilth Certified Organic
2525 SE 3rd Street
Corvallis, OR 97333

Dear Ms. Karr,

On August 25-29, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Oregon Tilth Certified Organic (OTCO) organic certification program as part of its USDA Mid-term Accreditation Assessment. On November 17, 2014, the NOP reviewed the results of the onsite audit to determine OTCO's compliance to the USDA organic regulations. A copy of the assessment report, NP4237AKA, is enclosed for your reference.

As the report indicates, there were no prior noncompliances from your previous audit. Two new noncompliances, NP4237AKA.NC1 through NC.2, were identified during the onsite audit. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the OTCO management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renée Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney". The signature is written in a cursive, flowing style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Oregon Tilth Certified Organic (OTCO) accreditation renewal application on June 14, 2016. The NOP reviewed OTCO's application, conducted an onsite audit, and reviewed the audit report to determine OTCO's capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Oregon Tilth Certified Organic (OTCO)
Physical Address	2525 SE 3rd Street Corvallis, OR 97333
Mailing Address	2525 SE 3rd Street Corvallis, OR 97333
Contact & Title	Connie Karr, Certification Director
E-mail Address	connie@tilth.org
Phone Number	(503) 378-0690
Reviewer & Auditors	Graham Davis, NOP Reviewer; Niki Adams, Penny Zuck, Graham Davis, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: December 15, 2016 Onsite audit: October 3 – 6, 2016
Audit Identifier	NP6217ADA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of OTCO's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	OTCO's certification services during the period: August 26, 2014 through October 3, 2016

Oregon Tilth Certified Organic (OTCO) is a non-profit organization whose mission is to support and promote sustainable agriculture through education, research, advocacy, and certification. OTCO provides certification services for agricultural producers, product manufacturers, and other handlers of organic products. OTCO has one main office located in Corvallis, OR and has one small office in Mexico, which oversees inspection assignments in Latin America. This office's functions primarily to help answer calls and direct to proper information for operations

in Latin America. All certification activities, however, take place in the main office in Corvallis, Oregon.

Initial accreditation by the NOP was granted on April 29, 2002 in the scopes of crops, wild crops, livestock, and handling. OTCO also maintains accreditation for COR, EU, Mexico, and ISO 17065. OTCO certifies operations in the United States, Canada, Costa Rica, Panama, Iceland, and Mexico. The current client list identifies 1,576 NOP certified operations (785 crop, 18 wild crop, 286 livestock, and 846 handlers). OTCO has 11 grower groups, all of which are in Mexico.

The OTCO main office staff consists of the Executive Director, Certification Director, Operations Director, Materials Review Officer, Inspections Manager and Assistant, Farm Program Manager and Assistant, Processing Program Manager and Assistant, Processing Program Technical Specialist, Farms Program Technical Specialist (the Tech Specialists also perform the quarterly internal audit), Education Director, Latin American Specialist, 19 Certification Officers (Reviewers and Inspectors), and administrative staff. OTCO currently has a staff of 43 individuals, of which 32 are involved in certification, 11 are administrative, IT, customer service, finance or education activities. There is also a Board of Directors to govern the business side of the organization. OTCO uses 48 contract and 17 staff inspectors. Resumes and personnel records were provided for all staff members and inspectors. Based on the records reviewed and interviews conducted, the auditor verified that personnel had the necessary qualifications to perform assigned certification duties.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED:

In conjunction with this onsite assessment, five witness inspections were conducted in the scopes of crops, livestock, and handling/processing. Four were annual renewal inspections and were announced, and both a staff inspector and a contracted inspectors were observed. Also an unannounced inspection of a first year handler operation was conducted.

The first witness inspection was an annual inspection conducted at a large beef harvest/fabricator/ further processor. The second witness inspections was an annual inspection conducted at a dairy operation which is certified for crop and livestock. The third witness inspection was a handler operation which is a brand name owner of frozen meals which contracts a certified organic co-packer who is certified organic by another ACA to process the frozen products. The fourth witness inspection was of a handler operation in. The unannounced inspection conducted during the audit was at a new organic processing operation.

The inspectors were thorough and covered all areas of the operation. Product trace-back audits were performed with satisfactory results. All materials observed were either OMRI, WSDA or CDFA approved or in direct compliance to the National List. The inspectors conducted exit interviews as required.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether OTCO's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to OTCO.

Noncompliances from Prior Assessments

NP4155ADA.NC1 – Cleared. 7 CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through 205.406 and 205.670.”

Comments: *Two cosmetic product labels approved by OTCO were found to be non-compliant. One “Made with organic (specified ingredients)” label was not compliant with §205.304(a)(1)(iii) because the percentage statement on the panel was highlighted with bold type. For the other product label, the percentage statement did not comply with §205.304(a)(2) because the “Made with” statement was 56% of the largest type on the panel when it should not exceed more than one-half the largest type size.*

2015 Corrective Action: OTCO submitted a revised and approved label for the product that was noncompliant because the percentage statement was highlighted. The percentage statement has been removed from the new product label. OTCO plans to address and request correction of the other labeling issue at the client's next renewal/update for the product with the “made with” notify the inspector through the Inspection Work Order (IWO) and the reviewer through their workflow of the issue and the need to address it with the client during their 2015 audit. OTCO staff underwent training on the made with label reviews in December 2014. In 2015 OTCO plans to conduct random internal audits with a focus on made with labels and their compliance with the regulations.

2016 Verification of Corrective Action: OTCO completed the training stated above as well as random internal audits with a focus on labels. Interviews with staff found them well aware of the organic labeling regulations. The auditors' review of random labels as well as those in question above found them compliant.

NP4155ADA.NC2 – Cleared. 7 CFR §205.403(a)(2)(ii) states, “The purpose of determining compliance with the Act and the regulations in this part.”

Comments: *The percentage of unannounced inspections (4.5%) conducted in 2013 did not achieve the 5% benchmark described in the NOP 2609 instruction.*

2015 Corrective Action: OTCO performed 5.7% unannounced inspections in 2014 and plans to conduct unannounced inspections of more than 5% of their certified operations in 2015. OTCO submitted their unannounced inspection plan for 2015, which documents the requirement for unannounced inspection of NOP certified operations at 5%.

2016 Verification of Corrective Action: During 2015, OTCO conducted 86 unannounced inspections. This accounts for 6.1% of operations.

AIA15244RKA.NC2 – Cleared. 7 CFR § 205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must...Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.”

Furthermore, under the terms of the U.S.-European Union Organic Equivalency Arrangement, certifiers shall verify that the export documents comply with the terms of the arrangement, including the verification of the issuing authority.

Comments: *Over the course of two certification cycles of a certified processing operation, OTCO did not verify that NOP Import Certificates accompanied shipments of oils from the European Union (EU) in accordance with the U.S.-EU Organic Equivalency Arrangement. Furthermore, OTCO did not verify that the organic certificates for the imported oils were valid.*

2016 Corrective Actions: OTCO addressed the issue directly with the client by issuing a notice of noncompliance, and the client provided corrective actions that resolved the noncompliance. To prevent future occurrence, OTCO updated their handler inspection report outline to include a section for the inspector to verify NOP import certificates under USDA organic trade equivalencies; this update was communicated to all inspectors via e-mail on December 9, 2015. OTCO also provided staff training on 9/23/15 and 10/21/15 about compliance under the EU-U.S. equivalency.

2016 Verification of Corrective Actions: Training was conducted by OTCO. Inspectors were interviewed by the auditors and are aware of the international trade arrangements. A notice of non-compliance and resolution was issued to the operation as mentioned above.

AIA15244RKA.NC3 – Cleared. 7 CFR § 205.405(c)(1)(ii) states, “When the certifying agent has reason to believe, based on a review of the information specified in §205.402 or §205.404, that an applicant for certification is not able to comply or is not in compliance with the requirements of this part, the certifying agent must provide a written notification of noncompliance to the applicant. After issuance of a notification of noncompliance, the certifying agent must... When the corrective action or rebuttal is not sufficient for the applicant to qualify for certification, issue the applicant a written notice of denial of certification.”

Comments: *OTCO issued a “Notice of Proposed Denial” to a certified operation for its proposed use of conventional product (hay). The USDA organic regulations allow certifiers to issue a Notice of Denial to new applicants, not to currently certified operations. Furthermore, the USDA organic regulations do not allow a Notice of “Proposed” Denial.*

2016 Corrective Actions: OTCO rescinded the “Notice of Proposed Denial” that was originally issued to the operation and provided a letter of explanation regarding the status of the noncompliant hay. To prevent future occurrences, OTCO updated their Procedures and Quality Manuals to reflect compliant use of denials, and updated their letter templates for issuing denials. OTCO also provided staff training in March 2016 about the denial process.

2016 Verification of Corrective Actions: A review of OTCO’s current denial of certification template, including current procedures for issuance are compliant. No issues were identified during the review of two denial cases.

Noncompliances Identified During the Current Assessment

NP6217ADA.NC1 – 7 C.F.R. §205.403(c)(1) states that “The on-site inspection of an operation must verify... The operation's compliance or capability to comply with the Act and the regulations in this part...”

Comments: *The inspector did not verify compliance to international trade arrangement requirements when conducting a review of vendor ingredient certificates:*

- *Several certificates indicated certification to the European Union (EU) organic standard. These certificates did not demonstrate compliance with the US/EU organic equivalency since the products were handled in non-EU member states.*
- *For one EU certificate where the ingredient was handled and shipped from an EU member state, the inspector did not verify that the operator maintained a record of the NOP Import Certificate.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

DEC 16 2016

Connie Karr
Oregon Tilth Certified Organic
2525 SE 3rd Street
Corvallis, OR 97333

Dear Ms. Karr:

On October 3 – 6, 2016, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Oregon Tilth Certified Organic (OTCO) organic certification program as part of its USDA Renewal Accreditation Assessment. On December 15, 2016, the NOP reviewed the results of the onsite audit to determine OTCO's compliance to the USDA organic regulations. A copy of the assessment report, NP6217ADA, is enclosed for your reference.

As the report indicates, four noncompliances, NP4155ADA.NC1 and NC2, and AIA15244RKA.NC2 and NC3 were cleared and determined to be implemented and effective. One new noncompliance, NP6217ADA.NC1 was identified during the onsite audit. Please submit corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All corrective actions must indicate how the noncompliances will be corrected and how the OTCO management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of ACO's USDA accreditation.

If you have questions regarding this notice, please contact, Graham Davis, Accreditation Manager, at Graham.Davis@ams.usda.gov or (202) 692-0047.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report NP6217ADA

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

Applicant Name:	Oregon Tilth (OTCO)
Physical Address:	2525 SE 3rd Street, Corvallis, OR 97333
Mailing Address:	2525 SE 3rd Street, Corvallis, OR 97333
Contact & Title:	Connie Karr, Certification Director
E-mail Address:	connie@tilth.org
Phone Number:	503-566-3022
Auditor(s):	Robert Yang, Accreditation Manager
Program:	USDA National Organic Program (NOP)
Review Date(s):	May 21, 2015
Audit Identifier:	AIA15030RK
Action Required:	None
Audit Type:	Corrective Action Audit
Audit Objective:	To evaluate the corrective actions submitted by the certifying agent in response to the non-compliance identified.
Audit Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit Scope:	OTCO's rebuttal and corrective action plans submitted on March 5 and May 11, 2015 in response to the Notice of Noncompliance issued on February 5, 2015
Location(s) Audited:	Desk

GENERAL INFORMATION

Oregon Tilth (OTCO) is a non-profit organization whose mission is to support and promote sustainable agriculture through education, research, advocacy, and certification. OTCO provides certification services for agricultural producers, product manufacturers, and other handlers of organic products. Initial accreditation by the NOP was granted on April 29, 2002 in the scopes of crops, wild crops, livestock, and handling. OTCO also maintains accreditation for the Global Organic Textile Standard (GOTS). OTCO certifies operations in the United States, Canada, Chile, China, Costa Rica, Guatemala, and Mexico.

BACKGROUND INFORMATION

On February 5, 2015, the United States Department of Agriculture (USDA), National Organic Program (NOP) issued a Notice of Noncompliance to OTCO.

FINDINGS

The findings below describe the NOP's issues of concern and identify the relevant section of the regulation for each issue. We also outline the certifying agent's response to these issues, which

describe how they will correct the problem and prevent it from recurring in the future. During the next on-site assessment, the NOP will review the corrective actions below to verify that the certifying agent has effectively addressed all concerns.

Non-Compliances – Certifier Response

The NOP has reviewed the corrective actions submitted by the certifying agent and determined the following:

AIA15030RK.NC1 – Withdrawn. 7 CFR § 205.642 states, “Charge applicants for certification and certified production and handling operations only those fees and charges for certification activities that it has filed with the Administrator.”

Comments: *The current billing process between OTCO, its production partners, and certified operations is not apparent to state departments of agriculture; the fees identified on the Organic Valley receipts are not detailed enough to determine if they are allowable for cost share reimbursement. As such, operations certified through OTCO who use production partners Organic Valley/CROPP Cooperative, may unknowingly submit erroneous cost share applications to state agencies. It is not clear if certified operations can claim the total amount charged to them by Organic Valley, as it is understood that an unidentified portion of the fees pay for Organic Valley’s administrative expenses, which are not identified on OTCO’s grower group member receipts. Furthermore, it appears that the Organic Valley receipts may include a cooperative membership fee, a charge that is ineligible for reimbursement under the Organic Certification Cost Share Program (OCCSP). Finally, Organic Valley is not an accredited certifying agent and may not collect fees for certification activities.*

Rebuttal: OTCO provided clarification that the fees and charges associated with its Production Partnership Program have been submitted to the Administrator annually as part of its update submission. OTCO additionally explained that they do not charge partner operations certified under the Partnership Program certification fees. OTCO only charges the primary operation certification fees, including all certification and inspection fees associated with the certification of its partner operation(s). OTCO provides only the primary operation with an invoice and receipt for payment of certification fees. OTCO stated that they were not aware of the manner in which Organic Valley was issuing statements to their partner operations since it is not part of their billing process.

AIA15030RK.NC2 – Accepted. 7 CFR § 205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provisions of §§ 205.402 through 205.406 and 205.670.”

Comments: *OTCO was allowing the sale of certified organic livestock, which were handled by an uncertified auction facility. The OFPA requires that agricultural products sold or labeled as organically produced must be produced only on certified farms and handled only through certified handling operations per 7 U.S. Code § 6501. The USDA organic regulations reiterate these requirements in 7 CFR 205.100 and [NOP 4009](#), which describe “What has to be certified.”*

Corrective Action: OTCO certified the livestock auction facility on February 3, 2015. On January 28, 2015 OTCO notified its certification staff, inspectors, certified organic livestock and

Page 3

slaughter operations that effective immediately organic animals must be purchased/sold via certified organic auction yards. OTCO updated the Livestock Origin Mammalian and Livestock Product Marketing and Sales sections of its livestock organic system plan to include questions for verifying whether the operation is purchasing/selling animals at certified organic auction yards. OTCO submitted copies of the auction facility's organic certificate; the notification sent to staff and its certified operations; and the updated livestock organic system plan.

OTCO Noncompliance Chronology Log

Audit Identifier (if any): AIA14273RK

Audit Type:

Accredited Certifying Agent Name: Oregon Tilth (OTCO)

Accreditation Manager: Renée Gebault King (RGK); Robert Yang

Date	Activity
9/29/14	RGK received notice to prepare an NC Report to OTCO because it appears they are collecting inspection/certification fees from Organic Valley (OV) instead of directly from the individual farmers they certify. This has become an issue because farmers do not have receipts when they apply for cost-share funding showing they have paid OTCO for organic certification services.
9/30/14	<p>RGK spoke with Connie Karr at OTCO and asked for explanation of the Production Partnership agreement.</p> <ul style="list-style-type: none"> • The “Production Partnership” is explained in OTCO’s 2014 fee structure. Fee scales are based on total sales. • There is a flat partner fee (\$750 base fee + \$100 livestock fee = \$850) for each producer member under this structure with a company (in this case, Organic Valley) • OV collects partner fees from individual farmers and pays them to OTCO in one lump sum. Each partner must submit an OSP and other requisite documents; OTCO conducts certification activities and issues each farmer with their own organic certificate. • OTCO sends invoices to OV showing the fees have been paid and invoices reflect individual farmer/operation names. <i>SEE attached example invoices.</i>
10/1/14	<p>RGK spoke with Beth Unger at OV and asked for details on their partnership agreement with farmers.</p> <ul style="list-style-type: none"> • OV conducts “pass through” billing; each partner pays the fees: \$850 + \$700 inspection fees + \$100 admin. fees = \$1650 total fees per partner • OV pays OTCO on behalf of the farmers in a lump sum • OV issues invoices for each individual farmer partner. <i>SEE attached example invoices.</i>
10/2/14	RGK received invoices from E. O’Donnell at OTCO showing billing process for Wells, Inc. and California Cloverleaf Farms (OV clients) showing charges for inspection and OV administrative fees.
11/13/14	Meeting with D. Stahl, RGK, MM, and CC to discuss the issue. D. Stahl will draft a letter regarding this issue to OTCO and submit draft for approval by AIA.
11/19/14	D. Stahl shared draft letter with RM, RGK, CC, MM, J Tucker for input.
12/18/14	A similar issue with OTCO production partnerships was raised with MCIA (via K.

	<p>Nelson): “Minnesota has outlined a case very similar to Iowa’s regarding OTCO and Organic Valleys’ use of Production Partnerships. See email and attachment for additional details</p> <ol style="list-style-type: none"> 1. AIA should include this incident in the NOP-AIA non-compliance letter to OTCO. 2. Dana will respond to the MN inquiry by stating they should reimburse the producers for the legitimate receipts they submitted under the cost share program.” <p>Response from CC: “Thank you Kristen, we will look at adding this to the NC.” Response from MM: “Reimbursement must be based on eligible fees paid to OTCO.”</p> <p>Add this issue to the draft NoNC letter for OTCO.</p>
01/12/15	RGK finalized draft NoNC letter for OTCO and submitted electronically to RM for review.
01/15/15	RGK received edits and updated letter.
01/27/15	RGK edited letter further per RM comments.
01/30/15	RGK met with M. Michael to discuss auction barn issues. RGK edited letter and submitted to RM for approval; RM approved draft letter. RGK sent to CC electronically for further review.
02/03/15	RGK reviewed letter with CC and prepared letter for submission to MM.
02/04/15	RGK further edited letter and submitted file to CC for approval.
3/5/15	NOP received OTCO response
4/30/15	Response review reassigned from RGK to RY
5/4/15	<p>RY reviewed response.</p> <ul style="list-style-type: none"> • OTCO (Connie) submitted a rebuttal for NC1 – stated in response letter that at ACA training and from follow-up emails on 2/18, 2/19 RGK had indicated that NC1 would be revised • OTCO stated that they are compliant with the citation in the NC (205.642) because they have filed the fees and charges associated with the Production Partnership Program with the Administrator, and have been charging according to those fees.
5/5/15	<p>RY emailed RGK requesting clarification of revision referred to in OTCO’s response letter.</p> <p>RGK responded that Connie had asked that we revise the NoNC because it was confusing; her initial interpretation was that the NC was referring to the fees OTCO was charging; was actually for their billing process whereby a third party (Organic Valley) was collecting fees on behalf of the certifier.</p>
5/7/15	RY discussed with Renee M OTCO’s rebuttal -- discussed option of accepting rebuttal due to the fact that the NC citation refers to only charging fees that have been filed with the Administrator, and reissuing NC based on original issue of not billing directly
5/11/18	RY requested from OTCO via email objective evidence for all corrective actions in

	<p>response to NC2. Connie submitted:</p> <ul style="list-style-type: none"> • Lebanon Auction Yard Certificate • Copy of the notification sent to all livestock producers and slaughter facilities • Updated Livestock OSP module (L8 and L2M) • Copy of email to inspectors informing them
5/13/15	RY drafted CA Rpt, NoNC Res
5/18/15	<p>RY discussed draft report w/ Renee M Decided to follow up with OTCO to verify.</p> <p>RY spoke with Connie via phone to confirm:</p> <ol style="list-style-type: none"> 1. How does OTCO charge each partner operation? <i>OTCO does not charge the partner operation certification fees; the primary is charged the fees associated with the certification of the partner operation.</i> 2. How does OV invoice its partner operation fees? <i>OTCO was not aware of how OV invoices the operation since they do not ask them to collect fees on their behalf. Connie was surprised to hear that OV issued a Production Partnership Statement stating “2014 Organic Certification Renewal Fees paid in full - \$1,650. Thank you for this payment” She agreed that it appears as if OV is issuing a statement for payment of certification fees, that if this was passed on to state agencies for cost share reimbursement it would be confusing. Clarified that if they received inquiry from state would inform them that the operation has not paid any certification fees (feels that the operation is not eligible for cost share in that respect)</i> 3. How does the partner operation pay its certification fees? <i>According to OTCO the partner operation is not paying certification fees; the primary is paying the partner operation’s certification fees.</i> 4. How and when does OV pay the fees? (lump sum) <i>OV may pay per invoice or lump sum referencing multiple invoice numbers.</i> 5. How does the partner operation receive a receipt for payment of fees? <i>Only the primary receives a receipt since they are the one charged/ paying. Will send receipt if OV asks for it. Doesn’t ask for all the receipts for cost share purposes since it would exceed OV’s cost share reimbursement amount.</i>
5/21/15	<p>RY, CC, RGK, MM met to discuss rebuttal and additional information received from OTCO regarding their fees billing/receiving process. Determined that OTCO’s rebuttal is accepted; that OTCO and OV need to work together to resolve the underlying issue that the partner operations will not be eligible for cost share if they are not receiving an invoice for the fees that are being paid for their certification.</p>

	Agreed that RGK will set up conference call with OV and OTCO to further discuss the need for the two to work together to resolve the cost share issue for their clients. RY revised CA Report, NoNCRes; submitted to CC for review.
05/22/15	Rcvd signed doc back from CC. JH emailed out to OTCO and closed in WTL.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Pennsylvania Certified Organic (PCO). An onsite audit was conducted, and the audit report reviewed to determine PCO's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Pennsylvania Certified Organic (PCO)
Physical Address	106 School Street, Suite 20, Spring Mills, PA 16875-8118
Mailing Address	Same
Contact & Title	Leslie Zuck, Executive Director
E-mail Address	leslie@paorganic.org
Phone Number	(814) 422-0251
Reviewer & Auditor	Janna Howley, NOP Reviewer Rick Skinner, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: December 30, 2014 Onsite audit: July 22-25, 2014
Audit Identifier	NP4203EEA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of PCO's certification.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	PCO's certification services in carrying out the audit criteria during the period: April 2012 through July 2014.

Pennsylvania Certified Organic (PCO) is an organic, non-profit, membership certification program that is owned by members of the organization. The membership structure has three levels: Business, Associate, and Certified Operations; however, membership is not a pre-requisite to certification.

PCO has been accredited as a certifying agent since April 29, 2002, to the National Organic Program (NOP) for the scopes of crop, wild crop, livestock, and handling. Currently, PCO has 586 clients certified to the NOP that includes 463 crop, 6 wild crop, 297 livestock, and 145 handling operations, including 131 processors and 14 distributors. Most certified operations are located within the State of Pennsylvania; however, the geographic scope of certification includes, Delaware, Maryland, New Jersey, New York, North Carolina, Ohio, Virginia, West Virginia, and the District of Columbia. PCO does not have any other accreditations at this time.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether PCO corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to PCO.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP213000A.NC1 – Rebutted and accepted.

NP213000A.NC2 – Cleared – 7 CFR §205.642 states, “The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification.”

2012 Comments: *A review of 10 certification files indicated that an estimate for total cost of certification was not being provided to applicants or clients. This was further substantiated by interviews with PCO personnel who indicated that cost estimates are not being provided to applicants or clients.*

2012 Corrective Action: PCO submitted new procedures for providing cost estimates to new and renewing applicants. The Office Manager shall develop templates for cost estimates, and the new procedure will be implemented starting November 1, 2012. PCO will conduct an internal training session for PCO staff prior to implementation of the new procedures.

2014 Verification of Corrective Action: PCO created new templates and new procedures for providing cost estimates. Training was conducted prior to the implementation of the new procedure and template. Cost estimates are being provided to applicants and clients.

Noncompliances Identified during the Current Assessment

None.

Audit Resolution Chronology Log

Audit Identifier (if any): NP4203EEA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: Pennsylvania Certified Organic
Accreditation Manager (who is working on the project): Janna Howley

Date	Activity
11/06/14	Audit documents sent to 01 Reports Folder. Assigned to RGK.
12/22/14	NC report reassigned to JH. Updated in WTL.
12/30/14	JH reviewed audit report. No NCs identified during the audit; one previous NC CAs verified, one NC rebutted and accepted. Drafted NoCont Accred and NC Report.
12/31/14	<ul style="list-style-type: none"> • Emailed docs to RM for review. • Rcvd feedback: (b) (5)
01/05/15	JH reviewed report; emailed LC for guidance on whether it should be a NC.
01/07/15	Rcvd response from LC. JH updated CA report. Also edited audit report to list the narrative comment in the "Observations" section of the checklist. Emailed Rick Skinner.
01/08/15	Approval from RM to print for MM signature. JH submitted additional questions to RM regarding report.
01/20/15	RM signed off on report; hard copy to CC for MM signature.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a compliance assessment of Primus Labs (PL) in accordance with the terms in PL's notice of deferred accreditation dated February 8, 2017. An onsite audit was conducted, and the audit report reviewed to determine ETKO's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Primus Labs (PL)
Physical Address	1259 Furukawa Way, Santa Maria, CA 93458
Mailing Address	1259 Furukawa Way, Santa Maria, CA 93458
Contact & Title	Josie Quevedo, Audit Coordinator
E-mail Address	josie.quevedo@primusauditingops.com
Phone Number	805-922-0055
Reviewer & Auditor	Rebecca Claypool NOP Reviewer; Jason Lopez, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: August 17, 2017 Onsite audit: May 8-11, 2017
Audit Identifier	NP7128JZA
Action Required	Yes
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of PL's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	PL's certification services in carrying out the audit criteria during the period: February 2017 through May 2017

The National Organic Program (NOP) conducted an accreditation compliance audit of Primus Labs (PL) on May 8-11, 2017.

PL was accredited on April 29, 2002 to the USDA National Organic Program (NOP) for crops and handling. The PL Organic Certification Program certifies 278 operations to the following certification scopes: crops (153), and handlers (152). PL's office is located in Santa Maria, California and provides certification services in Arizona, California, Florida, Georgia, Massachusetts, Missouri, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, Wisconsin, Coata Rica, El Salvador, Guatamala, Honduras, and Mexico.

Certification services are performed by the program director, six organic certification specialists, administrative personnel and inspectors. PL inspectors are staff and contracted.

Auditors conducted two witness audits; one in Florida and the other in California. Witness audits were conducted on a crops and a handling operation. The crops operation produces assorted vegetables. The handling operation stores and processes grains.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether PL's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to PL.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP0215EEA.NC2 – Cleared - 7 CFR §205.501(a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: (11) Prevent conflicts of interest by: (v) Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.”

Comments: *Records showed that of the 16 Primus Labs and contract employees, none had a current Conflict of Interest on file. One record was from 2008, and the balance is from 2007 or earlier. Two of the inspectors listed in the inspector pool had actually performed audits and did not have a Conflict of Interest or Declaration of Confidentiality of any date.*

2011 Corrective Action: PL updated their system to require annual submission by all personnel of a Confidentiality, Independence and Disclosure Statement (Cert-006). For 2011, these forms were completed by March 31, 2011. Copies of completed forms were provided for review.

2013 Verification of Corrective Action: The conflict of interest document as completed by staff personnel does not clearly convey conflicts of interest. One inspector did not list a conflict of interest on the disclosure statement as identified during staff interviews with the auditor, and one inspector listed a conflict of interest but checked a separate box stating there were no conflicts identified.

2014 Corrective Action: Primus Labs created an updated conflict of interest document, *NOP-001 Confidentiality, Independence and Disclosure Statement*. This document was sent to all staff and contractors in May 2014 and will now be completed annually by all staff and contractors. *Primus Labs Quality Manual, “Chapter 3 – Accreditation”* also includes the requirement for the completion of the *NOP-001 Confidentiality, Independence and Disclosure Statement*. Copies of all documents were provided to the NOP.

2016 Verification of Corrective Action: Primus Labs continues to utilize a combined conflict of interest and confidentiality agreement for certification personnel. The auditor identified 20 annual conflict of interest disclosure records that were more than one year out of date.

2016 Corrective Action: PL provided evidence that staff submitted confidentiality and conflict of interest (COI) declarations for 2016. PL will use annual calendar reminders to staff to submit timely COI declarations. PL's new policy is to inactivate personnel who fail to submit the required annual COI by the required deadline.

2017 Verification of Corrective Actions: Auditor reviewed completed conflict of interest (COI) and confidentiality agreement (CA) documents and found them to be complete and current. PL has added an update reminder to the staff and scheme manager's calendar for December 1st of each year. On this date, the COI and CA forms are emailed to all certification staff, requesting the completed form be returned through the electric DocuSign program. This process was used to obtain all 2016 COI and CA's.

NP0215EEA.NC3 – Cleared – 7 CFR §205.662I states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.... The notification of proposed suspension or revocation of certification shall state: (1) The reasons for the proposed suspension or revocation; (2) The proposed effective date of such suspension or revocation; (3) The impact of a suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.”

Comments: *The standard noncompliance letter being sent to the client states, “The finding of points of noncompliance requires written corrective action in order to continue to maintain organic certification. A lack of response to points of any issued noncompliance point may suggest that you are unable to provide written corrective actions or no longer wish to maintain/obtain organic certification at this time. As a function of this notification if corrective responses are not received within 30 days of your inspection you may file a request for mediation with PrimuLabs.com per 205.663 of the 7 CFR-NOP page 57 of the NOP. If a response is not received in 30 days Primus will be required to suspend your certification.” This procedure is not in accordance to §205.662.*

2011 Corrective Action: Template letters for Notices of Noncompliance, Notices of Noncompliance Resolution, Notices of Proposed Suspension / Revocation, and Notices of Suspension / Revocation were provided as updates to the PL system; all letters were found to be in compliance with §205.662 requirements.

2013 Verification of Corrective Action: The former noncompliant Primus Labs Notice of Noncompliance, that implied a suspension was to occur within 30 days if a response was not received, was recently used for multiple issuances.

2014 Corrective Action: All letters are now issued only by the Audit Coordinator. The outdated templates have been removed from the computer system; the Audit Coordinator provided signed documentation that this practice was completed. Examples of the current templates for sending Notice of Noncompliance letters from the Quality Manual document, *SOP Non Compliance and Adverse Actions*, were provided to the NOP. Several Primus Labs personnel, including the Audit

Coordinator, attended the February 2014 Professional Development Training for Organic Certification Agencies in San Diego. In addition, the Primus Labs Scheme Manager attended the March 2014 NOP training in Costa Rica. As a result, all staff members who deal with the management of Primus Labs organic certification became much better versed on NOP policies and procedures. Confirmation of attendance was provided to the NOP.

2016 Verification of Corrective Action: The auditors reviewed one notice of proposed suspension issued by PL and determined that the notice complied with the USDA organic regulations. No additional notices of proposed suspension or revocation were identified in additional files reviews. However, the auditor identified one notice of noncompliance (based on an older version of the notice template) that did not specify a deadline for response or inform the operation of response options (i.e. rebuttal or submission of corrective actions).

2016 Corrective Action: PL's current template for proposed suspension complies with the USDA organic regulations. To ensure consistency across staff, PL notified staff of the current, correct templates available via the PL server and staff were directed to delete any old template versions. PL provided evidence of this communication to staff.

2017 Verification of Corrective Actions: Primus has designated one staff member to maintain all document templates in the quality control system. This staff member maintains all template versions and provides the communication of new versions to employees. Current forms are maintained on PL's shared drive. The auditor interviewed staff to confirm the process and objective of the document quality control system, and there were no concerns.

NP3259JHA.NC2 – Cleared - 7 CFR §205.404(b)(3) states, “The certifying agent must issue a certificate of organic operation which specifies the: Categories of organic operation, including crops... or processed products produced by the certified operation...”

Comments: *Two operations certified for both Crops and Handling were issued certificates listing the organic scope as Handling/Field.*

2014 Corrective Action: Certificates will now be issued only by the Audit Coordinator. Outdated templates were removed from the computer files and only compliant templates are being used. The Audit Coordinator provided signed documentation that this practice was completed. Current certificate templates and the signed statement were provided to the NOP. Several Primus Labs personnel, including the Audit Coordinator, attended the February 2014 Professional Development Training for Organic Certification Agencies in San Diego. As a result, all staff members who deal with the management of Primus Labs organic certification became much better versed on NOP policies and procedures related to the requirements for certificates. Confirmation of attendance was provided to the NOP.

2016 Verification of Corrective Action: The auditors' review of organic certificates confirmed that the certification categories of Crops and Handling are correctly displayed. The auditors did identify that organic certificates issued to grower groups specify “Grower Group” as the category of organic certification, but “Grower Group” is not a certification category or scope under the USDA organic regulations.

2016 Corrective Action: PL updated the organic certificate template and associated work instruction to specify that certification scope options are limited to crops and/or handlers. The work instruction allows for additional modifications, such as listing a grower group as a

subordinate detail within the crop scope. PL provided verification that staff received training on the updated template and work instruction.

2017 Verification of Corrective Actions: Organic certificates reviewed by the auditor correctly identified certification scopes. Auditor interviews with staff confirmed they understood Primus is accredited to certify the crops and handling/processing organic scopes. The staff were notified and trained on the Primus work instruction covering this subject. The auditor reviewed revised organic certificate template available to the staff and the work instruction and both are clear and complete.

NP5152EEA.NC1 – Cleared - 7 CFR §205.501(a)(21) “A private or governmental entity accredited as a certifying agent under this subpart must... Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOSB Recommendation 2002, Criteria for Certification of Grower Groups and Recommendation 2008, Certification of Operations with Multiple Production Units, Sites and Facilities under the NOP states, “...participation in the group is limited to producers who sell all of their organic production through the group. Recommendation 2008 states, “...While it is the [certifier’s] role to inspect at the level of the production units, sites and facilities, and ensure that the Internal Control System (ICS) is functioning properly, the ICS peers deeper into the units, production sites and facilities. For the person seeking organic certification to be in compliance with the NOP, all non-compliances detected at the production unit, site or facility or at the sub-unit or member level are required to be reported to the certifier (not just ICS) as per §205.400(f). Additionally, Section I of Recommendation 2008 states, “...the ICS must include the application of sanctions to those members who do not comply with the organizations OSP, the OFPA or the NOP Regulations. It must inform the [certifier] of the irregularities and minor non-compliances found. It must communicate back to the source the minor non-compliance, and the corrective actions imposed with an agreed upon time for completion.”

Comments: An interview with the principal at PL’s Costa Rica office indicated that it does not require the ICS to submit NCs issued to members of the grower group unless it is a violation that would jeopardize the certification of the members of the group. This is contrary to the NOSB recommendation.

2015 Corrective Action: PL Costa Rica revised the Community Grower Group Inspection Report to include procedures of reporting noncompliances to the certifier discovered by the ICS. The new procedure requires a list of growers to be submitted who received a noncompliance(s) at least once a year as part of the annual renewal of the management plan, before the on-site inspection is conducted. In addition, the ICS will file all communications of exclusion, suspension and corrective actions sent to its members and communications with PL Costa Rica regarding major noncompliances that jeopardize the organic integrity of the product. PL Costa Rica sent notification to all clients and inspectors to inform them of these changes. New copies of the addendum were distributed on October 8, 2015, and older versions will become obsolete as per the implemented date to prevent this from occurring in the future.

2016 Verification of Corrective Action: PL could not provide the auditors with records that indicate grower groups are reporting internal irregularities, noncompliances, corrective actions, and/or sanctions to PL.

2016 Corrective Action: PL provided verification that all grower groups were reminded via e-mail (October 2015 and July 2016) that they must submit a list of growers who received

noncompliances at least annually as part of their certification renewal process. PL provided verification that grower group clients responded with operator lists and information about any group member noncompliances per PL's request.

2017 Verification of Corrective Actions: The auditor verified Primus certified grower groups have begun to comply with this requirement on a yearly interval by submitting lists of ICS issued notices. The information submission is verified by the Primus reviewer of the annual update and included on the reviewer's checklist.

NP5152EEA.NC3 – Cleared - 7 CFR §205.501(a)(15)(i) “A private or governmental entity accredited as a certifying agent under this subpart must submit to the Administrator a copy of any notice of denial of certification issued pursuant to §205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance.”

Comments: A copy of the Notice of Noncompliance identified in Noncompliance NP5152EEA.NC2 was not submitted to the NOP.

2015 Corrective Action: PL Costa Rica explained that since all noncompliances were identified as minor, Audit Administration understood that the NOP did not have to be copied in notifications. The notice should have been titled as Certification Resolution, notifying the client that certification was granted with minor conditions. Using the template of a Notice of Noncompliance was a mistake in the case of NP5152EEA.NC2. PL Costa Rica reminded its reviewers that as they draft the certification decision letter, they need to propose which specific Notice template should be used. This topic was covered in the Reviewers' refresher training on October 7th, 2015. A reviewer coordinator has been appointed to be the contact person for all reviewers. All draft decisions will be passed to the reviewer coordinator prior to final submission to the certification decision maker. The reviewer coordinator will make sure that all draft decisions include the selection of the appropriate type of notice being issued. This provides a two-level control and offers an opportunity for homogeneity of decisions. PL Costa Rica's Audit Administration re-reviewed the Noncompliance and Adverse Action SOP including all template letters. Audit Administration participated in a 16 hour training in August 2015 that included 8 hours of certification process and the Primus Labs Quality Manual. The training attendance list was submitted to NOP.

2016 Verification of Corrective Action: The auditor reviewed six notices of noncompliance issued after October 2015 and found that four were not submitted to the USDA NOP as required.

2016 Corrective Action: PL's work instructions specify that notices of noncompliance, depending upon the operation's location, be submitted to the NOP or California Department of Food and Agriculture (CDFA), respectively. PL provided evidence that recent notices of noncompliance issued to operations were submitted to the NOP or CDFA as required.

2017 Verification of Corrective Actions: The auditor verified the Primus work instruction correctly states notices of noncompliance and adverse action notices are to be submitted to the NOP or California Department of Food and Agriculture (CDFA), as appropriate. The auditor verified notices have continued to be correctly submitted to the NOP or CDFA. These notices were submitted via email using the DocuSign program for documented delivery and receipt. Interviews with staff confirmed their understanding of this requirement.

NP6025PZA.NC1 – Cleared - 7 CFR §205.403(d) states, “The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.”

Comments: *During a witness audit of a handling operation, the inspector did not conduct an exit interview despite completing the certifier’s form indicating that an exit interview was conducted. The form was signed by both the inspector and the operation at the conclusion of the inspection, but without any verbal description or summary of the inspection provided by the inspector.*

2016 Corrective Action: PL provided verification that inspection staff was provided with the updated procedure (SOP 22-01) for conducting inspections. The updated procedure explicitly states that inspectors are required to conduct opening and closing meetings as part of all onsite inspections.

2017 Verification of Corrective Actions: The auditor witnessed inspection staff conduct proper opening and exit meetings during a witness audit. The auditor reviewed PL’s inspection instruction (SOP 22-01) and verified the inspector’s knowledge of this procedure in an interview.

NP6025PZA.NC2 – Cleared - 7 CFR §205.403(c)(1-3) states, “The on-site inspection of an operation must verify: (1) The operation's compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples.”

Comments: *During the witness audit of a handling operation, the inspector did not verify the organic system plan (OSP), including inputs, sanitation practices and processing aids, with the onsite processes of the operation.*

2016 Corrective Action: PL provided verification that inspection staff were provided with the updated procedure (SOP 22-01) for conducting inspections. The updated procedure explicitly states that inspectors are required to verify the organic system plan, including sanitation practices, processing aids, and inputs as part of the onsite inspection process.

2017 Verification of Corrective Actions: The auditor witnessed the PL’s inspector verify the operations OSP during a witness audit. The inspector reviewed the entire OSP with the operation representative and made updates as the inspection progressed.

NP6025PZA.NC3 – Cleared - 7 CFR §205.501(a)(6) states, “Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services...” Furthermore, in accordance with NOP 2027 *Personnel*

Performance Evaluations, section 3.2(b) states, “Inspectors should be evaluated during an onsite inspection by a supervisor or peer (another inspector) at least annually. This field evaluation should be conducted at the certifying agent’s expense.”

Comments: *The auditor reviewed seven personnel files and found that annual performance evaluations were not conducted for one staff member and four contract inspectors. Two of these four contract inspectors also did not receive annual field evaluations.*

2016 Corrective Action: PL incorporated a tracking system on the internal activities calendar to track due dates for staff performance (including field) evaluations. PL also updated their inspection report review form (ORG-008) to include a section where the inspector is evaluated for every report they submit; report feedback is provided quarterly. PL’s policy requires annual performance evaluations be completed by November annually. PL implemented their field evaluation plan in August 2016 and provided verification that one field evaluation had been conducted as of December 2016. The remaining field evaluations are scheduled for completion in the first quarter of 2017.

2017 Verification of Corrective Actions: The auditor confirmed all employees received an annual performance evaluation. Inspectors were all additionally evaluated in the field. The program manager and a staff member have calendar reminders set for January to annually schedule field evaluations of inspectors.

NP6025PZA.NC4 – Cleared - 7 CFR §205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator. The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification. The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant’s fees-for-service account. The certifying agent may set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator. The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable....”

Comments: *The auditor’s review of the certifier’s fee estimate stated that a “cancellation fee” would be applied in the event of a cancellation. The current fee schedule has no listed “cancellation fee” or description of the conditions under which it would be applied.*

2016 Corrective Action: PL updated their fee schedule to include a cancellation fee and description of conditions under which this would apply. PL provided verification that the updated fee schedule was presented to the USDA NOP. PL’s revised work instructions specify that in the event of changes to the fee schedule, the USDA NOP shall be notified and receive the updated schedule.

2017 Verification of Corrective Actions: The NOP approved fee schedule are the fees applied by PL when billing certified operations. The cancellation fee has been defined and to date has not been applied to an operation. Interview with staff confirmed their understanding of the fee schedule and familiarity of the fee schedule work instruction.

NP6025PZA.NC5 – Cleared - 7 CFR §205.404(c) states, “Once certified, a production or

handling operation's organic certification continues in effect until surrendered by the organic operation or suspended or revoked by the certifying agent, the State organic program's governing State official, or the Administrator.”

Comments: *The auditors review of an operation file revealed a “letter of good standing” that states the organic certificate would only remain current for an additional three months past the date of the letter or until another certificate was issued. PL staff explained to the auditor that the letter is only provided at the operation’s request and only after the operation has submitted the annual update per the anniversary date on the certificate. The “letter of good standing” implies the operation’s organic certification is discontinued in a manner other than surrender, suspension or revocation.*

2016 Corrective Action: PL updated the “letter of good standing” template to clarify that the operation is currently undergoing annual review (renewal) and that the operation’s certification is valid unless surrendered, suspended or revoked. PL provided documentation that staff were informed of this change and were instructed to use the new template as appropriate.

2017 Verification of Corrective Actions: The auditor reviewed “Letter of Good Standing” letters and confirmed the letter was issued correctly and the staff understood the proper use of the letter. The staff were reminded of the template at the annual calibration training in April 2017.

NP6025PZA.NC6 – Cleared - 7 CFR §205.501(c)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.” Furthermore, in accordance with instruction NOP 2610 *Sampling Procedures for Residue Testing*, section 4.1 describes the variety of conditions under which inspectors should be prepared to collect samples.

Comments: *During the witness audit, the inspector was not prepared to collect samples if warranted during the inspection nor did he have sample collection equipment in the vehicle.*

2016 Corrective Action: PL developed a procedure (SOP 22-27) for unannounced sampling of a minimum of 5% of PL’s certified operations; the policy also requires inspectors to be prepared with gloves and bags to collect samples at any time. PL provided documentation that inspectors were notified of this procedural update via e-mail. PL’s procedures require that, prior to conducting an inspection, the quality manager talk with the inspector to review the inspection plan and any sampling requirements, including being prepared with the necessary equipment should a sample collection be deemed necessary.

2017 Verification of Corrective Actions: The auditor confirmed the witness audit inspector was prepared to take a sample. An interview with the inspector confirmed the inspectors understanding of taking a sample and the PL’s sampling procedures. This subject was included in the April 2017 calibration training.

NP6025PZA.NC7 – Cleared - 7 CFR §205.500(a) states, “The Administrator shall accredit a qualified domestic or foreign applicant in the areas of crops, livestock, wild crops, or handling or any combination thereof to certify a domestic or foreign production or handling operation as a certified operation.”

Comments: *The certifier granted a wild crop harvest scope certification. The certifier’s current*

accreditation is for the crop and handling scopes only.

2016 Corrective Action: PL no longer has this client because they surrendered their certification. PL has not certified any other operations as “wild crop.”

2017 Verification of Corrective Actions: The auditor’s interviews with staff verified Primus only granted Crops and Handling organic certifications. The auditor additionally confirmed this information in the Organic INTEGRITY Database. PL has only granted certification in the scopes of Crops and Handling.

NP6025PZA.NC8 – Cleared - 7 CFR §205.660(d) states, “Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.”

Comments: *The auditor reviewed six notices of noncompliance sent via email but none were sent via a service that provided dated return receipts. The certifier does not use a delivery service that provides dated return receipts for notices delivered electronically.*

2016 Corrective Action: PL provided verification that they have implemented an e-mail delivery confirmation system that confirms when e-mails are delivered, opened or returned as undeliverable.

2017 Verification of Corrective Actions: The auditor confirmed PL is sending all notices via the DocuSign service. This service confirms delivery and the opening of sent e-mails. In the event an e-mail is not delivered or opened, PL will print and send the letter via certified mail to the operation’s address. Auditor interviews with staff verified their understanding of the process and necessary records.

NP6025PZA.NC9 – Outstanding - 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.”

Comments: *During file reviews, the auditor found an operation that was providing attestation statements for organic product shipped to Canada under the U.S.-Canada organic equivalency arrangement. However, PL staff told the auditors that no operations conduct international export or import activities. The PL OSP templates do not ask applicants to describe any international activities, nor do inspection report templates instruct the inspectors to verify international activity during inspections. Additionally, PL does not have procedures for inspectors or reviewers to verify that operations comply with the requirements of USDA NOP international arrangements.*

2016 Corrective Action: PL developed a procedure that requires an addendum be sent to all new or renewing clients; the addendum includes questions on international trade activities (import/export). The new procedure also requires the inspector to verify the answers on the addendum at the onsite inspection. For the U.S.-Canada equivalency arrangement, clients who comply with the requirements will have the attestation statement included on their organic certificate. In addition, clients will be given a self-attestation document to complete and issue with each shipment of product. PL also developed a work instruction describing compliant

language for the attestation statement. PL verified that training for the certification staff members was conducted in July 2016 on the requirements for product traded under the U.S.-Canada Equivalency Arrangement.

2017 Verification of Corrective Actions: The auditor verified that the international trade activities addendum is utilized. The addendum does not cover all of the international arrangements and does not indicate other arrangements may apply. The inspector's checklist does not require the inspector to verify any other arrangements except the US-Canada and the US-EU equivalency. This corrective action does not completely address the noncompliance in that PL does not have procedures to verify compliance with all of the USDA international arrangements.

NP6025PZA.NC10 – Cleared - 7 CFR §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662.”

Comments: *The auditor reviewed a grower group file and noted that the onsite inspection identified eight findings (nonconformities), but no noncompliances were issued to the operation by the certifier even though the eight findings (nonconformities) merited a notice of noncompliance.*

2016 Corrective Action: PL provided documentation that staff were reminded via e-mail that they may not accept corrective actions from the operation.

2017 Verification of Corrective Action: Primus issued a reminder to staff and inspectors clarifying that all identified findings during an inspection must be recorded and forwarded to the certifier for review. The acceptance of corrective actions prior to the completion of the inspection is not acceptable. A review of grower group inspection reports show no evidence of corrective actions being accepted prior to the end of the inspection.

NP6025PZA.NC11 – Cleared - 7 CFR §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector.”

Comments: *The auditor reviewed five files with sampling events and noted that none of the five operations received receipt for the samples collected by PL staff.*

2016 Corrective Action: PL created a procedure for sampling (SOP 22-27) that requires the audit coordinator to provide PL's inspectors with NOP 2610 “Sampling Procedures for Residue Testing” prior to sampling, which includes the requirement that the certified operation shall receive documentation (i.e. a receipt) when a sample is collected for analysis. PL provided verification that staff were informed via e-mail of the new procedure and that training for the audit coordinators was conducted.

2017 Verification of Corrective Actions: PL implemented the sampling procedure and document in 2016 and used the sample receipt for samples taken in 2016. The auditor verified the receipts were left with the operation and were properly completed. PL has not conducted

sampling in 2017 to date. Additional training on the sampling procedure was conducted in April 2017 at the annual PL calibration training.

NP6025PZA.NC12 – Cleared - 7 CFR §205.403(e)(2) states, “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.”

Comments: *The auditor reviewed five files with sampling events and noted that PL could not confirm that the test results were provided to four of the five operations.*

2016 Corrective Action: PL created a procedure for sampling (SOP 22-27) that requires the quality assurance staff to follow NOP 2613 Responding to Results from Pesticide Residue Testing, which includes the requirement that the operation shall be informed of the analytical results. PL provided verification that staff were informed via e-mail of the new procedure and that training for the quality assurance staff was conducted. PL also provided an example e-mail notifying one of their operations of the analytical results.

2017 Verification of Corrective Actions: The auditor verified that 2016 sampling results were provided to the operations via email and confirmed delivery of the information via the DocuSign service. PL’s sampling procedure (SOP 22-27) states results will be emailed to the operations via DocuSign. Interviews with staff confirmed their understanding of this procedure.

NP6025PZA.NC13 – Cleared - 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” Furthermore, the instruction NOP 2025 “*Internal Program Review*” states, “Internal program reviews are conducted by personnel different from those who perform certification activities.”

Comments: *The internal audit of PL completed in December 2015 was conducted by a PL employee who also performs certification activities, which is noncompliant per the instruction in NOP 2025.*

2016 Corrective Action: PL revised their internal procedure (22-03) to clarify that staff involved in USDA certification activities are prohibited from also conducting the PL internal audit for USDA compliance.

2017 Verification of Corrective Actions: The 2016 annual review was conducted by an independent consultant. Interviews with the management verified their understanding of the annual reviewer requirements and restrictions and the NOP 2025 “*Internal Program Review*”.

NP6025PZA.NC14 – Outstanding - 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” The instruction NOP 2609 *Unannounced Inspections*, section 4.1.8 states “... if a visit of the operation is to be considered as both an instance of sample collection and an unannounced inspection, the inspector must review some aspects of the operation besides collecting a sample.”

Comments: *The certifier reported having conducted unannounced inspections in 2015, but the auditors determined that the number of unannounced inspections reported was only for the collection of samples. The auditors clarified the minimum requirements for unannounced inspections as described in NOP 2609.*

2016 Corrective Action: PL developed two new procedures (22-26 and 22-27) requiring unannounced inspections and unannounced sampling of a minimum of 5% of PL's USDA certified operations. PL provided verification that staff were informed via e-mail of the new procedures.

2017 Verification of Corrective Actions: PL did not conduct unannounced inspections of 5% of their certified operations in 2016.

NP6025PZA.NC15 – Cleared - 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” The instruction NOP 2603 *Organic Certificates*, section 3.1.5 states “Anniversary date (when the certified operation must submit its annual update). Organic certificates cannot include expiration dates...”

Comments: *PL defines the anniversary date as the deadline when the operation must complete its annual certification renewal process, including the inspection and certification decision from PL. The USDA, however, defines the anniversary date as the date by which the operation must submit the annual update.*

2016 Corrective Action: PL now defines the anniversary date in accordance with the USDA organic regulations (i.e., when the annual update is due). PL created a work instruction that explains the “anniversary date” as the date when the operation must submit its annual renewal. PL provided verification that training was conducted on the work instruction.

2017 Verification of Corrective Actions: Primus has implemented the NOP definition of “anniversary date” in the renewal process. The auditor reviewed an operation in the renewal process to confirm the correct application of the requirement by Primus staff. Primus informed staff of this change via email, April 2017.

NP6025PZA.NC16 – Cleared - 7 CFR §205.501(a)(11)(iv) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification.”

Comments: *The auditors' file review found that PL issues noncompliance(s) that include corrective actions for the operation to implement.*

2016 Corrective Action: PL conducted training for staff about how to complete the inspection review report (ORG-008) and prepare noncompliances or other correspondence without providing consulting services to the operation. PL provided an example of an inspection report review and a notice of noncompliance issued to an operation to verify that PL staff do not provide consulting in their client communications.

2017 Verification of Corrective Actions: Auditor reviewed several noncompliances and found no corrective actions in notices of noncompliance. Interviews with staff verified their understanding of the Primus training regarding consulting services. Primus reviewed this subject in the April 2017 annual training.

NP6025PZA.NC17 – Cleared - 7 CFR §205.303(a)(5) states, “Agricultural products in

packages described in §205.301(a) and (b) may display, The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: *Provided*, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: *Provided further*, That, such seals or marks are not individually displayed more prominently than the USDA seal.”

Comments: *The auditors reviewed 30 product labels and found 2 labels on which the PL seal was displayed more prominently than the USDA organic seal.*

2016 Corrective Action: PL conducted training for staff on label reviews, which focused on compliant use of the USDA organic seal and other label requirements. The training also involved a label review exercise for all staff to complete. PL provided verification of staff attendance at the training session.

2017 Verification of Corrective Actions: Auditors review of approved labels verified PL’s label training effectively informed staff of the label regulations. Label review was also covered in the April 2017 annual calibration training.

NP6025PZA.NC18 – Cleared - 7 CFR §205.303(b)(2) states, “Agricultural products in packages described in §205.301(a) and (b) must: On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by * * *,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.”

Comments: *The auditors reviewed 30 product labels and found 6 that were missing the “Certified organic by...” statement and 28 that showed the certifier’s information above the handler’s information.*

2016 Corrective Action: PL conducted training for staff on label reviews, which focused on compliant use of the “certified organic by ...” statement and other label requirements. The training also involved a label review exercise for all staff to complete. PL provided verification of staff attendance at the training session.

2017 Verification of Corrective Actions: Auditors review of approved labels verified the “Certified organic by...” statement was properly located on the label. Interviews with staff revealed a correct understanding of the labeling regulations.

Noncompliances Identified during the Current Assessment

NP7128JZA.NC1 – 7 C.F.R. §205.403(d) states, “The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.”

Comments: *The auditor’s review of completed inspection exit interview forms found that inspectors were not consistently citing the USDA regulation associated with the area of concern identified during the inspection.*

NP7128JZA.NC2 – 7 C.F.R. §205.670(d) states, “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number...”

Comments: *Primus did not sample and test from a minimum of 5% of total 2016 certified operations.*

NP7128JZA.NC3 – 7 C.F.R. §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must:... Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 4002, “*Enforcement of the USDA Organic Regulations: Penalty Matrix*,” Section 4.2 Notices of Noncompliances (NONC) states, “Violations that warrant a NONC are more significant than minor issues. They are serious or complex enough to require an approved corrective action plan and the certifier is to verify the implementation of the approved plan.”

Comments: *The auditor reviewed a certification letter which described minor issues to be corrected prior to the next annual inspection. The certifier classified the absence of harvest records and field activity records as a minor issue. These records constitute a large portion of information needed for traceability and organic integrity verification. The absence of these records are a significant failure to implement the operations OSP.*

NP7128JZA.NC4 – 7 C.F.R. §205.642 states, “... The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification...”

Comments: *The auditor’s review of a 2017 cost estimate to the operation stated inspection travel costs as “vary-inspection.” The annual cost estimate of an updating application for certification is incomplete.*

Audit Resolution Chronology Log

Audit Identifier (if any): NP4174EEA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: Pro-Cert
Accreditation Manager: Janna Howley

Date	Activity
11/06/14	Rcvd files from RM.
11/21/14	<ul style="list-style-type: none"> • Reviewed audit documents and drafted NC report and letter. • Emailed Rick Skinner with a question about the audit report: he highlighted two items related to a review of a staff member's files, but they weren't listed in the findings. Wanted to determine if they should be a finding, or if he'd highlighted the items for his own use during the audit.
12/01/14	Emailed Rick again regarding highlighted items in audit report.
12/02/14	<ul style="list-style-type: none"> • Rick replied back that the highlighted items were for his own reference; he simply forgot to un-highlight them before submitting the report. • Emailed draft letter and report to RM for review.
12/04/14	Rcvd edits back from RM.
12/05/14	Edited letter and report; sent back to RM for review.
12/08/14	RM reviewed and ok; forwarded electronically to CC for review.
12/10/14	Rcvd edits back from CC; updated, answered two questions she had, and emailed back for review.
12/11/14	<ul style="list-style-type: none"> • CC wanted further clarification as to whether Ontario office of Pro-Cert is an official satellite office, per NOP 2000. • Reviewed NOP 2000, prior audit (audit narrative stated that certification activities happened at both offices) and Pro-Cert org charts from after their name/business structure change. Org charts indicated that certification activities were to happen in Ontario; LC suggested confirming that NOP certification– and not just other scheme – activities were being conducted in Ontario. • Contacted Dave Lockman at Pro-Cert and he confirmed that all of the activities listed in the NOP satellite office spreadsheet were indeed happening. Sent LC and CC an email with this update. As a result, Ontario office will need to be audited as some point. • Updated report and printed hard copy report, letter, chrono log, etc. for CC review. • Signed by CC; sent to MM for review.
12/17/14	MM reviewed and approved.
12/19/14	JH sent letter and report to Pro-Cert.
01/21/15	JH rcvd VM from Pro-Cert, requesting extension to send in CAs by 01/23/15.
01/22/15	JH emailed Pro-Cert to grant extension until 01/26/15.
01/27/15	Rcvd CAs from Pro-Cert. Added to WTL.
02/26/15	Added Pro-Cert CA docs to folder. Began document review:

Audit Resolution Chronology Log

Audit Identifier (if any): NP4174EEA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: Pro-Cert
Accreditation Manager: Janna Howley

	<ul style="list-style-type: none">• 1501 Instructions – Use of Export Certificates 012515• Japan TM-11 & Instructions NOP 012015• Taiwan TM-11 & Instructions NOP 012015
02/27/15	Drafted CA report and NoCont Accred letter. Emailed to RM for review.
03/08/15	OK from RM to print for CC review.
03/10/15	Printed letter and report; gave to CC for review.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

DEC 19 2014

J. Wallace Hamm
Pro-Cert Organic Systems, Ltd
475 Valley Road, Saskatoon, Saskatchewan, S7K3J6
Canada

Dear Mr. Hamm:

On June 24-26, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Pro-Cert Organic Systems, Ltd (Pro-Cert) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On November 19, 2014, the NOP reviewed the results of the onsite audit to determine Pro-Cert's compliance to the USDA organic regulations. A copy of the assessment report, **NP4174EEA**, is enclosed for your reference.

As the report indicates, two corrective actions for prior noncompliances, **NP222600A.NC1-NC2**, were cleared and determined to be implemented and effective. One new noncompliance, **NP4174EEA.NC1**, was a finding identified during the onsite audit and determined to be a noncompliance. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the Pro-Cert management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Janna Howley, at (202) 692-0047 or JannaB.Howley@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Pro-Cert Organic Systems, Ltd. An onsite audit was conducted, and the audit report reviewed to determine Pro-Cert’s capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Pro-Cert Organic Systems, Ltd (Pro-Cert)
Physical Address	475 Valley Road, Saskatoon, Saskatchewan, S7K3J6, Canada
Mailing Address	475 Valley Road, Saskatoon, Saskatchewan, S7K3J6, Canada
Contact & Title	J. Wallace Hamm, President
E-mail Address	procertorganic@yahoo.com
Phone Number	306.382.1299
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer Rick Skinner, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: November 19, 2014 Onsite audit: June 24-26, 2014
Audit Identifier	NP4174EEA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of Pro-Cert’s certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	Pro-Cert’s certification services in carrying out the audit criteria during the period: September 5, 2012 through June 26, 2014.

ORGANIZATIONAL STRUCTURE

Pro-Cert Organic Systems, Ltd. (Pro-Cert) is a for-profit organization, initially accredited as a certifying agent as OCPP/Pro-Cert Canada, Inc. (OCPP) on May 24, 2002 to the USDA National Organic Program (NOP) for the scopes of crop, livestock, wild crop, and handling. In 2013, Pro-Cert had 159 clients certified to the NOP, including 122 crop, 97 livestock, 1 wild crop, and 35 handling operations. Pro-Cert no longer certifies grower groups under the NOP. Pro-Cert NOP clients are certified in the United States.

In addition to the USDA NOP, Pro-Cert also is accredited to the European Union Regulations (EC 834 /2007 and EC 889/2008), the Canadian Organic Standards, Quebec Organic Standards, and Japanese Agricultural Standards (JAS/MAFF). Pro-Cert also assists applicants in obtaining Bio-Suisse (Switzerland) certification and certification to the Brazil Regulations and Standards.

Pro-Cert has two offices from which certification activities are conducted. The main office is in Saskatoon, Saskatchewan, and a subsidiary office is located in Cambray, Ontario. Pro-Cert staff consists of a General Manager, 2 Certification Managers, 2 Processor Certification Coordinators, 2 Producer Certification Coordinators, 13 Certification/Evaluation Committee members, and 8 staff and 6 contract inspectors. The Saskatoon office was the location of this assessment; however, certification files from both locations were assessed.

Records verified during this assessment showed that Pro-Cert meets the requirements for annual performance evaluations, confidentiality, and annual conflicts of interest disclosure reports for all personnel. Personnel files/resumes reviewed indicated that all personnel involved in the certification process had the required education, training, and/or experience in organic agricultural production and handling techniques to perform the duties assigned and interviews conducted verified that the personnel had an understanding of the USDA organic regulations and their application.

CERTIFICATION PROCESS:

Applicants are provided with a comprehensive number of documents and information, based on the scope requested. More complex operations may also require the completion of additional forms and information. All documents are available to operations both online and in hard copy form.

When initial applications are received, the file is reviewed for completeness and compliance by a member of the certification/evaluation committee. This could be the same person or two different persons, depending on the complexity of the application. Once the reviewer determines that the file is complete and ready for an onsite inspection, an inspector is assigned. The inspector reviews any labels and inputs for compliance and submits any labels, input labels and/or documents for final review. Once the inspection is complete, the inspection report and all other documentation pertaining to the application are presented to a certification/evaluation member or several members, depending on the complexity of the operation. These staff members were not part of the previous review. The file is reviewed for compliance and a final decision is made. The annual update process is similar to the initial application process.

Pro-Cert has policies and procedures in place for investigation of complaints, denials, proposed suspensions and revocations. There were two denials of certification documented since the 2012 assessment. There have been several proposed suspensions issued, followed by suspensions of up to three years. No revocations were issued by Pro-Cert. Several successful settlement agreements were documented and achieved, each with guidance directly from the National Organic Program. All adverse actions processed by Pro-Cert were according to the Regulation and were simultaneously provided to the Administrator as required.

MATERIALS REVIEW:

Pro-Cert has a comprehensive materials review program. Pro-Cert uses other sources such as OMRI as a reference only during the review. The company conducts an independent review of products requested for use by their certified operations. The results of the reviews are documented in a dynamic database that is managed within the system.

Onsite evaluations are conducted for suppliers that produce liquid nitrogen fertilizers with nitrogen content greater than 3%, as well as other suppliers where Pro-Cert determines that an onsite review is necessary. Onsite evaluations are documented by Pro-Cert on an Input Substance Approval Inspection Report.

FEES:

The Pro-Cert fee schedule is supplied to applicants who submit information requesting certification. The fee schedule clearly outlines the various set costs for the certified operations, and includes non-refundable fee information. Each operation file reviewed during the assessment contained an original estimate associated with initial or renewal of certification that was compatible with the supplied fee schedule.

ADMINISTRATIVE RECORDS AND PROCESSES:

The primary document for NOP certification is the Pro-Cert Organic Systems Ltd. Quality System Manual (Part I – Certification Policies and Part II – Certification Procedures). This manual is supported by various documents and procedures. All forms and templates are mailed or emailed, and are also available on Pro-Cert’s website. Annual reviews are conducted in accordance with procedures. Review of training indicated that ongoing training is conducted.

WITNESS INSPECTIONS:

As part of the mid-term assessment, one review audit and one witness inspection were conducted. The review audit included a tour of a handling facility that provides custom commercial packaging of 100% organic coconut oil and flax. The results of the February inspection were verified along with the company’s ongoing ability to receive, segregate, and manufacture organic product according to the procedures specific to NOP.

The witness inspection was conducted at a handling operation in Glendale, California. The inspection was an initial inspection conducted by a staff inspector. The operation requested certification to allow for the manufacture of organic bakery products.

Both inspectors were qualified and very knowledgeable of the NOP Rule. Observations and records also indicate that inspectors were well prepared for the inspections, had reviewed the previous inspection reports, and verified all areas as required by the NOP standards. Exit interviews, which included the identification of issues of concern, were conducted with the operation representative at the end of each inspection.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether Pro-Cert’s corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to Pro-Cert.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance

labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP222600A.NC1 – Cleared. 7 CFR §205.404(b)(3) states, “The certifying agent must issue a certificate of organic operation which specifies the: (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.”

Comments: Certificates for 9 of the 10 certification files reviewed contained the type of products that were being certified but did not contain the correct categories of organic operation as defined in this section (crops, wild crops, livestock, or processed products).

Corrective Action: Pro-Cert submitted a revised certificate template, showing the category of certification. Pro-Cert also submitted two examples of certificates issued on March 31, 2013. Both certificates correctly classified the products produced under one of the 4 NOP certification categories. As evidence of preventive actions, Pro-Cert submitted two emails from December 2012 and December 2013 instructing staff to use the new certificate template. The emails identified the following four categories of certification for NOP certificates: crops, livestock, wild crops, and processed products. In 2014, Pro-Cert plans to implement electronic certificate software to further reduce certificate errors.

Verification of Corrective Action: Pro-Cert amended its Certificate of Conformity to be in full compliance with NOP 2603. Changes include listing the categories of certification per the following: crops, livestock, wild crops and processed products. The template change became effective on December 15, 2012 and was implemented by Pro-Cert staff at both offices. All obsolete templates have been archived and are no longer used by Pro-Cert staff. All certificates reviewed during the assessment complied with the USDA organic regulations.

NP222600A.NC2 – Cleared. 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.”

Comments: Review of 1 grower group file showed Pro-Cert is not in compliance with NOP Program Handbook Policy Memo (PM) 11-10, Certification of Grower Groups. Specifically, the evidence showed that the producers in the grower group were not operating under the guidance of the NOSB Recommendation 2002, Criteria for Certification of Grower Groups, Recommendation # 1: “The NOSB recommends that, in order to be certified as a grower group, the following conditions must be met: 1) The crops and farming practices of the producers must be uniform and reflect a consistent process or methodology, using the same inputs.” Review of the certification file showed 5 growers conducting a variety of production methods, such as dairy, beef cattle, laying hens, and crop and greenhouse production. It is unclear which producer is doing which activity; but it is clear that one, uniform OSP is not used. Pro-Cert management indicated that this operation was classified as a grower group because they used one singular marketing and distribution entity. Though this is a requirement of grower group certification; this type of certification begins with a uniform OSP for all producers.

Corrective Action: In August 2012, Pro-Cert contacted the head of the grower group to state that the NOSB’s 2011 memo meant that they did not qualify as a grower group. Pro-Cert

requested that each individual group member apply for certification. The responsible party submitted an application for individual certification, and the other four members applied to a different certifying agent. In May 2013, Pro-Cert sent a memo to its staff stating that grower groups must consist of uniform crops and farming practices, using the same inputs. The memo informed staff that all NOP grower group certification must follow the policies outlined in the NOSB policy. Pro-Cert no longer has any NOP-certified grower groups. According to their policies, any future grower group applications must be evaluated by the certification manager.

Verification of Corrective Action: The updated grower group procedure has been amended to preclude the certification of a similar group/family unit as previously certified. As of the date of the audit, Pro-Cert does not certify any grower groups to the USDA organic regulations.

Noncompliances Identified during the Current Assessment

NP4174EEA.NC1 – 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP §205.500(c)(2) states, “The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.” NOP 2403 states, “When exported to Japan and Taiwan, U.S Department of Agriculture (USDA) organic products must be accompanied by an organic export certificate (TM-11).” The agreement requires the certifier to assign a unique identification number to each export certificate and for all export certificates that were issued under the Taiwan arrangement for processed products and crops have the required statement, “Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances.”

Comments: The review of two TM-11 documents issued in March 2013 did not contain the unique identifier for Pro-Cert Organic Systems Ltd (PRO) provided on the list of Certifying Agents Approved to Issue TM-11 Export Certificates under an Export Arrangement between the USDA and a Foreign Government, dated June 24, 2014. Additionally, the certificates did not contain the statement, “Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances.”

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Pro-Cert Organic Systems, Ltd. An onsite audit was conducted, and the audit report reviewed to determine Pro-Cert's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Pro-Cert Organic Systems, Ltd (Pro-Cert)
Physical Address	475 Valley Road, Saskatoon, Saskatchewan, S7K3J6, Canada
Mailing Address	475 Valley Road, Saskatoon, Saskatchewan, S7K3J6, Canada
Contact & Title	J. Wallace Hamm, President
E-mail Address	procertorganic@yahoo.com
Phone Number	306.382.1299
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer Rick Skinner, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: November 19, 2014 Onsite audit: June 24-26, 2014
Audit Identifier	NP4174EEA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of Pro-Cert's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	Pro-Cert's certification services in carrying out the audit criteria during the period: September 5, 2012 through June 26, 2014.

ORGANIZATIONAL STRUCTURE

Pro-Cert Organic Systems, Ltd. (Pro-Cert) is a for-profit organization, initially accredited as a certifying agent as OCPP/Pro-Cert Canada, Inc. (OCPP) on May 24, 2002 to the USDA National Organic Program (NOP) for the scopes of crop, livestock, wild crop, and handling. In 2013, Pro-Cert had 159 clients certified to the NOP, including 122 crop, 97 livestock, 1 wild crop, and 35 handling operations. Pro-Cert no longer certifies grower groups under the NOP. Pro-Cert NOP clients are certified in the United States.

In addition to the USDA NOP, Pro-Cert also is accredited to the European Union Regulations (EC 834 /2007 and EC 889/2008), the Canadian Organic Standards, Quebec Organic Standards, and Japanese Agricultural Standards (JAS/MAFF). Pro-Cert also assists applicants in obtaining Bio-Suisse (Switzerland) certification and certification to the Brazil Regulations and Standards.

Pro-Cert has two offices from which certification activities are conducted. The main office is in Saskatoon, Saskatchewan, and a subsidiary office is located in Cambray, Ontario. Pro-Cert staff consists of a General Manager, 2 Certification Managers, 2 Processor Certification Coordinators, 2 Producer Certification Coordinators, 13 Certification/Evaluation Committee members, and 8 staff and 6 contract inspectors. The Saskatoon office was the location of this assessment; however, certification files from both locations were assessed.

Records verified during this assessment showed that Pro-Cert meets the requirements for annual performance evaluations, confidentiality, and annual conflicts of interest disclosure reports for all personnel. Personnel files/resumes reviewed indicated that all personnel involved in the certification process had the required education, training, and/or experience in organic agricultural production and handling techniques to perform the duties assigned and interviews conducted verified that the personnel had an understanding of the USDA organic regulations and their application.

CERTIFICATION PROCESS:

Applicants are provided with a comprehensive number of documents and information, based on the scope requested. More complex operations may also require the completion of additional forms and information. All documents are available to operations both online and in hard copy form.

When initial applications are received, the file is reviewed for completeness and compliance by a member of the certification/evaluation committee. This could be the same person or two different persons, depending on the complexity of the application. Once the reviewer determines that the file is complete and ready for an onsite inspection, an inspector is assigned. The inspector reviews any labels and inputs for compliance and submits any labels, input labels and/or documents for final review. Once the inspection is complete, the inspection report and all other documentation pertaining to the application are presented to a certification/evaluation member or several members, depending on the complexity of the operation. These staff members were not part of the previous review. The file is reviewed for compliance and a final decision is made. The annual update process is similar to the initial application process.

Pro-Cert has policies and procedures in place for investigation of complaints, denials, proposed suspensions and revocations. There were two denials of certification documented since the 2012 assessment. There have been several proposed suspensions issued, followed by suspensions of up to three years. No revocations were issued by Pro-Cert. Several successful settlement agreements were documented and achieved, each with guidance directly from the National Organic Program. All adverse actions processed by Pro-Cert were according to the Regulation and were simultaneously provided to the Administrator as required.

MATERIALS REVIEW:

Pro-Cert has a comprehensive materials review program. Pro-Cert uses other sources such as OMRI as a reference only during the review. The company conducts an independent review of products requested for use by their certified operations. The results of the reviews are documented in a dynamic database that is managed within the system.

Onsite evaluations are conducted for suppliers that produce liquid nitrogen fertilizers with nitrogen content greater than 3%, as well as other suppliers where Pro-Cert determines that an onsite review is necessary. Onsite evaluations are documented by Pro-Cert on an Input Substance Approval Inspection Report.

FEES:

The Pro-Cert fee schedule is supplied to applicants who submit information requesting certification. The fee schedule clearly outlines the various set costs for the certified operations, and includes non-refundable fee information. Each operation file reviewed during the assessment contained an original estimate associated with initial or renewal of certification that was compatible with the supplied fee schedule.

ADMINISTRATIVE RECORDS AND PROCESSES:

The primary document for NOP certification is the Pro-Cert Organic Systems Ltd. Quality System Manual (Part I – Certification Policies and Part II – Certification Procedures). This manual is supported by various documents and procedures. All forms and templates are mailed or emailed, and are also available on Pro-Cert’s website. Annual reviews are conducted in accordance with procedures. Review of training indicated that ongoing training is conducted.

WITNESS INSPECTIONS:

As part of the mid-term assessment, one review audit and one witness inspection were conducted. The review audit included a tour of a handling facility that provides custom commercial packaging of 100% organic coconut oil and flax. The results of the February inspection were verified along with the company’s ongoing ability to receive, segregate, and manufacture organic product according to the procedures specific to NOP.

The witness inspection was conducted at a handling operation in Glendale, California. The inspection was an initial inspection conducted by a staff inspector. The operation requested certification to allow for the manufacture of organic bakery products.

Both inspectors were qualified and very knowledgeable of the NOP Rule. Observations and records also indicate that inspectors were well prepared for the inspections, had reviewed the previous inspection reports, and verified all areas as required by the NOP standards. Exit interviews, which included the identification of issues of concern, were conducted with the operation representative at the end of each inspection.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether Pro-Cert’s corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to Pro-Cert.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance

labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP222600A.NC1 – Cleared. 7 CFR §205.404(b)(3) states, “The certifying agent must issue a certificate of organic operation which specifies the: (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.”

Comments: Certificates for 9 of the 10 certification files reviewed contained the type of products that were being certified but did not contain the correct categories of organic operation as defined in this section (crops, wild crops, livestock, or processed products).

Corrective Action: Pro-Cert submitted a revised certificate template, showing the category of certification. Pro-Cert also submitted two examples of certificates issued on March 31, 2013. Both certificates correctly classified the products produced under one of the 4 NOP certification categories. As evidence of preventive actions, Pro-Cert submitted two emails from December 2012 and December 2013 instructing staff to use the new certificate template. The emails identified the following four categories of certification for NOP certificates: crops, livestock, wild crops, and processed products. In 2014, Pro-Cert plans to implement electronic certificate software to further reduce certificate errors.

Verification of Corrective Action: Pro-Cert amended its Certificate of Conformity to be in full compliance with NOP 2603. Changes include listing the categories of certification per the following: crops, livestock, wild crops and processed products. The template change became effective on December 15, 2012 and was implemented by Pro-Cert staff at both offices. All obsolete templates have been archived and are no longer used by Pro-Cert staff. All certificates reviewed during the assessment complied with the USDA organic regulations.

NP222600A.NC2 – Cleared. 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.”

Comments: Review of 1 grower group file showed Pro-Cert is not in compliance with NOP Program Handbook Policy Memo (PM) 11-10, Certification of Grower Groups. Specifically, the evidence showed that the producers in the grower group were not operating under the guidance of the NOSB Recommendation 2002, Criteria for Certification of Grower Groups, Recommendation # 1: “The NOSB recommends that, in order to be certified as a grower group, the following conditions must be met: 1) The crops and farming practices of the producers must be uniform and reflect a consistent process or methodology, using the same inputs.” Review of the certification file showed 5 growers conducting a variety of production methods, such as dairy, beef cattle, laying hens, and crop and greenhouse production. It is unclear which producer is doing which activity; but it is clear that one, uniform OSP is not used. Pro-Cert management indicated that this operation was classified as a grower group because they used one singular marketing and distribution entity. Though this is a requirement of grower group certification; this type of certification begins with a uniform OSP for all producers.

Corrective Action: In August 2012, Pro-Cert contacted the head of the grower group to state that the NOSB’s 2011 memo meant that they did not qualify as a grower group. Pro-Cert

requested that each individual group member apply for certification. The responsible party submitted an application for individual certification, and the other four members applied to a different certifying agent. In May 2013, Pro-Cert sent a memo to its staff stating that grower groups must consist of uniform crops and farming practices, using the same inputs. The memo informed staff that all NOP grower group certification must follow the policies outlined in the NOSB policy. Pro-Cert no longer has any NOP-certified grower groups. According to their policies, any future grower group applications must be evaluated by the certification manager.

Verification of Corrective Action: The updated grower group procedure has been amended to preclude the certification of a similar group/family unit as previously certified. As of the date of the audit, Pro-Cert does not certify any grower groups to the USDA organic regulations.

Noncompliances Identified during the Current Assessment

NP4174EEA.NC1 – 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP §205.500(c)(2) states, “The foreign government authority that accredited the foreign certifying agent acted under an equivalency agreement negotiated between the United States and the foreign government.” NOP 2403 states, “When exported to Japan and Taiwan, U.S Department of Agriculture (USDA) organic products must be accompanied by an organic export certificate (TM-11).” The agreement requires the certifier to assign a unique identification number to each export certificate and for all export certificates that were issued under the Taiwan arrangement for processed products and crops have the required statement, “Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances.”

Comments: The review of two TM-11 documents issued in March 2013 did not contain the unique identifier for Pro-Cert Organic Systems Ltd (PRO) provided on the list of Certifying Agents Approved to Issue TM-11 Export Certificates under an Export Arrangement between the USDA and a Foreign Government. Additionally, the certificates did not contain the statement, “Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances.”

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of Quality Assurance International (QAI) organic program was conducted February 7 - March 23, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess QAI's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Quality Assurance International (QAI)
Physical Address	9191 Towne Center Drive, Suite 200, San Diego, CA 92122
Mailing Address	9191 Towne Center Drive, Suite 200, San Diego, CA 92122
Contact & Title	Iris Rendon
E-mail Address	irendon@nsf.org
Phone Number	519.821.1246 xt. 6433
Reviewer(s) & Auditor(s)	Penny Zuck, NOP Reviewer; Nikki Adams and Lars Crail, Onsite Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective action review: October 16, 2017 NOP assessment review: July 10, 2017 Onsite office audit: March 20-23, 2017 Handler witness audits: February 7-8, 2017 Crop/Handler & Livestock/ Handler witness audits: March 16-17, 2017
Audit Identifier	NP7038ADA
Action Required	None
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of QAI's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	QAI's certification services in carrying out the audit criteria during the period: April 2014 through March 2017

QAI is a subsidiary of NSF International and provides certification services for agricultural producers, product manufacturers, and other handlers of organic products. QAI maintains accreditation for the COR, EU, NSF 305 (personal care products), ISO 17065 (through IOAS), DEKRA ISO 17001, Quebec Ice Cider and CAEQ (Quebec labeling standard for COR). QAI certifies operations in the United States (all states except Alaska), Canada, Iceland, Columbia, Sri Lanka, Taiwan, Japan, UK and Mexico.

QAI certifies 1,536 operations; 84 crops, 59 livestock, and 1429 handlers; of which 1117 are processors, 203 are distributors, 121 are trader/brokers and 4 are retailers. QAI does not certify any grower groups. All of the certification activities are carried out from the main office in San Diego, CA.

The QAI staff consists of 2 Senior Management, 3 Quality, 15 Reviewers, 20 Certification Project Managers, 7 Administrative staff and 51 Inspectors (46 contract and 5 staff inspectors).

In conjunction with the onsite office audit, four witness audits were conducted during the inspections of operations certified to the scopes of crops, livestock, and handling/processing. All four witness audits were annual renewal inspections and were announced. The witness audits included a handler operation, a beef processor, a crop (citrus fruit) operation and a poultry operation.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether QAI's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance. Any noncompliance labeled as "**Accepted**" indicates acceptance of the corrective actions and verification of corrective action implementation will be conducted during the next onsite audit.

AIA6055JZ.NC1 – Cleared

AIA6055JZ.NC2 - Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP7038ADA.NC1 – Accepted. 7 C.F.R. §205.501(a)(21) states, "Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." NOP 2603, Organic Certificates, Section 3.1, indicates the elements of an organic certificate.

Comments: *The following issues were identified on issued certificates:*

1. *"Certified to the USDA organic regulations, 7 C.F.R. Part 205." is not accurately stated.*
2. *The statement "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked." is missing.*

Corrective Action: QAI revised the certificate template to include the correct statements, “Certified to the USDA organic regulations, 7 C.F.R. Part 205” and “Once certified, a production or handling operation’s organic certification continues in effect until surrendered, suspended, or revoked.” The revised certificate template is a controlled document in the IQ system. An example of the corrected certificate was submitted to the NOP.

NP7038ADA.NC2 – Accepted. 7 C.F.R. §205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator....”

Comments: *QAI does not have a process to submit fee schedules to the NOP. The current fee schedule, dated February 13, 2017, has not been sent to the NOP. The actual fees did not change; however, statements in the document were modified.*

Corrective Action: QAI submitted a copy of its current fee schedule, which was updated in June 2017, to the NOP. QAI also added the following note to its fee schedule: “*ANY changes to this fee schedule must be promptly reported to the NOP administrator.*” This requirement has been communicated to the Operations Manager, who will ensure follow through.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of Quality Assurance International (QAI) organic program was conducted February 7 - March 23, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess QAI's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Quality Assurance International (QAI)
Physical Address	9191 Towne Center Drive, Suite 200, San Diego, CA 92122
Mailing Address	9191 Towne Center Drive, Suite 200, San Diego, CA 92122
Contact & Title	Iris Rendon
E-mail Address	irendon@nsf.org
Phone Number	519.821.1246 xt. 6433
Reviewer & Auditors	Penny Zuck, NOP Reviewer; Nikki Adams & Lars Crail, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: July 10, 2017 Onsite office audit: March 20-23, 2017 Handler witness audits: February 7-8, 2017 Crop/Handler & Livestock/ Handler witness audits: March 16-17, 2017
Audit Identifier	NP7038ADA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of QAI's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	QAI's certification services in carrying out the audit criteria during the period: April 2014 through March 2017

QAI is a subsidiary of NSF International and provides certification services for agricultural producers, product manufacturers, and other handlers of organic products. QAI maintains accreditation for the COR, EU, NSF 305 (personal care products), ISO 17065 (through IOAS), DEKRA ISO 17001, Quebec Ice Cider and CAEQ (Quebec labeling standard for COR). QAI certifies operations in the United States (all states except Alaska), Canada, Iceland, Columbia, Sri Lanka, Taiwan, Japan, UK and Mexico.

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The QAI staff consists of 2 Senior Management, 3 Quality, 15 Reviewers, 20 Certification Project Managers, 7 Administrative staff and 51 Inspectors (46 contract and 5 staff inspectors).

In conjunction with the onsite office audit, four witness audits were conducted on operations certified to the scopes of crops, livestock, and handling/processing. All four witness audits were annual renewal inspections and were announced. The witness audits included a handler operation, a beef processor, a crop (citrus fruit) operation and a poultry operation.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether QAI's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to QAI.

Noncompliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

AIA6055JZ.NC1 – Cleared - 7CFR 205.662(a) states, "When an inspection, review, or investigation of a certified operation by a certifying agent... reveals any non-compliance with the Act or regulations in this part, a written notification of non-compliance shall be sent to the certified operation."

Comments: *QAI failed to issue a notice of non-compliance when the conditions of certification were not resolved within the prescribed time period.*

2016 Corrective Actions: QAI has issued the operation a notice of non-compliance and is amending its notice of conditions for continued accreditation template to state: "Please include a written response to each item prior to next annual renewal. Responses to each point will be required before we can begin the renewal process. QAI suggests that responses be submitted ninety days from the issue date of this letter. Responses must be received by the due date for the Application for Organic Certification Annual Monitoring form.

Verification of Corrective Actions: Files reviewed by the auditor confirmed that QAI is issuing the revised letter.

AIA6055JZ.NC2 – Cleared - 7CFR 205.662(c)(4) states, "The right to request mediation pursuant to 205.663 or to file an appeal pursuant to 205.681."

Comments: *QAI issued a notice of proposed suspension indicating three methods or options to resolve the proposed adverse action. QAI's notice stated incorrectly that the operation could submit corrective actions to resolve the notice of proposed suspension. Operations are allowed two methods of resolutions: request mediation or file an appeal.*

2016 Corrective Actions: QAI has amended its notice of proposed suspension template to correctly offer the options of mediation or appeal. QAI will notify its clients of the QAI policy changes in a newsletter article. QAI will begin sending a warning letter prior to due dates explaining the consequences of untimely responses to non-compliances.

Verification of Corrective Actions: Files and notices reviewed by the auditor confirmed that QAI is issuing notices with the proper verbiage. Additionally, QAI is issuing warning letters prior to the due dates.

Noncompliances Identified during the Current Assessment

NP7038ADA.NC1 - 7 C.F.R. §205.501(a)(21) states, "Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." NOP 2603, Organic Certificates, Section 3.1, indicates the elements of an organic certificate.

Comments: *The following issues were identified on issued certificates:*

- 1. "Certified to the USDA organic regulations, 7 C.F.R. Part 205." is not accurately stated.*
- 2. The statement "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked." is missing.*

NP7038ADA.NC2 – 7 C.F.R. §205.642 states, "Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator...."

Comments: *QAI does not have a process to submit fee schedules to the NOP. The current fee schedule, dated February 13, 2017, has not been sent to the NOP. The actual fees did not change; however, statements in the document were modified.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

JUL 28 2017

NOTICE OF NONCOMPLIANCE

Iris Rendon
Quality Assurance International (QAI)
9191 Towne Center Drive, Suite 200
San Diego, CA 92122

Dear Ms. Rendon:

On March 20-23, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Quality Assurance International (QAI) organic certification program as part of its USDA Renewal Accreditation Assessment. On July 10, 2017, the NOP reviewed the results of the onsite audit to determine QAI's compliance to the USDA organic regulations. A copy of the assessment report, NP7038ADA, is enclosed for your reference.

As the report indicates, two prior noncompliances, AIA6055JZ.NC1 and NC2, were cleared and their corrective actions determined to be implemented and effective. Two new noncompliances, NP7038ADA.NC1 and NC2, were identified during the onsite audit. Please submit corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All corrective actions must indicate how the noncompliances will be corrected and how the QAI management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of QAI's USDA accreditation.

If you have questions regarding this notice, please contact, Penny Zuck, Accreditation Manager, at Penelope.zuck@ams.usda.gov or (202) 260-9444.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney". The signature is written in a cursive, flowing style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

Quality Assurance International, Inc. (QAI) was accredited as a USDA organic certifying agent on April 29, 2002. An onsite Mid-Term assessment of QAI occurred April 8 - 10, 2014. Verification of corrective actions for previous non-compliances was conducted; no new non-compliances were identified. This report records NOP's decision.

GENERAL INFORMATION

Applicant Name:	Quality Assurance International, Inc. (QAI)
Physical Address:	9191 Towne Centre Drive, Suite 200, San Diego, CA 92122
Mailing Address:	9191 Towne Centre Drive, Suite 200, San Diego, CA 92122
Contact & Title:	Craig Morr, Quality Director
E-mail Address:	cmorr@nsf.org
Phone Number:	734-769-5143
Auditor(s):	Meg Kuhn, NOP Reviewer; Martin Friesenhahn & David Hildreth, On-site Auditor(s).
Program:	USDA National Organic Program (NOP)
Audit Date(s):	April 8 – 10, 2014
Audit Identifier:	NP4057BBA
Action Required:	None
Audit Type:	Mid-Term Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of QAI's certification system.
Audit Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit Scope:	QAI's certification services in carrying out the audit criteria during the period: April 12, 2012 – April 10, 2014

ORGANIZATIONAL STRUCTURE:

QAI is currently approved as a certifying agent to the USDA National Organic Program (NOP) for the scopes of crops, livestock, and handling/processing. QAI currently has 1,562 clients certified to the NOP standard; 102 for crops, 47 for livestock, and 1,459 for handling of which 921 are processors, 252 are retailers, 180 are distributors, 116 are traders, 25 are post-harvest, and 3 are feed processors. QAI certifies clients to the NOP in the United States, Canada, Mexico, Taiwan, and the United Kingdom. QAI does not currently certify any grower groups. All certification activities are carried out of the main office in San Diego, California.

QAI is also accredited by the International Organic Accreditation Service (IOAS) for ISO Guide 65, Canada Organic Regime (COR), and the European Recognition Program (EU), Japanese Agricultural Standards (JAS/MAFF), DEKRA (ISO 14001) and CARTV, Canada.

QAI is a wholly owned subsidiary of NSF International. The QAI personnel consists of a Director of NSF Agriculture, North America, 14 Certification Project Managers, 11 staff and 6 contract Reviewers, 7 staff and 58 contract Inspectors, and 6 Administrative staff. QAI also has a Global Managing Director, 5 customer service staff, and 7 additional Managers and supervisors. QAI is managed onsite by the Director of NSF Agriculture who reports to an NSF International Vice-President who in turn reports to the NSF International Holding Board of Directors.

The current conflict of interest disclosure reports and confidentiality statements were available for certification staff members and subcontracted reviewers or inspectors. A review of the files and interviews conducted verified that the organic certification staff had sufficient experience, training, and education or a combination thereof in agriculture, organic production, and organic handling. A review of training records indicated that all staff, inspectors, and sub-contracted inspectors had received current training on the NOP regulations and requirements.

CERTIFICATION PROCESS:

The QAI certification process begins with initial contact from the client through the Certification Project Manager (CPM). Applications are reviewed by Application Reviewers for completeness and compliance. Once the application is approved, the inspector is assigned by the Inspection Coordinator. The inspections are usually conducted by contract inspectors but could also be conducted by staff inspectors. After inspection, the completed Organic System Plan (OSP) and inspection reports are reviewed by a Level 1 (L1) reviewer who proposes corrective action(s) areas, identifies products for certificate listing, and identifies minor non-compliances. The entire file is then reviewed by a Level 2 (L2) Reviewer. This is a re-review of the findings identified by the L1 reviewer. The L2 reviewer can make changes to the findings if necessary, identify major non-compliances, identify additional minor non-compliances, and complete the notification of non-compliance, which is then sent to clients thru the CPM. The Level 3 (L3) Reviewer then conducts a re-review of the file and makes the final certification decision including any non-compliances or conditions for continued certification. The L3 reviewer or the CPM also reviews the corrective actions submitted by the clients with the final approval by the L3 Reviewer. The L3 Reviewer submits the organic certificate with the QAI seal including the organic product list after certification requirements are met. Organic certificates are updated annually or as certificate information changes. Changes to the OSP are required to be submitted annually or as required by changes throughout the year. Material inputs and labels are reviewed by Reviewers or CPMs with the initial application, annual updates or through the year as needed. The certification process is completed and monitored through a computerized electronic system called "IQ" which maintains checks and balances for the certification process.

QAI also has procedures for verification and oversight activities of International exports and Import activities for Canada, Japan, Taiwan, and the European Union. A review of these activities and oversight were confirmed during the on-site audit.

ADMINISTRATIVE RECORDS AND PROCESSES:

QAI has a Quality Manual, Inspection Manual and Program Policies for Organic System Plan Certification. These manuals include standard operating procedures and forms used for NOP certification activities. Forms and letters reviewed for the NOP certification activities were found to meet NOP requirements. QAI conducts internal audits and has an annual program review relating to requirements that are specific to the NOP. Non-conformances are identified and corrective actions are implemented as needed. Annual reports and updates are submitted to the NOP as required. Training is both internal and external and training records and documentation has been maintained. Refresher training or additional training is completed as needed.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED:

The audit included one witness inspection and a review audit. The witness inspection was a renewal inspection of a company in Lewisville, TX that produces botanical extracts for the cosmetic industry. This company produces approximately 5% of their volume in organic products and the retail products are processed at other facilities. The renewal inspection was conducted by a contract inspector. A detailed inspection was observed including the verification of the Organic Compliance Plan and the applicable NOP requirements. An exit interview was conducted providing a summary of the inspection results. The inspector was very knowledgeable of the NOP requirements and the process of conducting an organic inspection for QAI.

The review audit included a crop producer in Heber, CA that had their initial organic certification the previous year. This company is producing various organic vegetables and melons including squash, peppers, and others for the Asian market. The company also is a conventional hay broker for the Asian market. The company was currently in the application review process and the renewal inspection had not yet been conducted. The review audit confirmed that QAI was reviewing and verifying the updated changes to the Organic Compliance Plan (OCP) and additional information from the client as requested. The review audit also confirmed the results of the previous inspection and that QAI was completing the organic certification and renewal process as required by the NOP Standards.

NOP DETERMINATION

NOP's assessment and accreditation decision of QAI's compliance to the USDA organic regulations is based on a sample of its certification system records and activities. This section describes the NOP's review and determination of the certifying agent's noncompliance response.

Prior Non-compliance Corrective Actions

The NOP auditor reviewed information during the assessment to verify that the certifying agent effectively implemented the corrective actions from previous assessments. The auditor was able to verify all the items labeled "cleared."

1. **NP2094AKA.NC1 – Cleared** - NOP §205.402(a)(2) states, "Upon acceptance of an application for certification, a certifying agent must: determine by a review of the

application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part.” *A review of a crop producer’s Annual Input Record indicated that input materials (i.e. composts) have been used from two sources with the following findings:*

Source 1- There is no evidence indicating that these composts or material inputs comply with the regulations. There is no evidence indicating that the feed stocks (i.e. ingredients) of the composts are compliant; furthermore, there is no record that these inputs meet the requirements of 205.203(c)(2), the NOP composting process.

Source 2- This compost was a new input (2011); a change from the previously used source of compost material. This new input was not identified or questioned by the initial certification reviewer. Additionally, the inspector reviewed some material documentation on-site, but this documentation did not indicate the compost ingredients, nor whether the compost complied to the NOP compost processing criteria (e.g. C/N ratio, temperature, etc...).

Corrective Actions: Compost from Source 1 was approved by QAI in 2009. The addition of compost from Source 2 to QAI’s Annual Input Record (AIR) made the record appear to list a new input; however, Source 2 is a contract applicator who purchases and applies the Source 1 compost to the client’s fields. A corrected AIR was obtained from the client listing the input suppliers rather than the applicators. QAI did not document its justification of the approval of the former AIR prior to inspection which resulted in the appearance of an unapproved input from a new supplier being applied to the field. QAI internal procedures have been revised to clarify review procedures. Specifically, QAI reviewers will cross check the submitted AIR updates against the previously approved inputs in the database and records.

Documentation of the compost’s compliance was on file with QAI including the compost process protocol, laboratory analysis, and time/temperature turn logs. The evidence of compliance of the Source 1 compost to NOP regulation 205.203(c)(2) and NOP Program Handbook 5021 section 4.1 and 4.2 was provided to the NOP for review. Updated compost information was obtained by QAI which corroborates the initial compliance determination made by QAI. The corrective measures for NC1 are accepted by the NOP.

Verification at Mid-Term assessment: Annual Input Records (AIR) verified during the audit through file reviews and the on-site review audit confirmed that any new inputs are reviewed and verified. In addition, compost usage was verified as meeting the NOP requirements. Compost requirements and protocol was also verified through documentation that was provided during the review audit.

- 2. NP2094AKA.NC2 – Cleared** - NOP §205.402(a)(2) states, “Upon acceptance of an application for certification, a certifying agent must: determine by a review of the application materials whether the applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part.” *A review of a crop producer file indicated that the certified operation was using a fertilizer, Allganic 12-0-12, where the label disclosed that sodium nitrate was an ingredient at the rate of 12%. Sodium nitrate is restricted for use at no more than 20% of the crops total nitrogen requirement.*

There was no documentation on file that indicated that the calculation for total nitrogen derived from sodium nitrate was performed. Two other files reviewed included soil amendments which included sodium nitrate as an ingredient and were correctly calculated and verified for nitrogen content. **Corrective Actions:**

QAI internal procedures have been revised to clarify material input review procedures. Reviewers are directed to cross check the submitted material updates against any previously approved inputs. QAI management distributed and reviewed the updated procedural requirements with review staff on June 1, 2012. QAI conducted the sodium nitrate calculations for the client cited in this noncompliance and found the client to be in compliance with NOP205.602 (g). Documented evidence of the procedural updates, training, and verification of sodium nitrate calculations were provided by QAI for NOP review. The corrective measures for NC2 are accepted by the NOP. **Verification at Mid-Term assessment:** The on-site audit at QAI confirmed current internal procedures were being followed to verify any material updates to any previously approved inputs. Interviews and files reviewed also confirmed that any soil amendments including sodium nitrate were correctly calculated for nitrogen content as required.

- 3. NP2094AKA.NC3 - Cleared** - NOP §205.670(d)(1) states, “Results of all analyses and tests performed under this section must be promptly provided to the Administrator; *Except, that, where a State organic program exists, all test results and analyses shall be provided to the State organic program’s governing State official by the applicable certifying party that requested testing.” In one case, results of pesticide residue testing were not sent to the California state organic program. Additionally, the ACA’s procedures indicated that only positive results are to be sent, whereas the regulations require that all results be sent to the State organic program.* **Corrective Actions:** QAI issued the California State Organic Program on April 12, 2012 results of the residue test. QAI revised the associated procedure to ensure the relevant authorities receive all test results. QAI conducted a review of issued test results over the preceding year and confirmed that this was an isolated incident. QAI provided NOP documented evidence of all corrective actions for review. The corrective measures for NC3 are accepted by the NOP. **Verification at Mid-Term assessment:** Records reviewed and interviews conducted during the on-site audit confirmed that all test results are being sent to the California State Organic Program as required.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

Applicant Name	Quality Certification Services (QCS)
Physical Address	214 W. University, Suite A, Gainesville, FL 32601
Mailing Address	PO Box 12311, Gainesville, FL 32604
Contact & Title	Ramkrishnan Balasubramanian, Chief Executive Officer
E-mail Address	ram@qcsinfo.org
Phone Number	352-377-0133
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Miles McEvoy and Renee Mann, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP Review: November 19, 2014 On-site audit: July 7-11, 2014
Audit Identifier	NP4188MVA
Action Required	Yes, response to noncompliances
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the settlement agreement and to verify the implementation and effectiveness of QCS's corrective actions in response to the settlement agreement.
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	QCS's certification services in carrying out the audit criteria during the period: July 24, 2012 – July 11, 2014

GENERAL INFORMATION:

Quality Certification Services (QCS) is the Certification Program of Florida Certified Organic Growers and Consumers, Inc., which is a non-profit organization. QCS was accredited as a certifying agent on April 29, 2002 to the National Organic Program (NOP) for crops, wild crops, livestock, and handling operations. QCS also offers certification to the following international standards: Global Gap; European Union (EC 834/2007 and EC 889/2008), Canadian Organic Regime (COR), and Taiwan Export Standards.

QCS has two offices which are located in Gainesville, FL and Quito, Ecuador. The QCS main office is located in Gainesville, FL and all certification activities are finalized in this office. QCS has an Executive Director, a Chief Operating Officer, Certification Coordinators (CC), and administrative personnel. Some of the CC's can and do act as staff inspectors. QCS also uses contracted inspectors. Records reviewed verified that QCS was meeting the requirements for annual performance evaluations, confidentiality, and conflicts of interest disclosure reports for all personnel. In the spring of 2014, QCS reevaluated the livestock inspection staff and found two staff members who were not qualified to conduct ruminant livestock inspections. These staff members are no longer conducting ruminant inspections.

As part of the on-site assessment, two witness inspections and six review audits were conducted on certified operations (dairy livestock, crops), which were located in Northern Indiana. This compliance audit focused on activities at the Gainesville office.

Non-Compliances – Certifier Response Accepted

The NOP has reviewed the corrective actions submitted by the certifying agent and determined that they demonstrate sufficient compliance.

NP4188MVA.NC1 – Adequately Addressed – 7 CFR §205.403(c) states, “Verification of information. The on-site inspection of an operation must verify: (1) The operation’s compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plants tissue; and plant, animal, and processed product samples.” *Overall, during the witness inspections and review audits it was found that the OSPs were not complete regarding the list of inputs used. The QCS process for updating the OSP at the time of inspection is not standardized.*

- A) *During the review audits it was found that inspectors had not verified all of the operation’s compliance or capability to comply with the regulations. One inspector indicated that the producer had a closed herd with no purchased replacement animals. However, the producer indicated that two replacement heifers were purchased. One inspector did not indicate any health care practices or inputs used for pink eye or milk fever, nor were the products on the OSP or previous inspection report, yet the producer used products for both of these health issues. Some additional health inputs were not listed on the plan, including bolus products, but the inspector reported that the health product input list in the plan was complete.*
- B) *During one review audit the auditor discovered that the operator had 14 inputs onsite that were not described in the OSP or in the input list verified by QCS. One review audit found 27 inputs onsite that were not in the OSP or noted in the inspection report. This issue had been mentioned as a minor noncompliance in 2012 or addressed in 2013. The operation did not seem to maintain a complete record of the inputs it used. The operation used a product containing zinc sulfate, which is not allowed as a foot bath, but the operator stated that a previous inspector had approved the product.*

Corrective Actions: QCS revised the Input Review Procedure, which requires that all clients receive written confirmation of the approval status of each new input, in addition to sending a full list of approved inputs when client organic certificates are issued. QCS also revised the Combined Certification Docs template to incorporate a check-box to remind staff to send the full list of approved inputs when client certificates are issued. QCS issued guidance to inspectors to standardize the process for inspectors regarding OSP updates at the time of inspection. QCS conducted inspector training in early October 2014 to explain updated policies and procedures, with refresher training planned for early 2015. QCS will issue Notices of Noncompliance to each of the four operations for use of inputs that were not pre-approved by QCS or included on the operations’ OSPs. QCS plans to conduct witness or review audits on four operations during the

grazing season in 2015 in order to verify that client OSPs are accurate and being followed, and inspectors are properly reviewing or updating the OSP per QCS procedures. Furthermore, QCS is no longer using two of the three inspectors associated with the inspection issues identified as a result of the recent audit.

NP4188MVA.NC2 – Adequately Addressed – 7 CFR §205.403(d) states, “Exit Interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.” *Overall, the exit interviews did not clearly summarize the findings, issues of concern, or clearly indicate the status of materials. The body of the inspection report specifies the materials used or requested for use but not in the OSP.*

- A) *During one of the witness inspections, the inspector did not observe records for: 1) feed fed (corn silage) to dry cows in separate pasture down the road; 2) which animal(s) received an immune-booster and the reasons for treatment; and 3) a record of the search for organic seeds. The inspector noted in the exit interview that any calves treated with the immune booster were not identified (ear tag), and stated this would be reviewed by QCS for compliance to §205.103. Also, the exit interview did not include reference to other missing records and did not clearly indicate that the incomplete records were an issue of concern.*
- B) *During one of the review audits it was noted that the dairy operation had requested certification on a neighbor’s adjoining four acre parcel. The operation had requested certification for the crop that was harvested in the previous year. There was no mention of the four acre parcel in the inspector’s exit interview, which should have been noted as an issue of concern.*
- C) *During the review audit it was noted that the inspector’s exit interview contained five findings, including that the producer would send certain items to QCS and record some practices. The exit interview included an inconsistent and unclear explanation of what was needed from the operation and what would occur between inspection and certification. The operation did not complete all the activities outlined in exit interview, including documenting temporary confinement, adjoining land use agreements, equipment cleaning, and livestock housing.*

Corrective Actions: QCS addressed this noncompliance with inspectors and staff via an annual conference call, through two reminder memos, and with scheduled training sessions. QCS reminded staff and inspectors that the exit interview must clearly indicate the following items: use of any materials not approved by QCS, issues of concern, all potential noncompliances, and any issues found that were not consistent with the QCS approved OSP. Inspectors and their inspection reports are evaluated by a reviewer for each inspection conducted. Annual evaluations of inspectors are conducted and QCS will not continue using an inspector whose exit interviews are found inadequate. QCS plans to conduct witness or review audit of four inspectors in 2015 to verify that procedures from the training are being implemented. QCS will continue to evaluate inspectors and inspection reports on an annual basis to ensure exit interviews are adequate. In addition, QCS issued Notices of Noncompliance to noncompliant operations identified through this assessment. QCS plans an additional evaluation by mid-December 2014 of the four-acre parcel associated with one of the operations noted in the audit to determine if comingling

occurred or non-certified product was marketed as organic.

NP4188MVA.NC3 – Adequately Addressed – 7 CFR §205.501(a)(2) states, “Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

- A) *During various review and witness audits, livestock supplements containing nonorganic agricultural ingredients were observed and not identified as issues of concern by the inspector. Many of these products are specific to one manufacturer; products have been reviewed by QCS and found to contain organic ingredients even though these are not listed on the label. The labels provided to QCS by the manufacturer were sometimes inconsistent with labels found onsite at the farms: some labels identified organic ingredients while others did not. Feed supplement products from a different manufacturer that contain nonorganic molasses, apple cider vinegar, yucca, garlic, and aloe vera are being allowed by QCS because another certifier also allows the product. This product was not listed on the client’s input list nor was not identified as an issue by the previous inspector. It is unclear when the operation started using the product or if QCS has ever reviewed the product label.*
- B) *QCS Input Review procedure (QCS-08-01) does not require a written response to the applicant confirming the materials approved for use in response to changes to the OSP during inspection or in response to changes submitted throughout the year. It requires that the client be notified, but this can be via phone with a note to QCS’s internal file. As a result, it is not clear if QCS’s clients know, or have record of, which inputs have been approved for use.*
- C) *An operation in Indiana was inspected in 2012 and issued a minor noncompliance on December 10, 2012. The noncompliance was to §205.201, indicating that the OSP did not include a list of each livestock health care product in use or planned for use. On January 22, 2013, QCS received a hand written update from the client indicating the materials he currently used. On January 24, 2013, QCS issued a letter to the client indicating that the issue was resolved and the materials or actions were sufficient to resolve the noncompliance. However, QCS did not explicitly confirm which materials had been added to the OSP and the farmer did not appear to keep a record. During the NOP’s review audit of this operation in July 2014, several products not on the OSP or approved input list were discovered onsite. One product discovered to be currently in use by the operation contains zinc sulfate, which is prohibited for use in organic livestock production as a foot bath, but the operator stated that he was told the product was acceptable for use by a QCS inspector during a training held in the region in 2013. During the June 2014 inspection, which had not yet been submitted to QCS, the inspector documented the product as a new product found during the inspection, but did not identify that the material contained zinc sulfate. The inspector also documented 27 other products onsite that were not documented on the client’s input list.*
- D) *During another review audit, 14 products were found to be present at the farm (some in use) that were not identified on the current OSP or input list approved by QCS.*

Corrective Actions: QCS has reviewed many of the livestock feed or feed supplement products from the manufacturer identified during the witness and review audits to verify their compliance with the USDA organic regulations. QCS provided documentation to the manufacturer regarding the status of the approved products. During a conference call with the NOP on October 9, 2014, QCS explained that the livestock feed/feed supplement labeling issue stems from a state

livestock product labeling law, which prohibits the use of the term “organic” on the label for any ingredients. Feed supplement products from the other manufacturer in question are currently being reviewed for compatibility with the USDA organic regulations. Operators with incomplete OSPs or input lists will receive Notices of Noncompliance from QCS. QCS addressed this noncompliance with inspectors and staff via an annual conference call, through two reminder memos, and with scheduled training sessions. QCS reminded staff and inspectors that the exit interview must clearly indicate the following items: use of any materials not approved by QCS, issues of concern, all potential noncompliances, and any issues found that were not consistent with the QCS approved OSP. QCS plans to conduct witness or review audit of four inspectors in 2015 to verify that procedures from the training are being implemented. QCS will continue to evaluate inspectors and inspection reports on an annual basis to ensure exit interviews are adequate. The specific inspector associated with the issues identified in NC3 is no longer employed by QCS.

NP4188MVA.NC4 – Adequately Addressed – 7 CFR §205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through §205.406 and §205.670.” Specifically, §205.200 General that states, “The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must comply with the applicable provisions of this subpart...” *QCS certified a beef operation that stated that it does not slaughter its animals in a certified organic slaughter facility. However, the operation provided a brochure to QCS that identifies the slaughtered cows (whole or half) as “organically raised” and the operation’s promotional brochure uses the USDA organic seal. The company is representing processed beef as certified organic when it has been processed in a noncertified facility.*

Corrective Actions: QCS spoke with the client on October 17, 2014 and was informed by the client that they had already discontinued use of the brochure six months ago. QCS issued a Notice of Noncompliance to the operator on October 28, 2014, and the client responded with corrective actions that are currently under review by QCS. In addition, QCS is planning to conduct an unannounced inspection of this operation during November 2014, and a surveillance audit of the operation’s website and point-of-sale marketing materials. On October 28, 2014, QCS conducted a staff training about product labeling and marketing materials, which included a review of guidance document NOP 4012 *Use of Brand or Company Names Containing the Word “Organic.”*

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

Applicant Name	Quality Certification Services (QCS)
Physical Address	214 W. University, Suite A, Gainesville, FL 32601
Mailing Address	PO Box 12311, Gainesville, FL 32604
Contact & Title	Ramkrishnan Balasubramanian, Chief Executive Officer
E-mail Address	ram@qcsinfo.org
Phone Number	352-377-0133
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Miles McEvoy and Renee Mann, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP Review: November 19, 2014 On-site audit: July 7-11, 2014
Audit Identifier	NP4188MVA
Action Required	Yes, response to noncompliances
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the settlement agreement and to verify the implementation and effectiveness of QCS's corrective actions in response to the settlement agreement.
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	QCS's certification services in carrying out the audit criteria during the period: July 24, 2012 – July 11, 2014

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As part of the on-site assessment, two witness inspections and six review audits were conducted on certified operations (dairy livestock, crops), which were located in Northern Indiana. This compliance audit focused on activities at the Gainesville office.

Non-Compliances – Certifier Response Accepted

The NOP has reviewed the corrective actions submitted by the certifying agent and determined that they demonstrate sufficient compliance.

NP4188MVA.NC1 – Accepted – 7 CFR §205.403(c) states, “Verification of information. The on-site inspection of an operation must verify: (1) The operation’s compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plants tissue; and plant, animal, and processed product samples.” *Overall, during the witness inspections and review audits it was found that the OSPs were not complete regarding the list of inputs used. The QCS process for updating the OSP at the time of inspection is not standardized.*

- A) *During the review audits it was found that inspectors had not verified all of the operation’s compliance or capability to comply with the regulations. One inspector indicated that the producer had a closed herd with no purchased replacement animals. However, the producer indicated that two replacement heifers were purchased. One inspector did not indicate any health care practices or inputs used for pink eye or milk fever, nor were the products on the OSP or previous inspection report, yet the producer used products for both of these health issues. Some additional health inputs were not listed on the plan, including bolus products, but the inspector reported that the health product input list in the plan was complete.*
- B) *During one review audit the auditor discovered that the operator had 14 inputs onsite that were not described in the OSP or in the input list verified by QCS. One review audit found 27 inputs onsite that were not in the OSP or noted in the inspection report. This issue had been mentioned as a minor noncompliance in 2012 or addressed in 2013. The operation did not seem to maintain a complete record of the inputs it used. The operation used a product containing zinc sulfate, which is not allowed as a foot bath, but the operator stated that a previous inspector had approved the product.*

Corrective Actions: QCS revised the Input Review Procedure, which requires that all clients receive written confirmation of the approval status of each new input, in addition to sending a full list of approved inputs when client organic certificates are issued. QCS also revised the Combined Certification Docs template to incorporate a check-box to remind staff to send the full list of approved inputs when client certificates are issued. QCS issued guidance to inspectors to standardize the process for inspectors regarding OSP updates at the time of inspection. QCS conducted inspector training in early October 2014 to explain updated policies and procedures, with refresher training planned for early 2015. QCS will issue Notices of Noncompliance to each of the four operations for use of inputs that were not pre-approved by QCS or included on the operations’ OSPs. QCS plans to conduct witness or review audits on four operations during the

grazing season in 2015 in order to verify that client OSPs are accurate and being followed, and inspectors are properly reviewing or updating the OSP per QCS procedures. Furthermore, QCS is no longer using two of the three inspectors associated with the inspection issues identified as a result of the recent audit.

NP4188MVA.NC2 – Accepted – 7 CFR §205.403(d) states, “Exit Interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.” *Overall, the exit interviews did not clearly summarize the findings, issues of concern, or clearly indicate the status of materials. The body of the inspection report specifies the materials used or requested for use but not in the OSP.*

- A) *During one of the witness inspections, the inspector did not observe records for: 1) feed fed (corn silage) to dry cows in separate pasture down the road; 2) which animal(s) received an immune-booster and the reasons for treatment; and 3) a record of the search for organic seeds. The inspector noted in the exit interview that any calves treated with the immune booster were not identified (ear tag), and stated this would be reviewed by QCS for compliance to §205.103. Also, the exit interview did not include reference to other missing records and did not clearly indicate that the incomplete records were an issue of concern.*
- B) *During one of the review audits it was noted that the dairy operation had requested certification on a neighbor’s adjoining four acre parcel. The operation had requested certification for the crop that was harvested in the previous year. There was no mention of the four acre parcel in the inspector’s exit interview, which should have been noted as an issue of concern.*
- C) *During the review audit it was noted that the inspector’s exit interview contained five findings, including that the producer would send certain items to QCS and record some practices. The exit interview included an inconsistent and unclear explanation of what was needed from the operation and what would occur between inspection and certification. The operation did not complete all the activities outlined in exit interview, including documenting temporary confinement, adjoining land use agreements, equipment cleaning, and livestock housing.*

Corrective Actions: QCS addressed this noncompliance with inspectors and staff via an annual conference call, through two reminder memos, and with scheduled training sessions. QCS reminded staff and inspectors that the exit interview must clearly indicate the following items: use of any materials not approved by QCS, issues of concern, all potential noncompliances, and any issues found that were not consistent with the QCS approved OSP. Inspectors and their inspection reports are evaluated by a reviewer for each inspection conducted. Annual evaluations of inspectors are conducted and QCS will not continue using an inspector whose exit interviews are found inadequate. QCS plans to conduct witness or review audit of four inspectors in 2015 to verify that procedures from the training are being implemented. QCS will continue to evaluate inspectors and inspection reports on an annual basis to ensure exit interviews are adequate. In addition, QCS issued Notices of Noncompliance to noncompliant operations identified through this assessment. QCS plans an additional evaluation by mid-December 2014 of the four-acre parcel associated with one of the operations noted in the audit to determine if comingling

occurred or non-certified product was marketed as organic.

NP4188MVA.NC3 – Accepted – 7 CFR §205.501(a)(2) states, “Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

- A) *During various review and witness audits, livestock supplements containing nonorganic agricultural ingredients were observed and not identified as issues of concern by the inspector. Many of these products are specific to one manufacturer; products have been reviewed by QCS and found to contain organic ingredients even though these are not listed on the label. The labels provided to QCS by the manufacturer were sometimes inconsistent with labels found onsite at the farms: some labels identified organic ingredients while others did not. Feed supplement products from a different manufacturer that contain nonorganic molasses, apple cider vinegar, yucca, garlic, and aloe vera are being allowed by QCS because another certifier also allows the product. This product was not listed on the client’s input list nor was not identified as an issue by the previous inspector. It is unclear when the operation started using the product or if QCS has ever reviewed the product label.*
- B) *QCS Input Review procedure (QCS-08-01) does not require a written response to the applicant confirming the materials approved for use in response to changes to the OSP during inspection or in response to changes submitted throughout the year. It requires that the client be notified, but this can be via phone with a note to QCS’s internal file. As a result, it is not clear if QCS’s clients know, or have record of, which inputs have been approved for use.*
- C) *An operation in Indiana was inspected in 2012 and issued a minor noncompliance on December 10, 2012. The noncompliance was to §205.201, indicating that the OSP did not include a list of each livestock health care product in use or planned for use. On January 22, 2013, QCS received a hand written update from the client indicating the materials he currently used. On January 24, 2013, QCS issued a letter to the client indicating that the issue was resolved and the materials or actions were sufficient to resolve the noncompliance. However, QCS did not explicitly confirm which materials had been added to the OSP and the farmer did not appear to keep a record. During the NOP’s review audit of this operation in July 2014, several products not on the OSP or approved input list were discovered onsite. One product discovered to be currently in use by the operation contains zinc sulfate, which is prohibited for use in organic livestock production as a foot bath, but the operator stated that he was told the product was acceptable for use by a QCS inspector during a training held in the region in 2013. During the June 2014 inspection, which had not yet been submitted to QCS, the inspector documented the product as a new product found during the inspection, but did not identify that the material contained zinc sulfate. The inspector also documented 27 other products onsite that were not documented on the client’s input list.*
- D) *During another review audit, 14 products were found to be present at the farm (some in use) that were not identified on the current OSP or input list approved by QCS.*

Corrective Actions: QCS has reviewed many of the livestock feed or feed supplement products from the manufacturer identified during the witness and review audits to verify their compliance with the USDA organic regulations. QCS provided documentation to the manufacturer regarding the status of the approved products. During a conference call with the NOP on October 9, 2014, QCS explained that the livestock feed/feed supplement labeling issue stems from a state

livestock product labeling law, which prohibits the use of the term “organic” on the label for any ingredients. Feed supplement products from the other manufacturer in question are currently being reviewed for compatibility with the USDA organic regulations. Operators with incomplete OSPs or input lists will receive Notices of Noncompliance from QCS. QCS addressed this noncompliance with inspectors and staff via an annual conference call, through two reminder memos, and with scheduled training sessions. QCS reminded staff and inspectors that the exit interview must clearly indicate the following items: use of any materials not approved by QCS, issues of concern, all potential noncompliances, and any issues found that were not consistent with the QCS approved OSP. QCS plans to conduct witness or review audit of four inspectors in 2015 to verify that procedures from the training are being implemented. QCS will continue to evaluate inspectors and inspection reports on an annual basis to ensure exit interviews are adequate. The specific inspector associated with the issues identified in NC3 is no longer employed by QCS.

NP4188MVA.NC4 – Accepted – 7 CFR §205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through §205.406 and §205.670.” Specifically, §205.200 General that states, “The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must comply with the applicable provisions of this subpart...” *QCS certified a beef operation that stated that it does not slaughter its animals in a certified organic slaughter facility. However, the operation provided a brochure to QCS that identifies the slaughtered cows (whole or half) as “organically raised” and the operation’s promotional brochure uses the USDA organic seal. The company is representing processed beef as certified organic when it has been processed in a noncertified facility.*

Corrective Actions: QCS spoke with the client on October 17, 2014 and was informed by the client that they had already discontinued use of the brochure six months ago. QCS issued a Notice of Noncompliance to the operator on October 28, 2014, and the client responded with corrective actions that are currently under review by QCS. In addition, QCS is planning to conduct an unannounced inspection of this operation during November 2014, and a surveillance audit of the operation’s website and point-of-sale marketing materials. On October 28, 2014, QCS conducted staff training about product labeling and marketing materials, which included a review of guidance document NOP 4012 *Use of Brand or Company Names Containing the Word “Organic.”*

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a Mid-term Assessment of Quality Certification Services. During July 2014, QCS underwent a NOP Compliance Assessment involving several Witness and Review Audits, focused on certified livestock operation activities. This onsite Mid-term Assessment was conducted and the audit report was reviewed to determine Quality Certification Services' capability to continue operating as a USDA accredited certifier. This two-day audit was limited in scope and intentionally did not conduct full file reviews of any livestock operations. One Witness Audit of a certified crop operation was conducted in Virginia during the month of July. A USDA ISO 17065 Program Reassessment was conducted concurrently with the NOP Mid-Term Assessment.

GENERAL INFORMATION

Applicant Name	Quality Certification Services (QCS)
Physical Address	1810 NW 6th Street, Suite F, Gainesville, FL 32604
Mailing Address	P.O. Box 12311, Gainesville, FL 32604
Contact & Title	Ram Balasubramanian, Chief Operating Officer
E-mail Address	ram@qcsinfo.org
Phone Number	(352) 377-0133
Reviewer & Auditors	Janna Howley, NOP Reviewer Lars Crail and Miguel Caceres, Onsite Auditors Mike Lopez, Grower Group Review Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: December 23, 2014 Onsite audit: August 18-19, 2014 Grower group review audit: October 30-31, 2014
Audit Identifier	NP4230LCA
Action Required	None
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of QCS' certification system.
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	QCS' certification services in carrying out the audit criteria during the period: April 25, 2013 through August 19, 2014.

Quality Certification Services (QCS) is the Certification Program of Florida Certified Organic Growers and Consumers, Inc., a non-profit organization. QCS has been accredited as a certifying agent since April 29, 2002, to the National Organic Program (NOP) for crops, wild crops,

livestock, and handling scopes. QCS is currently certifying operations in the United States, China, Bahamas, Ecuador, Dominican Republic, Guatemala, Mexico, Malaysia, Sweden, Peru, and South Africa. The QCS client list (at the time of this assessment) included a total of 727 certified operations, of which there were 569 crop, three wild crop, 156 livestock, and 212 handling operations certified to the NOP. In addition, QCS currently certifies five grower groups.

QCS has four offices, located in Gainesville, FL; Columbia, MO; Louisa, VA; and Quito, Ecuador. The main office is located in Gainesville and all certification activities are finalized in this office.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether QCS' corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP215500A.NC1 – Cleared

NP215500A.NC2 – Cleared

AIA4086MMK.NC1 – Cleared

AIA4086MMK.NC2 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as “**Accepted**,” indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4230LCA.NC1 – Accepted - 7 CFR §205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provision of §§205.402 through 205.406 and §205.670.” Furthermore, 7 CFR §205.404(c) states, “Once certified, a production or handling operation’s organic certification continues in effect until surrendered by the organic operation...”

Comments: *The Notices of Proposed Suspension and Notices of Suspension state that QCS does not accept the surrender of certification under these circumstances. USDA organic regulations do not permit certifying agents to deny an operation the ability to surrender their organic certification in response to an adverse action.*

Corrective Actions: QCS' current policy is that the operator is provided the option of surrendering their certificate at any time. To improve compliance, QCS updated its process for accepting a surrender at any time. When a client requests to surrender their certification during adverse actions proceedings, a Surrender Form, along with the adverse action, is issued to the operator. The method for handling surrenders has been updated in the *QCS Certification Review*

Standard Operating Procedures, Section VII. Adverse action letters have been updated to remove any statements that would imply that surrender is denied based on any circumstances. The Organic System Plan template was also updated to remove similar statements. QCS reviewed the surrender policy with staff during its November 2014 staff meeting. A Training Memo regarding this change was also issued to staff. QCS provided the NOP with copies of the corrected and updated documents.

NP4230LCA.NC2 – Accepted - 7 CFR §205.662(c)(3) states, “The notification of proposed suspension shall state... The impact of a suspension or revocation on future eligibility for certification...”

Comments: *One Notice of Proposed Suspension that was issued stated a six month suspension period, while the subsequent Notice of Suspension that was issued indicated a suspension period of one year.*

Corrective Actions: QCS updated its *Certification Policies* to include a timetable guideline for suspensions and revocations. These guidelines state the recommended time periods and reiterate that when drafting the notice of suspension or revocation, the staff member must refer back to the stated timeframe in the proposed suspension or proposed revocation letter. Additionally, all variations of the notice of proposed suspension/revocation letters have been revised, with options to select for the specific periods of suspension/revocation. QCS provided the NOP with copies of the corrected and updated documents. QCS concluded that this was an isolated clerical error. The situation was discussed with the staff member that drafted the letter and their correspondence is currently being monitored for consistency. However, QCS also reviewed the suspension and revocation time period policy with staff during a November 2014 staff meeting. A Training Memo regarding this change was also issued to staff.

NP4230LCA.NC3 – Accepted - 7 CFR §205.501 (a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP PM 11-10, Grower Group Certification, states in the 2008 NOSB Recommendation that as criteria for group certification, “The certification is owned by the group, not any individual member or subunit, which may not represent itself as certified other than through the group.”

Comments: *One reviewed file indicated that QCS granted organic certification to a Grower Group owned by one entity, but this entity (an individual producer/processor) does not meet the requirements as a Grower Group and they contract with other producers to obtain additional product. Furthermore, QCS’ Certification Manual, Section 2.6, does not describe criteria in accordance with the USDA NOP policy for certification of a Grower Group.*

Corrective Actions: QCS’ criteria in its *QCS Certification Manual* are identical to the 2008 NOSB recommendations. QCS reviewed the grower group policy with staff during its November 2014 staff meeting. To date, QCS only certifies five grower groups, all of whose members are owned by the group, versus individual ownership. The operation reviewed by the USDA NOP has since been suspended from QCS; it was the only certified grower group with an individual owner. A Training Memo regarding NOP PM 11-10, Grower Group Certification was also issued to staff.

NP4230LCA.NC4 - Accepted - 7 CFR §205.670(d) states, “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number.”

Comments: *QCS’ January 2, 2013 submitted List of Certified Operations indicates 661 total operations and a minimum of 33 operations are required to be sampled for 2013. During 2013, QCS conducted residue testing sampling of 29 operations.*

Corrective Actions: At the beginning of 2014 the *QCS Certification Policy Manual* and *QCS Certification Standard Operating Procedure (SOP)* were both amended to reflect the five percent residue sampling requirement. The QCS Administrative Manager was also tasked with meeting this regulatory requirement. QCS has 835 total operations based on the January 2, 2014 list sent to the NOP; a minimum of 41 operations were required to have samples taken in 2014. QCS took a total of 44 samples by the end of 2014. The *2014 QCS Unannounced Inspection List, Policy Manual and Standard Operating Procedures* were provided to the NOP. QCS reviewed and discussed the progress of the five percent sampling requirement with staff during its November 2014 staff meeting. A Training Memo regarding this change was also issued to staff. The minimum requirement will also be addressed as an agenda item during a January 2015 staff meeting.

NP4230LCA.NC5 – Accepted - 7 CFR §205.403(a)(2)(ii) and NOP 2609, Unannounced Inspections states that, “... certifying agents conduct unannounced inspections of 5 percent of their total certified operations per year...”

Comments: *QCS’ January 2, 2013 submitted List of Certified Operations indicates 661 total operations and a minimum of 33 operations are expected to receive unannounced inspections for 2013. During 2013, QCS conducted unannounced inspections of 29 operations.*

Corrective Actions: At the beginning of 2014 the *QCS Certification Policy Manual* and *QCS Certification Standard Operating Procedure (SOP)* were both amended to reflect the five percent unannounced inspection requirement. The QCS Administrative Manager was also tasked with meeting this regulatory requirement. QCS has 835 total operations based on the January 2, 2014 list sent to the NOP; a minimum of 41 operations were required to have an unannounced inspection in 2014. QCS conducted a total of 42 unannounced inspections by the end of 2014. The *2014 QCS Unannounced Inspection List, Policy Manual and Standard Operating Procedures* were provided to the NOP. QCS reviewed and discussed the progress of the five percent unannounced inspections for operations with staff during its November 2014 staff meeting. A Training Memo regarding this change was also issued to staff. The minimum requirement will also be addressed as an agenda item during a January 2015 staff meeting.

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Quality Certification Services (QCS) accreditation renewal application to maintain U.S. Department of Agriculture (USDA) accreditation as an organic certifier on November 2, 2016. The NOP has reviewed QCS' renewal application, conducted an onsite audit, and reviewed the audit report to determine QCS' capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Quality Certification Services (QCS)
Physical Address	214 W. University Avenue, Suite A, Gainesville, FL 32601
Mailing Address	P.O. Box 12311, Gainesville, FL 32604
Contact & Title	Ramkrishnan Balasubramanian, Chief Executive Officer
E-mail Address	ram@qcsinfo.org
Phone Number	(352) 377-0133
Reviewer & Auditors	Penny Zuck, NOP Reviewer; Patty Heckart and Robert Yang, On-site Auditors
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: March 17, 2017 Onsite audit: January 23-26, 2017; February 6-9, 2017 (grower group witness audit)
Audit Identifier	NP7023NNA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of QCS' certification program.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	QCS' certification services in carrying out the audit criteria during the period: August 19, 2014 through February 9, 2017

QCS is the Certification Program of Florida Certified Organic Growers and Consumers, Inc., which is a non-profit organization. QCS was accredited as a certifying agent on April 29, 2002 to the National Organic Program (NOP) for crops, wild crops, livestock, and handling operations.

QCS certifies 1096 operations to the following scopes: Crops (753), Wild Crops (3), Livestock (228), and Handler/Processor/Exporters (300). QCS certifies 13 grower groups outside of the U.S. Certification services occur in the following countries: Belgium, Bahamas, Dominican

Republic, Ecuador, France, Guatemala, Jamaica, Malaysia, Mexico, Puerto Rico, South Africa, Vietnam, and the Virgin Islands.

QCS' office is located in Gainesville, Florida. QCS' staff consists of: Technical Staff (21), Inspectors (56), and Administrative/support staff (8).

As part of the onsite accreditation audit activities, two witness audits (WA) were conducted on a crops grower group operation and one handler/processor operation. A witness audit will be conducted at a livestock (cattle)/crops operation at a later date during grazing season and reported with another audit identifier.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether QCS' corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to QCS.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP4188MVA.NC1 – Cleared. 7 CFR §205.403(c) states, “Verification of information. The on-site inspection of an operation must verify: (1) The operation’s compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plants tissue; and plant, animal, and processed product samples.”

Comments: *Overall, during the witness inspections and review audits it was found that the OSPs were not complete regarding the list of inputs used. The QCS process for updating the OSP at the time of inspection is not standardized.*

A) *During the review audits it was found that inspectors had not verified all of the operation’s compliance or capability to comply with the regulations. One inspector indicated that the producer had a closed herd with no purchased replacement animals. However, the producer indicated that two replacement heifers were purchased. One inspector did not indicate any health care practices or inputs used for pink eye or milk fever, nor were the products on the OSP or previous inspection report, yet the producer used products for both of these health issues. Some additional health inputs were not listed on the plan, including bolus products, but the inspector reported that the health product input list in the plan was complete.*

B) *During one review audit the auditor discovered that the operator had 14 inputs onsite that were not described in the OSP or in the input list verified by QCS. One review audit found 27 inputs onsite that were not in the OSP or noted in the inspection report. This issue had been mentioned as a minor noncompliance in 2012 or addressed in 2013. The operation did not seem to maintain a complete record of the inputs it used. The operation used a product containing zinc sulfate, which is not allowed as a foot bath, but the operator stated that a previous inspector had approved the product.*

Corrective Actions: QCS revised the Input Review Procedure, which requires that all clients receive written confirmation of the approval status of each new input, in addition to sending a full list of approved inputs when client organic certificates are issued. QCS also revised the Combined Certification Docs template to incorporate a check-box to remind staff to send the full list of approved inputs when client certificates are issued. QCS issued guidance to inspectors to standardize the process for inspectors regarding OSP updates at the time of inspection. QCS conducted inspector training in early October 2014 to explain updated policies and procedures, with refresher training planned for early 2015. QCS will issue Notices of Noncompliance to each of the four operations for use of inputs that were not pre-approved by QCS or included on the operations' OSPs. QCS plans to conduct witness or review audits on four operations during the grazing season in 2015 in order to verify that client OSPs are accurate and being followed, and inspectors are properly reviewing or updating the OSP per QCS procedures. Furthermore, QCS is no longer using two of the three inspectors associated with the inspection issues identified as a result of the recent audit.

2016 Verification of Corrective Actions: QCS revised the Input Review Procedure. Interviews with QCS personnel revealed that QCS now issues a communication to the operator stating approval status of each requested new input after review by the materials review specialist. An updated Input List is issued with each approval and new organic certificate. Training records were available regarding the additional training for this new procedure. Previously approved inputs are subject to additional review after a set number of years to verify continued approval. Review of client files and interviews verified that QCS provides inspectors a complete list of inputs to be checked during inspections along with updated OSP information.

NP4188MVA.NC2 – Cleared. 7 CFR §205.403(d) states, “Exit Interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.”

Comments: *Overall, the exit interviews did not clearly summarize the findings, issues of concern, or clearly indicate the status of materials. The body of the inspection report specifies the materials used or requested for use but not in the OSP.*

A) *During one of the witness inspections, the inspector did not observe records for: 1) feed fed (corn silage) to dry cows in separate pasture down the road; 2) which animal(s) received an immune-booster and the reasons for treatment; and 3) a record of the search for organic seeds. The inspector noted in the exit interview that any calves treated with the immune booster were not identified (ear tag), and stated this would be reviewed by QCS for compliance to §205.103. Also, the exit interview did not include reference to other missing records and did not clearly indicate that the incomplete records were an issue of concern.*

- B) *During one of the review audits it was noted that the dairy operation had requested certification on a neighbor's adjoining four acre parcel. The operation had requested certification for the crop that was harvested in the previous year. There was no mention of the four acre parcel in the inspector's exit interview, which should have been noted as an issue of concern.*
- C) *During the review audit it was noted that the inspector's exit interview contained five findings, including that the producer would send certain items to QCS and record some practices. The exit interview included an inconsistent and unclear explanation of what was needed from the operation and what would occur between inspection and certification. The operation did not complete all the activities outlined in exit interview, including documenting temporary confinement, adjoining land use agreements, equipment cleaning, and livestock housing.*

Corrective Actions: QCS addressed this noncompliance with inspectors and staff via an annual conference call, through two reminder memos, and with scheduled training sessions. QCS reminded staff and inspectors that the exit interview must clearly indicate the following items: use of any materials not approved by QCS, issues of concern, all potential noncompliances, and any issues found that were not consistent with the QCS approved OSP. Inspectors and their inspection reports are evaluated by a reviewer for each inspection conducted. Annual evaluations of inspectors are conducted and QCS will not continue using an inspector whose exit interviews are found inadequate. QCS plans to conduct witness or review audit of four inspectors in 2015 to verify that procedures from the training are being implemented. QCS will continue to evaluate inspectors and inspection reports on an annual basis to ensure exit interviews are adequate. In addition, QCS issued Notices of Noncompliance to noncompliant operations identified through this assessment. QCS plans an additional evaluation by mid-December 2014 of the four-acre parcel associated with one of the operations noted in the audit to determine if comingling occurred or non-certified product was marketed as organic.

2016 Verification of Corrective Actions: QCS conducted training sessions for the inspectors on multiple occasions. Training agendas and logs were available. Review of files and witness audits verified the effectiveness of the training. Review of certification files and exit interview records indicated that summaries were made by the inspectors for clarification to the operator. In addition, witness audits conducted showed that implementation of corrective actions are effective.

NP4188MVA.NC3 – Cleared. 7 CFR §205.501(a)(2) states, “Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments:

- A) *During various review and witness audits, livestock supplements containing nonorganic agricultural ingredients were observed and not identified as issues of concern by the inspector. Many of these products are specific to one manufacturer; products have been reviewed by QCS and found to contain organic ingredients even though these are not listed on the label. The labels provided to QCS by the manufacturer were sometimes inconsistent with labels found onsite at the farms: some labels identified organic ingredients while others did not. Feed supplement products from a different manufacturer that contain nonorganic molasses, apple cider vinegar, yucca, garlic, and aloe vera are being allowed by QCS because another certifier also allows the product. This product was not listed on the client's input list nor was not identified as an issue by*

- the previous inspector. It is unclear when the operation started using the product or if QCS has ever reviewed the product label.*
- B) QCS Input Review procedure (QCS-08-01) does not require a written response to the applicant confirming the materials approved for use in response to changes to the OSP during inspection or in response to changes submitted throughout the year. It requires that the client be notified, but this can be via phone with a note to QCS's internal file. As a result, it is not clear if QCS's clients know, or have record of, which inputs have been approved for use.*
- C) An operation in Indiana was inspected in 2012 and issued a minor noncompliance on December 10, 2012. The noncompliance was to §205.201, indicating that the OSP did not include a list of each livestock health care product in use or planned for use. On January 22, 2013, QCS received a hand written update from the client indicating the materials he currently used. On January 24, 2013, QCS issued a letter to the client indicating that the issue was resolved and the materials or actions were sufficient to resolve the noncompliance. However, QCS did not explicitly confirm which materials had been added to the OSP and the farmer did not appear to keep a record. During the NOP's review audit of this operation in July 2014, several products not on the OSP or approved input list were discovered onsite. One product discovered to be currently in use by the operation contains zinc sulfate, which is prohibited for use in organic livestock production as a foot bath, but the operator stated that he was told the product was acceptable for use by a QCS inspector during a training held in the region in 2013. During the June 2014 inspection, which had not yet been submitted to QCS, the inspector documented the product as a new product found during the inspection, but did not identify that the material contained zinc sulfate. The inspector also documented 27 other products onsite that were not documented on the client's input list.*
- D) During another review audit, 14 products were found to be present at the farm (some in use) that were not identified on the current OSP or input list approved by QCS.*

Corrective Actions: QCS has reviewed many of the livestock feed or feed supplement products from the manufacturer identified during the witness and review audits to verify their compliance with the USDA organic regulations. QCS provided documentation to the manufacturer regarding the status of the approved products. During a conference call with the NOP on October 9, 2014, QCS explained that the livestock feed/feed supplement labeling issue stems from a state livestock product labeling law, which prohibits the use of the term "organic" on the label for any ingredients. Feed supplement products from the other manufacturer in question are currently being reviewed for compatibility with the USDA organic regulations. Operators with incomplete OSPs or input lists will receive Notices of Noncompliance from QCS. QCS addressed this noncompliance with inspectors and staff via an annual conference call, through two reminder memos, and with scheduled training sessions. QCS reminded staff and inspectors that the exit interview must clearly indicate the following items: use of any materials not approved by QCS, issues of concern, all potential noncompliances, and any issues found that were not consistent with the QCS approved OSP. QCS plans to conduct witness or review audit of four inspectors in 2015 to verify that procedures from the training are being implemented. QCS will continue to evaluate inspectors and inspection reports on an annual basis to ensure exit interviews are adequate. The specific inspector associated with the issues identified in NC3 is no longer employed by QCS.

2016 Verification of Corrective Actions: QCS revised the Input review Procedure. After a

consideration of an input by the material review specialist, QCS issues a communication to the operator stating approval status of each input. An updated Input List is issued to the operator with each material approval and each new organic certificate. Training records were available regarding the additional training for this new procedure. QCS conducted training for all inspectors regarding the input review process and the need for inspectors to verify all inputs used by an operation during an inspection. Review of client files verified that inspectors are clarifying issues of concern during exit interviews.

NP4188MVA.NC4 – Cleared. 7 CFR §205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through §205.406 and §205.670.” Specifically, §205.200 General that states, “The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must comply with the applicable provisions of this subpart...”

Comments: *QCS certified a beef operation that stated that it does not slaughter its animals in a certified organic slaughter facility. However, the operation provided a brochure to QCS that identifies the slaughtered cows (whole or half) as “organically raised” and the operation’s promotional brochure uses the USDA organic seal. The company is representing processed beef as certified organic when it has been processed in a noncertified facility.*

Corrective Actions: QCS spoke with the client on October 17, 2014 and was informed by the client that they had already discontinued use of the brochure six months ago. QCS issued a Notice of Noncompliance to the operator on October 28, 2014, and the client responded with corrective actions that are currently under review by QCS. In addition, QCS is planning to conduct an unannounced inspection of this operation during November 2014, and a surveillance audit of the operation’s website and point-of-sale marketing materials. On October 28, 2014, QCS conducted a staff training about product labeling and marketing materials, which included a review of guidance document NOP 4012 *Use of Brand or Company Names Containing the Word “Organic.”*

2016 Verification of Corrective Actions: QCS did issue a Notice of Noncompliance to the operator as stated. The follow-up unannounced inspection confirmed that the marketing materials were discontinued. QCS staff training was conducted with the scope of labeling and marketing materials.

NP4230LCA.NC1 – Cleared. 7 CFR §205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provision of §§205.402 through 205.406 and §205.670.” Furthermore, 7 CFR §205.404(c) states, “Once certified, a production or handling operation’s organic certification continues in effect until surrendered by the organic operation...”

Comments: *The Notices of Proposed Suspension and Notices of Suspension state that QCS does not accept the surrender of certification under these circumstances. USDA organic regulations do not permit certifying agents to deny an operation the ability to surrender their organic certification in response to an adverse action.*

Corrective Actions: QCS' current policy is that the operator is provided the option of surrendering their certificate at any time. To improve compliance, QCS updated its process for accepting a surrender at any time. When a client requests to surrender their certification during adverse actions proceedings, a Surrender Form, along with the adverse action, is issued to the

operator. The method for handling surrenders has been updated in the *QCS Certification Review Standard Operating Procedures, Section VII*. Adverse action letters have been updated to remove any statements that would imply that surrender is denied based on any circumstances. The Organic System Plan template was also updated to remove similar statements. QCS reviewed the surrender policy with staff during its November 2014 staff meeting. A Training Memo regarding this change was also issued to staff. QCS provided the NOP with copies of the corrected and updated documents.

2016 Verification of Corrective Actions: Review of QCS procedures and forms for surrender of certification reveals that all statements that imply that an operation cannot surrender certification during adverse action proceedings have been removed.

NP4230LCA.NC2 – Cleared. 7 CFR §205.662(c)(3) states, “The notification of proposed suspension shall state... The impact of a suspension or revocation on future eligibility for certification...”

Comments: *One Notice of Proposed Suspension that was issued stated a six month suspension period, while the subsequent Notice of Suspension that was issued indicated a suspension period of one year.*

Corrective Actions: QCS updated its *Certification Policies* to include a timetable guideline for suspensions and revocations. These guidelines state the recommended time periods and reiterate that when drafting the notice of suspension or revocation, the staff member must refer back to the stated timeframe in the proposed suspension or proposed revocation letter. Additionally, all variations of the notice of proposed suspension/revocation letters have been revised, with options to select for the specific periods of suspension/revocation. QCS provided the NOP with copies of the corrected and updated documents. QCS concluded that this was an isolated clerical error. The situation was discussed with the staff member that drafted the letter and their correspondence is currently being monitored for consistency. However, QCS also reviewed the suspension and revocation time period policy with staff during a November 2014 staff meeting. A Training Memo regarding this change was also issued to staff.

2016 Verification of Corrective Actions: All letters of proposed suspension and letters of suspension that were reviewed by the auditors stated the same time period for suspension.

NP4230LCA.NC3 – Cleared. 7 CFR §205.501 (a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP PM 11-10, Grower Group Certification, states in the 2008 NOSB Recommendation that as criteria for group certification, “The certification is owned by the group, not any individual member or subunit, which may not represent itself as certified other than through the group.”

Comments: *One reviewed grower group operation file indicated that QCS granted organic certification to a Grower Group owned by one entity, but this entity (an individual producer/processor) does not meet the requirements as a Grower Group and they contract with other producers to obtain additional product. Furthermore, QCS’ Certification Manual, Section 2.6, does not describe criteria in accordance with the USDA NOP policy for certification of a Grower Group.*

Corrective Actions: QCS’ criteria in its *QCS Certification Manual* are identical to the 2008 NOSB recommendations. QCS reviewed the grower group policy with staff during its November

2014 staff meeting. To date, QCS only certifies five grower groups, all of whose members are owned by the group, versus individual ownership. The operation reviewed by the USDA NOP has since been suspended from QCS; it was the only certified grower group with an individual owner. A Training Memo regarding NOP PM 11-10, Grower Group Certification was also issued to staff.

2016 Verification of Corrective Actions: QCS conducted training for applicable reviewers regarding the requirement that grower groups included ownership of more than one entity. Review of files indicated that new grower group approvals were for groups of operators.

NP4230LCA.NC4 – Cleared. 7 CFR §205.670(d) states, “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number.”

Comments: *QCS’ January 2, 2013 submitted List of Certified Operations indicates 661 total operations and a minimum of 33 operations are required to be sampled for 2013. During 2013, QCS conducted residue testing sampling of 29 operations.*

Corrective Actions: At the beginning of 2014 the *QCS Certification Policy Manual* and *QCS Certification Standard Operating Procedure (SOP)* were both amended to reflect the five percent residue sampling requirement. The QCS Administrative Manager was also tasked with meeting this regulatory requirement. QCS has 835 total operations based on the January 2, 2014 list sent to the NOP; a minimum of 41 operations were required to have samples taken in 2014. QCS took a total of 44 samples by the end of 2014. The *2014 QCS Unannounced Inspection List, Policy Manual and Standard Operating Procedures* were provided to the NOP. QCS reviewed and discussed the progress of the five percent sampling requirement with staff during its November 2014 staff meeting. A Training Memo regarding this change was also issued to staff. The minimum requirement will also be addressed as an agenda item during a January 2015 staff meeting.

2016 Verification of Corrective Actions: QCS met the five percent of total operations requirement for residue sampling in 2015 and 2016.

NP4230LCA.NC5 – Outstanding. 7 CFR §205.403(a)(2)(ii) and NOP 2609, Unannounced Inspections states that, “... certifying agents conduct unannounced inspections of 5 percent of their total certified operations per year...”

Comments: *QCS’ January 2, 2013 submitted List of Certified Operations indicates 661 total operations and a minimum of 33 operations are expected to receive unannounced inspections for 2013. During 2013, QCS conducted unannounced inspections of 29 operations.*

Corrective Actions: At the beginning of 2014 the *QCS Certification Policy Manual* and *QCS Certification Standard Operating Procedure (SOP)* were both amended to reflect the five percent unannounced inspection requirement. The QCS Administrative Manager was also tasked with meeting this regulatory requirement. QCS has 835 total operations based on the January 2, 2014 list sent to the NOP; a minimum of 41 operations were required to have an unannounced inspection in 2014. QCS conducted a total of 42 unannounced inspections by the end of 2014. The *2014 QCS Unannounced Inspection List, Policy Manual and Standard Operating Procedures* were provided to the NOP. QCS reviewed and discussed the progress of the five percent unannounced inspections for operations with staff during its November 2014 staff

meeting. A Training Memo regarding this change was also issued to staff. The minimum requirement will also be addressed as an agenda item during a January 2015 staff meeting.

2016 Verification of Corrective Actions: QCS did not meet the five percent of operations requirement for unannounced inspections in 2016. QCS indicated there were 955 operations on Jan 1, 2016, which would require 48 unannounced inspections. 44 unannounced inspections were conducted during 2016.

Noncompliances Identified during the Current Assessment

NP7023NNA.NC1 – 7 C.F.R. §205.662(e) states, “If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent shall send the certified operation a written notification of suspension or revocation.”

Comments: *QCS is issuing proposed settlement agreements to operations that are in proposed suspension without receiving a request for mediation or appeal, and/or completing the mediation process.*

NP7023NNA.NC2 - 7 C.F.R. §205.663 Mediation states, “Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent.”

Comments: *QCS has a procedure for mediation after a proposed suspension is issued to an operator. However, QCS does not require the operator to request mediation in writing.*

NP7023NNA.NC3 – 7 C.F.R. § 205.501(a)(21) states, “... a certifying agent under this subpart must: Comply with, implement, and carry out any terms and conditions determined by the Administrator to be necessary.” Specifically, the U.S. – Korea Equivalency Arrangement is limited to “processed food” products that meet the definition of the Korean Food Code.

Comments: *QCS approved a tobacco strip product, which does not meet the definition of “processed food” under the Korean Food Code, for export under the U.S - Korea Equivalency Arrangement. A review of documentation and interviews with staff indicated that the product has not been exported to Korea.*

NP7023NNA.NC4 – 7 C.F.R. § 205.501(a)(21) states, “... a certifying agent under this subpart must: Comply with, implement, and carry out any terms and conditions determined by the Administrator to be necessary.”

Comments: *A review of export certificates issued by QCS for products exported to Japan under the U.S. – Japan Equivalency Arrangement indicated that the compliance statement in the Remarks section was incorrect. The certificates either stated, “Products covered under this export certificate are not known to be produced with alkali-extracted humic acid, or lignin sulfonate as a flotation agent” or “Organic agricultural products and organic processed products, accompanied by this Certificate, were produced or processed using zero prohibited substances.”*

NP7023NNA.NC5 – 7 C.F.R. § 205.504 states, “... a certifying agent must submit the following documents and information to demonstrate ... its ability to fully comply with and implement the organic program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 205.406, and §§ 205.661 and 205.662; ...”

Comments: *QCS’ Certification Manual does not demonstrate QCS’ ability to fully comply in the following manner:*

1. *The manual incorrectly states that products intended for export to Japan must not be produced with alkali-extracted humic acid or lignin sulfonate as a flotation agent. Such requirements do not exist under the U.S. – Japan Equivalency Arrangement.*
2. *The manual incorrectly states the U.S. – Korea Equivalency Arrangement is limited to organic products for which the final processing or packaging occurs within the country of export either U.S. or Korea. The equivalency arrangement is limited to “processed food” products that meet the definition of the Korean Food Code. The code defines “processed food” as a “food manufactured, processed, and packaged”*
3. *The manual does not address the requirements for trade under the U.S. – Switzerland Equivalency Arrangement.*
4. *The manual states that if a client willfully violates, QCS reserves the right to not accept the client’s request to surrender certification. Additionally, the manual incorrectly cites § 205.504 as the applicable citation. QCS’s standard operating procedures, forms, and templates were corrected to allow surrender, but the Certification Manual was not updated.*
5. *The QCS Certification Process flow chart in the manual incorrectly states that a client can respond with corrective actions upon receiving a notice of proposed suspension. Pursuant to the USDA organic regulations, upon receiving a notice of proposed suspension, a certified operation may only request mediation or file an appeal.*
6. *The manual states that certificates are not issued until all fees have been paid or other arrangements have been made. This policy does not comply with the USDA organic regulations for issuing organic certificates.*

NP7023NNA.NC6 - 7 C.F.R. § 205.403(c)(2) states, “The onsite inspection of an operation must verify: That the information, including the organic production and handling system plan, provided ... accurately reflects the practices used or to be used by the certified operation”

Comments: *During the annual onsite inspection of a handling operation, it was observed that the inspector did not verify whether the operation’s handling system plan accurately reflected the practices used by the operation. Example of sections in the operation’s Organic Handling Plan that were observed to be inaccurate during the witness inspection, but were not addressed by the inspector to be inaccurate included Pest Management; Cleaning and Sanitizing Substances; and Storage.*

NP7023NNA.NC7 - 7 C.F.R. § 205.501(a)(5) states, “A certifying agent under this subpart must: Ensure that its ... contractors with inspection ... have sufficient expertise to successfully perform the duties assigned.”

Comments: *During the exit interview of the inspection, it was observed that the inspector incorrectly informed the operation that one of its supplier organic certificates was expired. The expired organic certificate was an EU organic certificate; not a USDA organic certificate.*

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Quality Certification Services (QCS) accreditation renewal application to maintain U.S. Department of Agriculture (USDA) accreditation as an organic certifier on November 2, 2016. The NOP has reviewed QCS' renewal application, conducted an onsite audit, and reviewed the audit report to determine QCS' capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Quality Certification Services (QCS)
Physical Address	214 W. University Avenue, Suite A, Gainesville, FL 32601
Mailing Address	P.O. Box 12311, Gainesville, FL 32604
Contact & Title	Ramkrishnan Balasubramanian, Chief Executive Officer
E-mail Address	ram@qcsinfo.org
Phone Number	(352) 377-0133
Reviewer & Auditors	Penny Zuck, NOP Reviewer; Patty Heckart and Robert Yang, On-site Auditors
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: March 17, 2017 Onsite audit: January 23-26, 2017; February 6-9, 2017 (grower group witness audit)
Audit Identifier	NP7023NNA
Action Required	Yes
Audit & Review Type	Renewal Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of QCS' certification program.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	QCS' certification services in carrying out the audit criteria during the period: August 19, 2014 through February 9, 2017

QCS is the Certification Program of Florida Certified Organic Growers and Consumers, Inc., which is a non-profit organization. QCS was accredited as a certifying agent on April 29, 2002 to the National Organic Program (NOP) for crops, wild crops, livestock, and handling operations.

QCS certifies 1096 operations to the following scopes: Crops (753), Wild Crops (3), Livestock (228), and Handler/Processor/Exporters (300). QCS certifies 13 grower groups outside of the U.S. Certification services occur in the following countries: Belgium, Bahamas, Dominican

Republic, Ecuador, France, Guatemala, Jamaica, Malaysia, Mexico, Puerto Rico, South Africa, Vietnam, and the Virgin Islands.

QCS' office is located in Gainesville, Florida. QCS' staff consists of: Technical Staff (21), Inspectors (56), and Administrative/support staff (8).

As part of the onsite accreditation audit activities, two witness audits (WA) were conducted on a crops grower group operation and one handler/processor operation. A witness audit will be conducted at a livestock (cattle)/crops operation at a later date during grazing season and reported with another audit identifier.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether QCS' corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to QCS.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP4188MVA.NC1 – Cleared. 7 CFR §205.403(c) states, “Verification of information. The on-site inspection of an operation must verify: (1) The operation’s compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plants tissue; and plant, animal, and processed product samples.”

Comments: *Overall, during the witness inspections and review audits it was found that the OSPs were not complete regarding the list of inputs used. The QCS process for updating the OSP at the time of inspection is not standardized.*

A) *During the review audits it was found that inspectors had not verified all of the operation’s compliance or capability to comply with the regulations. One inspector indicated that the producer had a closed herd with no purchased replacement animals. However, the producer indicated that two replacement heifers were purchased. One inspector did not indicate any health care practices or inputs used for pink eye or milk fever, nor were the products on the OSP or previous inspection report, yet the producer used products for both of these health issues. Some additional health inputs were not listed on the plan, including bolus products, but the inspector reported that the health product input list in the plan was complete.*

B) *During one review audit the auditor discovered that the operator had 14 inputs onsite that were not described in the OSP or in the input list verified by QCS. One review audit found 27 inputs onsite that were not in the OSP or noted in the inspection report. This issue had been mentioned as a minor noncompliance in 2012 or addressed in 2013. The operation did not seem to maintain a complete record of the inputs it used. The operation used a product containing zinc sulfate, which is not allowed as a foot bath, but the operator stated that a previous inspector had approved the product.*

Corrective Actions: QCS revised the Input Review Procedure, which requires that all clients receive written confirmation of the approval status of each new input, in addition to sending a full list of approved inputs when client organic certificates are issued. QCS also revised the Combined Certification Docs template to incorporate a check-box to remind staff to send the full list of approved inputs when client certificates are issued. QCS issued guidance to inspectors to standardize the process for inspectors regarding OSP updates at the time of inspection. QCS conducted inspector training in early October 2014 to explain updated policies and procedures, with refresher training planned for early 2015. QCS will issue Notices of Noncompliance to each of the four operations for use of inputs that were not pre-approved by QCS or included on the operations' OSPs. QCS plans to conduct witness or review audits on four operations during the grazing season in 2015 in order to verify that client OSPs are accurate and being followed, and inspectors are properly reviewing or updating the OSP per QCS procedures. Furthermore, QCS is no longer using two of the three inspectors associated with the inspection issues identified as a result of the recent audit.

2016 Verification of Corrective Actions: QCS revised the Input Review Procedure. Interviews with QCS personnel revealed that QCS now issues a communication to the operator stating approval status of each requested new input after review by the materials review specialist. An updated Input List is issued with each approval and new organic certificate. Training records were available regarding the additional training for this new procedure. Previously approved inputs are subject to additional review after a set number of years to verify continued approval. Review of client files and interviews verified that QCS provides inspectors a complete list of inputs to be checked during inspections along with updated OSP information.

NP4188MVA.NC2 – Cleared. 7 CFR §205.403(d) states, “Exit Interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.”

Comments: *Overall, the exit interviews did not clearly summarize the findings, issues of concern, or clearly indicate the status of materials. The body of the inspection report specifies the materials used or requested for use but not in the OSP.*

A) *During one of the witness inspections, the inspector did not observe records for: 1) feed fed (corn silage) to dry cows in separate pasture down the road; 2) which animal(s) received an immune-booster and the reasons for treatment; and 3) a record of the search for organic seeds. The inspector noted in the exit interview that any calves treated with the immune booster were not identified (ear tag), and stated this would be reviewed by QCS for compliance to §205.103. Also, the exit interview did not include reference to other missing records and did not clearly indicate that the incomplete records were an issue of concern.*

- B) *During one of the review audits it was noted that the dairy operation had requested certification on a neighbor's adjoining four acre parcel. The operation had requested certification for the crop that was harvested in the previous year. There was no mention of the four acre parcel in the inspector's exit interview, which should have been noted as an issue of concern.*
- C) *During the review audit it was noted that the inspector's exit interview contained five findings, including that the producer would send certain items to QCS and record some practices. The exit interview included an inconsistent and unclear explanation of what was needed from the operation and what would occur between inspection and certification. The operation did not complete all the activities outlined in exit interview, including documenting temporary confinement, adjoining land use agreements, equipment cleaning, and livestock housing.*

Corrective Actions: QCS addressed this noncompliance with inspectors and staff via an annual conference call, through two reminder memos, and with scheduled training sessions. QCS reminded staff and inspectors that the exit interview must clearly indicate the following items: use of any materials not approved by QCS, issues of concern, all potential noncompliances, and any issues found that were not consistent with the QCS approved OSP. Inspectors and their inspection reports are evaluated by a reviewer for each inspection conducted. Annual evaluations of inspectors are conducted and QCS will not continue using an inspector whose exit interviews are found inadequate. QCS plans to conduct witness or review audit of four inspectors in 2015 to verify that procedures from the training are being implemented. QCS will continue to evaluate inspectors and inspection reports on an annual basis to ensure exit interviews are adequate. In addition, QCS issued Notices of Noncompliance to noncompliant operations identified through this assessment. QCS plans an additional evaluation by mid-December 2014 of the four-acre parcel associated with one of the operations noted in the audit to determine if comingling occurred or non-certified product was marketed as organic.

2016 Verification of Corrective Actions: QCS conducted training sessions for the inspectors on multiple occasions. Training agendas and logs were available. Review of files and witness audits verified the effectiveness of the training. Review of certification files and exit interview records indicated that summaries were made by the inspectors for clarification to the operator. In addition, witness audits conducted showed that implementation of corrective actions are effective.

NP4188MVA.NC3 – Cleared. 7 CFR §205.501(a)(2) states, “Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

Comments:

- A) *During various review and witness audits, livestock supplements containing nonorganic agricultural ingredients were observed and not identified as issues of concern by the inspector. Many of these products are specific to one manufacturer; products have been reviewed by QCS and found to contain organic ingredients even though these are not listed on the label. The labels provided to QCS by the manufacturer were sometimes inconsistent with labels found onsite at the farms: some labels identified organic ingredients while others did not. Feed supplement products from a different manufacturer that contain nonorganic molasses, apple cider vinegar, yucca, garlic, and aloe vera are being allowed by QCS because another certifier also allows the product. This product was not listed on the client's input list nor was not identified as an issue by*

- the previous inspector. It is unclear when the operation started using the product or if QCS has ever reviewed the product label.*
- B) QCS Input Review procedure (QCS-08-01) does not require a written response to the applicant confirming the materials approved for use in response to changes to the OSP during inspection or in response to changes submitted throughout the year. It requires that the client be notified, but this can be via phone with a note to QCS's internal file. As a result, it is not clear if QCS's clients know, or have record of, which inputs have been approved for use.*
- C) An operation in Indiana was inspected in 2012 and issued a minor noncompliance on December 10, 2012. The noncompliance was to §205.201, indicating that the OSP did not include a list of each livestock health care product in use or planned for use. On January 22, 2013, QCS received a hand written update from the client indicating the materials he currently used. On January 24, 2013, QCS issued a letter to the client indicating that the issue was resolved and the materials or actions were sufficient to resolve the noncompliance. However, QCS did not explicitly confirm which materials had been added to the OSP and the farmer did not appear to keep a record. During the NOP's review audit of this operation in July 2014, several products not on the OSP or approved input list were discovered onsite. One product discovered to be currently in use by the operation contains zinc sulfate, which is prohibited for use in organic livestock production as a foot bath, but the operator stated that he was told the product was acceptable for use by a QCS inspector during a training held in the region in 2013. During the June 2014 inspection, which had not yet been submitted to QCS, the inspector documented the product as a new product found during the inspection, but did not identify that the material contained zinc sulfate. The inspector also documented 27 other products onsite that were not documented on the client's input list.*
- D) During another review audit, 14 products were found to be present at the farm (some in use) that were not identified on the current OSP or input list approved by QCS.*

Corrective Actions: QCS has reviewed many of the livestock feed or feed supplement products from the manufacturer identified during the witness and review audits to verify their compliance with the USDA organic regulations. QCS provided documentation to the manufacturer regarding the status of the approved products. During a conference call with the NOP on October 9, 2014, QCS explained that the livestock feed/feed supplement labeling issue stems from a state livestock product labeling law, which prohibits the use of the term "organic" on the label for any ingredients. Feed supplement products from the other manufacturer in question are currently being reviewed for compatibility with the USDA organic regulations. Operators with incomplete OSPs or input lists will receive Notices of Noncompliance from QCS. QCS addressed this noncompliance with inspectors and staff via an annual conference call, through two reminder memos, and with scheduled training sessions. QCS reminded staff and inspectors that the exit interview must clearly indicate the following items: use of any materials not approved by QCS, issues of concern, all potential noncompliances, and any issues found that were not consistent with the QCS approved OSP. QCS plans to conduct witness or review audit of four inspectors in 2015 to verify that procedures from the training are being implemented. QCS will continue to evaluate inspectors and inspection reports on an annual basis to ensure exit interviews are adequate. The specific inspector associated with the issues identified in NC3 is no longer employed by QCS.

2016 Verification of Corrective Actions: QCS revised the Input review Procedure. After a

consideration of an input by the material review specialist, QCS issues a communication to the operator stating approval status of each input. An updated Input List is issued to the operator with each material approval and each new organic certificate. Training records were available regarding the additional training for this new procedure. QCS conducted training for all inspectors regarding the input review process and the need for inspectors to verify all inputs used by an operation during an inspection. Review of client files verified that inspectors are clarifying issues of concern during exit interviews.

NP4188MVA.NC4 – Cleared. 7 CFR §205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provisions of §205.402 through §205.406 and §205.670.” Specifically, §205.200 General that states, “The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must comply with the applicable provisions of this subpart...”

Comments: *QCS certified a beef operation that stated that it does not slaughter its animals in a certified organic slaughter facility. However, the operation provided a brochure to QCS that identifies the slaughtered cows (whole or half) as “organically raised” and the operation’s promotional brochure uses the USDA organic seal. The company is representing processed beef as certified organic when it has been processed in a noncertified facility.*

Corrective Actions: QCS spoke with the client on October 17, 2014 and was informed by the client that they had already discontinued use of the brochure six months ago. QCS issued a Notice of Noncompliance to the operator on October 28, 2014, and the client responded with corrective actions that are currently under review by QCS. In addition, QCS is planning to conduct an unannounced inspection of this operation during November 2014, and a surveillance audit of the operation’s website and point-of-sale marketing materials. On October 28, 2014, QCS conducted a staff training about product labeling and marketing materials, which included a review of guidance document NOP 4012 *Use of Brand or Company Names Containing the Word “Organic.”*

2016 Verification of Corrective Actions: QCS did issue a Notice of Noncompliance to the operator as stated. The follow-up unannounced inspection confirmed that the marketing materials were discontinued. QCS staff training was conducted with the scope of labeling and marketing materials.

NP4230LCA.NC1 – Cleared. 7 CFR §205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provision of §§205.402 through 205.406 and §205.670.” Furthermore, 7 CFR §205.404(c) states, “Once certified, a production or handling operation’s organic certification continues in effect until surrendered by the organic operation...”

Comments: *The Notices of Proposed Suspension and Notices of Suspension state that QCS does not accept the surrender of certification under these circumstances. USDA organic regulations do not permit certifying agents to deny an operation the ability to surrender their organic certification in response to an adverse action.*

Corrective Actions: QCS' current policy is that the operator is provided the option of surrendering their certificate at any time. To improve compliance, QCS updated its process for accepting a surrender at any time. When a client requests to surrender their certification during adverse actions proceedings, a Surrender Form, along with the adverse action, is issued to the

operator. The method for handling surrenders has been updated in the *QCS Certification Review Standard Operating Procedures, Section VII*. Adverse action letters have been updated to remove any statements that would imply that surrender is denied based on any circumstances. The Organic System Plan template was also updated to remove similar statements. QCS reviewed the surrender policy with staff during its November 2014 staff meeting. A Training Memo regarding this change was also issued to staff. QCS provided the NOP with copies of the corrected and updated documents.

2016 Verification of Corrective Actions: Review of QCS procedures and forms for surrender of certification reveals that all statements that imply that an operation cannot surrender certification during adverse action proceedings have been removed.

NP4230LCA.NC2 – Cleared. 7 CFR §205.662(c)(3) states, “The notification of proposed suspension shall state... The impact of a suspension or revocation on future eligibility for certification...”

Comments: *One Notice of Proposed Suspension that was issued stated a six month suspension period, while the subsequent Notice of Suspension that was issued indicated a suspension period of one year.*

Corrective Actions: QCS updated its *Certification Policies* to include a timetable guideline for suspensions and revocations. These guidelines state the recommended time periods and reiterate that when drafting the notice of suspension or revocation, the staff member must refer back to the stated timeframe in the proposed suspension or proposed revocation letter. Additionally, all variations of the notice of proposed suspension/revocation letters have been revised, with options to select for the specific periods of suspension/revocation. QCS provided the NOP with copies of the corrected and updated documents. QCS concluded that this was an isolated clerical error. The situation was discussed with the staff member that drafted the letter and their correspondence is currently being monitored for consistency. However, QCS also reviewed the suspension and revocation time period policy with staff during a November 2014 staff meeting. A Training Memo regarding this change was also issued to staff.

2016 Verification of Corrective Actions: All letters of proposed suspension and letters of suspension that were reviewed by the auditors stated the same time period for suspension.

NP4230LCA.NC3 – Cleared. 7 CFR §205.501 (a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP PM 11-10, Grower Group Certification, states in the 2008 NOSB Recommendation that as criteria for group certification, “The certification is owned by the group, not any individual member or subunit, which may not represent itself as certified other than through the group.”

Comments: *One reviewed grower group operation file indicated that QCS granted organic certification to a Grower Group owned by one entity, but this entity (an individual producer/processor) does not meet the requirements as a Grower Group and they contract with other producers to obtain additional product. Furthermore, QCS’ Certification Manual, Section 2.6, does not describe criteria in accordance with the USDA NOP policy for certification of a Grower Group.*

Corrective Actions: QCS’ criteria in its *QCS Certification Manual* are identical to the 2008 NOSB recommendations. QCS reviewed the grower group policy with staff during its November

2014 staff meeting. To date, QCS only certifies five grower groups, all of whose members are owned by the group, versus individual ownership. The operation reviewed by the USDA NOP has since been suspended from QCS; it was the only certified grower group with an individual owner. A Training Memo regarding NOP PM 11-10, Grower Group Certification was also issued to staff.

2016 Verification of Corrective Actions: QCS conducted training for applicable reviewers regarding the requirement that grower groups included ownership of more than one entity. Review of files indicated that new grower group approvals were for groups of operators.

NP4230LCA.NC4 – Cleared. 7 CFR §205.670(d) states, “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number.”

Comments: *QCS’ January 2, 2013 submitted List of Certified Operations indicates 661 total operations and a minimum of 33 operations are required to be sampled for 2013. During 2013, QCS conducted residue testing sampling of 29 operations.*

Corrective Actions: At the beginning of 2014 the *QCS Certification Policy Manual* and *QCS Certification Standard Operating Procedure (SOP)* were both amended to reflect the five percent residue sampling requirement. The QCS Administrative Manager was also tasked with meeting this regulatory requirement. QCS has 835 total operations based on the January 2, 2014 list sent to the NOP; a minimum of 41 operations were required to have samples taken in 2014. QCS took a total of 44 samples by the end of 2014. The *2014 QCS Unannounced Inspection List, Policy Manual and Standard Operating Procedures* were provided to the NOP. QCS reviewed and discussed the progress of the five percent sampling requirement with staff during its November 2014 staff meeting. A Training Memo regarding this change was also issued to staff. The minimum requirement will also be addressed as an agenda item during a January 2015 staff meeting.

2016 Verification of Corrective Actions: QCS met the five percent of total operations requirement for residue sampling in 2015 and 2016.

NP4230LCA.NC5 – Outstanding. 7 CFR §205.403(a)(2)(ii) and NOP 2609, Unannounced Inspections states that, “... certifying agents conduct unannounced inspections of 5 percent of their total certified operations per year...”

Comments: *QCS’ January 2, 2013 submitted List of Certified Operations indicates 661 total operations and a minimum of 33 operations are expected to receive unannounced inspections for 2013. During 2013, QCS conducted unannounced inspections of 29 operations.*

Corrective Actions: At the beginning of 2014 the *QCS Certification Policy Manual* and *QCS Certification Standard Operating Procedure (SOP)* were both amended to reflect the five percent unannounced inspection requirement. The QCS Administrative Manager was also tasked with meeting this regulatory requirement. QCS has 835 total operations based on the January 2, 2014 list sent to the NOP; a minimum of 41 operations were required to have an unannounced inspection in 2014. QCS conducted a total of 42 unannounced inspections by the end of 2014. The *2014 QCS Unannounced Inspection List, Policy Manual and Standard Operating Procedures* were provided to the NOP. QCS reviewed and discussed the progress of the five percent unannounced inspections for operations with staff during its November 2014 staff

meeting. A Training Memo regarding this change was also issued to staff. The minimum requirement will also be addressed as an agenda item during a January 2015 staff meeting.

2016 Verification of Corrective Actions: QCS did not meet the five percent of operations requirement for unannounced inspections in 2016. QCS indicated there were 955 operations on Jan 1, 2016, which would require 48 unannounced inspections. 44 unannounced inspections were conducted during 2016.

Noncompliances Identified during the Current Assessment

NP7023NNA.NC1 – 7 C.F.R. §205.662(e) states, “If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent shall send the certified operation a written notification of suspension or revocation.”

Comments: *QCS is issuing proposed settlement agreements to operations that are in proposed suspension without receiving a request for mediation or appeal, and/or completing the mediation process.*

NP7023NNA.NC2 - 7 C.F.R. §205.663 Mediation states, “Any dispute with respect to denial of certification or proposed suspension or revocation of certification under this part may be mediated at the request of the applicant for certification or certified operation and with acceptance by the certifying agent. Mediation shall be requested in writing to the applicable certifying agent.”

Comments: *QCS has a procedure for mediation after a proposed suspension is issued to an operator. However, QCS does not require the operator to request mediation in writing.*

NP7023NNA.NC3 – 7 C.F.R. § 205.501(a)(21) states, “... a certifying agent under this subpart must: Comply with, implement, and carry out any terms and conditions determined by the Administrator to be necessary.” Specifically, the U.S. – Korea Equivalency Arrangement is limited to “processed food” products that meet the definition of the Korean Food Code.

Comments: *QCS approved a tobacco strip product, which does not meet the definition of “processed food” under the Korean Food Code, for export under the U.S - Korea Equivalency Arrangement. A review of documentation and interviews with staff indicated that the product has not been exported to Korea.*

NP7023NNA.NC4 – 7 C.F.R. § 205.501(a)(21) states, “... a certifying agent under this subpart must: Comply with, implement, and carry out any terms and conditions determined by the Administrator to be necessary.”

Comments: *A review of export certificates issued by QCS for products exported to Japan under the U.S. – Japan Equivalency Arrangement indicated that the compliance statement in the Remarks section was incorrect. The certificates either stated, “Products covered under this export certificate are not known to be produced with alkali-extracted humic acid, or lignin sulfonate as a flotation agent” or “Organic agricultural products and organic processed products, accompanied by this Certificate, were produced or processed using zero prohibited substances.”*

NP7023NNA.NC5 – 7 C.F.R. § 205.504 states, “... a certifying agent must submit the following documents and information to demonstrate ... its ability to fully comply with and implement the organic program established in §§ 205.100 and 205.101, §§ 205.201 through 205.203, §§ 205.300 through 205.303, §§ 205.400 through 205.406, and §§ 205.661 and 205.662; ...”

Comments: *QCS’ Certification Manual does not demonstrate QCS’ ability to fully comply in the following manner:*

1. *The manual incorrectly states that products intended for export to Japan must not be produced with alkali-extracted humic acid or lignin sulfonate as a flotation agent. Such requirements do not exist under the U.S. – Japan Equivalency Arrangement.*
2. *The manual incorrectly states the U.S. – Korea Equivalency Arrangement is limited to organic products for which the final processing or packaging occurs within the country of export either U.S. or Korea. The equivalency arrangement is limited to “processed food” products that meet the definition of the Korean Food Code. The code defines “processed food” as a “food manufactured, processed, and packaged”*
3. *The manual does not address the requirements for trade under the U.S. – Switzerland Equivalency Arrangement.*
4. *The manual states that if a client willfully violates, QCS reserves the right to not accept the client’s request to surrender certification. Additionally, the manual incorrectly cites § 205.504 as the applicable citation. QCS’s standard operating procedures, forms, and templates were corrected to allow surrender, but the Certification Manual was not updated.*
5. *The QCS Certification Process flow chart in the manual incorrectly states that a client can respond with corrective actions upon receiving a notice of proposed suspension. Pursuant to the USDA organic regulations, upon receiving a notice of proposed suspension, a certified operation may only request mediation or file an appeal.*
6. *The manual states that certificates are not issued until all fees have been paid or other arrangements have been made. This policy does not comply with the USDA organic regulations for issuing organic certificates.*

NP7023NNA.NC6 - 7 C.F.R. § 205.403(c)(2) states, “The onsite inspection of an operation must verify: That the information, including the organic production and handling system plan, provided ... accurately reflects the practices used or to be used by the certified operation”

Comments: *During the annual onsite inspection of a handling operation, it was observed that the inspector did not verify whether the operation’s handling system plan accurately reflected the practices used by the operation. Example of sections in the operation’s Organic Handling Plan that were observed to be inaccurate during the witness inspection, but were not addressed by the inspector to be inaccurate included Pest Management; Cleaning and Sanitizing Substances; and Storage.*

NP7023NNA.NC7 - 7 C.F.R. § 205.501(a)(5) states, “A certifying agent under this subpart must: Ensure that its ... contractors with inspection ... have sufficient expertise to successfully perform the duties assigned.”

Comments: *During the exit interview of the inspection, it was observed that the inspector incorrectly informed the operation that one of its supplier organic certificates was expired. The expired organic certificate was an EU organic certificate; not a USDA organic certificate.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

APR 04 2017

NOTICE OF NONCOMPLIANCE

Ramkrishnan Balasubramanian
Quality Certification Services
P.O. Box 12311
Gainesville, FL 32604

Dear Mr. Balasubramanian:

On January 23-26, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Quality Certification Services (QCS) organic certification program as part of its USDA Renewal Accreditation Assessment. On March 17, 2017, the NOP reviewed the results of the onsite audit to determine QCS' compliance to the USDA organic regulations. A copy of the assessment report, NP7023NNA, is enclosed for your reference.

As the report indicates, one noncompliance, NP4230LCA.NC5, remains outstanding from a previous audit. Seven new noncompliances, NP7023NNA.NC1-NC7, were identified during the onsite audit. Please submit corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All corrective actions must indicate how the noncompliances will be corrected and how the QCS management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of QCS' USDA accreditation.

If you have questions regarding this notice, please contact, Penny Zuck, Accreditation Manager, at Penelope.zuck@ams.usda.gov or (202) 260.9444.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report

cc: AIA Inbox



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Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report

cc: AIA Inbox

QCS Compliance Assessment Chronology Log

Audit Identifier (if any): NP4188MVA
Audit Type: Compliance Audit
Accredited Certifying Agent Name: QCS
Accreditation Manager: Renee Mann, Renée Gebault King

Date	Activity
6/3/2014	Mann drafted quote. Sent to Miles McEvoy for review.
6/4/2014	McEvoy reviewed and approved with edit.
6/5/2014	Mann sent request for confirmation of audit to Ram Balasubramanian and Denise @ QCS.
6/9/2014	QCS sent signed audit documents.
6/12/2014	Mann sent revised audit schedule to QCS (reduces time spent in Indiana). QCS confirmed acceptance of revised audit schedule on 6/12. Confirmed witness inspection locations too.
6/13/2014	Rec'd witness inspection files.
6/17/2014	McEvoy and Mann met to discuss review audits and witness inspections.
6/19/2014	Mann and Ram discussed potential review audits.
6/20/2014	Mann sent review audit list to Ram for scheduling.
6/20-7/7	Lots of audit planning activities occurred – scheduling multiple review audits and witness audits.
7/2/2014	QCS sent review audit materials to Mann. Matthew Michael, C&E Director, sent email regarding timing of inspections and potential Temporary Variance for Cottonwood.
7/3/2014	Michael sent follow-up email. It appears that a temporary variance will not be requested by Cottonwood.
7/7 to 7/11	QCS on-site audit conducted by Miles McEvoy & Renee Mann.
7/24/14	QAD submitted completed audit reports to NOP.
8/22/14	Mann drafted NoNC and NoNC Report for management review.
8/26-9/11	Some back-and-forth on the draft and then RM went on vacation for 2 weeks.
9/19/14	RM drafted new version of NoNC report and letter
9/23/14	Miles reviewed NoNC and letter

9/24/14	Submitted NoNC report and letter for approval by Rex Barnes
9/25/14	Signed by Rex Barnes
9/29/14	RM received approved documents. Sent NoNC report and NoNC letter to QCS (Ram and Denise) via RPost.
10/29/14	Assigned to RGK and entered into Workload Tracking Log.
11/14- 12/08/14	RGK reviewed CAs and supporting documents; prepared CA report and Notice of NC Resolution letter.
12/08/14	RGK completed review of CAs. Submitted to R Mann (RM) electronically for review.

QCS Mid-term Audit Resolution Chronology Log

Audit Identifier (if any): NP4230LCA

Audit Type: 12.5 Mid-term Assessment

Accredited Certifying Agent Name: QCS

Accreditation Manager: Renee Mann; Lars Crail (onsite auditor); Renée Gebault King (RGK).
Janna Howley handling the CA Report and NoCont Accred.

Date	Activity
6/12/14	Ram confirmed July 8 witness inspection of Brightwood Vineyard and Farm, LLC, in Brightwood, Virginia.
7/1/14	LC sent Ram the Mid-term Initiation Letter, a blank LS-313, Audit Cost Estimate, and Audit Schedule.
9/16/14	Assigned to RGK.
9/26/14	Reviewed 2005 checklists and prepared NoNC report and letter.
9/29/14	Submitted for review.
10/2/14	Approved; issued electronically to QCS.
11/17/14	QCS sent in proposed Corrective Actions and supporting documentation.
12/22/14	QCS CA report and continued accreditation assigned to JH. Changed from RGK to JH in WTL.
12/23/14	JH reviewed corrective actions, supporting documentation. Drafted CA Report and Notice of Continued Accreditation.
12/24/14	JH emailed docs to RM for review.
01/06/15	Rcvd comments back from RM; need to follow up w QCS to get more detail about strategies and preventing the same NCs in the future.
01/08/15	<ul style="list-style-type: none"> • Edited report; added comment/question in response to RM comment. • Emailed QCS.
01/08/15	Rcvd email from Ram, forwarding email he sent to RGK on 01/05/15. It answered some of the clarifying questions.
01/12/15	Ram also LVM on JH's phone letting her know he would provide additional response the week of 01/12/15.
01/14/15	<ul style="list-style-type: none"> • Rcvd registered mail with answers to the questions emailed to QCS on 01/08/15. • Updated CA report; emailed back to RM for review.
01/20/15	Rcvd approval from RM to forward on electronically to CC for review. Emailed to CC.
01/21/15	Cleaned up track changes and resent to CC for review.
02/06/15	Approval from CC to print hard copies. Gave to CC for review.



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NOTICE OF NONCOMPLIANCE

Ramkrishnan Balasubramanian
Quality Certification Services
P.O. Box 12311
Gainesville, FL 32604

Dear Mr. Balasubramanian:

On July 7-11, 2014, two representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a Compliance Assessment of the Quality Certification Services (QCS) organic certification program. The objective of the assessment was to evaluate QCS's livestock accreditation activities in compliance with the USDA organic regulations at 7 CFR 205. A copy of the assessment report, NP4188MVA, is enclosed.

As the report indicates, four noncompliances, NP4188MVA.NC1-4 were identified during the assessment. The report also indicates that clauses 6a-6e of the settlement agreement were cleared. Please submit proposed corrective actions for the four new noncompliances, NP4188MVA.NC1-4, to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how QCS's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Renee Gebault King, at (202) 690-4540 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
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29 SEP 2014

NOTICE OF NONCOMPLIANCE

Ramkrishnan Balasubramanian
Quality Certification Services
P.O. Box 12311
Gainesville, FL 32604

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If you have questions regarding this notice, please contact your Accreditation Manager, Renee Gebault King, at (202) 690-4540 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney". The signature is written in a cursive, flowing style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted an on-site compliance audit of Quality Certification Services (QCS) from July 7-11, 2014. The audit was conducted to review QCS's corrective actions in response to a settlement agreement between the USDA and QCS.

The corrective actions submitted by QCS and the on-site compliance audit conducted by the NOP confirmed that QCS is operating in compliance with the USDA organic regulations at 7 CFR 205, except for several new noncompliances that were identified during the audit. QCS met the terms of the original settlement agreement and this issue is now closed.

History:

On September 12, 2012, the NOP issued a notice of non-compliance to QCS as a result of an informal visit conducted by NOP staff at a QCS client's livestock operation. In response to the non-compliance, QCS submitted corrective actions in October, 2012. However, the NOP deemed these to be inadequate and issued a notice of proposed suspension for QCS's livestock accreditation on March 5, 2013. At the same time, the NOP proposed a settlement agreement to allow QCS to maintain its livestock accreditation if certain conditions were met. QCS submitted corrective actions in response to this settlement agreement throughout 2013 and 2014.

GENERAL INFORMATION

Applicant Name	Quality Certification Services (QCS)
Physical Address	1810 NW 6th St, Suite F
Mailing Address	PO Box 12311, Gainesville, FL 32604
Contact & Title	Ramkrishnan Balasubramanian, Chief Executive Officer
E-mail Address	ram@qcsinfo.org
Phone Number	352-377-0133
Reviewer(s) & Auditor(s)	Renee Mann, NOP Reviewer; Miles McEvoy and Renee Mann, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	On-site audit dates: July 7-11, 2014
Audit Identifier	NP4188MVA
Action Required	Yes, response to noncompliances
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the settlement agreement and to verify the implementation and effectiveness of QCS's corrective actions in response to the settlement agreement.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	QCS's certification services in carrying out the audit criteria during the period: July 24, 2012 – July 11, 2014

CERTIFIER OVERVIEW NARRATIVE:

GENERAL INFORMATION:

Quality Certification Services (QCS) is the Certification Program of Florida Certified Organic Growers and Consumers, Inc., which is a non-profit organization. QCS was accredited as a certifying agent on April 29, 2002 to the National Organic Program (NOP) for crops, wild crops, livestock, and handling operations. QCS is currently certifying operations in the U.S., Bahamas, Ecuador, Dominican Republic, Guatemala, Malaysia, Mexico, Peru, and South Africa.

QCS also offers certification to the following international standards: GlobalGap; European Union (EC 834/2007 and EC 889/2008), Canadian Organic Regime (COR), and Taiwan Export Standards.

OFFICES:

QCS has two offices which are located in Gainesville, FL and Quito, Ecuador. The QCS main office is located in Gainesville, FL and all certification activities are finalized in this office. This compliance audit focused on activities at the Gainesville office.

PERSONNEL:

QCS has an Executive Director, a Chief Operating Officer, Certification Coordinators (CC), and administrative personnel. Some of the CC's can and do act as staff inspectors. QCS also uses contracted inspectors. Records reviewed verified that QCS was meeting the requirements for annual performance evaluations, confidentiality, and conflicts of interest disclosure reports for all personnel. Personnel files/resumes reviewed indicated that most personnel involved in the certification process had the required education, training, and/or experience in organic agricultural production and handling techniques to perform the duties assigned. Interviews conducted verified that the personnel had an understanding of the NOP standards. In the spring of 2014, QCS reevaluated the livestock inspection staff and found two staff members who were not qualified to conduct ruminant livestock inspections. These staff members are no longer conducting ruminant inspections.

CERTIFICATION PROCESS:

When requests for certification are received, the applicant is sent a certification package consisting of an application, fee schedule, QCS Guidance Handbook, the NOP standards (verbatim), the OMRI Products List and Generic Materials List, an estimate, and the applicable organic system plan (OSP) forms. When the completed documents are received, the initial review is conducted by one of the CC's. The inspection is conducted by one of the staff inspectors or a subcontracted inspector. After the inspection, the file is reviewed by a second CC which is different from the one that conducted the initial review. The second CC makes the certification decision. Records reviewed verified that in all cases the CC which made the certification decision was different from the one that conducted the initial review and the inspection. Annual updates to the OSP's and annual inspections are required in accordance with the standards.

MATERIAL REVIEW:

Material reviews are conducted on all inputs. An approved list is maintained for internal use at QCS. The CC's in the Gainesville office review the materials and then consult with the

materials CC in the Columbia, MO office before the input is added to the approved list. Sources such as OMRI, WSDA, and other ACA's, which publish lists, are used as references to assist the CC's in reviewing products. If the product is not on any of the lists of the sources, the CC's review the product in-house. If the CC's are unable to determine that 100% of the ingredients comply with the National List, then the input is not added to the approved list. An input tracking form is used to document the reason for material approval.

WITNESS INSPECTIONS AND REVIEW AUDITS:

As part of the on-site assessment, two witness inspections were conducted on certified operations in Northern Indiana. The two operations were dairy livestock and crop operations. All areas required to be verified, including the inputs utilized, were verified during the inspection by the inspector except as outlined in the Findings. The inspector was a staff inspector. An exit interview was conducted with the operation's representative at the end of each inspection.

Six review audits were conducted in Northern Indiana of organic dairy and crop operations.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether QCS's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the Findings identified during the onsite audit to determine whether noncompliances should be issued to QCS.

Noncompliances from Settlement Agreement

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

Settlement Agreement, March 5, 2013

Settlement Clauses 6a-6e – Cleared -

- a. **7 CFR § 205.237(c)(1).** "All livestock operations with ruminants allow the animals to graze *throughout the entire grazing season*, as defined for the geographical region. The grazing season shall be clearly identified in the organic system plan, shall be not less than 120 days of the calendar year, per 7 CFR § 205.237(c)(1), and could be more depending on the geographical conditions of the region where a producer is located; for example, if an operation's grazing season is 250 days, ruminants must be provided access to pasture for that entire grazing season, not just 120 days and/or when 30% DMI from pasture has been met."
- b. **7 CFR § 205.237(c)(2).** "During the grazing season, all ruminants are provided with an average of not less than 30 percent of their dry matter intake from pasture."

- c. **7 CFR § 205.239(a)(1).** “The total confinement of ruminants in yards, feeding pads and feedlots is not permitted.”
- d. **7 CFR § 205.240.** “Operations manage and provide pasture per 7 CFR § 205.240, and specifically the requirements therein concerning the use of irrigation to promote pasture growth.”
- e. **7 CFR § 205.237(c)(1-2).** “When/if pasture is or becomes available in the geographic region *for a time longer than the grazing season described in the Organic System Plan* (whether earlier or later), then all ruminants are provided an average of not less than 30 percent of their dry matter intake from pasture during the time when pasture is available.”

Verification of Corrective Actions (during July 2014 audit): QCS revised its Livestock OSPs and Livestock Inspection Reports to ensure the above pasture rule criteria were explicitly covered in its certification process for ruminant operations. The revised forms were provided to QCS staff in May 2013 and to all ruminant inspectors by mid-August 2013. The new inspection forms were used for all 2013 QCS ruminant livestock inspections in 2013. Training was provided to ruminant livestock inspectors and reviewers in the fall of 2013. Overall, the NOP auditors were able to verify that QCS was effectively implementing the terms of the settlement agreement.

Noncompliances Identified during the July 7-11, 2014 Assessment:

NP4188MVA.NC1 – 7 CFR § 205.403(c) states, “Verification of information. The on-site inspection of an operation must verify: (1) The operation’s compliance or capability to comply with the Act and the regulations in this part; (2) That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; (3) That prohibited substances have not been and are not being applied to the operation through means which, at the discretion of the certifying agent, may include the collection and testing of soil; water; waste; seeds; plants tissue; and plant, animal, and processed product samples.” *Overall, during the witness inspections and review audits it was found that the OSPs were not complete regarding the list of inputs used. The QCS process for updating the OSP at the time of inspection is not standardized.*

- A) *During the review audits it was found that inspectors had not verified all of the operation’s compliance or capability to comply with the regulations. One inspector indicated that the producer had a closed herd with no purchased replacement animals. However, the producer indicated that two replacement heifers were purchased. One inspector did not indicate any health care practices or inputs used for pink eye or milk fever. However, the producer used products for both of these health issues. These products used were not within OSP. One inspector missed a Nutritional Supplement from Crystal Creek – Pivot – that was not listed on the OSP or in the recent inspector’s report. Some available health inputs were not listed on the plan – including bolus products. The inspector reported that the health input list in the plan was complete.*

- B) *During one review audit it was determined that the operator had 14 inputs on-site that were not described in his OSP or in the input list verified by QCS. One review audit found 27 inputs on-site that were not in the OSP or noted in the inspection report. This issue had been mentioned as a minor noncompliance in 2012 and addressed in 2013. The operation did not seem to maintain a complete record of the inputs it used. The operation used a product containing zinc sulfate, which is not allowed as a foot bath. The operator stated that a previous inspector had approved the product.*

NP4188MVA.NC2 – 7 CFR § 205.403(d) states, “Exit Interview. The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.” *Overall, the exit interviews did not clearly summarize the findings/issues of concern. The exit interviews did not clearly indicate the status of materials. The body of the inspection report indicates materials requested for use and materials used but not in the OSP.*

- A) *During one of the witness inspections, the inspector observed no records for: 1) feed fed (corn silage) to dry cows in separate pasture down the road; 2) Which animal(s) were treated with Calf Shield and reasons for treating animals; and 3) record of organic seed search. The inspector made a note in the exit interview about not identifying calf treated (ear tag) and stated that this would be reviewed by QCS for compliance to §205.103. The exit interview did not include reference to other missing records and did not clearly indicate that the incomplete records were an issue of concern.*
- B) *During one of the review audits it was noted that the dairy operation had requested certification on a neighbor’s adjoining 4 acre parcel. The operation had requested certification for the crop that was harvested in the previous year. There was no mention of the 4 acre parcel in the inspector’s exit interview. The inspector should have noted the request for certification in the exit interview as an issue of concern.*
- C) *During the review audit it was noted that the inspector’s exit interview contained five findings including that the producer would send certain items to QCS and record some practices. The exit interview included an inconsistent and unclear explanation of what was needed from the operation and what would occur between inspection and certification. The operation did not complete all the activities outlined in exit interview, including documenting temporary confinement, adjoining land use agreements, equipment cleaning, and livestock housing.*

NP4188MVA.NC3 – 7 CFR § 205.501(a)(2) states, “Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.”

- A) *During various review and witness audits, livestock supplements containing non-organic agricultural ingredients were observed and not identified as issues of concern by the inspector. Many of these products are by Crystal Creek (2:1, 1:2, and Pellets) that have been reviewed by QCS and found to contain organic ingredients even though these are not listed on the label. The labels provided to QCS by Crystal Creek were sometimes inconsistent with what was found on-site at the farms. Some*

- labels provided to QCS identified organic ingredients, but the labels at farms did not identify organic ingredients. Another product, High Energy Blend Green, is being allowed by QCS because PCO allows the product. The product label viewed on-site showed that it contains nonorganic molasses, apple cider vinegar, yucca, garlic, and aloe vera. This was not listed on the Input List maintained by the client and was not identified as an issue by the previous inspector, and it is unclear when the operation started using the product, so it is unclear if QCS has ever reviewed the product label.*
- B) QCS Input Review procedure (QCS-08-01) does not require a written response to the applicant confirming the materials approved for use in response to changes to the OSP during inspection or in response to changes submitted throughout the year. It requires that the client be notified, but this can be via phone with a note to QCS's internal file. It is not clear if QCS's clients know, or have record of, which inputs have been approved for their use.*
- C) An operation in Indiana was inspected in 2012 and issued a minor noncompliance on December 10, 2012. The noncompliance was to 205.201, indicating that the organic system plan did not include a list of each livestock health care product in use or planned to be used. On January 22, 2013, QCS received a hand written update from the client indicating the materials he currently used. On January 24, 2013, QCS issued a letter to the client indicating that the issue was resolved and the materials or actions were sufficient to resolve the noncompliance. However, QCS did not explicitly confirm which materials had been added to the OSP and the farmer did not appear to keep a record. During the NOP's review audit of this operation in July 2014, several products not on the OSP or approved input list were discovered onsite. One product, Intra Hoof-Sol, was discovered to be currently in use by the operation. The product contains zinc sulfate and is not allowed for use in organic livestock production as a foot bath. Also, the operator stated that he was told the product was acceptable for use by a QCS inspector during a training held in the region in 2013. During the June 2014 inspection, which had not yet been submitted by the inspector to QCS, QCS's inspector documented Intra Hoof-Sol as a new product found during the inspection, but did not identify that the material contained zinc sulfate. The inspector also documented 27 other products on-site but not documented on the client's Input List.*
- D) During another review audit, 14 products were found to be present at the farm (some in use) that were not identified on the current OSP or Input List approved by QCS.*

NP4188MVA.NC4 – 7 CFR § 205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.” Specifically, §205.200 General that states, “The producer or handler of a production or handling operation intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must comply with the applicable provisions of this subpart...” *QCS certified a beef operation that stated that it does not slaughter its animals in a certified organic slaughter facility. However, the operation provided a brochure to QCS that identifies to the customer that the customer can purchase slaughtered cows (whole or half) as “organically raised” and uses the USDA organic seal. The company is therefore representing processed beef that has been slaughtered in a non-certified organic facility as certified organic.*

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a Mid-term Assessment of Quality Certification Services. During July 2014, QCS underwent an NOP Compliance Assessment involving several Witness and Review Audits focused on certified livestock operation activities. This onsite Mid-term Assessment was conducted and the audit report was reviewed to determine Quality Certification Services' capability to continue operating as a USDA accredited certifier. This two-day audit was limited in scope and intentionally did not conduct full file reviews of any livestock operations. One Witness Audit of a certified crop operation was conducted in Virginia during the month of July. A USDA ISO 17065 Program Reassessment was conducted concurrently with the NOP Mid-Term Assessment.

GENERAL INFORMATION

Applicant Name	Quality Certification Services, QCS
Physical Address	1810 NW 6th St. Ste F., Gainesville, FL 32604
Mailing Address	PO Box 12311, Gainesville, FL 32604
Contact & Title	Ram Balasubramanian, Chief Operating Officer
E-mail Address	ram@qcsinfo.org
Phone Number	(352) 377-0133
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Lars Crail and Miguel Caceres, Onsite Auditors; Mike Lopez, Grower Group Review Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: September 22, 2014 Onsite audit: August 18-19, 2014 Grower group review audit: October 30-31, 2014
Audit Identifier	NP4230LCA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of QCS' certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	QCS' certification services in carrying out the audit criteria during the period: April 25, 2013 through August 19, 2014.

ORGANIZATIONAL STRUCTURE:

Quality Certification Services (QCS) is the Certification Program of Florida Certified Organic Growers and Consumers, Inc., is a non-profit organization. QCS has been accredited as a certifying

agent since April 29, 2002, to the National Organic Program (NOP) for crops, wild crops, livestock, and handling scopes. QCS is currently certifying operations in the U.S., China, Bahamas, Ecuador, Dominican Republic, Guatemala, Mexico, Malaysia, Sweden, Peru, and South Africa. The QCS client list (at the time of this assessment) included a total of 727 certified operations, of which there were 569 crop, three wild crop, 156 livestock, and 212 handling operations certified to the NOP. In addition, QCS currently certifies five Grower Groups.

QCS also offers certification to the following international standards: European Union (EC 834/2007 and EC 889/2008 per the US-EU Equivalency Arrangement; Canadian Organic Regime (COR) per the US-Canada Equivalency Arrangement; and US-Taiwan Export Arrangement.

QCS has four offices located in Gainesville, FL; Columbia, MO; Louisa, VA; and, Quito, Ecuador. The QCS main office is located in Gainesville, FL and all certification activities are finalized in this office. Several of these office locations are essentially home offices and the personnel at these offices are used as reviewers and inspectors. The personnel in the offices located in Ecuador conduct initial reviews, inspections, and make recommendations for certification decisions. Final decisions are either made in the Gainesville office or by Certification Coordinators located in U.S. locations.

QCS has twenty-two staff members including an Executive Director; a Chief Operating Officer; an Operations Director; an Inspection Coordinator; a Marketing Coordinator; 12 Certification Coordinators of which 10 are also staff inspectors; a Customer Service Specialist; an Ecuador Office Manager who is also a Certification Coordinator; a Food Safety Manager; and two administrative assistants. The Food Safety Manager oversees the QCS Global Good Agricultural Practices (GAP) program and is not involved in the NOP organic certification program. QCS also utilizes 56 subcontracted inspectors of which one can and does conduct initial reviews. At the time of the onsite assessment, QCS did not have any certification committees.

Records reviewed verified that QCS was meeting the requirements for annual performance evaluations, confidentiality, and conflicts of interest disclosure reports for all personnel. However, the 2013 annual performance evaluation for the Chief Operating Officer was conducted four months late. A review of the personnel files/resumes indicated that most personnel involved in the certification process had the required education, training, and/or experience in organic agricultural production and handling techniques to perform the duties assigned. Interviews conducted during the onsite assessment verified that the personnel had an understanding of the NOP standards.

CERTIFICATION PROCESS:

When requests for certification are received the applicant is sent a certification package consisting of an application, fee schedule, QCS Guidance Handbook, the NOP standards (7 CFR 205), the OMRI Products List and Generic Materials List, a cost estimate worksheet, and the applicable organic system plan (OSP) form(s). When the completed documents are received by QCS along with the client's deposit, the initial review is conducted by one of the Certification Coordinators. The inspection is conducted by one of the staff inspectors or a subcontracted inspector. After the inspection, the file is reviewed by the same or a different Certification

Coordinator. Annual updates made to the OSP's and annual inspections are required in accordance with the standards. Labels and inputs are reviewed and approved by the Certification Coordinators and verified by the inspectors.

Material reviews are conducted on all inputs. An approved list is maintained for internal use at QCS. The Certification Coordinators in the Gainesville office review the materials and then consult with the materials Certification Coordinator in the Columbia, MO office before the input is added to the approved list. Sources that publish lists, such as OMRI, WSDA, and other certifying agents, are used as references to assist the Certification Coordinators in reviewing products. If the product is not on any of the lists of the sources, the Certification Coordinators review the product in-house. If the Certification Coordinators are unable to determine that 100% of the ingredients comply with the National List, the input is not added to the approved list. An input tracking form is used to document upon what criteria the approval (or denial) are based. QCS does not conduct evaluations for nitrogen fertilizers with nitrogen content greater than 3%; instead they rely on third-party determinations such as those made by OMRI.

QCS conducts residue sampling and unannounced inspections but the five percent sampling of total operations was not achieved during 2013. QCS appears to be on course to attain the five percent minimum for 2014.

QCS has policies and procedures in place for denial, proposed suspension and revocation, as well as complaint investigations. Since the previous NOP onsite audit, QCS has denied certification to one applicant and conducted one mediation process. A review of records verified that the denial of certification, notification of non-compliances, notifications of proposed suspension/revocation, and actual suspension/revocation requirements were in accordance with the NOP standards (except as indicated in Noncompliances Identified section of this report).

QCS international trade activities were not reviewed during this assessment.

FEES

The QCS fee schedule and fee worksheet are used to determine the deposit required for applicants who request certification. The fee schedule includes information on deadlines or activities that render the deposit non-refundable. The fee schedule outlines the various pre-determined costs for the certified operations. The fees appear to be reasonable and the schedule is clear in the amounts to be charged.

SUMMARY OF WITNESS AND REVIEW AUDITS CONDUCTED:

As part of the mid-term assessment, one witness review of an annual inspection was conducted on a certified crop operation located in Virginia. The operation was a diversified farm (~ 10 acres) producing strictly organic mixed vegetables and fruit. Greenhouses and hoop houses are used to extend the growing season. Produce sales occur at local farmers markets, some retail stores, and through their Community Supported Agriculture (CSA). The operation also has a certified kitchen (per food safety regulations) for processing jams, wine, and canned products, but is not currently certified for organic handling. No organic claims are made on processed products; the labels and inputs utilized were verified during the inspection. No issues of concern were identified by the inspector. A complete and thorough exit interview was conducted with the

operation's representative at the end of the inspection. No pesticide sample was taken; however, the inspector was equipped to obtain samples if needed. The inspector that conducted the inspection was a QCS inspector and Certification Coordinator.

A Review Audit is scheduled for a Grower Group located in Ecuador during the month of October. The results of the audit will be announced and discussed with QCS personnel separately from this report.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether QCS corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to QCS.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP215500A.NC1 – Cleared – 7 CFR §205.404(b) states, “The certifying agent must issue a certificate of organic operation which specifies the: (2) Effective date of certification; (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation.”

- *During the review of 10 certification files it was found that one of the files reviewed was for a client that was previously certified by another ACA. The effective date on the certificate did not represent the effective date when the operation was initially certified to the NOP regulations, instead it represented the initial date for which the operation was certified under the QCS certification program. In this case certification was maintained by the previous ACA until certification was granted by QCS. **Corrective Action:** QCS provided a correction to the specific issue and included a copy of the revised certificate as objective evidence. For preventive action, QCS included a revised policy from the QCS Certification Policy Manual detailing how effective dates are determined for long-time QCS clients (i.e., certified prior to the NOP taking effect) or for clients transferring from a previous certifier. QCS intends to use 10/21/02 as the effective date for clients certified prior to the NOP coming into effect; or, the initial effective date from the first certification. QCS conducted staff training on this issue on January 9, 2013; a copy of the training agenda and meeting minutes were provided as objective evidence. If effectively implemented, QCS' response demonstrates the ability to comply with NOP*

accreditation requirements. **Verification of corrective action:** A review of organic certificates indicated that they were issued in compliance with the regulations and according to NOP 2603, Organic Certificates.

- *Also during the review of the certification files, two of the 10 files for clients certified for both crop and livestock found that the certificates did not include livestock as part of the scope of certification. **Corrective Action:** QCS provided a correction to the specific issue and included copies of the revised certificates (2) as objective evidence. For preventive action, QCS included a revised policy from the QCS Certification Policy Manual detailing how the scope must be verified and documented on the certificate before printing and issuing to the operation. QCS conducted staff training on this issue on January 9, 2013; a copy of the training agenda and meeting minutes were provided as objective evidence. If effectively implemented, QCS' response demonstrates capability to comply with NOP accreditation requirements. **Verification of corrective action:** A review of an issued organic certificate of a livestock operation confirmed that QCS is listing both livestock and crops as certification scopes.*

NP215500A.NC2 – Cleared - 7 CFR §205.662(c)(3) states, “Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance. When correction of a noncompliance is not possible, the notification of noncompliance and the proposed suspension or revocation of certification may be combined in one notification. The notification of proposed suspension or revocation of certification shall state: The impact of a suspension or revocation on future eligibility for certification.” *A review of two proposed suspension notifications revealed that the impact of the suspension was not included in the notices. **Corrective Action:** QCS submitted new templates for all proposed suspension letters on file. The templates now adequately explain the impact of the suspension on future eligibility for certification. As a preventive measure, QCS aligned letters with the NOP templates presented at the 2011 NOP ACA training. QCS also conducted an audit of all proposed suspension letters to ensure that all templates have been revised. If effectively implemented, QCS' response demonstrates the capacity to comply with NOP accreditation requirements. **Verification of corrective action:** Several issued Notices of Proposed Suspension were reviewed and all stated the impact of suspension on future certification eligibility.*

AIA4086MMK.NC1 – Cleared - 7 CFR §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: (2) Demonstrate the ability to fully comply with the requirements for accreditation set forth in this part.” The “Policy and Procedure” section of the NOP 2605 Instruction, as well as section 3.4(c), requires that the certifier submit the reinstatement request to the NOP within a three month period following the reinstatement inspection. In the case of this operation, the inspection was conducted August 30, 2013, however the reinstatement

request was not sent to the NOP until February 26, 2014, six months after the inspection. QCS did not request a deviation to the NOP 2605 Instruction requirements. **Corrective Action:** QCS' corrective action response indicates that the delay in sending the reinstatement request to the NOP was due to an exchange of requests for information from the operation that took place over a four-month period. QCS admits it did not follow NOP 2605 Instruction procedures in requesting a deviation from the NOP when the reinstatement process took longer than the three months allowed. QCS has revised its review SOP, within the Certification Standard Operating Procedures, section V. F. 5., to include the requirement that a deviation must be requested from the NOP if the reinstatement process is expected to take longer than three months to complete. QCS conducted training with staff members on April 28, 2014, specifically noting the three month reinstatement timeframe and deviation requirements in the NOP 2605 Instruction. QCS has also added a static agenda item to weekly staff meetings to review any Instruction or Guidance updates released by the NOP, as well as any NOP Insider messages, to ensure staff is current on requirements. **Verification of corrective action:** A review of subsequent reinstatement requests indicated that the requests were submitted within three months of the onsite inspections.

AIA4086MMK.NC2 – Cleared -7 CFR §205.662(f)(1) states, “A certified operation whose certification has been suspended under this section may at any time... submit a request to the Secretary for reinstatement of its certification...” The NOP suspended Tim Smith/Organic Creekside Farm for a six-month period as of September 17, 2012, which was made public in the List of Suspended/Revoked Operations on the NOP website. On October 24, 2012, QCS received and accepted an application for certification from this operation; conducted an organic inspection on February 5, 2013; and issued an organic certificate on February 21, 2013, before the operation was eligible for reinstatement and without first requesting reinstatement to the NOP. Accredited Certifying Agents do not have the authority to certify or reinstate suspended operations. **Corrective Action:** QCS indicated that their standard operating procedure for review of new client applications now includes checking the NOP's Suspended/Revoked Operations list on the NOP website to ensure the operation is eligible for certification. QCS staff checked this list when the application for Tim Smith/Organic Creekside Farm was received (October 24, 2012) and noted that it did not find the operation listed at that time. Additionally, the operation did not indicate on the application that it was in suspension status. When QCS was informed of the operation's suspended status in July 2013, QCS began the reinstatement process. To ensure this type of noncompliance does not occur in the future, QCS has revised its Incoming Application Checklist to include a record verifying that the operation's suspended/revoked status was checked on the NOP website and/or with the previous certifier, if the applicant has provided information regarding prior certification. The Administrative SOP was revised to note this change to the form and procedure. QCS also added a second check of the operation's suspended/revoked status, to be verified by the final reviewer, as documented in the revised Certification Standard Operating Procedure, section IX. On April 28, 2014, QCS conducted training with staff members with regard to this topic and new procedures/forms that were implemented to prevent reoccurrence. **Verification of corrective action:** A review of several new applicant files and the associated reviewer

checklists (pre- and post-inspection) indicated that QCS is verifying the certification status (suspension or revocation) on the NOP website.

Noncompliances Identified during the Current Assessment

NP4230LCA.NC1 - 7 CFR §205.501(a)(3) states, “Carry out the provisions of the Act and the regulations in this part, including the provision of §§205.402 through 205.406 and §205.670.” Furthermore, 7 CFR §205.404(c) states, “Once certified, a production or handling operation’s organic certification continues in effect until surrendered by the organic operation...” *The Notices of Proposed Suspension and Notices of Suspension state that QCS does not accept the surrender of certification under these circumstances. USDA organic regulations do not permit certifying agents to deny an operation the ability to surrender their organic certification in response to an adverse action.*

NP4230LCA.NC2 - 7 CFR §205.662(c)(3) states, “The notification of proposed suspension shall state... The impact of a suspension or revocation on future eligibility for certification...” *One Notice of Proposed Suspension that was issued stated a six month suspension period while the subsequent Notice of Suspension that was issued indicated a suspension period of one year.*

NP4230LCA.NC3 – 7 CFR §205.501 (a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP PM 11-10, Grower Group Certification, states in the 2008 NOSB Recommendation that as criteria for group certification, “The certification is owned by the group, not any individual member or subunit, which may not represent itself as certified other than through the group.” *One reviewed file indicated that QCS granted organic certification to a Grower Group owned by one entity, but this entity (an individual producer/processor) does not meet the requirements as a Grower Group and they contract with other producers to obtain additional product. Furthermore, QCS’ Certification Manual, Section 2.6, does not describe criteria in accordance with the USDA NOP policy for certification of a Grower Group.*

NP4230LCA.NC4 - 7 CFR §205.670(d) states, “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number.” *QCS’s January 2, 2013 submitted List of Certified Operations indicates 661 total operations and a minimum of 33 operations are required to be sampled for 2013. During 2013, QCS conducted residue testing sampling of 29 operations.*

NP4230LCA.NC5 – 7 CFR §205.403(a)(2)(ii) and NOP 2609, Unannounced Inspections states that, “... certifying agents conduct unannounced inspections of 5 percent of their total certified operations per year...” *QCS’s January 2, 2013 submitted List of Certified Operations indicates 661 total operations and a minimum of 33 operations are expected to receive unannounced inspections for 2013. During 2013, QCS conducted unannounced inspections of 29 operations.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Ram Balasubramanian
Quality Certification Services
PO Box 12311
Gainesville, FL 32604

OCT 02 2014

Dear Mr. Balasubramanian,

On August 18-19, 2014, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Quality Certification Services (QCS) organic certification program as part of its USDA Mid-term Accreditation Assessment. On September 22, 2014, the NOP reviewed the results of the onsite audit to determine QCS' compliance to the USDA organic regulations. A copy of the assessment report, NP4230LCA, is enclosed for your reference.

As the report indicates, four corrective actions for prior noncompliances, NP241100A.NC1 through 2 and AIA4086MMK.NC1 through 2, were cleared as they were determined to be implemented and effective. Five new noncompliances, NP4230LCA.NC1 through 5, resulted from the onsite audit. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the QCS management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renée Gebault King, at (202) 360-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

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Quality Certification Services
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Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

Renewal Audit Chronology Log

Audit Identifier (if any): NP7023NNA

Audit Type: Renewal

Accredited Certifying Agent Name: Quality Certification Services (QCS)

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
3/15/17	Review of audit report assigned to PZ
3/17/17	PZ reviewed audit reports, prepared notice of noncompliance and noncompliance report. Emailed to RM for review.
3/23/17	PZ accepted RM edits and printed for Miles' review and signature.
3/24/17	Miles had 2 questions. One was in regards to finding 1 – asking for more details on the timely issue. The other question was in regards to finding 2 – requesting mediation in writing. The language was revised to be more clear.
3/30/17	<p>NP7023NNA.F1 – 7 C.F.R. §205.662(e) states, “If the certified operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension or revocation of certification, the certifying agent shall send the certified operation a written notification of suspension or revocation.”</p> <p><i>Comments: QCS is not issuing letters of suspension in a timely manner in cases of administrative non compliances after a notice of proposed suspension has been issued.</i></p> <p>PZ emailed Patty (auditor) to ask for more details about the timeliness. Is there any data on the time period between issuance and action? The noncompliance and adverse action worksheet states, “QCS is issuing NoNC, PS, and Suspension in compliance with the rule.” this seems to contradict the finding.</p>
3/31/17	<p>PZ emailed with Patty to clarify F1 – revised the noncompliance:</p> <p><i>Comments: QCS is issuing proposed settlement agreements to operations that are in proposed suspension without receiving a request for mediation or appeal, and/or completing the mediation process.</i></p> <p>Printed NC Report for Miles approval and signature.</p>
4/4/17	JR processed and issued NoNC to Certifier via RPost

Renewal Audit Chronology Log

Audit Identifier (if any): NP7023NNA

Audit Type: Renewal

Accredited Certifying Agent Name: Quality Certification Services (QCS)

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

Corrective actions from the 2012 Renewal Audit were verified and found to be implemented and effective during the 2014 on-site assessment. The non-compliances were cleared during this review assessment.

GENERAL INFORMATION

Applicant Name	Rhode Island Department of Environmental Management (RIDEM)
Physical Address	235 Promenade Street, Providence, RI, 02908
Mailing Address	Same
Contact & Title	Matt Green, Program Coordinator
E-mail Address	Matt.Green@dem.ri.gov
Phone Number	401-222-2781 Ext 4516
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer; David J. Hildreth, Onsite Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Review Date: October 8, 2014 Audit Dates: August 19-20, 2014
Audit Identifier	NP4231ACA
Action Required	None
Audit & Review Type	Corrective Action Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of RIDEM's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	RIDEM's certification services in carrying out the audit criteria during the period: 2012-2014

The Rhode Island Department of Environmental Management (RIDEM) Organic Certification Program is administered by the Plant Industry Section of the Agriculture and Resource Marketing Division. RIDEM has been accredited as a certifying body since October 22, 2002, to the National Organic Program (NOP). RIDEM was initially accredited for the scopes of crops and handling and on September 17, 2008 for livestock. However, on January 20, 2014, RIDEM surrendered its handling certification (scope).

RIDEM currently has 13 clients certified to the NOP and all 13 operations are certified to the crop scope. The operations are all located in Rhode Island. There are no grower groups or livestock operations certified by RIDEM. RIDEM consists of one office and all certification activities are conducted at the Providence, Rhode Island office.

BACKGROUND:

In response to RIDEM's 2012 renewal audit, RIDEM submitted corrective actions to the NOP on October 8, 2013 and November 14, 2013. The proposed corrective actions demonstrated how existing noncompliances were remedied and also indicated how RIDEM's quality management system would be modified to prevent future noncompliances. In December 2013, the NOP renewed RIDEM's accreditation on the condition that it receives an additional compliance audit in 2014. The corrective actions from 2013 were verified during the August 19-20, 2014 Corrective Action Audit.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether RIDEM's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2253ACA.NC1 – Cleared - NOP § 205.406 (b) states, "Following the receipt of the information specified in paragraph (a) of this section, the certifying agent shall within a reasonable time arrange and conduct an on-site inspection of the certified operation pursuant to §205.403..."

Comments from 2012 audit: *As of September 2012, four of the eight certification files reviewed had not yet been inspected. RIDEM completed the initial reviews of these four files between February and May 2012.*

RIDEM's Corrective Actions (2013): RIDEM inspected four of the eight operations by March 2013; two others surrendered their certification. The remaining two inspections were still being scheduled as of October 2013. RIDEM has assigned an additional staff member to the program to complete organic inspections. The new staff member conducts other inspections for RIDEM. RIDEM submitted a training plan through April 2014 for the new inspector covering 10 online NOP training modules and 17 NOP handbook documents. She will also attend IOIA crop and livestock inspector training in May 2014, and she is shadowing the currently RIDEM inspector in the field. In addition, RIDEM will surrender its handling accreditation on January 20, 2014 in order to decrease its workload. This will reduce its total clients from 22 to 16.

Verification of Corrective Action (2014): With the reduction in clients and the hiring of two interns to help with the Program Coordinator's additional duties of Nursery Inspections, the additional staff member is not needed, although the Program Manager stated she is available if needed. A review of RICO Form 805 and Form 806 indicates that with the reduction in scope the program is being kept up to date.

NP2253ACA.NC2 – Cleared - NOP § 205.403(a)(1) states, “A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested. An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.”

Comments from 2012 audit: *One crop operation has not been inspected since 2010. RIDEM received an annual update from the farm in both 2011 and 2012; however, the Program Coordinator stated that other priorities prevented them from completing an inspection. In addition, two orchards were not inspected in 2011. The operations submitted annual updates in both 2011 and 2012.*

RIDEM’s Corrective Actions (2013): RIDEM completed all inspections for the 2011 annual updates between August 2011 and December 2012. In addition, RIDEM will surrender its handling accreditation on January 20, 2014 in order to decrease its workload. This will reduce its total clients from 22 to 16. The program manager will now review all applications weekly to ensure timely inspections are scheduled. RIDEM submitted a new organic certification checklist and a revised program manual as evidence.

Verification of Corrective Action (2014): The total client list consists of 13 certified clients as of the day of the assessment. RIDEM does not expect any new applications this year. All applications are reviewed daily and the form, RICO 805, is filled out to keep track of what is due and when. It appears that all update inspections will be accomplished this year.

NP2253ACA.NC3 – Cleared - NOP § 205.406 (d) states, “If the certifying agent determines that the certified operation is complying with the Act and the regulations in this part and that any of the information specified on the certificate of organic operation has changed, the certifying agent must issue an updated certificate of organic operation pursuant to § 205.404(b).”

Comments from 2012 audit: *At the September 2012 audit, two of the eight files reviewed showed that RIDEM had not yet made certification decisions or issued certification decisions on applications from the 2011 certification cycle.*

RIDEM’s Corrective Actions (2013): *RIDEM completed all certification decisions for the 2011 annual updates between August 2012 and March 2013. RIDEM has assigned an additional staff member to the program to complete organic inspections. In addition, RIDEM will surrender its handling accreditation on January 20, 2014 in order to decrease its workload.*

Verification of Corrective Action (2014): A review of the records indicates that with the reduction in scope the program is being kept up to date. All inspections are up to date; as of the time of the audit, only six currently certified operations remained due for inspection in 2014. The Program Coordinator is actively working with its clients to schedule the inspections prior to the end of the season.

NP2253ACA.NC4 – Cleared - NOP § 205.662(a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent or a State organic program's governing State official reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

Comments from 2012 audit: *Two operations did not submit updated organic system plans in response to RIDEM’s annual reminder. RIDEM did not issue these operations a Notice of Noncompliance for failure to comply with §205.406, Continuation of certification.*

RIDEM's Corrective Actions (2013): In November 2012, RIDEM issued a Notice of Noncompliance to all of the operations which did not submit an updated organic system plan by the deadline. RIDEM will now conduct an application processing review to ensure that notices are issued in a timely manner. The program manager will review the status of all notices and responses on a weekly basis. RIDEM submitted a new application processing form and a revised program manual as evidence.

Verification of Corrective Action (2014): The auditor reviewed all recently issued Notices of Noncompliance. RIDEM's application processing review was verified and the auditor confirmed notices are being issued in a timely manner.

NP2253ACA.NC5 – Cleared - NOP § 205.662(b) states, “When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent or the State organic program's governing State official, as applicable, shall send the certified operation a written notification of noncompliance resolution.”

Comments from 2012 audit: *After receiving a Notice of Noncompliance for failure to submit an updated organic system plan, one operation responded with an updated OSP and corrective actions. RIDEM did not send this operation a Notice of Noncompliance Resolution.*

RIDEM's Corrective Actions (2013): RIDEM issued this operation a Notice of Noncompliance Resolution on October 2, 2012. RIDEM instituted a new certification checklist to record all steps of the certification process, and the program manager will audit this information weekly.

Verification of Corrective Action (2014): The new certification checklist was found to be in use and all notices of Non-Compliance Resolution have been issued as required.

NP2253ACA.NC6 – Cleared - NOP § 205.662(c) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program's governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.”

Comments from 2012 audit: *RIDEM sent a Notice of Noncompliance to an operation in April 2012 for failure to submit its 2011 annual update. The operation did not respond within 30 days, as required by the notice. As of the September 2012 audit, RIDEM had not issued a Notice of Proposed Suspension to the operation.*

RIDEM's Corrective Actions (2013): RIDEM issued a Notice of Noncompliance to the operation for failure to submit an annual update in August 2012. The operation responded with a completed update form in September, and RIDEM issued a Notice of Noncompliance Resolution in October. At the time of the corrective action report, all certified operations had submitted their annual updates to RIDEM.

Verification of Corrective Action (2014): The review found that with the new certification checklist, all Notices of Noncompliance and notices of Non-Compliance Resolution have been issued as required.

NP2253ACA.NC7 – Cleared - NOP § 205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must use a sufficient number of adequately trained

personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part.”

Comments from 2012 audit: *File reviews indicate that RIDEM has not completed application reviews or onsite inspection for numerous clients. Interviews with the staff indicated that there is only one inspector on staff, and that the inspector’s other assignments were too time-consuming to accomplish inspections.*

RIDEM’s Corrective Actions (2013): RIDEM has assigned an additional staff member to the program to complete organic inspections, which will allow the current inspector and program reviewer more time to complete file reviews and issue notices. In addition, RIDEM will surrender its handling accreditation on January 20, 2014 in order to decrease its workload.

Verification of Corrective Action (2014): With the reduction in clients and the hiring of two interns to help with the Program Coordinator’s additional duties of Nursery Inspections the additional staff member is not needed, although the Program Manager stated she is available if needed. A review of the records indicates that with the reduction in scope the program is being kept up to date.

Mid-Term Audit Resolution Chronology Log

Audit Identifier (if any): NP4217ZZA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: SCS
Accreditation Manager: Janna Howley

Date	Activity
09/15/14	Audit report received from Corey Gilbert. MLC sent to JH for review and processing.
10/21/14	<ul style="list-style-type: none"> JH reviewed file; all findings appear to be NCs. However, Finding 11 (NC11) regarding unannounced inspections, is not required by NOP regulations. Regulations and guidance document language indicates “may” and “should.” Left in report, but would appreciate RM or CC feedback on this. Seems kind of gray area-ish... Emailed draft letter and report to RM for review.
10/23/14	RM reviewed docs and had substantial questions about NP2129BBA.NC3 and Finding 4. The original finding in .NC3 indicated that four of five staff members had not completed COI reports, but *did* email that they did not have COIs. Finding 4 indicated that label review was not adequate, but no noncompliant labels were found in review. RM thought it was not a good application of Sound and Sensible to issue a noncompliance in this instance.
10/28/14	Email to RM and CC from JH: I reviewed audit report and in regard to the COI forms auditor does indicate the SCS has allowed emails as a way to confirm no COI: Annual signed COI forms not current; have been using an email confirmation and kept on file (language in QM section for COI reflects email confirmation is adequate). So in this case, if one staff member did complete the COI form, and four staff members used the email procedure, then Renee is correct that the first part of NP2129BBA.NC3 should be taken out.
10/29/14	<ul style="list-style-type: none"> NP2129BBA.NC3 revised to take out “four of five staff members did not have completed COI reports.” NC4 removed completely. All other NCs renumbered. Final number of new NCs is now ten. Revised letter and report and sent to RM and CC for final review.
10/31/14	Updated NC report to spell out Cleared NCs. Printed report and doc; gave to RM.
11/10/14	<ul style="list-style-type: none"> Updated report and letter per CC edits. Emailed SCS to get a copy of their QM to better determine meaning of auditor’s finding related to unannounced inspections. Sent email to RM and CC
11/13/14	CC computer not working for the past two days, so has not been able to respond.
11/14/14	Per CC: certifiers are absolutely required to conduct unannounced inspections and as a result, their Quality Manual, in fact, does not provide an adequate amount of detail about the unannounced inspection scope and process. Auditor’s finding is correct. Edited report and emailed to CC for review.
11/25/14	Sent letter and report to CC for review.
11/26/14	Rcvd edits from CC. Updated document and sent back to CC for review. Rcvd approval from CC to print hard copy.
12/01/14	Took hard copy upstairs for CC signature.
12/02/14	Rcvd signed copy back. Emailed NoNC report and letter to SCS.
12/23/14	Rcvd proposed CAs from SCS.

Mid-Term Audit Resolution Chronology Log

Audit Identifier (if any): NP4217ZZA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: SCS
Accreditation Manager: Janna Howley

02/06/14	Began working on CA report. Emailed SCS with some clarification questions. Rcvd response same day with some docs that supported a few of their proposed CAs that had January and/or February deadlines.
02/17/15	Finished CA report and NoCont Accred letter. Emailed to RM for review.
02/18/15	Rcvd edits and comments from RM; they need to submit a plan and objective evidence of how the NCs will be resolved and prevented from happening in the future.
02/19/15	<ul style="list-style-type: none"> • RM emailed JH to let her know she'd forwarded the report/letter to CC to determine whether SCS needs a compliance audit. CC added comments to the report. • JH emailed RM to let her know she'd contacted SCS on 02/19/15 to request additional information.
02/25/15	SCS responded; they will submit requested information by March 6 th . JH let Brandon know she was out of office on an audit until March 9 th .
02/27/15	Brandon emailed, I have completed implementation of our corrective actions due on February 28, nearly all of which required updates to our program manuals and documents. As the new documents and the new versions of the manuals are going through our internal document control, I will be able to submit them early next week so they'll be available for your review when you are back in town."
03/03/15	SCS emailed additional documentation.
03/20/15	<ul style="list-style-type: none"> • JH begins document review. • Emailed SCS to determine whether SCS "got 2014 conflict of interest statements from the staff member, four board members, and inspectors, who had been missing them? And have the 2015 statements for all staff, board and inspectors been received at this time?"
03/23/15	<ul style="list-style-type: none"> • Rcvd response back from SCS. They also wanted to know, " For the rest of the program employees, as well as the one contract inspector that remains in the program – do you need new forms filled out each year (with wet signature), or may we request annual confirmation via email that the Conflict of Interest Statement on file is current (as attached)? We've had auditors differ on this requirement in years' past. If we need new forms with wet signatures, just let me know and I'll see to it that they are submitted right away." • Emailed LC and RM to determine whether email acceptable or hard copy required. LC suggested that hard copies required; RM suggested that email is acceptable: Regarding the signed confidentiality disclosures, I don't think they're required. We recently allowed another certifier to simply have emails, not signed "wet" signatures. I briefly mentioned this to Lars today and said we need to get on the same page. For now, please don't require SCS to gather new, signed COI disclosure statements. We can't hold the certifier accountable to ISO 17065 requirements, although I understand where Lars is coming from. At a certain point, you're not sure if the certifier is complying with the regulations because our regulations don't describe in enough detail how to gather confidentiality agreements. As a result, we sometimes rely on best practices from other common

Mid-Term Audit Resolution Chronology Log

Audit Identifier (if any): NP4217ZZA
Audit Type: Mid-Term Assessment
Accredited Certifying Agent Name: SCS
Accreditation Manager: Janna Howley

	<p>quality management schemes, such as ISO 17065.</p> <ul style="list-style-type: none"> Emailed Brandon at SCS to let him know emails he submitted are sufficient. SCS also submitted an updated QM that provided even more updates related to previous NCs.
03/27/15	<ul style="list-style-type: none"> Emailed report and letter to RM for review. RM wanted clarification on one additional question. Emailed SCS.
03/30/15	Updated report and sent to RM for review.
04/01/15	Rcvd approval from RM to email on to CC for review.
04/02/15	Emailed letter and report to CC for review.
04/03/15	OK from CC to print docs. Printed and gave to her for final approval and MM signature.
04/07/15	<ul style="list-style-type: none"> File back from MM: “I’m not comfortable signing this. Numerous significant findings should lead to settlement with specific requirements for ensuring compliance.” CC discussed with MM, and it was decided that a conditional accreditation would be granted to SCS, with the condition being an additional compliance audit within one calendar year of letter, at SCS’s expense. JH will use MD Dept of Ag letter as template for SCS letter, since it was a very similar situation.
04/10/15	JH drafted conditional accreditation letter. Emailed to CC for review and MM signature.
04/13/15	CC approved; made one edit. OK to print. JH printed and gave to CC for review, MM signature.
04/14/15	CC made further edits to the document and gave back to JH.
04/16/15	<ul style="list-style-type: none"> JH updated the document, reprinted the letter, and gave to CC to review. Rcvd signed doc back from MM.
04/17/15	<ul style="list-style-type: none"> JH will give Brandon a call this morning to give him a verbal heads up about the Notice Conditional Accreditation that she will be sending him, so SCS understands the reasons and can ask any questions about the compliance audit process.
04/20/15	JH LVM for Brandon.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

DEC 02 2014

Brandon Nauman
SCS Global Services (SCS)
2000 Powell Street, Suite 600
Emeryville, CA 94608

Dear Mr. Nauman:

On August 5-7, 2014, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the SCS Global Services (SCS) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On November 25, 2014 the NOP reviewed the results of the onsite audit to determine SCS's compliance to the USDA organic regulations. A copy of the assessment report, **NP4217ZZA**, is enclosed for your reference.

As the report indicates, five (5) corrective actions for prior noncompliances (**NP2129BBA.NC1, NC2 and NC4-NC6**), were cleared and determined to be implemented and effective. One (1) noncompliance, (**NP2129BBA.NC3**), remains outstanding from your previous audit. Ten (10) new noncompliances (**NP4217ZZA.NC1-NC10**) were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the SCS management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Janna Howley, at (202) 692-0047 or JannaB.Howley@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney". The signature is written in a cursive, flowing style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Brandon Nauman
SCS Global Services (SCS)
2000 Powell Street, Suite 600
Emeryville, CA 94608

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Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of SCS. An onsite audit was conducted, and the audit report reviewed to determine SCS’s capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	SCS Global Services (SCS)
Physical Address	2000 Powell Street, Suite 600, Emeryville, CA 94608
Mailing Address	Same
Contact & Title	Brandon Nauman, Project Manager
E-mail Address	bnauman@scsglobalservices.com
Phone Number	510-452-8052
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer; Corey D. Gilbert and Kathryn Matejovsky (Training), On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: October 21, 2014 Onsite audit: August 5-7, 2014
Audit Identifier	NP4217ZZA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of SCS’s certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	SCS’s certification services in carrying out the audit criteria during the period: June 2012 through August 2014.

Organizational Structure:

Scientific Certification Systems, Inc. (SCS), doing business as SCS Global Services, is a for-profit privately owned company accredited as a certifying agent to the USDA National Organic Program (NOP) since April 29, 2002. SCS Global Services is accredited for the scopes of crops, wild crops, and handling. It currently has 40 operations certified to the NOP Standard with 14 crop, 0 wild crop, 18 handling, and 8 crop/handling operations including 1 grower group. Its certified operations are located primarily in the USA (36) with 3 in Mexico and 1 in Haiti. SCS Global Services conducts all certification activities, except contract inspector activities, at its headquarters in Emeryville, CA. A subsidiary office located in Culiacán, Sinaloa, Mexico receives inquiries and applications for organic certification; however, all information is forwarded to the headquarters office for the technical review and any certification decisions.

SCS Global Services provides third-party certification for numerous environmental, natural resources, and food & agriculture standards and is also accredited as a certification body for most of these standards. It is accredited as a certification body under ISO 17065 by the American National Standards Institute (ANSI) covering multiple standards including food safety auditing for Safe Quality Foods (SQF), British Retail Consortium (BRC), and Global GAP.

SGS Global Services is divided into three service divisions: Environmental Certification Services, Natural Resources, and Food and Agriculture. The organic certification program is located within the Food and Agriculture division and personnel involved in organic certification include the Quality Assurance Manager, Project Manager for Food & Agriculture, Client Coordinator, Client Services Manager, one (1) staff Technical Associate (Organic Program Inspector), and four (4) contract inspectors. SCS Global Services also has a five member Board of Directors for general oversight and direction of the organization; however, none of the members have certification decision making roles.

A review of personnel files and interviews conducted verified the organic certification staff had sufficient experience, training, and education in agriculture, organic production, and handling, except as identified in the findings. SCS Global Services conducts annual performance evaluations for all staff. A review of training records indicated the staff reviewers, staff inspector, and all contracted inspectors had received current training on the NOP regulations. The Project Manager (organic program manager) for the Food and Agriculture Division and the staff organic inspector were registered to attend a week-long IOIA organic certification training course in October 2014.

Certification Process:

Requests for certification are received by phone and email and initial correspondence is handled by the Client Coordinator. Interested applicants are sent an Organic Application Package consisting of the application form and organic system/handling plan, SCS Global Services' organic certification procedures, a fee schedule, and a link to the NOP Rule. After all required information is submitted, an assigned reviewer (typically the Project Manager and occasionally the staff inspector) will determine if the applicant appears to comply and is ready for an inspection. The Client Coordinator assigns the inspector based on qualifications, location, and availability. The inspector is provided the complete organic system/handling plan, conducts the inspection, and submits a completed inspection checklist/report with recommendations regarding certification. A final review is conducted by the Project Manager or Client Services Manager and the certification decision is made by one or the other. SCS Global Services is primarily using a three person certification system; however, in some cases a two person certification system is used. In all cases, the person making the certification decision is different from the inspector. The operation is issued the approved inspection report, any notification of minor issues or notice of noncompliance, notification of noncompliance resolution, and a certificate as applicable.

An annual update reminder is sent to all certified operations sixty days prior to their annual renewal date, and they are all required to submit an annual update form along with any changes to their organic system/handling plans and supporting documentation. The Client Coordinator reviews for completeness, the Project Manager or staff organic inspector conducts the technical

review, and the inspection assigned to a qualified inspector. The inspection is completed, the report is submitted, and a final review and certification decision is made by the Project Manager and/or Client Services Manager. The approved inspection report and updated certificate are issued to the certified operation.

SCS Global Services has certified one grower group operation, located in Haiti.

Material reviews are conducted by the Project Manager and Technical Associate (staff organic inspector) using the organic regulations, OMRI lists, and information from the Washington State Department of Agriculture. SCS Global Services also accepts the material reviews conducted by other certifying agents as long as adequate documentation is provided.

Label reviews are conducted by the Project Manager using their label procedure, NOP regulations, and NOP Program Handbook.

SCS Global Services is approved to issue TM-11 export certificates to Taiwan, but they have not had any requests, nor issued any. SCS has also not issued any export certificates to Japan. Interviews and file reviews confirmed that SCS Global Services is appropriately implementing the terms and conditions of the US-Canada equivalency arrangement. They have not received any requests for imports or exports under the US-European Union equivalency arrangement.

Administrative Records and Processes:

SCS Global Services has an Organic Quality Manual, Organic Certification Manual, Organic Program Inspector Manual, Guidance on Label Reviews, Input Material Review Request Procedure, initial application form, template organic system/handling plans, inspection checklists, annual update form, and numerous additional template forms for adverse actions, etc.

SCS Global Services conducts an annual internal audit and program review and implements corrective actions based on the audit findings. SCS has annual organic training and the Project Manager attends annual external NOP training which is used to provide additional internal training.

Summary of Review Audit Conducted:

The assessment included a review audit conducted at a crop and handling operation in San Marcos, California first certified by SCS Global Services in April 2014. The operation included onsite growing and packaging of organic mushrooms for sale in the USA and Canada. The operation had dedicated organic production only which included receiving of mushroom spores, production of generational spawn, inoculation of grow bottles, mushroom growing, and final cleaning, packaging, and shipping of raw mushrooms to retailers.

The initial inspection was conducted in March 2014 by SCS Global Services' staff organic inspector, who also attended the review audit. The operation was previously certified from May 6, 2010 to May 5, 2014 by another certifying agent. Overall, the review audit verified compliance to the organic regulations.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether SCS corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to SCS.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

N2129BBA.NC1 – Cleared – 7 CFR §205.501 (a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: SCS is accredited for the scope of livestock to the NOP but does not have any updated OSP’s, forms, documents, inspection checklists, or guidance addressing the requirements of the pasture rule or the latest livestock requirements. In addition, SCS has conducted limited or no training on NOP livestock requirements for the SCS staff or subcontractor inspectors. However, SCS has no livestock clients currently certified for the scope of livestock.

Corrective Actions: On July 11, 2012, SCS notified NOP of its request to remove the scope of livestock from its accreditation renewal request.

Verification of Corrective Action (August 2014): SCS Global Services removed all references to livestock certification from its documentation, does not offer livestock certification, and has not certified any livestock operations. SCS Global Services confirmed understanding that any amendment to their scope of accreditation must be submitted in accordance to NOP §205.510(f).

NP2129BBA.NC2 – Cleared – 7 CFR §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”

Comments: Three SCS staff members have not had documented annual performance evaluations since April 30, 2009, November 22, 2009, and April 22, 2010.

Corrective Actions: SCS’s Food Safety Division was restructured to ensure that personnel policies, including timely performance evaluations, are conducted. All annual employee performance evaluations will now occur by March 1st each year. SCS further indicated that all organic program staff will receive a 2012 performance evaluation by August 31, 2012.

Verification of Corrective Action (August 2014): SCS Global Services conducted annual performance evaluations for all staff in 2012, 2013, and 2014; therefore, this noncompliance was cleared.

NP2129BBA.NC3 – Outstanding – 7 CFR §205.501 (a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.”

Comments: A review of the SCS Annual Confidentiality Agreement and Declaration Agreement for Conflict of Interest (COI) forms showed that 1 of the 2 subcontractor inspectors and 1 of the 5 responsibly connected parties were not completed. In addition, 1 staff and 3 responsibly connected parties COI’s had not been completed annually with last signed dates being October 1 and 3, 2008, August 11, 2010, and September 20, 2010.

Corrective Actions: Conflict of interest disclosure reports are to be collected annually by January from all required parties, including parties responsibly connected to SCS. Program management will notify all affected staff members and subcontractors about the new procedure and deadline. SCS submitted completed 2012 Conflict of Interest and Confidentiality Agreement reports for NOP’s review.

Verification of Corrective Action (August 2014): Four of five staff did not complete an annual conflict of interest report in 2014; although, four submitted emails stating no conflicts of interest as allowed by their procedures. None of the contracted inspectors submitted conflict of interest reports in 2014. None of the members of the board of directors submitted conflict of interest reports in 2013 or 2014; although, one member submitted an email in 2014 stating no conflicts.

NP2129BBA.NC4 – Cleared – 7 CFR §205.501 (a)(11)(vi) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.”

Comments: On 1 of the 8 files reviewed, the same person conducted the initial review documents and made the final certification decision.

Corrective Actions: SCS has reinstated a person responsible for making final certification decisions in the certification process. This person will not conduct any document reviews or on-site inspections. SCS clarified the role of the decision maker by updating their quality manual and providing a record reflecting the roles of SCS staff.

Verification of Corrective Action (August 2014): SCS Global Services used a three person system from July 2012 to February 2014; however, their current system also allows a two person system when necessary as long as the final review and certification decision is made by someone other than the inspector that conducted the inspection. Both of these systems comply with NOP 2006.

NP2129BBA.NC5 – Cleared – 7 CFR §205.501 (a)(15)(ii) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Submit to the Administrator a copy of: A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year.”

Comments: SCS had removed one client from the list of Certified Operations that had not officially withdrawn or been suspended. This client was currently in the proposed suspension status at the time of the audit.

Corrective Actions: SCS conducted training for its staff on July 10, 2012 using materials from the NOP "NOP 2024" and the list of certified operations was reviewed and corrected.

Improvements were made to SCS’s Data Management System to ensure proper tracking of SCS certified operations.

Verification of Corrective Action (August 2014): SCS Global Services submitted an accurate list of certified operations in 2013 and 2014 which identified all certified operations.

NP2129BBA.NC6 – Cleared – 7 CFR §205.662(c) states, “Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.”

Comments: SCS granted certification of an operation with conditions on September 10, 2010 to respond by December 9, 2010 to avoid proposed suspension. SCS did not issue a notice of proposed suspension but issued another noncompliance on December 8, 2011 with an additional timeframe to reply by December 28, 2011. SCS finally issued the notice of proposed suspension on April 4, 2012. The Notice of Proposed Suspension should have been issued after the original deadline of December 9, 2010.

Corrective Actions: SCS issued the suspension notice to the client on June 4, 2012. SCS management implemented document management system procedures for tracking all notification deadlines.

Verification of Corrective Action (August 2014): SCS Global Services has issued two notices of proposed suspension since the last assessment; however, in both cases the operations submitted corrective actions addressing the notices and no adverse actions were necessary. SCS Global Services has not had a reoccurrence of the previous issue and reviews verified the document management system procedures for tracking notification deadlines were in place.

Noncompliances Identified during the Current Assessment

NP4217ZZA.NC1 – 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP Policy Memo 11-10 Certification of Grower Groups states, “...accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies.”

Comments: *SCS Global Services does not have grower group certification procedures and grower groups are not addressed in their organic system and handling plan templates. Grower groups are addressed in Section 9 of their crop inspection checklist. SCS Global Services has only certified one grower group (mangoes in Haiti) and the file review verified the operation was certified in accordance to the NOSB Recommendations.*

NP4217ZZA.NC2 – 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 5022 Guidance Wild Crop Harvesting addresses the ways accredited certifying agents and certified operations can demonstrate compliance with NOP §205.207 wild-crop harvesting practice standard.

Comments: *SCS Global Services does not have procedures for certifying to the wild crop harvesting practice standard, does not address wild crop harvest in their template organic system plans or inspection checklists, and does not currently have staff trained in the wild crop harvest requirements. SCS Global Services has never had any applicants for wild crop certification.*

NP4217ZZA.NC3 – 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2604 Instruction Responsibilities of Certified Operations Changing Certifying Agents, Section 4.2 states, “Certified operations that change certifying agents voluntarily and have labels which identify their prior certifying agent on products they produce or handle, may not use up existing supplies of labels. New labels must be used immediately identifying the new certifying agent.” NOP 2604, Section 5.2.8 states, “To receive applications from operations currently or previously certified by another accredited certifying agent, the new certifying agent must: Prohibit the new client from using labels which do not correctly identify the certifying agent of the finished product beyond the tolerances allowed in this instruction.”

Comments: *SCS Global Services allowed a new crop and handling applicant to continue using labels with the name of their previous certifier. A review audit was conducted on August 6, 2014 at this operation as part of the NOP Mid-Term Assessment and the operation was still using the labels with the name of the previous certifier and expected to take 3-6 months to complete the process to obtain new labels. The operation representative stated neither the previous certifier nor SCS Global Services provided these requirements for labels when they were in the process of changing certifying agents. The operation was first certified by SCS Global Services on April 22, 2014 and surrendered their certification to the previous certifier on May 6, 2014. SCS Global Services first provided the NOP 2604 Instruction to the operation and informed them of the labeling requirements when changing certifying agents on April 22, 2014. SCS Global Services reminded the certified operation on May 6, 2014 they had ninety days to use up the labels with the name of the previous certifier and to begin using approved labels identifying SCS Global Services as the certifier. The operation had been informed by an SCS Global Services sales representative during the application process that they had “until the packaging runs out or within 1 year after certification, whichever comes first” to replace the labels.*

NP4217ZZA.NC4 – 7 CFR §205.670(d) states, “A certifying agent must, on an annual basis, sample and test from a minimum of five percent of the operations it certifies, rounded to the nearest whole number. A certifying agent that certifies fewer than thirty operations on an annual basis must sample and test from at least one operation annually. Tests conducted under paragraphs (b) and (c) of this section will apply to the minimum percentage of operations.”

Comments: *SCS Global Services did not conduct any testing in 2013. This was identified as a noncompliance in their June 2014 internal audit; as a result, 3 samples were taken from 2 certified operations in July 2014 and a reminder set in their tracking system to check every six months to ensure sampling and testing was completed.*

NP4217ZZA.NC5 – 7 CFR §205.403(e)(1) states, “At the time of inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector.”

Comments: *SCS Global Services did not provide the certified operations receipts for three samples taken in July 2014.*

NP4217ZZA.NC6 – 7 CFR §205.403(a)(1) states, “...An on-site inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether to approve the request for certification or whether the certification of the operation should continue.”

Comments: *In 2013 SCS Global Services did not conduct an annual inspection for one certified crop operation. In December 2013 the operation was issued a Notice of Noncompliance for not submitting an annual update or having an onsite inspection; they were then issued a Notice of Proposed Suspension in January 2014, and subsequently submitted the required information and consented to an onsite inspection.*

NP4217ZZA.NC7 – 7 CFR §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who...perform on-site inspections...and implement measures to correct any deficiencies in certification services.”

Comments: *SCS Global Services did not conduct annual performance evaluations for the four contract inspectors used in 2012 and 2013. SCS Global Services identified this as a noncompliance in their June 2014 internal audit; however, the finding was still open and performance evaluations for the contract inspectors had not been completed. SCS Global Services’ procedures do not require annual performance evaluations for contract inspectors. Their “Procedure for Assessing Competency of Auditors and Audit Teams” specifies an initial witness assessment prior to being identified as a qualified auditor and an additional witness assessment every three years; however, an annual performance evaluation is not required.*

NP4217ZZA.NC8 – 7 CFR §205.406(c) NOP §205.662(a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent...reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the

certified operation.” NOP §205.662(c) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent...shall send the certified operation a written notification of proposed suspension....”

Comments: *SCS Global Services issued a Notice of Proposed Suspension (NoPS) to a certified handling operation, for not paying required certification fees, without first issuing a Notice of Noncompliance and providing the operation an opportunity to respond. The operation subsequently addressed the NoPS by paying the required fees and a Notice of Noncompliance Resolution was issued without any suspension taking place.*

NP4217ZZA.NC9 – 7 CFR §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662. NOP §205.662(a) states, “When an inspection, review, or investigation of a certified operation by a certifying agent...reveals any noncompliance with the Act or regulations in this part, a written notification of noncompliance shall be sent to the certified operation.”

Comments: *SCS Global Services issued a continuation of certification with conditions for a certified organic handling operation; however, three of the findings should have been issued as a formal Notice of Noncompliance and appropriate corrective actions verified prior to making the certification decision. The noncompliances included not having the cleaning and sanitation standard operating procedures; not identifying the cleaners and sanitizers used; and not documenting cleaning of the equipment and system flushes between conventional and organic production. SCS Global Services identified the findings as minor non-compliances, used appropriate citations, gave a submission deadline, reviewed the corrective actions, and issued a Notice of Noncompliance Resolution. However, the non-compliances were not minor and the operation should not have been issued a Notice of Continuation of Certification until corrective actions were received and verified.*

NP4217ZZA.NC10 – 7 CFR §205.504(b)(2) requires the submission of “a copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator;” and NOP §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2609 Instruction Unannounced Inspections addresses the requirements for unannounced inspections under the authority of NOP §205.403(a)(2)(iii) and Section 4.1.1 states, “We recommend that certifying agents conduct unannounced inspections of 5 percent of their total certified operations per year as a tool in ensuring compliance with the regulations.”

Comments: *SCS Global Services procedures (Quality Manual, Section 15) do not provide adequate detail regarding the unannounced inspection process; additionally, SCS did not conduct any unannounced inspections in 2012-2014.*

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of SCS. An onsite audit was conducted, and the audit report reviewed to determine SCS’s capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	SCS Global Services (SCS)
Physical Address	2000 Powell Street, Suite 600, Emeryville, CA 94608
Mailing Address	Same
Contact & Title	Brandon Nauman, Project Manager
E-mail Address	bnauman@scsglobalservices.com
Phone Number	510-452-8052
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer; Corey D. Gilbert and Kathryn Matejovsky (Training), On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: October 21, 2014 Onsite audit: August 5-7, 2014
Audit Identifier	NP4217ZZA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of SCS’s certification
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	SCS’s certification services in carrying out the audit criteria during the period: June 2012 through August 2014.

Organizational Structure:

Scientific Certification Systems, Inc. (SCS), doing business as SCS Global Services, is a for-profit privately owned company accredited as a certifying agent to the USDA National Organic Program (NOP) since April 29, 2002. SCS Global Services is accredited for the scopes of crops, wild crops, and handling. It currently has 40 operations certified to the NOP Standard with 14 crop, 0 wild crop, 18 handling, and 8 crop/handling operations including 1 grower group. Its certified operations are located primarily in the USA (36) with 3 in Mexico and 1 in Haiti. SCS Global Services conducts all certification activities, except contract inspector activities, at its headquarters in Emeryville, CA. A subsidiary office located in Culiacán, Sinaloa, Mexico receives inquiries and applications for organic certification; however, all information is forwarded to the headquarters office for the technical review and any certification decisions.

SCS Global Services provides third-party certification for numerous environmental, natural resources, and food & agriculture standards and is also accredited as a certification body for most of these standards. It is accredited as a certification body under ISO 17065 by the American National Standards Institute (ANSI) covering multiple standards including food safety auditing for Safe Quality Foods (SQF), British Retail Consortium (BRC), and Global GAP.

SGS Global Services is divided into three service divisions: Environmental Certification Services, Natural Resources, and Food and Agriculture. The organic certification program is located within the Food and Agriculture division and personnel involved in organic certification include the Quality Assurance Manager, Project Manager for Food & Agriculture, Client Coordinator, Client Services Manager, one (1) staff Technical Associate (Organic Program Inspector), and four (4) contract inspectors. SCS Global Services also has a five member Board of Directors for general oversight and direction of the organization; however, none of the members have certification decision making roles.

A review of personnel files and interviews conducted verified the organic certification staff had sufficient experience, training, and education in agriculture, organic production, and handling, except as identified in the findings. SCS Global Services conducts annual performance evaluations for all staff. A review of training records indicated the staff reviewers, staff inspector, and all contracted inspectors had received current training on the NOP regulations. The Project Manager (organic program manager) for the Food and Agriculture Division and the staff organic inspector were registered to attend a week-long IOIA organic certification training course in October 2014.

Certification Process:

Requests for certification are received by phone and email and initial correspondence is handled by the Client Coordinator. Interested applicants are sent an Organic Application Package consisting of the application form and organic system/handling plan, SCS Global Services' organic certification procedures, a fee schedule, and a link to the NOP Rule. After all required information is submitted, an assigned reviewer (typically the Project Manager and occasionally the staff inspector) will determine if the applicant appears to comply and is ready for an inspection. The Client Coordinator assigns the inspector based on qualifications, location, and availability. The inspector is provided the complete organic system/handling plan, conducts the inspection, and submits a completed inspection checklist/report with recommendations regarding certification. A final review is conducted by the Project Manager or Client Services Manager and the certification decision is made by one or the other. SCS Global Services is primarily using a three person certification system; however, in some cases a two person certification system is used. In all cases, the person making the certification decision is different from the inspector. The operation is issued the approved inspection report, any notification of minor issues or notice of noncompliance, notification of noncompliance resolution, and a certificate as applicable.

An annual update reminder is sent to all certified operations sixty days prior to their annual renewal date, and they are all required to submit an annual update form along with any changes to their organic system/handling plans and supporting documentation. The Client Coordinator reviews for completeness, the Project Manager or staff organic inspector conducts the technical

review, and the inspection assigned to a qualified inspector. The inspection is completed, the report is submitted, and a final review and certification decision is made by the Project Manager and/or Client Services Manager. The approved inspection report and updated certificate are issued to the certified operation.

Material reviews are conducted by the Project Manager and Technical Associate (staff organic inspector) using the organic regulations, OMRI lists, and information from the Washington State Department of Agriculture. SCS Global Services also accepts the material reviews conducted by other certifying agents as long as adequate documentation is provided.

Label reviews are conducted by the Project Manager using their label procedure, NOP regulations, and NOP Program Handbook.

SCS Global Services is approved to issue TM-11 export certificates to Taiwan, but they have not had any requests, nor issued any. SCS has also not issued any export certificates to Japan. Interviews and file reviews confirmed that SCS Global Services is appropriately implementing the terms and conditions of the US-Canada equivalency arrangement. They have not received any requests for imports or exports under the US-European Union equivalency arrangement.

Administrative Records and Processes:

SCS Global Services has an Organic Quality Manual, Organic Certification Manual, Organic Program Inspector Manual, Guidance on Label Reviews, Input Material Review Request Procedure, initial application form, template organic system/handling plans, inspection checklists, annual update form, and numerous additional template forms for adverse actions, etc.

SCS Global Services conducts an annual internal audit and program review and implements corrective actions based on the audit findings. SCS has annual organic training and the Project Manager attends annual external NOP training which is used to provide additional internal training.

Summary of Review Audit Conducted:

The assessment included a review audit conducted at a crop and handling operation in San Marcos, California first certified by SCS Global Services in April 2014. The operation included onsite growing and packaging of organic mushrooms for sale in the USA and Canada. The operation had dedicated organic production only which included receiving of mushroom spores, production of generational spawn, inoculation of grow bottles, mushroom growing, and final cleaning, packaging, and shipping of raw mushrooms to retailers.

The initial inspection was conducted in March 2014 by SCS Global Services' staff organic inspector, who also attended the review audit. The operation was previously certified from May 6, 2010 to May 5, 2014 by another certifying agent. Overall, the review audit verified compliance to the organic regulations.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether SCS corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to SCS.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

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Comments: SCS is accredited for the scope of livestock to the NOP but does not have any updated OSP’s, forms, documents, inspection checklists, or guidance addressing the requirements of the pasture rule or the latest livestock requirements. In addition, SCS has conducted limited or no training on NOP livestock requirements for the SCS staff or subcontractor inspectors. However, SCS has no livestock clients currently certified for the scope of livestock.

Corrective Actions: On July 11, 2012, SCS notified NOP of its request to remove the scope of livestock from its accreditation renewal request.

Verification of Corrective Action (August 2014): SCS Global Services removed all references to livestock certification from its documentation, does not offer livestock certification, and has not certified any livestock operations. SCS Global Services confirmed understanding that any amendment to their scope of accreditation must be submitted in accordance to NOP §205.510(f).

NP2129BBA.NC2 – Cleared – 7 CFR §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”

Comments: Three SCS staff members have not had documented annual performance evaluations since April 30, 2009, November 22, 2009, and April 22, 2010.

Corrective Actions: SCS’s Food Safety Division was restructured to ensure that personnel policies, including timely performance evaluations, are conducted. All annual employee performance evaluations will now occur by March 1st each year. SCS further indicated that all organic program staff will receive a 2012 performance evaluation by August 31, 2012.

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Verification of Corrective Action (August 2014): One staff member did not complete an annual conflict of interest report in 2014. None of the contracted inspectors submitted conflict of interest reports in 2014. None of the five members of the board of directors submitted conflict of interest reports in 2013. Only one member submitted an email in 2014 stating no conflicts.

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NP4217ZZA.NC10 – 7 CFR §205.504(b)(2) requires the submission of “a copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations in this part and the reporting of violations of the Act and the regulations in this part to the Administrator;” and NOP §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2609 Instruction Unannounced Inspections addresses the requirements for unannounced inspections under the authority of NOP §205.403(a)(2)(iii) and Section 4.1.1 states, “We recommend that certifying agents conduct unannounced inspections of 5 percent of their total certified operations per year as a tool in ensuring compliance with the regulations.”

Comments: *SCS Global Services procedures (Quality Manual, Section 15) do not provide adequate detail regarding the unannounced inspection process; additionally, SCS did not conduct any unannounced inspections in 2012-2014.*

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of SCS. An onsite audit was conducted, and the audit report reviewed to determine SCS's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	SCS Global Services (SCS)
Physical Address	2000 Powell Street, Suite 600, Emeryville, CA 94608
Mailing Address	Same
Contact & Title	Brandon Nauman, Project Manager
E-mail Address	bnauman@scsglobalservices.com
Phone Number	510-452-8052
Reviewer(s) & Auditor(s)	Janna Howley, NOP Reviewer; Corey D. Gilbert and Kathryn Matejovsky (Training), On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: November 25, 2014 Onsite audit: August 5-7, 2014
Audit Identifier	NP4217ZZA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of SCS's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	SCS's certification services in carrying out the audit criteria during the period: June 2012 through August 2014.

Organizational Structure:

Scientific Certification Systems, Inc. (SCS), doing business as SCS Global Services, is a for-profit privately owned company accredited as a certifying agent to the USDA National Organic Program (NOP) since April 29, 2002. SCS Global Services is accredited for the scopes of crops, wild crops, and handling. It currently has 40 operations certified to the NOP Standard with 14 crop, 0 wild crop, 18 handling, and 8 crop/handling operations including 1 grower group. Its certified operations are located primarily in the USA (36) with 3 in Mexico and 1 in Haiti. SCS Global Services conducts all certification activities, except contract inspector activities, at its headquarters in Emeryville, CA. A subsidiary office located in Culiacán, Sinaloa, Mexico receives inquiries and applications for organic certification; however, all information is forwarded to the headquarters office for the technical review and any certification decisions.

SCS Global Services provides third-party certification for numerous environmental, natural resources, and food & agriculture standards and is also accredited as a certification body for most of these standards. It is accredited as a certification body under ISO 17065 by the American National Standards Institute (ANSI) covering multiple standards including food safety auditing for Safe Quality Foods (SQF), British Retail Consortium (BRC), and Global GAP.

SGS Global Services is divided into three service divisions: Environmental Certification Services, Natural Resources, and Food and Agriculture. The organic certification program is located within the Food and Agriculture division and personnel involved in organic certification include the Quality Assurance Manager, Project Manager for Food & Agriculture, Client Coordinator, Client Services Manager, one (1) staff Technical Associate (Organic Program Inspector), and four (4) contract inspectors. SCS Global Services also has a five member Board of Directors for general oversight and direction of the organization; however, none of the members have certification decision making roles.

A review of personnel files and interviews conducted verified the organic certification staff had sufficient experience, training, and education in agriculture, organic production, and handling, except as identified in the findings. SCS Global Services conducts annual performance evaluations for all staff. A review of training records indicated the staff reviewers, staff inspector, and all contracted inspectors had received current training on the NOP regulations. The Project Manager (organic program manager) for the Food and Agriculture Division and the staff organic inspector were registered to attend a week-long IOIA organic certification training course in October 2014.

Certification Process:

Requests for certification are received by phone and email and initial correspondence is handled by the Client Coordinator. Interested applicants are sent an Organic Application Package consisting of the application form and organic system/handling plan, SCS Global Services' organic certification procedures, a fee schedule, and a link to the NOP Rule. After all required information is submitted, an assigned reviewer (typically the Project Manager and occasionally the staff inspector) will determine if the applicant appears to comply and is ready for an inspection. The Client Coordinator assigns the inspector based on qualifications, location, and availability. The inspector is provided the complete organic system/handling plan, conducts the inspection, and submits a completed inspection checklist/report with recommendations regarding certification. A final review is conducted by the Project Manager or Client Services Manager and the certification decision is made by one or the other. SCS Global Services is primarily using a three person certification system; however, in some cases a two person certification system is used. In all cases, the person making the certification decision is different from the inspector. The operation is issued the approved inspection report, any notification of minor issues or notice of noncompliance, notification of noncompliance resolution, and a certificate as applicable.

An annual update reminder is sent to all certified operations sixty days prior to their annual renewal date, and they are all required to submit an annual update form along with any changes to their organic system/handling plans and supporting documentation. The Client Coordinator reviews for completeness, the Project Manager or staff organic inspector conducts the technical

review, and the inspection assigned to a qualified inspector. The inspection is completed, the report is submitted, and a final review and certification decision is made by the Project Manager and/or Client Services Manager. The approved inspection report and updated certificate are issued to the certified operation.

Material reviews are conducted by the Project Manager and Technical Associate (staff organic inspector) using the organic regulations, OMRI lists, and information from the Washington State Department of Agriculture. SCS Global Services also accepts the material reviews conducted by other certifying agents as long as adequate documentation is provided.

Label reviews are conducted by the Project Manager using their label procedure, NOP regulations, and NOP Program Handbook.

SCS Global Services is approved to issue TM-11 export certificates to Taiwan, but they have not had any requests, nor issued any. Interviews and file reviews confirmed that SCS Global Services is appropriately implementing the terms and conditions of the US-Canada equivalency arrangement. They have not received any requests for imports or exports under the US-European Union equivalency arrangement.

Administrative Records and Processes:

SCS Global Services has an Organic Quality Manual, Organic Certification Manual, Organic Program Inspector Manual, Guidance on Label Reviews, Input Material Review Request Procedure, initial application form, template organic system/handling plans, inspection checklists, annual update form, and numerous additional template forms for adverse actions, etc.

SCS Global Services conducts an annual internal audit and program review and implements corrective actions based on the audit findings. SCS has annual organic training and the Project Manager attends annual external NOP training which is used to provide additional internal training.

Summary of Review Audit Conducted:

The assessment included a review audit conducted at a crop and handling operation in San Marcos, California first certified by SCS Global Services in April 2014. The operation included onsite growing and packaging of organic mushrooms for sale in the USA and Canada. The operation had dedicated organic production only which included receiving of mushroom spores, production of generational spawn, inoculation of grow bottles, mushroom growing, and final cleaning, packaging, and shipping of raw mushrooms to retailers.

The initial inspection was conducted in March 2014 by SCS Global Services' staff organic inspector, who also attended the review audit. The operation was previously certified from May 6, 2010 to May 5, 2014 by another certifying agent. Overall, the review audit verified compliance to the organic regulations.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether SCS corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to SCS.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

N2129BBA.NC1 – Cleared – 7 CFR §205.501 (a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: SCS is accredited for the scope of livestock to the NOP but does not have any updated OSP’s, forms, documents, inspection checklists, or guidance addressing the requirements of the pasture rule or the latest livestock requirements. In addition, SCS has conducted limited or no training on NOP livestock requirements for the SCS staff or subcontractor inspectors. However, SCS has no livestock clients currently certified for the scope of livestock.

Corrective Actions: On July 11, 2012, SCS notified NOP of its request to remove the scope of livestock from its accreditation renewal request.

Verification of Corrective Action (August 2014): SCS Global Services removed all references to livestock certification from its documentation, does not offer livestock certification, and has not certified any livestock operations. SCS Global Services confirmed understanding that any amendment to their scope of accreditation must be submitted in accordance to NOP §205.510(f).

NP2129BBA.NC2 – Cleared – 7 CFR §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.”

Comments: Three SCS staff members have not had documented annual performance evaluations since April 30, 2009, November 22, 2009, and April 22, 2010.

Corrective Actions: SCS’s Food Safety Division was restructured to ensure that personnel policies, including timely performance evaluations, are conducted. All annual employee performance evaluations will now occur by March 1st each year. SCS further indicated that all organic program staff will receive a 2012 performance evaluation by August 31, 2012.

Verification of Corrective Action (August 2014): SCS Global Services conducted annual performance evaluations for all staff in 2012, 2013, and 2014; therefore, this noncompliance was cleared.

NP2129BBA.NC3 – Outstanding – 7 CFR §205.501 (a)(11)(v) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Requiring all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and all parties responsibly connected to the certifying agent to complete an annual conflict of interest disclosure report.”

Comments: A review of the SCS Annual Confidentiality Agreement and Declaration Agreement for Conflict of Interest (COI) forms showed that 1 of the 2 subcontractor inspectors and 1 of the 5 responsibly connected parties were not completed. In addition, 1 staff and 3 responsibly connected parties COI’s had not been completed annually with last signed dates being October 1 and 3, 2008, August 11, 2010, and September 20, 2010.

Corrective Actions: Conflict of interest disclosure reports are to be collected annually by January from all required parties, including parties responsibly connected to SCS. Program management will notify all affected staff members and subcontractors about the new procedure and deadline. SCS submitted completed 2012 Conflict of Interest and Confidentiality Agreement reports for NOP’s review.

Verification of Corrective Action (August 2014): One staff member did not complete an annual conflict of interest report in 2014. None of the contracted inspectors submitted 2014 conflict of interest reports. None of the five members of the board of directors submitted 2013 conflict of interest reports. Four board members did not submit 2014 conflict of interest reports.

NP2129BBA.NC4 – Cleared – 7 CFR §205.501 (a)(11)(vi) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.”

Comments: On 1 of the 8 files reviewed, the same person conducted the initial review documents and made the final certification decision.

Corrective Actions: SCS has reinstated a person responsible for making final certification decisions in the certification process. This person will not conduct any document reviews or on-site inspections. SCS clarified the role of the decision maker by updating their quality manual and providing a record reflecting the roles of SCS staff.

Verification of Corrective Action (August 2014): SCS Global Services used a three person system from July 2012 to February 2014; however, their current system also allows a two person system when necessary as long as the final review and certification decision is made by someone other than the inspector that conducted the inspection. Both of these systems comply with NOP 2006.

NP2129BBA.NC5 – Cleared – 7 CFR §205.501 (a)(15)(ii) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Submit to the Administrator a copy of: A list, on January 2 of each year, including the name, address, and telephone number of each operation granted certification during the preceding year.”

Comments: SCS had removed one client from the list of Certified Operations that had not officially withdrawn or been suspended. This client was currently in the proposed suspension status at the time of the audit.

Corrective Actions: SCS conducted training for its staff on July 10, 2012 using materials from the NOP "NOP 2024" and the list of certified operations was reviewed and corrected. Improvements were made to SCS's Data Management System to ensure proper tracking of SCS certified operations.

Verification of Corrective Action (August 2014): SCS Global Services submitted an accurate list of certified operations in 2013 and 2014 that identified all certified operations.

NP2129BBA.NC6 – Cleared – 7 CFR §205.662(c) states, “Proposed suspension or revocation. When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification of the entire operation or a portion of the operation, as applicable to the noncompliance.”

Comments: SCS granted certification of an operation with conditions on September 10, 2010 to respond by December 9, 2010 to avoid proposed suspension. SCS did not issue a notice of proposed suspension but issued another noncompliance on December 8, 2011 with an additional timeframe to reply by December 28, 2011. SCS finally issued the notice of proposed suspension on April 4, 2012. The Notice of Proposed Suspension should have been issued after the original deadline of December 9, 2010.

Corrective Actions: SCS issued the suspension notice to the client on June 4, 2012. SCS management implemented document management system procedures for tracking all notification deadlines.

Verification of Corrective Action (August 2014): SCS Global Services has issued two notices of proposed suspension since the last assessment; however, in both cases the operations submitted corrective actions addressing the notices and no adverse actions were necessary. SCS Global Services has not had a reoccurrence of the previous issue and reviews verified the document management system procedures for tracking notification deadlines were in place.

Noncompliances Identified during the Current Assessment

NP4217ZZA.NC1 – 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP Policy Memo 11-10 Certification of Grower Groups states, “...accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies.”

Comments: *SCS Global Services does not have grower group certification procedures and grower groups are not addressed in their organic system and handling plan templates. Grower groups are addressed in Section 9 of their crop inspection checklist. SCS Global Services has only certified one grower group (mangoes in Haiti) and the file review verified the operation was certified in accordance to the NOSB Recommendations.*

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Comments: *SCS Global Services procedures (Quality Manual, Section 15) do not provide adequate detail regarding the unannounced inspection process; additionally, SCS did not conduct any unannounced inspections in 2012-2014.*

NATIONAL ORGANIC PROGRAM REPORT: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of SCS Global Services, Inc. (SCS) organic program was conducted on March 13 – 19, 2017. The National Organic Program (NOP) reviewed the auditor’s report to assess SCS’s compliance to the USDA organic regulations. This report provides the results of NOP’s assessment.

GENERAL INFORMATION

Applicant Name:	SCS Global Services, Inc. (SCS)
Physical Address:	2000 Powell St., Ste 600 Emeryville, CA 94608
Mailing Address:	2000 Powell St., Ste 600 Emeryville, CA 94608
Contact & Title:	Brandon Nauman, Program Manager
E-mail Address:	bnauman@scsglobalservices.com
Phone Number:	(510) 452-8052
Reviewer: Auditor:	Jason Lopez, NOP Reviewer Lars Crail, Lead Auditor; Devon Pattillo, Observer (Auditor In-Training).
Program:	USDA National Organic Program (NOP)
Review Date:	June 6, and September 2, 2017
Audit Dates:	March 13-19, 2017
Witness Audit:	March 29 – April 7, 2017
Audit Identifier:	NP7066LCA
Action Required:	Yes
Audit and Review Type:	Renewal Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of OC’s certification system.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	Assessment of OC’s certification services in carrying out the audit criteria

The National Organic Program (NOP) conducted an onsite accreditation renewal audit of SCS Global Services (SCS) on March 14-16, 2017.

SCS is a for-profit California Benefit Corporation accredited on April 29, 2002 to the scopes of crops, wild crops, and handling. Their current accreditation expires April 28, 2017. SCS certifies 67 operations to the following certification scopes: crops (42), wild crops (0), and handlers (55). SCS certifies two grower groups located outside the US. SCS’s office is located in Emeryville, California and they provide certification services in the following states and countries: Arizona, California, Colorado, Florida, Georgia, Illinois, Iowa, Maryland, Michigan,

New Jersey, New York, North Carolina, Oregon, Pennsylvania, Texas, Utah, Washington; Panama; Haiti; Mexico. Certification services are performed by eleven individuals: the program manager (1), technical associate (1), program associate (1), program coordinator (1), staff inspector (3), and contract inspector (4).

NOP auditors conducted four witness audits of SCS annual inspections of handling operations in San Francisco, California, and Miami, Florida; crops operation in Miami, Florida (3/30/17); and a handler/trader and crops grower group operation in Haiti (4/3 – 6/17).

Audit closing meetings were held in the SCS Global office on March 16 and a telephone conference call on April 18 covering the witness audit in Haiti.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether SCS corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to SCS.

Noncompliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP6069NNA.NC1 – Cleared

P6069NNA.NC2 – Cleared

NP6069NNA.NC3 - Cleared

NP6069NNA.NC4 - Cleared

NP6069NNA.NC5 – Cleared

NP6069NNA.NC6 – Cleared

NP6069NNA.NC7 – Outstanding 7 CFR §205.660(d) states, “Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §205.662, §205.663, and §205.665 and each response to such notification must be sent to the recipient's place of business via a delivery service which provides dated return receipts.”

Comments: SCS is not consistently using a delivery service that provides dated return receipts.

2016 Corrective Actions: SCS revised and updated their Program Quality Manual (DRAFT_FA-ORG_MAN_OrganicQualityManual_V9-0_061616) to specify that all notifications send to clients regarding compliance issues, are delivered via a service that provides dated return receipts. SCS will hold a calibration meeting in October 2016 to review/train staff on the revised policy.

Verification of Corrective Actions: Notifications of noncompliance and noncompliance resolution are not issued by SCS via a delivery service which provides dated return receipts.

2017 Corrective Actions: SCS has subscribed to a dated return receipt delivery service for notices of noncompliance and resolution on September 30, 2017. SCS has revise templates for notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation. The new templates instruct staff to send all such notices using delivery service that provides return receipts. SCS has made revisions and will train and implement the new process on October 6, 2017.

Non-compliances Identified during the Current Assessment

NP7066LCA.NC1 - 7 C.F.R. §205.501(a)(21) states, “Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” NOP 2603, Organic Certificates, Section 3.1, indicates the elements of an organic certificate.

Comments: *The labeling category (100% Organic, Organic, Made with Organic (specified ingredients or food groups)) is not consistently indicated for each product listed on certificates.*

Corrective Action: SCS has amended it database and organic certificate template to include and organic “CLAIM” column. SCS has reissued the noncompliant organic certificate and will issue all new certificates using the new template. Staff was notified of these changes in a team meeting held on July 25, 2017.

NP7066LCA.NC2 – 7 C.F.R. §205.642 states, “...The certifying agent shall provide each applicant with an estimate of the total cost of certification and an estimate of the annual cost of updating the certification....”

Comments: *SCS is not providing certification applicants and operations with a fee estimate for the total cost of certification. Fee estimates do not include the inspection portion of certification.*

Corrective Action: SCS has amended the work order template to include travel expense. The charges are included in SCS’s fee schedule. Staff was notified of these changes in a team meeting held on July 25, 2017.

NP7066LCA.NC3 – 7 C.F.R. §205.642 states, “Fees charged by a certifying agent must be reasonable, and a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator.

Comments: *SCS’s current fee schedule (Version 3-0 (January 2017)) was not filed with the NOP. The fee schedule does not disclose all fees that may be charged to operations. For example, SCS’s service agreement, clause 2, states that payments are due within 30 days. After that date, interest will be charged at 1.5% per month on any late payments. There is no statement on the fee schedule that a late charge is applicable on past due accounts.*

Corrective Action: SCS has amended and submitted its fee schedule to the NOP. SCS has made the program administrator responsible for filling all future updated SCS fee schedules with the NOP. Staff was notified of these changes in a team meeting held on July 25, 2017.

NP7066LCA.NC4 – 7 C.F.R. § 205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart; Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” The NOP website provides instructions and the terms of international trade arrangements.

Comments: *SCS’s current OSP template does not require operations to disclose whether they purchase or sell (or intend to) products or ingredients that are exported or imported. Without this information, SCS is unable to sufficiently determine and verify whether operations are complying with trade arrangement terms or record keeping requirements for products that are imported or exported.*

Corrective Action: SCS is in the process of amending OSP templates, OSP addendums, and inspection reports. Amended OSP’s and addendums will have operations disclose any organic purchases or sales under the international trade arrangements. Amended inspection reports prompt inspectors to verify compliance with international arrangement requirements. SCS will require all operations to complete or update OSP’s to disclose international trade information in the 2018 renewal cycle. SCS will have revisions to documents and conduct staff calibration of these changes by October 6, 2017.

NP7066LCA.NC5 – 7 C.F.R. §205.504(b)(5)(i-iv) states, “A copy of the procedures to be used, including any fees to be assessed, for making the following information available to any member of the public upon request: (i) Certification certificates issued during the current and 3 preceding calendar years; (ii) A list of producers and handlers whose operations it has certified, including for each the name of the operation, type(s) of operation, products produced, and the effective date of the certification, during the current and 3 preceding calendar years. (iii) The results of laboratory analyses for residues of pesticides and other prohibited substances conducted during the current and 3 preceding calendar years; and, (iv) Other business information as permitted in writing by the producer or handler.”

Comments: *SCS does not have procedures for complying with §205.504(b)(5)(i-iv).*

Corrective Action: SCS has added procedures for handling requests for public records back in to the Program Quality manual in Section 18. Staff was notified of these changes in a team meeting held on July 25, 2017.

NP7066LCA.NC6 – 7 C.F.R. §205.403(e)(2) states, “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.”

Comments: *One of the three reviewed residue sampling cases revealed no record that the analysis report was sent to the operator.*

Corrective Action: SCS has provided residue test reports to all operations that were sampled. On October 1, 2017, SCS has updated their data base to instruct the reviewer to send test results to the operation and informed reviewers of this change via email. SCS will update the residue sampling work instruction to provide detailed instructions on this process by January 31, 2018. This procedure will be reviewed with staff again during the March 30, 2018 calibration exercise.

NP7066LCA.NC7 – 7 C.F.R. §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must:… Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.”

Comments: *Inert ingredients in pesticides for crop production were reviewed by SCS certification staff using criteria recommended by the National Organic Standards Board (NOSB). No action has been taken by the National Organic Program (NOP) to permit inerts that appear on the EPA Safer Choice Ingredients List, as recommended by the NOSB. Section 205.601(m) permits inert ingredients in pesticide ingredients that appear on EPA List 4 and List 3 (passive pheromone dispensers only). SCS is not following USDA organic regulations, instead SCS is following NOSB recommendations that have not been permitted by NOP.*

Corrective Action: SCS reviewed all previous internal pesticide reviews. No revision of previous determinations was required. SCS corrected the material review work instruction to reference the correct EPA lists. Staff was notified of these changes in a team meeting held on July 25, 2017.

NP7066LCA.NC8 - 7 C.F.R. §205.501(a)(8) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part.”

Comments: *SCS organic system templates do not contain the requirement §205.201(a)(3) which allows certification applicants and continuing operations to describe the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented.*

Corrective Action: SCS is in the process of amending OSP templates (October 6, 2017). SCS will then conduct training for inspectors on auditing effective implementation of monitoring plans described in amended OSP’s by October 20, 2017. Finally, SCS will update inspection reports to reflect OSP revisions and (as applicable) include section(s) to more clearly identify findings related to effectiveness of monitoring plans implemented by operation by December 15, 2017. SCS will require all operation to complete or update OSP’s to describe monitoring processes in the 2018 renewal cycle.

NP7093LCA.NC9 – 7 C.F.R. §205.403(c)(2) states, “The on-site inspection of an operation must verify: That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation;…”

Comments: *Auditors did not witness the inspectors verifying the accuracy and completeness of the Organic System Plan (OSP) during the witness audit of a grower group annual inspection. The following issues were identified by the auditors:*

- *The operation’s OSP lacked procedures to comply with §205.201(a)(3), a description of the monitoring practices and procedures to be performed an maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented.*

- *Inspectors did not verify the accuracy of the organization chart and individuals that participate in the Internal Control System (ICS).*
- *The procedure for internal inspections is not clearly described in the OSP.*
- *There is no detail on the type of training occurring and the procedures to ensure all ICS staff and members are trained.*
- *There is no description of member sanctions for those who do not comply with ICS rules and/or USDA organic regulations.*
- *There is no procedure for reporting irregularities and minor and major noncompliances to the certifier.*
- *Conservation of Natural Resources is not fully addressed and described in the OSP.*

Corrective Action: SCS will require the certified grower group to submit additional information as requested in the revised OSP. The program manager will conduct an additional inspection of the grower group prior to December 29, 2017 to address the concerns stated above.

SCS will complete the following document changes and conduct staff calibration by October 2, 2017:

- Update OSP templates [handler, crops, private label, export addendum] to reflect all applicable requirements related to monitoring, including procedure, frequency, maintenance of associated records, and conservation of natural resources in a clear and auditable manner by October 6, 2017.
- Update Grower Group OSP addendum template to elicit more detailed information regarding the ICS, including organization, structure, training provided to members, sanctions used for those who do not comply, and reporting findings by December 29, 2017.
- Conduct inspector calibration training on auditing effective implementation of monitoring plans described in OSP by October 20, 2017.
- Update inspection reports to reflect OSP revisions and (as applicable) include section(s) to more clearly identify findings related to effectiveness of monitoring plans implemented by operation by December 15, 2017.

NP7093LCA.NC10 – 7 C.F.R. §205.403(c)(1) and (2) states, “The on-site inspection of an operation must verify: The operation’s compliance or capability to comply with the Act and the regulations of this part;... That the information, including the organic production or handling system plan, provided in accordance with §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation.”

Comments: *Inspectors during the grower group inspection did not demonstrate verification activities that would determine if the operation was compliant. Specifically, the inspectors did not:*

- *Request or conduct observations of internal inspections.*
- *Determine the adequacy of the internal inspections and whether 100% of the sub-units had been inspected during the past year.*
- *Assess whether Internal Control System (ICS) personnel conflict of interests issues were addressed adequately by the operation.*
- *Verify or conduct inspections of Producer Business Groups (PBG) product consolidation or collection locations.*

- *Verify the content of trainings or whether all members had received training.*
- *Verify production yields and conduct mass-balance activities.*
- *Review or verify records maintained at PBG locations to include trace-back and record keeping activities.*
- *Conduct sufficient identification of production site boundaries and verification of adequate buffers for the producers visited sites since the inspectors did not possess maps during the inspections.*
- *Conduct sufficient verification of conservation of resource including evidence of erosion.*
- *Use, refer to, or verify the handling facility map and product flow chart during the handling facility inspection.*
- *Request during the handling facility inspection review and verify the operation's labels.*
- *During the handling facility conduct adequate traceability and mass balances activities.*

Corrective Action: The SCS program manager will conduct an additional inspection of the grower group prior to December 29, 2017 to address the points stated above. SCS has amended its Program Quality Manual to require USDA organic grower group inspections be conducted by a lead inspector. The lead inspector will only audit to the USDA organic regulations during the inspection of the grower group. SCS will approve inspectors to conduct USDA inspections after an evaluation of capability. Staff was notified of these changes in a team meeting held on July 25, 2017.

NP7093LCA.NC11– 7 C.F.R. §205.501(a)(5) states “A private or governmental entity accredited as a certifying agent under this subpart must: Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned.”

Comments: *The inspectors did not demonstrate adequate expertise to successfully perform the inspection during the witness audit of a grower group:*

- *The inspectors have conducted few organic and grower group inspections. Their primary expertise is conducting inspections for Good Agricultural Practices (GAP) and Social certification schemes.*
- *The lead inspector has not received external training on organic grower group inspection procedures or processes.*
- *The inspectors were not using SCS documents/templates such as the OSP, Grower Group Inspection Report Addendum, in/out balance, traceability worksheets in order to verify compliance and record their activities, observations, and findings.*
- *The inspectors did not reference or mention USDA organic regulations when identifying issues or clarifying requirements with ICS personnel and group members.*
- *The inspectors did not follow SCS's Guidance for Organic Certification of Grower Groups in which they received training during February and March 2017.*
- *The inspectors did not possess sampling tools or documents to conduct residue test sampling if there had been evidence of contamination or a need to collect samples.*
- *The inspector did not use, refer to, or verify the handling facility map and product flow chart during the facility inspection.*

- *The lead inspector did not adequately complete traceability and mass balance activities during the handling facility inspection.*
- *Conservation of Natural Resources (§205.200) was not verified nor addressed during the inspection.*

Corrective Action: The SCS Program Manager (or designee) will assume the responsibility of signing off organic inspectors as “Lead Auditors” approved for inspection of grower groups. Program Manager (or designee) will use the USDA Organic Witness Audit Checklist for Grower Groups (NOP 2005-5). Inspectors designated as the Lead Auditor for a grower group inspection will have been evaluated by Program Manager or designee and have demonstrated satisfactory abilities to complete grower group inspections. The SCS program manager will conduct an additional audit of the stated grower group prior to December 29, 2017.

NP7093LCA.NC12 - 7 C.F.R. §205.403(d) states, “The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.”

Comments: *The following issues of concern were not addressed by the inspector during the exit interview of the witnessed grower group annual inspection:*

- *The inspector requested and received information from the operator including an updated Internal Control System (ICS) manual with significant changes from the version maintained by SCS. These updates to the Organic System Plan (OSP) were not provided to SCS with the annual update (§205.406(a)(1)(ii)) and the inspector did not identify this as an issue of concern.*
- *Erosion (§205.203(a)) was identified by the inspector in the field during member site inspections; however, this issue was not discussed nor recorded as an issue of concern.*
- *Evidence of cane burning (§205.203(e)(3)) was observed in the field, but not mentioned as an issue of concern.*

Corrective Action: SCS will conduct a review of evidence gathering, reporting, and exit interviews during inspector calibration training prior to October 20, 2017. The SCS program manager will conduct an additional inspection of the grower group to address the points above prior to December 29, 2017.

NP7093LCA.NC13 - 7 C.F.R. §205.501(a)(11)(iv) states, “A private or governmental entity accredited as a certifying agent under this subpart must... Not giving advice or providing consultancy services, to certification applicants or certified operations, for overcoming identified barriers to certification;” NOP 2614, Technical Assistance, clarifies for certifiers what constitutes allowable assistance to operations.

Comments: *During the inspections of the crop grower group and handling facility, the lead inspector provided opinions on growing conditions and projected production yields. Inspector opinions and statements regarding agriculture practices or conditions may influence the operation’s decision-making process and are outside the scope of the inspector’s duties.*

Corrective Action: SCS will perform inspector calibration by October 20, 2017 that will include the avoidance of consulting. The SCS Organic Program Manager, Technical Manager, or designee, will evaluate and record inspectors avoidance of consulting during witness assessments; these records to be made available to NOP during SCS's next assessment, or on request.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

JUL 03 2017

NOTICE OF NONCOMPLIANCE

Brandon Nauman
SCS Global Services
2000 Powell St. Ste 600
Emeryville, CA 94608

Dear Mr. Nauman:

On March 13-19, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit review of the SCS Global Services (SCS) organic certification program as part of its USDA Renewal Accreditation Assessment. On June 30, 2017, the NOP reviewed the results of the onsite audit to determine SCS's compliance to the USDA organic regulations. A copy of the assessment report, NP7066LCA, is enclosed for your reference.

As the report indicates, one noncompliance, (NP6069NNA.NC7), remains outstanding from a previous audit. Thirteen (13) new noncompliances (NP7066LCA.NC1 through NC8 and NP7093LCA.NC9 through NC.13)], were identified during the onsite audit. Please submit corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All corrective actions must indicate how the noncompliances will be corrected and how the SCS management system will be modified to prevent a recurrence of the noncompliances. If you wish to rebut any noncompliances, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice.

Please refer to [NOP 2608 Responding to Noncompliances](#) for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliances may result in proposed suspension or revocation of SCS's USDA accreditation.

If you have questions regarding this notice, please contact, Jason Lopez, Accreditation Manager, at JasonJ.Lopez@ams.usda.gov or (202) 260-9445.

Sincerely,

A handwritten signature in blue ink, appearing to read "Cheri Courtney for CC". The signature is stylized and includes a large loop at the end.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure: Noncompliance Report NP7093LCA

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Stellar Certification Services (STEL). An onsite audit was conducted, and the audit report reviewed to determine STEL's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Stellar Certification Services (STEL)
Physical Address	39609 Luckiamute Road, Philomath, OR 97370
Mailing Address	39609 Luckiamute Road, Philomath, OR 97370
Contact & Title	Sally Lammers, Executive Director
E-mail Address	sally@demeter-USA.org
Phone Number	541-92907148
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Alan Kohles and Steve Ross, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP corrective action review: December 8, 2014 NOP assessment review: September 10, 2014 Onsite audit: July 22-24, 2014; Witness audit: June 10, 2014
Audit Identifier	NP4203LLA
Action Required	No
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of STEL's certification system.
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	STEL's certification services in carrying out the audit criteria during the period: June 19, 2013 through July 24, 2014.

ORGANIZATIONAL STRUCTURE:

Stellar Certification Services (STEL) is a non-profit, non-tax exempt, sister company to Demeter that provides organic certification. STEL was initially accredited as a USDA National Organic Program (NOP) certifying agent on April 29, 2002 for crops, livestock, wild crops and handling operations. The STEL client list as of April 03, 2014 had 146 certified operations with 107 crops, 0 wild crop, 17 livestock and 67 handling (processing) operations certified to the USDA NOP. STEL certifies clients to the NOP in the United States and Costa Rica. STEL does not currently certify any grower groups. STEL is also accredited for ISO Guide 65 for the European Union (EC 834/2007 and EC 889/2008).

STEL has one administrative office located in Philomath, OR that performs all certification activities. The current STEL staff consists of three administrative staff, an executive director (also part of the technical staff), five technical staff (reviewers/evaluation circle), and 15 contracted inspectors. STEL also has a board of directors (BOD) with multiple responsibilities but it is not involved in the certification decision process. Records reviewed during the assessment verified that STEL is meeting the requirements for annual performance evaluations, annual confidentiality agreements and conflict of interest statements. Personnel files reviewed and interviews conducted indicated that all had the required education, training and experience in organic agricultural production and handling to perform the duties assigned.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether STEL's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2226EEA.NC1 – Cleared

NP226EEA.NC2 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4203LLA.NC1 – Accepted – 7 CFR §205.403(a)(2)(i-iii) states, "(i) A certifying agent may conduct additional onsite inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part. (ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part. (iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official." NOP 2609 Unannounced Inspections, section 4.1.1 states, "We recommend that certifying agents conduct unannounced inspections of five per cent of their total certified operations per year as a tool in ensuring compliance with the regulation." *A review of the STEL certified operations and the onsite inspections schedule found that there were no unannounced inspections conducted in 2013.*

Corrective Actions: STEL implemented a procedure to select operations for unannounced inspections based on 5% of the total number of certified operations as reported in the list submitted to the USDA NOP by January 2 each year. The preliminary list of operations chosen for unannounced inspections will be established by May 15th each year and all unannounced inspections are scheduled to be completed by December 31 of each year. STEL has established date checkpoints, August 30 and October 31, in the calendar to verify progress of the unannounced inspections schedule. STEL has updated the internal audit system to include verification of unannounced inspections per the new procedure.

NP4203LLA.NC2 – Accepted – 7 CFR § 205.403(b)(2) states, “All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced onsite inspections.” *During the review of files from 10 different certified operations, the onsite inspection reports from three of these files showed that livestock operations located in New York, Montana and Pennsylvania were inspected during December or February, which are outside of the grazing season.*

Corrective Actions: STEL’s program justified inspections of a ruminant livestock operation outside the grazing period as an opportunity to assess portions of the organic system plan (OSP) that can only be adequately evaluated during the period that cattle are not out on pasture. However, beginning in 2015 STEL will implement new procedures to schedule and track inspections of ruminant livestock operations during the grazing season. Annual inspector contracts will be updated to reflect that inspections of ruminant livestock operations be completed by September 30th unless express approval for a different schedule is granted by STEL. By May 1, the certification coordinator will compile the list of ruminant livestock operations requiring inspection and will track the completion of the inspections using established calendar checkpoints in June, July, August and September. STEL has updated the internal audit system to verify that inspections of ruminant livestock operations were conducted during the grazing season per the new procedure.

NP4203LLA.NC3 – Accepted – 7 CFR §205.505(b)(2) A private or governmental entity seeking accreditation as a certifying agent must...demonstrate its ability to comply with the requirements...Administrative policies and procedures. A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations... *A review of the STEL Policy and Quality Manuals indicated that there were no procedures for mediation, although the manual does mention the right to mediation. STEL personnel explained that the client is notified of the rights for mediation in the noncompliances/proposed suspension that would be issued.*

Corrective Actions: STEL’s Policy Manual and Procedure Manual A – Administration have been updated to include mediation procedures. The new procedures describe when mediation will be accepted, when it will be rejected, formal mediation steps, and the process for preparing a settlement agreement.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

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GENERAL INFORMATION

Applicant Name	Stellar Certification Services (STEL)
Physical Address	39609 Luckiamute Road, Philomath, OR 97370
Mailing Address	39609 Luckiamute Road, Philomath, OR 97370
Contact & Title	Sally Lammers, Executive Director
E-mail Address	sally@demeter-USA.org
Phone Number	541-92907148
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Alan Kohles and Steve Ross, On-site Auditors.
Program	USDA National Organic Program (NOP)
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Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	STEL's certification services in carrying out the audit criteria during the period: June 19, 2013 through July 24, 2014.

ORGANIZATIONAL STRUCTURE:

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STEL has one administrative office located in Philomath, OR that performs all certification activities. The current STEL staff consists of three administrative staff, an executive director (also part of the technical staff), five technical staff (reviewers/evaluation circle), and 15 contracted inspectors. STEL also has a board of directors (BOD) with multiple responsibilities but it is not involved in the certification decision process. Records reviewed during the assessment verified that STEL is meeting the requirements for annual performance evaluations, annual confidentiality agreements and conflict of interest statements. Personnel files reviewed and interviews conducted indicated that all had the required education, training and experience in organic agricultural production and handling to perform the duties assigned.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether STEL's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2226EEA.NC1 – Cleared

NP226EEA.NC2 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4203LLA.NC1 – Accepted – 7 CFR §205.403(a)(2)(i-iii) states, "(i) A certifying agent may conduct additional onsite inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part. (ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part. (iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official." NOP 2609 Unannounced Inspections, section 4.1.1 states, "We recommend that certifying agents conduct unannounced inspections of five per cent of their total certified operations per year as a tool in ensuring compliance with the regulation." *A review of the STEL certified operations and the onsite inspections schedule found that there were no unannounced inspections conducted in 2013.*

Corrective Actions: STEL implemented a procedure to select operations for unannounced inspections based on 5% of the total number of certified operations as reported in the list submitted to the USDA NOP by January 2 each year. The preliminary list of operations chosen for unannounced inspections will be established by May 15th each year and all unannounced inspections are scheduled to be completed by December 31 of each year. STEL has established date checkpoints, August 30 and October 31, in the calendar to verify progress of the unannounced inspections schedule. STEL has updated the internal audit system to include verification of unannounced inspections per the new procedure.

NP4203LLA.NC2 – Accepted – 7 CFR § 205.403(b)(2) states, “All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced onsite inspections.” *During the review of files from 10 different certified operations, the onsite inspection reports from three of these files showed that livestock operations located in New York, Montana and Pennsylvania were inspected during December or February, which are outside of the grazing season.*

Corrective Actions: STEL’s program justified inspections of a ruminant livestock operation outside the grazing period as an opportunity to assess portions of the organic system plan (OSP) that can only be adequately evaluated during the period that cattle are not out on pasture. However, beginning in 2015 STEL will implement new procedures to schedule and track inspections of ruminant livestock operations during the grazing season. Annual inspector contracts will be updated to reflect that inspections of ruminant livestock operations be completed by September 30th unless express approval for a different schedule is granted by STEL. By May 1, the certification coordinator will compile the list of ruminant livestock operations requiring inspection and will track the completion of the inspections using established calendar checkpoints in June, July, August and September. STEL has updated the internal audit system to verify that inspections of ruminant livestock operations were conducted during the grazing season per the new procedure.

NP4203LLA.NC3 – Accepted – 7 CFR §205.505(b)(2) A private or governmental entity seeking accreditation as a certifying agent must...demonstrate its ability to comply with the requirements...Administrative policies and procedures. A copy of the procedures to be used for reviewing and investigating certified operation compliance with the Act and the regulations... *A review of the STEL Policy and Quality Manuals indicated that there were no procedures for mediation, although the manual does mention the right to mediation. STEL personnel explained that the client is notified of the rights for mediation in the noncompliances/proposed suspension that would be issued.*

Corrective Actions: STEL’s Policy Manual and Procedure Manual A – Administration, have been updated to include mediation procedures. The new procedures describe when mediation will be accepted, when it will be rejected, formal mediation steps, and the process for preparing a settlement agreement.

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Stellar Certification Services (STEL). An onsite audit was conducted, and the audit report reviewed to determine STEL's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Stellar Certification Services (STEL)
Physical Address	39609 Luckiamute Road, Philomath, OR 97370
Mailing Address	39609 Luckiamute Road, Philomath, OR 97370
Contact & Title	Sally Lammers, Executive Director
E-mail Address	sally@demeter-USA.org
Phone Number	541-92907148
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Alan Kohles and Steve Ross, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: September 10, 2014 Onsite audit: July 22-24, 2014; Witness audit: June 10, 2014
Audit Identifier	NP4203LLA
Action Required	Yes
Audit & Review Type	Mid-Term Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of STEL's certification system.
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	STEL's certification services in carrying out the audit criteria during the period: June 19, 2013 through July 24, 2014.

ORGANIZATIONAL STRUCTURE:

Stellar Certification Services (STEL) is a non-profit, non-tax exempt, sister company to Demeter that provides organic certification. STEL was initially accredited as a USDA National Organic Program (NOP) certifying agent on April 29, 2002 for crops, livestock, wild crops and handling operations. The STEL client list as of April 03, 2014 had 146 certified operations with 107 crops, 0 wild crop, 17 livestock and 67 handling (processing) operations certified to the USDA NOP. STEL certifies clients to the NOP in the United States and Costa Rica. STEL does not currently certify any grower groups. STEL is also accredited for ISO Guide 65 for the European Union (EC 834/2007 and EC 889/2008).

STEL has one administrative office located in Philomath, OR that carries out all of the

certification activities. The current STEL staff consists of three Administrative Staff, an Executive Director (also part of the technical staff), five Technical Staff (reviewers/evaluation circle), and 15 contracted inspectors. STEL also has a Board of Directors (BOD) that has the responsibilities of setting goals and direction, overseeing finances and policies, and hiring/supervising the Executive Director. The BOD, however, is not involved in the certification decision process. The BOD of STEL has all power to control and manage STEL as stated in the by-laws of the corporation. Board member service is voluntary.

Records reviewed verified that STEL is meeting the requirements for annual performance evaluations, annual confidentiality agreements and conflict of interest statements. Personnel files reviewed and interviews conducted indicated that all had the required education, training and experience in organic agricultural production and handling to perform the duties assigned.

CERTIFICATION PROCESS:

Certification information and application material may be obtained by contacting STEL via telephone, e-mail, or fax. New applicants are sent a certification packet that includes: 1) Organic System Plan Questionnaire or Organic Handling Plan as required; 2) Three year land history form; 3) OSP Livestock if applicable; 4) Crop Materials Record; 5) Livestock Medications & Pest Control Record; 6) Purchase Feed Record; 7) Livestock Pasture Plan; 8) Livestock Materials; 9) Crop Plan; 10) Crop Production Record; 11) Seed Search Documentation; 12) Crop Material Inputs; 13) Sanitation Materials; 14) Processing – Individual Product Profile Sheet; 15) Processing – Non-Organic Processing Material Affidavit; 16) Organic Fee Schedule; and 17) the applicable organic standards, appropriate application forms, and Terms of Agreement contract. Documents are usually sent electronically but may be sent in hardcopy if requested.

Applications for certification are reviewed by a member of the Evaluation Circle (EC) to determine if the application is complete and whether the applicant appears to comply with the Final Rule. After the initial review, an inspector is assigned by the Executive/Certification Director based on qualifications, geographic location, and availability. Upon completion of the inspection, the inspection report is submitted to STEL for review by a member of the EC that conducted the initial review or to a different EC member. The final certification decision is usually made by the Executive/Certification Director. However, if there is a conflict of interest, then a member of the EC makes the final certification decision.

For continuing certification (annual updates), updates are required to be submitted by March 15th. At the beginning of every year, a renewal application and a copy of the Terms of Agreement are sent to the operator. The operator completes the forms, updates the OSP, and returns all documents with the annual renewal fees. If fees and the information updates are not complete within 90 days following the annual renewal date, STEL will begin the suspension process and notify the operator. The review process for continuing certification is the same after update materials are received as the application process.

Any staff reviewer with authority to review a new application or an update has the authority to review material inputs and labels. Reviewers use the OMRI and WSDA lists as references when appropriate. Labels reviewed and approved by staff reviewers during the initial review or update are verified during inspection.

STEL offers verification of TM-11 certificates for products exported to Taiwan under the trade arrangement and, as needed, issues TM-11 certificates for products exported to Japan under the equivalency arrangement. The STEL procedures are in place to issue Export Certification Certificates (TM-11) for Japan and Taiwan. A review of the procedures and files verified STEL is operating in compliance to the USDA procedures for issuing export certificates.

ADMINISTRATIVE RECORDS AND PROCESSES:

STEL has a Policy Manual and a Quality Manual describing procedures for the certification process. The manual includes standard operating procedures and forms used for NOP certification activities. Forms and letters reviewed for the NOP certification activities were found to meet the NOP requirements. STEL has an annual program review relating to requirements that are specific to the NOP. Non-conformances are identified and corrective actions are implemented as needed. Annual reports and updates are submitted to the NOP as required. Training is both internal and external and training records and documentation has been maintained. Refresher training or additional training is completed as needed.

STEL has conducted two internal audits in 2014. These were conducted by one of the STEL staff members. STEL is in the process of hiring an outside 3rd party to conduct the internal audit for 2015. When nonconformities are identified during the review, corrective actions are taken and implemented.

SUMMARY OF WITNESS AND REVIEW AUDITS CONDUCTED:

One witness inspection was completed as a part of the 2014 mid-term assessment for the scope of crop. The inspection was conducted by a contract inspector at the crop operation near Jennings, Kansas. The STEL Executive/Certification Director accompanied the contracted inspector during inspection.

The crop operation had been certified organic since 1994. The crop operation was 100% organic, with crops that included alfalfa, cane, clover wheat, hay, fallow, and pasture. The inspector reviewed the fields and the storage areas. The inspector also conducted a trace back of the organic crops and seed sales from 2012.

Overall, the operation's OSP was very detailed and contained maps, crop, and descriptions of seeds used. This information was verified to be accurate. The inspectors provided technical assistance appropriately and refrained from answering any questions which could help the operations overcome barriers to certification.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether STEL corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to STEL.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2226EEA.NC1 – Cleared – NOP §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector. There shall be no charge to the inspector for the samples taken.” *A sample was collected from one operation as part of an investigation and the inspector did not provide a receipt to the operation for the sample collected. It should be noted that STEL has written procedure for the collection of samples; however, the procedure is not routinely provided to contract inspectors, nor are the materials used for the collection of samples as described in those procedures.*

Corrective Action: The following measures are implemented by Stellar and effective May 25, 2013. A Receipt for Samples has been created. It will be produced in triple-copy format and a supply will be given to all inspectors. The top copy will be attached to the Sample Report, one copy will be given to the operator, and one copy will be for the inspector’s file. The receipt has a place for the operator and the inspector to initial. The Sample Collection Report has been updated to include check boxes to indicate that the top copy of the Sample Receipt is attached to the Sample Report, and that a copy was given to the operator. The instructions for the Sample Collection Report is updated to include specific guidance to inspectors requiring the Sample Receipt to be filled out, initialed, and given to the representative of the operation who is present during the sampling.

Verification of corrective actions: The Receipt for Samples form that was created was available for review. A review of the recent samples collected verified that the sample receipt form was included.

NP226EEA.NC2 – Cleared – NOP §205.501(a)(15)(i) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Submit to the Administrator a copy of: Any notice of denial of certification issued pursuant to §205.405, notification of noncompliance, notification of noncompliance correction, notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance.” *Records indicated that since July 28, 2011, there have been 129 Notices of Non-compliance, 78 Notices of Non-compliance resolution, four denials, and one suspension processed through the STEL certification system. Documented distribution of those notices indicated that only 62 of them were filed with the Administrator on August 8, 2012. This is contrary to the notification requirements.*

Corrective Action: STEL identified all notices that were not filed with the NOP and CDFR. On April 25, 2013, these notices were sent to the respective government entities. In addition, STEL has conducted the following actions and provided sufficient objective evidence: STEL staff members received a training notice on July 31, 2012 outlining the new procedures. The Adverse Action spreadsheet was reviewed to ensure that it is current and that it reflects all notices

issued. All notices are sent by certified mail and email (when applicable). The Certification Director implemented a practice of emailing the notices immediately copies to NOP/CDFR after emailing them to the operators. The practice of noting the date of NOP/CDFR filing on the certified mail slip was implemented and logging the date in the Adverse Action Spreadsheet. The STEL certification procedure manual, Section V, was updated to include the process of submitting notices to NOP/CDFR simultaneously with issued notice to the operation. The Certification Director will monitor the process for effective implementation at least twice per month.

Verification of corrective actions: The procedures addressed in the corrective actions were reviewed and verified for implementation. The Certification Director was able to show the implementation of the procedures to submit to the Administrator a copy of the following: notice of denial of certification issued pursuant to §205.405; notification of noncompliance; notification of noncompliance correction; notification of proposed suspension or revocation, and notification of suspension or revocation sent pursuant to §205.662 simultaneously with its issuance; the 2013 spreadsheet with the list of noncompliances issued, including dates sent to operation and dates of submission to the NOP. Notations included R-post – registered emails or by registered emails. The task calendar to verify and track emails was available for review.

Noncompliances Identified during the Current Assessment

NP4203LLA.NC1 – 7 CFR §205.403(a)(2)(i-iii) states, “(i) A certifying agent may conduct additional on-site inspections of applicants for certification and certified operations to determine compliance with the Act and the regulations in this part. (ii) The Administrator or State organic program's governing State official may require that additional inspections be performed by the certifying agent for the purpose of determining compliance with the Act and the regulations in this part. (iii) Additional inspections may be announced or unannounced at the discretion of the certifying agent or as required by the Administrator or State organic program's governing State official.” NOP 2609 Unannounced Inspections, section 4.1.1 states, “We recommend that certifying agents conduct unannounced inspections of five per cent of their total certified operations per year as a tool in ensuring compliance with the regulation.” *A review of the STEL certified operations and the onsite inspections found that there were no unannounced inspections conducted in 2013.*

NP4203LLA.NC2 – 7 CFR § 205.403(b)(2) states, “All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed, except that this requirement does not apply to unannounced on-site inspections.” *During the review of files from 10 different certified operations, the onsite inspection reports from three of these files showed that livestock operations located in New York, Montana and Pennsylvania were inspected during December or February, which are outside of the grazing season.*

NP4203LLA.NC3 – 7 CFR §205.505(b)(2) A private or governmental entity seeking accreditation as a certifying agent must...demonstrate its ability to comply with the requirements...Administrative policies and procedures. A copy of the procedures to be used for

reviewing and investigating certified operation compliance with the Act and the regulations... A review of the STEL Policy and Quality Manuals indicated that there were no procedures for mediation. STEL personnel explained that the client is notified of the rights for mediation in the noncompliances/proposed suspension that would be issued. The Policy Manual does state the rights of mediation.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Sally Lammers
Stellar Certification Services, Inc.
39609 Luckiamute Road
Philomath, OR 97370

OCT 02 2014

Dear Ms. Lammers,

On July 22-24, 2014, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Stellar Certification Services, Inc. (STEL) organic certification program as part of its USDA Mid-term Accreditation Assessment. On September 10, 2014, the NOP reviewed the results of the onsite audit to determine STEL's compliance to the USDA organic regulations. A copy of the assessment report, NP4203LLA, is enclosed for your reference.

As the report indicates, two corrective actions for prior noncompliances, NP226EEA.NC1 through 2, were cleared and determined to be implemented and effective. Four new noncompliances, NP4203LLA.NC1 through 3, were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the STEL management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renée Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney". The signature is written in a cursive, flowing style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Texas Department of Agriculture (TDA) organic program was conducted December 8-12, 16 and 18-19, 2014. The National Organic Program (NOP) reviewed the auditor’s report to assess TDA’s compliance with the USDA organic regulations. This report provided the results of NOP’s assessment.

GENERAL INFORMATION

Applicant Name	Texas Department of Agriculture (TDA)
Physical Address	1700 North Congress Avenue, Stephen F. Austin Building Austin, TX 78701
Mailing Address	P.O. Box 12847, Austin, TX 78711
Contact & Title	Mary Ellen Holliman, Coordinator for Organic Certification
E-mail Address	Mary.Holliman@texasagriculture.gov
Phone Number	512-936-4178
Reviewer(s) & Auditor(s)	Penny Zuck, Corrective Action Review Jason Lopez, NOP Review Corey Gilbert, Onsite Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action review: October 2, 2015 NOP assessment review: May 19, 2015 Onsite audit: December 8-12 and 16, 18-19, 2014
Audit Identifier	NP4342ZZA
Action Required	Corrective Action Progress Reports – see Notice of Continued Accreditation
Audit & Review Type	Mid-term (12.5 years) Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of TDA’s certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	TDA’s certification services in carrying out the audit criteria during the period: June 2012 through December 2014.

Organizational Structure:

The Texas Department of Agriculture (TDA) was accredited on April 29, 2002 by the USDA National Organic Program (NOP) as an accredited certifying agent for the scopes of crops, livestock, and handling. The TDA Organic Certification Program currently has 219 certified operations with 113 crop, 6 livestock, and 50 handlers, 32 distributors, 13 fiber processors, and 5 retailers. TDA does not accredit wild crop or grower group operations and only conducts certifications in Texas.

TDA has a Director, a Coordinator for Organic Certification, an Organic Certification Specialist, and 22 staff inspectors. TDA has five Regional Offices within the state, each office with a Lead Inspector and inspectors. TDA used one contract reviewer in 2014 for annual update reviews.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether TDA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance. Any noncompliances labeled as "**Accepted**," indicates the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP9320BBA.NC3 – Cleared

NP2135BBA.NC1 – Cleared

NP2135BBA.NC3 – Cleared

NP2135BBA.NC4 - Cleared

NP2135BBA.NC5 – Cleared

NP2135BBA.NC2 – Accepted – NOP § 205.403(c)(1) states, "The on-site inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part."

Comments: *TDA does not require inspectors to conduct trace-back and input/output sampling activities, nor does the inspection report or checklist provide for a section that documents these inspection verification activities.*

Corrective Action: TDA revised its inspection forms and procedures to include traceback and input/output audits within the inspection process for each NOP certification scope. Copies of the revised inspection forms were provided. TDA plans to train program inspectors on the revised procedures in April 2013. The implementation and effectiveness of the corrective action will be verified at the next on-site NOP accreditation assessment.

2014 Verification of Corrective Action: TDA has not updated their inspection procedures to conduct or document traceback audits in their checklists. The interview of the certified handler selected for the review audit verified an undocumented traceback audit was conducted for one product. Observation of the inspectors and interview of the certified operator during the crop witness audit verified a traceback audit was conducted on some products. The inspectors acknowledged there was no procedure for conducting or documenting traceback audits. Interview of the TDA Organic Coordinator revealed a consultant was contracted to help develop a traceback audit procedure and forms. The contracted work has not been completed.

2015 Corrective Action: TDA submitted a plan to create traceability inspection forms for all scopes by October 15, 2015, complete the review and approval process for all traceability inspection forms by October 31, 2015, and submit current drafts of traceability inspection forms to the NOP by November 05, 2015. TDA plans to conduct training for inspectors on the new forms for all scopes of certification on December 01, 2015 and inspectors will be expected to utilize the addendums immediately following the training. TDA will continue to submit progress reports to NOP.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as “**Accepted**,” indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4342ZZA.NC1 – Accepted. USDA organic regulations, 7 CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406...;” 7 CFR §205.406(a)(b) requires certified operations to submit an updated organic production or handling plan annually and for the certifier to review the updated information to determine compliance; and 7 CFR §205.403(a)(1) states, “...An onsite inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products...”

Comments: *TDA did not conduct the annual inspections for 49 certified operations (38 crop and 11 handling, representing ~22% of TDA’s clients) in 2014. TDA identified the annual inspections for those operations were not assigned as a result of the backlog of annual update reviews. TDA hired a contract reviewer to assist, and the annual update reviews were completed; however, 49 operations were not inspected in the past 12 months. TDA documented a plan to complete all crop inspections by March 1, 2015 and all handling inspections by May 1, 2015. The inspections were being assigned during the assessment.*

Corrective Action: TDA submitted a status report of these inspections on July 14, 2015 and again on August 26, 2015. Two inspections are still outstanding. One of these two operations will be issued a Notice of Proposed Suspension for failure to submit annual update fee payment and updated OSP documents. The 2015 inspection schedule was submitted to NOP and TDA plans to inspect all operations within 60 days of receipt of fee payment and completed OSP updates. TDA will continue to submit progress reports to NOP.

NP4342ZZA.NC2 – Accepted. USDA organic regulations, 7 CFR §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;”

Comments: *TDA did not have sufficient certification review personnel to comply with and implement the organic certification program. The 49 annual updates of certified operations (~22%) not reviewed in 2014 are a result of this noncompliance. The untimely reviews delayed inspections of the operations past the 12 month threshold. TDA realized the need for additional certification staff and was in the process of hiring one new full-time certification staff and one*

new administrative staff. The hiring of additional full-time certification staff was possible with the approved increase in the organic certification fees. TDA was reviewing applicants during the assessment with the intention of filling the positions in early 2015. In the interim, TDA was using a contract reviewer to assist in completing the annual update reviews.

Corrective Action: TDA hired a third full-time reviewer, who started March 1, 2015. TDA hired a Program Specialist who started August 17, 2015. This position will allow the hired staff person to perform occasional reviews in addition to administrative tasks.

NP4342ZZA.NC3 – Accepted. USDA organic regulations, 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” 7 CFR §205.501(a)(8) requires certifiers to, “Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;” As outlined in NOP 2609 Instruction Unannounced Inspections, the Administrator determined certifiers must conduct unannounced inspections on 5% of the total certified operations per year, have procedures for unannounced inspections, and clearly disclose the protocols for unannounced inspections to their certified operations.

Comments: *TDA did not conduct any unannounced inspections in 2013 and 2 in 2014 (<1%), their procedures do not adequately address unannounced inspections (procedures cover only complaint or investigative inspections and not 5%), and their unannounced inspection procedures are not provided to certified operations.*

Rebuttal: TDA has posted the revised protocol for unannounced inspections on its website, which includes conducting unannounced inspections of 5% of the total certified operations, as recommended in NOP 2609.

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Texas Department of Agriculture (TDA) organic program was conducted December 8-12, 16 and 18-19, 2014. The National Organic Program (NOP) reviewed the auditor’s report to assess TDA’s compliance with the USDA organic regulations. This report provided the results of NOP’s assessment.

GENERAL INFORMATION

Applicant Name	Texas Department of Agriculture (TDA)
Physical Address	1700 North Congress Avenue, Stephen F. Austin Building Austin, TX 78701
Mailing Address	P.O. Box 12847, Austin, TX 78711
Contact & Title	Mary Ellen Holliman, Coordinator for Organic Certification
E-mail Address	Mary.Holliman@texasagriculture.gov
Phone Number	512-936-4178
Reviewer(s) & Auditor(s)	Penny Zuck, Corrective Action Review Jason Lopez, NOP Review Corey Gilbert, Onsite Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action review: October 2, 2015 NOP assessment review: May 19, 2015 Onsite audit: December 8-12 and 16, 18-19, 2014
Audit Identifier	NP4342ZZA
Action Required	Corrective Action Progress Reports – see Notice of Continued Accreditation
Audit & Review Type	Mid-term (12.5 years) Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of TDA’s certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	TDA’s certification services in carrying out the audit criteria during the period: June 2012 through December 2014.

Organizational Structure:

The Texas Department of Agriculture (TDA) was accredited on April 29, 2002 by the USDA National Organic Program (NOP) as an accredited certifying agent for the scopes of crops, livestock, and handling. The TDA Organic Certification Program currently has 219 certified operations with 113 crop, 6 livestock, and 50 handlers, 32 distributors, 13 fiber processors, and 5 retailers. TDA does not accredit wild crop or grower group operations and only conducts certifications in Texas.

TDA has a Director, a Coordinator for Organic Certification, an Organic Certification Specialist, and 22 staff inspectors. TDA has five Regional Offices within the state, each office with a Lead Inspector and inspectors. TDA used one contract reviewer in 2014 for annual update reviews.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether TDA's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance. Any noncompliances labeled as "**Accepted**," indicates the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP9320BBA.NC3 – Cleared

NP2135BBA.NC1 – Cleared

NP2135BBA.NC3 – Cleared

NP2135BBA.NC4 - Cleared

NP2135BBA.NC5 – Cleared

NP2135BBA.NC2 – Accepted – NOP § 205.403(c)(1) states, "The on-site inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part."

Comments: *TDA does not require inspectors to conduct trace-back and input/output sampling activities, nor does the inspection report or checklist provide for a section that documents these inspection verification activities.*

Corrective Action: TDA revised its inspection forms and procedures to include traceback and input/output audits within the inspection process for each NOP certification scope. Copies of the revised inspection forms were provided. TDA plans to train program inspectors on the revised procedures in April 2013. The implementation and effectiveness of the corrective action will be verified at the next on-site NOP accreditation assessment.

2014 Verification of Corrective Action: TDA has not updated their inspection procedures to conduct or document traceback audits in their checklists. The interview of the certified handler selected for the review audit verified an undocumented traceback audit was conducted for one product. Observation of the inspectors and interview of the certified operator during the crop witness audit verified a traceback audit was conducted on some products. The inspectors acknowledged there was no procedure for conducting or documenting traceback audits. Interview of the TDA Organic Coordinator revealed a consultant was contracted to help develop a traceback audit procedure and forms. The contracted work has not been completed.

2015 Corrective Action: TDA submitted a plan to create traceability inspection forms for all scopes by October 15, 2015, complete the review and approval process for all traceability inspection forms by October 31, 2015, and submit current drafts of traceability inspection forms to the NOP by November 05, 2015. TDA plans to conduct training for inspectors on the new forms for all scopes of certification on December 01, 2015 and inspectors will be expected to utilize the addendums immediately following the training. TDA will continue to submit progress reports to NOP.

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as “**Accepted**,” indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4342ZZA.NC1 – Accepted. USDA organic regulations, 7 CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406...;” 7 CFR §205.406(a)(b) requires certified operations to submit an updated organic production or handling plan annually and for the certifier to review the updated information to determine compliance; and 7 CFR §205.403(a)(1) states, “...An onsite inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products...”

Comments: *TDA did not conduct the annual inspections for 49 certified operations (38 crop and 11 handling, representing ~22% of TDA’s clients) in 2014. TDA identified the annual inspections for those operations were not assigned as a result of the backlog of annual update reviews. TDA hired a contract reviewer to assist, and the annual update reviews were completed; however, 49 operations were not inspected in the past 12 months. TDA documented a plan to complete all crop inspections by March 1, 2015 and all handling inspections by May 1, 2015. The inspections were being assigned during the assessment.*

Corrective Action: TDA submitted a status report of these inspections on July 14, 2015 and again on August 26, 2015. Two inspections are still outstanding. One of these two operations will be issued a Notice of Proposed Suspension for failure to submit annual update fee payment and updated OSP documents. The 2015 inspection schedule was submitted to NOP and TDA plans to inspect all operations within 60 days of receipt of fee payment and completed OSP updates. TDA will continue to submit progress reports to NOP.

NP4342ZZA.NC2 – Accepted. USDA organic regulations, 7 CFR §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;”

Comments: *TDA did not have sufficient certification review personnel to comply with and implement the organic certification program. The 49 annual updates of certified operations (~22%) not reviewed in 2014 are a result of this noncompliance. The untimely reviews delayed inspections of the operations past the 12 month threshold. TDA realized the need for additional certification staff and was in the process of hiring one new full-time certification staff and one*

new administrative staff. The hiring of additional full-time certification staff was possible with the approved increase in the organic certification fees. TDA was reviewing applicants during the assessment with the intention of filling the positions in early 2015. In the interim, TDA was using a contract reviewer to assist in completing the annual update reviews.

Corrective Action: TDA hired a third full-time reviewer, who started March 1, 2015. TDA hired a Program Specialist who started August 17, 2015. This position will allow the hired staff person to perform occasional reviews in addition to administrative tasks.

NP4342ZZA.NC3 – Accepted. USDA organic regulations, 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” 7 CFR §205.501(a)(8) requires certifiers to, “Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;” As outlined in NOP 2609 Instruction Unannounced Inspections, the Administrator determined certifiers must conduct unannounced inspections on 5% of the total certified operations per year, have procedures for unannounced inspections, and clearly disclose the protocols for unannounced inspections to their certified operations.

Comments: *TDA did not conduct any unannounced inspections in 2013 and 2 in 2014 (<1%), their procedures do not adequately address unannounced inspections (procedures cover only complaint or investigative inspections and not 5%), and their unannounced inspection procedures are not provided to certified operations.*

Rebuttal: TDA has posted the revised protocol for unannounced inspections on its website, which includes conducting unannounced inspections of 5% of the total certified operations, as recommended in NOP 2609.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Mary Ellen Holliman
Texas Department of Agriculture
P.O. Box 12847
Austin, TX 78711

Dear Ms. Holliman:

On December 8-12, 16 and 18-19, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Texas Department of Agriculture (TDA) organic certification program as part of its USDA Mid-term Accreditation Assessment. On May 19, 2015, the NOP reviewed the results of the onsite audit to determine TDA's compliance to the USDA organic regulations. A copy of the assessment report, NP4342ZZA, is enclosed for your reference.

As the report indicates, five corrective actions for prior noncompliances (NP9320BBA.NC3, NP2135BBA.NC1, and NP2135BBA.NC3 through NC5), were cleared and determined to be implemented and effective. One noncompliance (NP2135BBA.NC2) remains outstanding from your previous audit. Three new noncompliances (NP4342ZZA.NC1 through NC3), were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the TDA management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Penny Zuck, at (202) 260-9444 or Penelope.Zuck@ams.usda.gov

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Mary Ellen Holliman
Texas Department of Agriculture
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Austin, TX 78711

MAY 22 2015

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If you have questions regarding this notice, please contact your Accreditation Manager, Penny Zuck, at (202) 260-9444 or Penelope.Zuck@ams.usda.gov

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Texas Department of Agriculture (TDA) organic program was conducted December 8-12, 16 and 18-19, 2014. The National Organic Program (NOP) reviewed the auditor's report to assess TDA's compliance with the USDA organic regulations. This report provided the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Texas Department of Agriculture (TDA)
Physical Address	1700 North Congress Avenue, Stephen F. Austin Building Austin, TX 78701
Mailing Address	P.O. Box 12847, Austin, TX 78711
Contact & Title	Mary Ellen Holliman
E-mail Address	Mary.Holliman@texasagriculture.gov
Phone Number	512-936-4178
Reviewer & Auditor	Jason Lopez, NOP Reviewer; Corey Gilbert, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date	NOP assessment review: May 19, 2015 Onsite audit: December 8-12 and 16, 18-19, 2014
Audit Identifier	NP4342ZZA
Action Required	Yes
Audit & Review Type	Mid-term (12.5 year) Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of TDA's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	Assessment of TDA's certification services in carrying out the audit criteria during the period: June 2012 through December 2014.

Organizational Structure:

The Texas Department of Agriculture (TDA) was accredited on April 29, 2002 by the USDA National Organic Program (NOP) as an accredited certifying agent for the scopes of crops, livestock, and handling. The TDA Organic Certification Program currently has 219 certified operations with 113 crop, 6 livestock, and 50 handlers, 32 distributors, 13 fiber processors, and 5 retailers. TDA does not accredit wild crop or grower group operations and only conducts certifications in Texas.

TDA has a Director, a Coordinator for Organic Certification, an Organic Certification Specialist, and 22 staff inspectors. TDA has five Regional Offices within the state, each office with a Lead Inspector and inspectors. TDA used one contract reviewer in 2014 for annual update reviews. TDA will hire an

additional full-time organic certification specialist and one additional administrative staff in early 2015.

Records reviewed verified that TDA is meeting the requirements for annual performance evaluations, confidentiality agreements, and annual conflict of interest statements. File reviews and interviews support that all personnel had the required education, training and experience in organic agricultural production and handling to perform the duties assigned.

TDA received approval on December 5, 2014 to increase their fees. The fee increase will allow TDA to maintaining an adequate number of organic certification and support staff to implement the TDA organic certification program. In December 2014, TDA was reviewing applicants for an organic certification specialist and an administrative staff position to start in early 2015. TDA was also implementing changes to their database to streamline the certification process. Anticipating significant changes to the certification program, TDA made a request that USDA conduct another assessment prior to the renewal assessment to evaluate the effectiveness of the certification program changes.

Certification Process:

The Coordinator for Organic Certification or the Organic Certification Specialist complete the initial and annual update application reviews. Inspections are assigned from the appropriate TDA Regional Office based on the qualifications and availability of staff inspectors. Completed inspection reports are uploaded into the TDA database and reviewed at TDA Headquarters Office in Austin, TX. Final reviews and certification decisions are made by the Coordinator for Organic Certification or the Organic Certification Specialist. The initial and final reviews of an initial applicant's documents are conducted by different people. The same person will conduct initial and final reviews of annual update documents and make the certification decision. Upon certification, TDA issues a letter and certificate with required information. TDA requires information to be updated annually or as changes are made to the operation. NOP certificates are updated annually or when information has changed. TDA requires annual renewal inspections for continued NOP certification; however, TDA did not complete all 2014 annual update reviews in a timely manner. The untimely completion of reviews resulted in the delay of inspection assignments and annual inspections. These delays did not allow TDA to complete inspections for 49 operations in 2014 (see Findings 1 & 2).

Material reviews are conducted by the Coordinator for Organic Certification and the Organic Certification Specialist using the USDA organic regulations, NOP Program Handbook, OMRI lists, and information from the Washington State Department of Agriculture. TDA also accepts the material reviews conducted by other certifying agents when adequate documentation is provided.

Label reviews are conducted by the Coordinator for Organic Certification and the Organic Certification Specialist using TDA's label procedure, USDA organic regulations, and the NOP Program Handbook. Labels are stamped with the approval status, review date, and name of the reviewer.

Administrative Records and Processes:

TDA has an Organic Program Procedures Manual, an Organic Inspector Manual, initial application forms, organic system/handling plan template, annual update forms, inspection checklists, inspection reports, and numerous additional templates for certificates, notices of noncompliance, adverse actions, etc.

TDA conducts an annual program review and implements corrective actions based on the findings. TDA has annual organic training for staff and inspectors based on external training attended by the Coordinator for Organic Certification.

The TDA fee schedule is supplied to applicants who submit information requesting certification. The fee schedule includes non-refundable information and outlines the various set costs for certified operations. The fees appear to be reasonable and the schedule is clear in the amounts to be charged. TDA received approval to increase their fees and will implement the increase in 2015. TDA will provide the new fee schedule to the USDA prior to use.

Summary of Review and Witness Audits Conducted:

The assessment included a review audit conducted at a handling operation in Austin, TX first certified by TDA in January 2003. The operation included processing, packaging and direct sales. The operation had designated storage areas for organic inputs, clean-out procedures for processing machines, and designated organic equipment. TDA staff last inspected the facility on October 22, 2014, and the review audit verified the operation's organic system plan, the inspector's checklist, TDA's final report, and the organic certificate reflecting the actual practices of the operation. Overall, the review audit verified compliance to the organic regulations.

The assessment also included a witness audit of an annual inspection conducted at a crop operation in Mission, TX certified by TDA since January 2003. The dedicated organic operation (organic only) was a primarily orchards with small plots of vegetable crops. The inspection was conducted by two TDA staff inspectors, all required areas were reviewed, and an exit interview was conducted with the certified operation. The witness audit verified compliance to the organic regulations. The inspectors conducted a traceback audit; however, as noted in the outstanding noncompliance (NP2135BBA.NC2), the inspectors did not have a specific procedure to follow and were not documenting the traceback audit.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether TDA's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to TDA.

Noncompliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP2135BBA.NC2 – Outstanding – NOP § 205.403(c)(1) states, "The on-site inspection of an operation must verify: The operation's compliance or capability to comply with the Act and the regulations in this part."

Comments: *TDA does not require inspectors to conduct trace-back and input/output sampling activities, nor does the inspection report or checklist provide for a section that documents these inspection verification activities.*

Corrective Action: TDA revised its inspection forms and procedures to include trace-back and input/output audits within the inspection process for each NOP certification scope. Copies of the revised inspection forms were provided. TDA plans to train program inspectors on the revised procedures in April 2013. The implementation and effectiveness of the corrective action will be verified at the next on-site NOP accreditation assessment.

Verification of Corrective Action (December 2014): TDA has not updated their inspection procedures to conduct or document traceback audits in their checklists. The interview of the certified handler selected for the review audit verified an undocumented traceback audit was conducted for one product. Observation of the inspectors and interview of the certified operator during the crop witness audit verified a traceback audit was conducted on some products. The inspectors acknowledged there was no procedure for conducting or documenting traceback audits. Interview of the TDA Organic Coordinator revealed a consultant was contracted to help develop a traceback audit procedure and forms. The contracted work has not been completed.

NP9320BBA.NC3 – Cleared – 7 CFR § 205.402(a)(1, 2) states, “Upon acceptance of an application for certification, a certifying agent must: (1) Review the application to ensure completeness pursuant to § 205.401; and (2) Determine by a review of the application materials whether the applicant appears to comply or may be able to comply...”

Comments: *The inspection observations of the farm, and processing facilities showed that the applications reviewed prior to the inspection were missing information regarding inputs and procedures. The missing information was then collected by the inspector during the audit. The review of files showed the required information in the organic system plans were not complete, updated or was inaccurate prior to the inspection. No non-compliances or issues of concern had been identified by TDA or the inspectors for the applicant having organic system plans that had not been updated or completed as required.*

Corrective Action (April 30, 2010): TDA submitted to USDA revised Organic Inspection Process Procedures and its revised Guidance Document for conducting Organic Producer Inspections. These documents were distributed to inspectors on April 12, 2010. The new procedures emphasize the purpose of the inspection process is to verify information in the operation’s organic system plan, and to identify potential noncompliances. In addition, a Strategic Plan and Timeline for Conducting Organic Training was submitted outlining training to be conducted in 2010 and 2011.

Verification of Corrective Action (May 17, 2012): TDA has improved its OSP review process, including review of materials, labels, and process for requesting additional information prior to inspections. TDA has issued more noncompliances for incomplete or inaccurate OSP’s. Inspectors are listing findings or areas of concern in the inspection reports. However, a review of files showed that a complete OSP review was not being conducted and that this noncompliance should remain outstanding.

Corrective actions on the outstanding noncompliance (August 23, 2012): As a result of TDA's internal program review, an action plan was developed to address this noncompliance. TDA identified the following critical control points of the OSP review process and has initiated amendment of its procedures to streamline its OSP review process:

- Amend Texas regulation to allow application reviews throughout the year, current statute requires program applications to be reviewed during the same annual time period.
- Improve application processing by identifying patterns within current annual update submissions, inspection scheduling, harvest dates and processing dates.
- Revise program OSP templates to streamline application and annual update submission by deleting repetitive or unnecessary information, and enhance electronic submission of applications / annual updates.
- Create a checklist to facilitate product label reviews.
- Develop OSP reviewer training modules specific to the scope of certification.

TDA plans to complete these actions by August 2013. TDA will use annual program reviews to assess effectiveness of these actions in preventing noncompliances and determine if additional actions are required. The corrective actions will be verified at the next on-site NOP accreditation assessment.

Verification of Corrective Action (December 2014): The auditor verified TDA is conducting thorough application reviews and requiring submission of relevant information prior to the inspection.

NP2135BBA.NC1 – Cleared – 7 CFR §205.402(b)(2) states, “The certifying agent shall within a reasonable time: Provide the applicant with a copy of the on-site inspection report, as approved by the certifying agent, for any on-site inspection performed.”

Comments: *TDA is submitting only the findings section of the inspection report to the inspected operation instead of the complete on-site inspection report.*

Corrective Action: TDA revised its Inspection Manual and Procedures to instruct staff to issue a copy of the complete inspection report to the inspected operation. TDA also revised its inspection procedures and forms to have TDA inspectors issue preliminary inspection findings at the conclusion of the exit interview. A copy of the revised manual was provided. TDA plans to conduct training on the revised inspection procedures for all program inspectors in April 2013. The implementation and effectiveness of the corrective action will be verified at the next on-site NOP accreditation assessment.

Verification of Corrective Action (December 2014): A review of records and interviews at the review and witness audits verified TDA is sending the complete on-site inspection report to the certified operation.

NP2135BBA.NC3 – Cleared – 7 CFR §205.501 (a)(11)(vi) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Prevent conflicts of interest by: Ensuring that the decision to certify an operation is made by a person different from those who conducted the review of documents and on-site inspection.”

Comments: *TDA is using the same person to review the updated documents and make the certification decision for the majority of certification files for continuation of certification that do not include any noncompliances.*

Corrective Action: TDA revised its review procedures to provide for a second reviewer to review a certification file and make the certification decision. The initial reviewer will continue to review the application / annual update for completeness and compliance before scheduling an inspection. TDA provided a copy of the revised procedures and began implementing this process in August 2012. The

implementation and effectiveness of the corrective action will be verified at the next on-site NOP accreditation assessment.

Verification of Corrective Action (December 2014): TDA used a three person system from August 2012 through July 2013 and then changed back to a two person system in August 2013 after the NOP 2006 instruction was issued. TDA uses a three person system for all new applicants and a two person system for certified operations. In all cases, the person making the final document review and final certification decision was a different person than the inspector.

NP2135BBA.NC4 – Cleared – 7 CFR §205.660 (d) states, “Each notification of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension or revocation, and suspension or revocation issued pursuant to §§ 205.662, 205.663, and 205.665 and each response to such notification must be sent to the recipient’s place of business via a delivery service which provides dated return receipts.”

Comments: *Although TDA appears to maintain a log book of return receipts, there was no record or receipts for the notifications of noncompliance, proposed suspension, and suspension issued to a crop operation in the file that was reviewed.*

Corrective Action: TDA revised its procedures for logging certified mail tracking numbers. TDA also revised its procedures to assign responsibility of logging each mail tracking number to the program coordinator instead of the program specialist conducting the file review. TDA provided a copy of the revised procedure. TDA also revised all program notices to include a tracking number on each notice. TDA provided copies of each revised program notice. The implementation and effectiveness of the corrective action will be verified at the next on-site NOP accreditation assessment.

Verification of Corrective Action (December 2014): TDA maintained dated return receipts for all notifications of noncompliance, proposed suspension, and suspension issued since the last assessment.

NP2135BBA.NC5 - Cleared – 7 CFR §205.662(c)(1) states, “When rebuttal is unsuccessful or correction of the noncompliance is not completed within the prescribed time period, the certifying agent or State organic program’s governing State official shall send the certified operation a written notification of proposed suspension or revocation of certification... The notification of proposed suspension or revocation of certification shall state: The reasons for the proposed suspension or revocation.”

Comments: *TDA correctly issued a noncompliance to a crop operation for failure to submit additional documentation to support its claims in the OSP. The noncompliance notification cited a violation of § 205.406(a)(4) that requires the submission of “other information as deemed necessary by the certifying agent to determine compliance...” TDA subsequently issued a proposed suspension notification when the crop operation failed to respond to the noncompliance; however, TDA incorrectly stated the reason for proposed suspension citing § 205.201, Organic production and handling system plans, rather than § 205.406(a)(4) stated in the noncompliance notification.*

Corrective Action: In April 2013, TDA plans to train program staff on noncompliance procedures to clearly state and implement the process that when a specific regulation citation is included in a notice of noncompliance, it must continue through the noncompliance and adverse action process until closed or resolved. TDA established procedures for implementing a separate process for the newly identified noncompliances when an operation is cited for any additional noncompliances. TDA also established procedures for retracting notices of noncompliance containing incorrect citations, and then reissuing notices with correct noncompliance citations and corrected timeline for response to the notice. TDA provided copies of the new/revised quality manual procedures. The implementation and

effectiveness of the corrective action will be verified at the next on-site NOP accreditation assessment.

Verification of Corrective Action (December 2014): TDA provided training to program staff and no additional incidences of incorrect citations were observed.

Noncompliances Identified during Current Audit

NP4342ZZA.NC1 – USDA organic regulations, 7 CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406...;” 7 CFR §205.406(a)(b) requires certified operations to submit an updated organic production or handling plan annually and for the certifier to review the updated information to determine compliance; and 7 CFR §205.403(a)(1) states, “...An onsite inspection shall be conducted annually thereafter for each certified operation that produces or handles organic products...”

Comments: *TDA did not conduct the annual inspections for 49 certified operations (38 crop and 11 handling, representing ~22% of TDA’s clients) in 2014. TDA identified the annual inspections for those operations were not assigned as a result of the backlog of annual update reviews. TDA hired a contract reviewer to assist, and the annual update reviews were completed; however, 49 operations were not inspected in the past 12 months. TDA documented a plan to complete all crop inspections by March 1, 2015 and all handling inspections by May 1, 2015. The inspections were being assigned during the assessment.*

NP4342ZZA.NC2 – USDA organic regulations, 7 CFR §205.501(a)(4) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part;”

Comments: *TDA did not have sufficient certification review personnel to comply with and implement the organic certification program. The 49 annual updates of certified operations (~22%) not reviewed in 2014 are a result of this noncompliance. The untimely reviews delayed inspections of the operations past the 12 month threshold. TDA realized the need for additional certification staff and was in the process of hiring one new full-time certification staff and one new administrative staff. The hiring of additional full-time certification staff was possible with the approved increase in the organic certification fees. TDA was reviewing applicants during the assessment with the intention of filling the positions in early 2015. In the interim, TDA was using a contract reviewer to assist in completing the annual update reviews.*

NP4342ZZA.NC3 – USDA organic regulations, 7 CFR §205.501(a)(21) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary.” 7 CFR §205.501(a)(8) requires certifiers to, “Provide sufficient information to persons seeking certification to enable them to comply with the applicable requirements of the Act and the regulations in this part;” As outlined in NOP 2609 Instruction Unannounced Inspections, the Administrator determined certifiers must conduct unannounced inspections on 5% of the total certified operations per year, have procedures for unannounced inspections, and clearly disclose the protocols for unannounced inspections to their certified operations.

Comments: *TDA did not conduct any unannounced inspections in 2013 and 2 in 2014 (<1%), their procedures do not adequately address unannounced inspections (procedures cover only complaint or*

investigative inspections and not 5%), and their unannounced inspection procedures are not provided to certified operations.

Mid-Term Audit Review Chronology Log

Audit Identifier (if any):NP4342ZZA

Audit Type: Mid-Term Review

Accredited Certifying Agent Name: Texas department of Agriculture (TDA)

Accreditation Manager (who is working on the project): Jason Lopez (JL)

Date	Activity
Dec 2014	Audit conducted
3-26-2015	Report received by AIA.
4-10-2015	RM assigned the TDA audit report to JL.
4-15-2015	JL begin review of audit. Previous outstanding noncompliance: <ol style="list-style-type: none"> 1. NP2135BBA.NC2 - TDA procedures do not allow the documentation of traceback audits. Current Noncompliances Identified: <ol style="list-style-type: none"> 1. NP4342ZZA.NC1 – TDA failed to complete 49 annual inspections approximately 22% of the total annual inspections. 2. NP4342ZZA.NC2 – TDA did not have sufficient personnel to implement the organic certification program. 3. NP4342ZZA.NC3 – TDA did not conduct unannounced inspections at the 5% level of sampling. Completed NC report.
4-20-2015	Completed NoNC and submitted documents to RM for review.
5-18-2015	JL was out of the office for IOIA training (4-26 through 5-1-2015) and annual leave (5-2 through 5-17-2015).
5-19-2015	Reviewed minor revisions with RM. I made corrections and resubmitted to RM for approval.
5/22/15	NoNC sent
6/18/15	RM assigned CAs to PZ for processing.
6/22/15	PZ reviewed corrective action documentation.
7/14/15	PZ received status report of CAs being implemented by TDA.
7/15/15	Reviewed status report and emailed TDA for more information regarding how many unannounced inspections they expect to conduct annually. This information was not included in the policy/procedure they submitted for NP4342ZZA.NC3.
7/31/15	Rec'd the following response from Mary Ellen @ TDA: I consulted with my General Counsel and supervisory staff and it was determined that TDA will continue to conduct unannounced inspections on an as-needed basis rather than defining a specific number of unannounced inspections that will be conducted annually. As stated in our rebuttal, TDA found no statutory requirement to conduct a specific number or percentage of unannounced inspections on an annual basis. Prior to submission of the rebuttal, I requested direction to the citation in the NOP Regulations or direction to a notice published in the Federal Register that required ACAs to conduct a certain

Mid-Term Audit Review Chronology Log

Audit Identifier (if any):NP4342ZZA

Audit Type: Mid-Term Review

Accredited Certifying Agent Name: Texas department of Agriculture (TDA)

Accreditation Manager (who is working on the project): Jason Lopez (JL)

Date	Activity
	percentage of inspections, but was referred back to the NOP Handbook, which states in its introduction that it is not a legally binding document.
8/5/15	PZ Requested a status report on the 2014 inspections, how many inspections have been conducted in 2015, and whether they are on track for getting all inspections completed in 2015.
8/7/15	Rec'd email with status of inspections from TDA.
8/14/15	PZ emailed Cheri information regarding the rebuttal above and scheduled a time to discuss the issue – 8/18/15.
8/21/15	PZ received email from Mike @ TDA they will be implementing unannounced inspections of 5% in their policy. Mary Ellen said the protocol will be updated on the TDA website by Sept 4, 2015.
9/2/15	<p>Processed CA Report. Also reviewed previous Noncompliance reports to see if any similar NCs were issued in previous years.</p> <p style="color: red;">NP2135BBA.NC2 – TDA not requiring inspectors to conduct traceback and input/output audits. This was previous noncompliance and TDA submitted a plan to train inspectors and revise documents. During the on-site audit the plans and revised documents were not being used and inspectors were still not conducting traceback and input/output audits as part of the inspection. TDA submitted a new plan to revise documents and train inspectors by early 2016. They were going to submit a status report of this project by August 14, 2015 but it has not yet been received by NOP.</p> <p style="color: red;">NP4342ZZA.NC2 – TDA does not have sufficient certification review personnel. TDA stated a recommendation for hire has been submitted to HR for another staff member who will be hired by August 17, 2015 – status?</p> <p>PZ Entered comments on the CA Report and emailed to RM for review.</p>
9/3/15	<p>PZ Emailed CA report to Cheri for review.</p> <p>PZ Emailed TDA to ask whether the staff person was hired in reference to NP4342ZZA.NC2</p> <p>Received response that a staff person was hired August 17, 2015.</p>

Mid-Term Audit Review Chronology Log

Audit Identifier (if any):NP4342ZZA

Audit Type: Mid-Term Review

Accredited Certifying Agent Name: Texas department of Agriculture (TDA)

Accreditation Manager (who is working on the project): Jason Lopez (JL)

Date	Activity
9/15/15	PZ, Cheri and Miles met to discuss the NoPS. Miles felt there was not enough evidence to issue a notice of proposed suspension but we want to continue to monitor their corrective actions closely.
9/16/15	PZ revised the CA report and Notice of Continued Accreditation to include a requirement of TDA to submit progress reports on a quarterly basis to TDA regarding noncompliances NP4342ZZA.NC1 and NP2135BBA.NC2. Emailed the documents to CC and RM for review.
9/17/15	PZ revised CA report with edits and comments from CC. Printed for CC review and approval.
9/17/15	PZ emailed TDA to let them know, the CA for NP2135BBA.NC2 was not acceptable. Gave them a deadline of 10/1/15 to submit a new timeline for the CA.
10/1/15	PZ received a new timeline from TDA for NC2
10/2/15	PZ reviewed the timeline and accepted it. Revised CA report and printed for CC review.
10/6/15	RY issued the NoContAccred and CA Rpt.
3/11/16	PZ received audit trail workbook and revised inspection procedures to include the audit trail and trace-back exercises. TDA will be training staff and inspectors on these new procedures that will become a part of every inspection. TDA will also develop an outreach and education flyer for the operations so they know what to expect during the inspection.

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

Tse-Xin Organic Certification Corporation (TOC) was accredited as a USDA organic certifying agent on February 1, 2012. An onsite Initial assessment of TOC occurred January 8 through 10, 2014. Verification of corrective actions for previous non-compliances was conducted and new non-compliances were identified. TOC submitted noncompliance corrective action measures and the National Organic Program (NOP) reviewed them and made a determination either to accept or not accept the measures. This report records NOP's decision.

GENERAL INFORMATION

Applicant Name:	Tse-Xin Organic Certification Corporation (TOC)
Physical Address:	N/A
Mailing Address:	7F, No. 75, Sec 4, Nanjing East Rd., Taipei 105, Taiwan R.O.C.
Contact & Title:	7F, No. 75, Sec 4, Nanjing East Rd., Taipei 105, Taiwan R.O.C.
E-mail Address:	Amy Chen, Administrative Staff and Inspector
Phone Number:	(b) (6)
Auditor(s):	Lars Crail, NOP Reviewer and Onsite Auditor.
Program:	USDA National Organic Program (NOP)
Audit Date(s):	Review of the TOC's submitted corrective actions occurred on April 15, 2014.
Audit Identifier:	NP4008LCA
Action Required:	None
Audit Type:	Initial Accreditation Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of TOC's certification system.
Audit Criteria:	7 CFR Part 205, National Organic Program as amended
Audit Scope:	TOC's certification services in carrying out the audit criteria during the period: February 1, 2012 through January 10, 2014.

TOC is accredited by the U.S. Department of Agriculture (USDA), Agricultural Marketing Service, NOP to the scopes of crops, wild crops, and handling. TOC's office is located in Taipei, Taiwan (R.O.C.). In addition to USDA organic certification, TOC certifies operations to the Taiwan national organic standards. TOC currently certifies eight operations (4 crop and 4 handlers) in Taiwan to the USDA organic regulations.

NOP DETERMINATION

NOP's assessment and accreditation decision of the TOC's compliance to the USDA organic regulations is based on a sample of its certification system records and activities.

Prior Non-compliance Corrective Actions

The NOP auditor reviewed information during the assessment to verify that the certifying agent effectively implemented the corrective actions from previous assessment non-compliances or the period since the last assessment. NOP determinations of those corrective action measures are as follows:

AIA101711LMC.NC1 – Cleared

AIA101711LMC.NC2 – Cleared

AIA101711LMC.NC3 – Cleared

Current Non-Compliances – Certifying Agent Response Accepted

The items below are new noncompliances identified during the 2014 Initial assessment. The NOP has reviewed the corrective actions submitted by the certifying agent and determined that they demonstrate sufficient compliance. Verification for effective implementation of the corrective action measures will be conducted during the next onsite assessment.

NP4008LCA.NC1 – Accepted - NOP §205.403(e)(1) states, “At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector.” *TOC is not providing operators a receipt when samples are taken.*

Corrective Action: TOC submitted for NOP's review a two page form (TOC-NOP-F33) that inspectors will complete and provide a copy to operations where sampling occurs. The procedure for providing the operator a receipt is described in TOC's Quality Manual.

NP4008LCA.NC2 – Accepted - NOP §205.403(e)(2) states, “A copy of the on-site inspection report and any test results will be sent to the inspected operation by the certifying agent.” *TOC is only providing the clients a copy of the Exit Interview Summary which is a portion of the inspection report.* **Corrective Action:** TOC created and submitted an inspection report form called the “USDA Organic Check List” (TOC-NOP-F31). Inspectors will record their inspection on this form and the inspected operation will receive a copy of it. There are sufficient sections in the form to allow inspectors to record sufficient descriptions and details of the inspection. The procedure for providing the operator an inspection report is described in TOC's Quality Manual.

NP4008LCA.NC3 – Accepted - NOP §205.642 states, “... a certifying agent shall charge applicants for certification and certified production and handling operations only those fees and charges that it has filed with the Administrator.” *TOC certification fees charged to applicants or certified operations include a fee based on the operation's sales information. The fee schedule filed with the Administrator does not indicate that fees are charged based on sales information.*

Corrective Action: TOC submitted for NOP's review a revised fee schedule (issued 2014/03/12) listing certification charges based on sales.

NP4008LCA.NC4 – Accepted - NOP §205.642 states, “The certifying agent may require applicants for certification to pay at the time of application a nonrefundable fee which shall be applied to the applicant's fees-for-service account. The certifying agent may set the

nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule submitted to the Administrator.” *TOC charges nonrefundable fees; however, its fee schedule does not explain what fee amounts are nonrefundable or at what stage during the certification process the fees become nonrefundable.*

Corrective Action: On page two of TOC’s submitted revised fee schedule (issued 2014/03/12); it states that the applicant who withdraws its application shall be liable for the costs of services up to the time of application withdrawal.



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

FEB 07 2014

Ms. Amy Chen
Tse-Xin Organic Certification Corporation
7F, No. 75, Sec 4, Nanjing East Rd
Taipei 105
TAIWAN R.O.C.

Dear Ms. Chen:

On January 8-10, 2014 a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an Initial Assessment of the Tse-Xin Organic Certification Corporation (TOC) organic certification program. The objective of the assessment was to determine TOC's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4008LCA, is enclosed for your reference.

As the report indicates, four noncompliances (NP4008LCA.NC1-NC4) were identified during the assessment. All noncompliances from the previous audit, AIA101711LMC, were cleared. Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the TOC's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to your Accreditation Manager.

If you have questions regarding this notice, please contact your Accreditation Manager, Lars Crail, at (202) 205-5536 or Lars.Crail@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Grading and Verification Division

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

A renewal assessment of the Utah Department of Agriculture and Food (UDAF) organic program was conducted in August 2012, and as part of the terms of accreditation, UDAF agreed to an additional audit to be conducted prior to the on-site mid-term assessment scheduled for 2014 or 2015. On April 22, 2014, the National Organic Program (NOP) conducted this additional audit, after which the NOP reviewed the auditor's report to assess UDAF's compliance to the USDA organic regulations. This report provides the results of NOP's assessment and UDAF's corrective actions.

GENERAL INFORMATION

Applicant Name:	Utah Department of Agriculture and Food (UDAF)
Physical Address:	350 North Redwood Rd., P.O. Box 146500, Salt Lake City, UT 84114
Mailing Address:	Same
Contact & Title:	Ron Larsen, Organic Program Manager
E-mail Address:	rlarsen@utah.gov
Phone Number:	801-538-7187
Auditor(s) and Reviewer(s):	Meg Kuhn and Renée Gebault King, NOP Reviewers; Nikki Adams, On-site Auditor(s).
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	On-site assessment date: April 22, 2014 NOP Review date: May 19, 2014 Review of Corrective Actions: August 18, 2014
Audit Identifier:	NP4112ADA
Action Required:	No
Audit and Review Type:	Compliance Assessment, Corrective Action Review
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of UDAF's certification system.
Audit and Determination Criteria:	7 CFR Part 205, National Organic Program as amended
Audit and Review Scope:	Review of corrective actions in response to the noncompliance issued on June 19, 2014. The noncompliance was issued in response to a compliance assessment to review UDAF's certification services in carrying out the audit criteria.

The Utah Department of Agriculture and Food (UDAF) was accredited by the USDA National Organic Program (NOP) as a certifying agent on April 29, 2002 for crops, wild crops, livestock, and handling operations. The UDAF list of certified operations includes 52 certified operations, consisting of 25 crop operations, 0 wild crops, 3 livestock operation, and 24 handlers, of which

14 are processors, 8 are retailers, 3 are distributors/retailers and 3 are traders. There are no grower groups certified by UDAF. UDAF has certified operations in the state of Utah only.

The UDAF office is located in Salt Lake City, Utah, and all certification activities are finalized in this office. All staff are full-time employees based out of the Salt lake City office, and all also conduct other duties for UDAF in addition to their work for the organic certification program. The UDAF organic certification staff consists of: the Director of Plant Industry, the Organic Program Manager; the Organic Coordinator, a Financial Analyst/ Internal Auditor and 8 staff Organic Inspectors (5 are currently performing inspections and 3 are newly trained inspectors who have not yet performed inspections independently). There is one Deputy Commissioner; however, he only participates in the UDAF Organic Program to help in mediation requests (of which there have been none). The Program Manager and the Organic Coordinator also act as the Reviewers. No staff are subcontracted.

NOP DETERMINATION

NOP's review of UDAF's onsite audit report was conducted. NOP has determined the following status of the prior noncompliance corrective actions and the current identified noncompliances:

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP9222BBA.NC4 – Cleared

NP9222BBA.NC5 – Cleared

NP9222BBA.NC9 – Cleared

AIA082211RLP.NC1 – Cleared

AIA082211RLP.NC2 – Cleared

AIA082211RLP.NC6 – Cleared

NP2226MMA.NC1 – Cleared

NP2226MMA.NC2 – Cleared

NP2226MMA.NC3 – Cleared

NP2226MMA.NC4 – Cleared

NP2226MMA.NC5 – Cleared

Non-compliances Identified during the Current Assessment

NP4112ADA.NC1 – Accepted – 7 CFR 205.403(e)(1) states "At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector." *A review of the 3 samples taken in 2013 found that no receipts were provided to the operation's representatives at the time of sampling.* **Corrective Action:** The UDAF submitted an updated Quality Manual describing their new procedure that states a receipt,

signed by both the client and the inspector, shall be issued at the time of sample collection, with a receipt copy provided to the client. An updated receipt form was also provided, illustrating the two signatories required on the form.

Audit Resolution Chronology Log

Audit Identifier (if any): NP4112ADA
Audit Type: Compliance Assessment
ACA Name: Utah Department of Agriculture and Food (UDAF)
Accreditation Manager: Renee Mann; report assigned to Meg Kuhn; follow-up by Renée Gebault King

Date	Activity
4/22/14	QAD auditor, Nikki Adams, conducted a compliance assessment of UDA.
5/2/14	NOP 2005 checklist was submitted to NOP for review.
5/19/14	Audit report assigned to Meg Kuhn for review and processing. MK reviewed checklist and found no issues requiring clarification or follow-up with the auditor. Eleven outstanding noncompliances were CLEARED at the audit; specifically: 1) NP9222BBA.NC4, NC5, and NC9 2) AIA082211RLP.NC1, NC2, and NC6 3) NP2226MMA.NC1 through NC5 One new noncompliance was identified (receipts not being provided when samples taken at inspection). MK prepared NC report, NoNC, and accompanying documents for management review and signature.
5/27/14	MK received and made formatting changes.
5/27/14	CC gives file to LC to contact the auditor and revise the checklist (NOP 2005) narrative. The narrative is an outline with bullets, not report ready. Auditor contacted and will revise checklist.
6/17/14	LC received revised checklist from QAD auditor and made adjustments to the NC report. LC compiled the documents and submitted the file for CC review and signature.
6/19/14	Further edits required to the NC report. LC made edits and resubmitted for CC's review.
6/19/14	Mann sent letter and NC report via RPost.
07/03/14	UDA submitted proposed resolution on for NC report issued 06/19/14.
08/12/14	Renée Gebault King (RGK) received.
08/13/14	RGK reviewed and drafted NoNC Resolution letter.
08/18/14	RGK drafted CA Report. Prepared file for submission to Renée Mann's (RM) review.
8/21/14	RGK prepared updated NoNC Resolution letter for RM review.
8/26/14	RGK updated per RM's edits. Resubmitted to RM for review.

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

A renewal assessment of the UDA organic program was conducted in August 2012, and as part of the terms of accreditation, UDA agreed to an additional audit to be conducted prior to the on-site mid-term assessment scheduled for 2014 or 2015. The NOP reviewed the auditor’s report to assess UDA’s compliance to the USDA organic regulations. This report provides the results of NOP’s assessment.

GENERAL INFORMATION

Applicant Name:	Utah Department of Agriculture (UDA)
Physical Address:	350 North Redwood Rd., P.O. Box 146500, Salt Lake City, UT 84114
Mailing Address:	Same
Contact & Title:	Ron Larsen, Organic Program Manager
E-mail Address:	rlarsen@utah.gov
Phone Number:	801-538-7187
Auditor(s) and Reviewer(s):	Meg Kuhn, NOP Reviewer; Nikki Adams, On-site Auditor(s).
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	On-site assessment date: April 22, 2014 NOP Review date: May 19, 2014
Audit Identifier:	NP4112ADA
Action Required:	Yes
Audit and Review Type:	Compliance Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of UDA’s certification system.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	Compliance assessment to review UDA’s certification services in carrying out the audit criteria

ORGANIZATIONAL STRUCTURE:

The Utah Department of Agriculture and Food (UDAF) were accredited as a USDA National Organic Program (NOP) as a certifying agent on April 29, 2002 for crops, wild crops, livestock, and handling operations. The UDAF list of certified operations includes 52 certified operations, consisting of 25 crop operations, 0 wild crops, 3 livestock operation, and 24 handlers of which are 14 processors, 8 retailers, 3 distributor/retailer and 3 traders. There are no grower groups certified by UDAF. UDAF has certified operations in the state of Utah only.

The UDAF office is located in Salt Lake City, Utah, and all certification activities are finalized in this office. All staff are full-time employees based out of the Salt lake City office, and all also conduct other duties for UDAF in addition to their work for the organic certification program. The UDAF organic certification staff consists of: the Director of Plant Industry, the Organic Program Manager; the Organic Coordinator, a Financial Analyst/ Internal Auditor and 8 staff Organic Inspectors (5 are currently performing inspections and 3 are newly trained inspectors who have not yet performed inspections independently). There is one Deputy Commissioner; however, he only participates in the UDAF Organic Program to help in mediation requests (of which there have been none). The Program Manager and the Organic Coordinator also act as the Reviewers. There is no subcontracted staff.

GENERAL INFORMATION:

A renewal assessment of the UDAF organic program was conducted in August 2012, and found that the previous outstanding non-compliance corrective actions were not effectively implemented within the prescribed timeframe to demonstrate compliance to the USDA NOP Regulations. Subsequently, a Notice of Proposed Suspension was issued on April 1, 2013. UDAF filed an appeal the suspension to the AMS Administrator and submitted corrective actions on April 26, 2013. The NOP reviewed the corrective actions on May 6-14 and July 12-26, 2013. The corrective actions appeared to be adequate; therefore, the NOP withdrew the Proposed Suspension and UDAF subsequently withdrew their appeal. A Settlement Agreement was reached and signed on September 12, 2013, which stipulated that UDAF agree to an on-site assessment in 2013 or 2014 at UDAF's expense for one auditor for one day to determine if UDAF has effectively implemented the submitted corrective actions.

PERSONNEL/ TRAINING:

Staff qualifications are based on a combination of an education degree in agriculture, job duties or expertise in agriculture and/ or organic training. A review of staff, and interviews conducted, verified that all UDAF staff has adequate qualifications and has had recent organic training thru IOIA, NOP ACA and / or in-house trainings.

ADMINISTRATIVE RECORDS & PROCESSES:

UDAF has developed a Program Applicant Processing Tracking Sheet UDAF has developed a staff file checklist to track training of all staff. A review of the tracking form for 2013-2014, training documentation and interviews conducted, verified that annual training is being conducted and the NOP regulations are understood.

NOP DETERMINATION

NOP's review of UDA's onsite audit report was conducted. NOP has determined the following status of the prior noncompliance correction actions and the current identified noncompliances:

Non-compliances from Prior Assessments

NP9222BBA.NC4 – Cleared - NOP § 205.403(a)(1) states, “A certifying agent must conduct an initial on-site inspection of each... An on-site inspection shall be conducted annually thereafter for each certified operation...” *Two of the nine files reviewed showed that the certified operations did not have the inspections completed annually. The processor observed for the on-site inspection during the audit showed that the initial inspection was completed on April 10, 2007 and the next inspection was not conducted until the observation inspection for the on-site audit on August 13, 2009 (16 months past the annual inspection date). The file for one crop operation showed that the last inspection was completed on November 21, 2007 and the next annual inspection had not been completed as of August 13, 2009 (so far 8 ½ months past the annual inspection date).* **Corrective Action (10/2/09 & 12/02/09):** UDA has stated that an Excel spreadsheet will be used to track and ensure that operations have submitted applications and that the required audits are completed. An Excel Spreadsheet was submitted that showed the completion of the 2009 organic inspections by UDA. **Verification ((08/22 - 24/11)):** *UDA’s internal audit report shows that as many as eleven operations continuing with NOP certification in 2010 were not inspected. In addition, UDA’s 2011 inspection records were not available at the time of the assessment. Records showing inspection reports being reviewed and approved in 2010 and 2011 were missing from client files.* **Corrective Action (11/30/11 & 03/07/12):** The corrective actions adequately address the noncompliance. UDA’s corrective action indicated that all operations would be inspected before the end of 2011 or a notice of noncompliance would be sent to the operations. After the August 22 – 24, 2011 compliance assessment, UDA conducted annual inspections on the operations that had not been inspected in 2011. Two of the eleven operations voluntarily surrendered NOP certification. UDA’s new program manager will be responsible for ensuring all required inspections are conducted. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** *This finding remains outstanding because it has not been adequately implemented. Records reviewed verified there were four operations which had not been inspected in 2011 and no further action had been taken on the files. UDA stated two of the operations had verbally informed them they would surrender their certification. However, there was nothing in the files to indicate they had surrendered.* **Corrective action (April 2013):** UDA established and submitted its 2012 program applicant (annual update) processing tracking spreadsheet which showed that required 2012 inspections were conducted. Operations receiving suspensions, surrendering certification or withdrawing applications are also recorded on the spreadsheet. To prevent this non-compliance, staff will use the tracking spreadsheet to monitor progress on completing OSP reviews, assigning inspections and reviewing inspection reports. **Compliance Assessment Verification (April 2014):** A review of the Excel Spreadsheet, four client files and interviews conducted verified that all 2012 and 2013 inspections had been conducted. Interviews conducted verified that the Organic Coordinator and Program Manager are keeping track of all inspections and assuring they are being performed annually, as required.

NP9222BBA.NC5 – Cleared - NOP §205.403(c) Verification of information states, “The on-site inspection of an operation must verify: (1) The operation’s compliance or capability to comply with the Act and the regulations in this part; and (2) That the information, including the organic production or handling system plan... accurately reflects the practices used or to be used by the

applicant for certification or by the certified operation.” *Some of the records and portions of the operation were not reviewed during two of the inspection observations.*

- *The inspector did not review some of the records applicable to the operation during the crop inspection including the production, planting, and harvesting records.*
- *The inspector did not review some of the records during the livestock inspection including the purchase records for the baby chicks and the laying hen chicken mash feed. In addition, the inspector did not observe the beef slaughter stock animals or the pasture where they were located.*

Corrective Action (10/02/09 & 12/09/09): UDA submitted a letter to the auditors listing the deficient areas during the USDA Audit. UDA has a mandatory training/update meeting scheduled for March 4, 2010 to discuss these issues. **Verification (08/22 – 24/11):** *During the poultry operation on-site evaluation, the UDA inspector reported that the operation’s feed mill and the egg handling facility were not inspected during the 2011 organic inspection of the operation.* **Corrective Action (11/30/11):** The corrective actions adequately address the noncompliance. UDA scheduled training on March 22, 2012 for the purpose of updating inspection staff on NOP inspection requirements, including the inspection of all facilities and equipment used for implementing an operation’s OSP. A copy of the training agenda and a list of staff attending the training were included in the corrective actions. UDA’s OSP review report includes recording issues identified during inspection into the report for consideration during the certification decision. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** Based on the livestock witness inspection and all areas which were not reviewed and/or verified, this finding remains outstanding. During the livestock witness inspection, the inspector did not:

- Identify that paper used in pullet houses was not removed as indicated in the organic system plan (OSP). The OSP stated for the pullet house, paper is placed on plastic slats for 2-3 weeks until chicks are big enough to walk on the slats at which point the paper is removed. At the time of the witness inspection, the pullets were 3 ½ weeks old and there was still paper in place although very little was left. An interview with the farm manager verified that it was typical for the paper to remain 3 ½ weeks as was the case during the inspection and that he would have to update the OSP.
- Verify the source of the paper used in the pullet house.
- Verify the source of the wood shavings.
- Review the invoice for purchased chicks.
- Identify an issue with the operation not providing outdoor access until 16 weeks with a sound reasoning as opposed to basing outdoor access on production practices (see details under AIA082211RLP.NC2).
- Review records maintained concerning the times outdoor access is not provided to the birds; or identify an issue with no records maintained to verify the birds are given outdoor access for a minimum of four hours when they are provided access as stated in the OSP.
- Identify an issue with the operation not providing clean dry bedding to all birds, at all times, in all houses. Of the three laying houses visited, only one (the youngest birds) had sufficient clean dry bedding.

Corrective action (April 2013): UDA plans to select and train new inspectors on organic livestock inspections. UDA will submit these training records in their annual report to NOP. The livestock operations certified by UDA will be inspected during August/ September 2013.

UDA will require staff inspectors, including livestock inspectors, to attend annual organic inspection training. **Compliance Assessment Verification (April 2014):** A review of the 'Program Applicant Processing Tracking Sheet', two of three livestock client files and interviews conducted with the livestock inspectors verified that all areas are being reviewed during inspections. Training documentation for training conducted on May 22, 2013 and February 26, 2014 were reviewed.

NP9222BBA.NC9 – Cleared - NOP §205.501 (a)(7) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Have an annual program review of its certification activities conducted by the certifying agent’s staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any non-compliances with the Act and the regulations in this part that are identified in the evaluation.” The UDA Organic Program requires a management review by the Program Manager, Commissioner, and the Division Directors in which the internal audit report is reviewed. *The internal audit was started in April 2009 but not completed. The management review was not conducted or documented for 2008 or 2009.* **Corrective Action (10/02/09 & 12/02/09):** The completed internal audit report for 2009 was submitted. The review with UDA Management is scheduled to occur in January 2010. **Verification (08/22 -24/11):** *UDA conducted internal audits in 2009 and 2010. Results of the internal audits indicated that one exit interview was not conducted, inspection reports were sent to less than 50% of the certified operations, and that inspections did not occur for eleven certified operations in 2010. There was no record of a management review of the internal audit findings or corrective actions to address the noncompliances that were identified by the internal audits.* **Corrective Action (11/30/11):** The corrective actions adequately address the noncompliance. UDA has amended its procedures for management reporting. The agency’s internal auditor and organic program manager will develop internal audit reports for consideration by the UDA Plant Industry Division Director. Based upon findings described within these reports, corrective actions for nonconformities will be developed and implemented. The agency will also monitor implementation of the internal audit corrective actions. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** This finding remains outstanding. The internal audit which was conducted was based on forms required to be completed, being in the file; that appropriate fees were assessed and paid; and interviews with a director and an inspector to see if they understood their responsibilities within the program. One interview was conducted with the Director of Regulatory Services instead of the Director of Division of Plant Industry (DPI) who oversees the program. An interview with the internal auditor verified that he was not familiar with the Final Rule and had never reviewed it. No technical review was conducted on certification files and the scope of the audit did not include the certification activities of UDA. Also in an interview with the Director of DPI, he stated that the management review had been conducted and he may have recorded the date and time it took place in his planner and he would check. However, there was no objective evidence presented by the end of closing meeting to verify the management review had occurred. **Corrective actions (April 2013):** UDA provided a copy of the 2012 internal audit report on the organic program, which included more technical review of the organic program. Results from this report were presented at inspector training held in May 2013. A copy of a list of training items was provided. To prevent this noncompliance, UDA will continue increasing the internal audit scope to include more technical review and they will add more auditors to the internal audit

review. **Compliance Assessment Verification (April 2014):** The latest internal audit conducted January 22, 2014 was reviewed. The scope of the internal audit covered the certification process, training, and a review of client files. The internal audit results were found to be adequate. Training records were reviewed and there has been one new associate trained to the NOP requirements to perform internal audits. The internal audit will be now performed between the new internal auditor, Program Manager and the Organic Certifier. Interviews and the review of the latest internal audit, verified that no one is auditing their own work.

AIA082211RLP.NC1 - Cleared - NOP 205.501(a)(4) states, A private or governmental entity accredited as a certifying agent under this subpart must use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part. *UDA does not appear to have a sufficient number of trained personnel to comply with, and implement the organic certification program. Nine of thirteen UDA corrective actions submitted in response to noncompliances identified in audit report NP9222BBA were not effectively implemented. The OSP review and the inspection review process are not documented. Notices of noncompliance are not copied to the Administrator as required. Follow up on notices of noncompliance is not conducted or not conducted in a timely manner. Notices of Surrender are not issued when certified operations surrender their certification. Notices of Resolution are not issued when certified operations correct their noncompliances.* **Corrective Action (11/30/11 & 03/07/12):** The corrective actions adequately address the noncompliance. A new program manager has been hired to administer the organic program. UDA amended its program quality manual to include procedures on how UDA will ensure OSP reviews and inspection are effectively implemented, and how UDA will monitor and administer noncompliances identified during NOP certification activities. UDA established an organic program documentation checklist to monitor OSP reviews and inspection activities. Noncompliances or issues of concern resulting from OSP review or inspections will be recorded onto an excel spreadsheet. UDA's amended noncompliance procedures for certified operations include procedures on: submitting noncompliance notices to the administrator; monitoring noncompliances and assessing an operation's corrective actions on noncompliances; and providing notices of surrender or notices of noncompliance resolution. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** This finding remains outstanding. There was objective evidence to verify that notices of noncompliance along with other notifications of adverse actions and of noncompliance resolution were being submitted to the Administrator via emails; and that follow-up was being conducted by UDA. However, the finding remains outstanding because, of the 24 inspection reports returned to UDA, only 6 had been reviewed and had gone through the full certification process for 2012 (with 14 of the 24 returned the week of the renewal assessment). Since these corrective actions were approved as adequately addressed in March and April 2012; there is insufficient data to assess implementation and effectiveness. The on-site audit indicates there may still be a problem for the staff assigned to review files, pre and post inspection because of other assignment responsibilities. **Corrective action (April 2013):** UDA provided a copy of its 2012 program applicant processing tracking sheet which indicated OSP reviews and inspections were conducted on 64 operations. Staff used the database to record when OSP reviews and inspections are conducted, when notices of noncompliance are issued, and when an operation's corrective actions were adequate and a Notice of Noncompliance Resolution was issued. In

2013, UDA will expand its applicant tracking system to include more information on inspection activities to reduce the time period committed to inspections. **Compliance Assessment Verification (April 2014):** A review of the 2012 and 2013 ‘*Program Applicant Tracking Form*’, adverse action notices, and resolution notices verified that inspections are being performed annually and follow up, including adverse action notices, are being issued and copied to the Administrator as required. The tracking form is being utilized to track when inspections are being submitted for review, when adverse actions are taken, resolved, and when the certification process is complete. UDA has trained and is in the process of training additional staff, including inspectors, to have sufficient staff to effectively handle the client load.

AIA082211RLP.NC2 - Cleared - NOP 205.662(a) – when an inspection, review, or investigation of a certified operation by a certifying agent reveals any noncompliance with the Act or regulations, a written notification of noncompliance shall be sent to the certified operation. *UDA did not issue a notice of noncompliance to an organic operation for failure to provide outdoor access. UDA did not issue notices of noncompliance to organic operations for failure to submit 2010 annual OSP updates. A file of handling operation showed that it repeatedly violated the NOP regulations by not complying with the requirements for the availability of records (§ 205.103).* **Corrective Action (11/30/11 & 03/07/12):** The corrective actions adequately address the noncompliance. UDA amended its quality manual to indicate that UDA will implement noncompliance procedures described in NOP instruction (NOP 4002) published in the Program Handbook when noncompliances are identified during NOP certification activities. Section 4 of the amended UDA quality manual includes instruction on issuing notices of noncompliance when noncompliances are identified during NOP certification activities. UDA recently hired a new program manager to administer the UDA organic program. UDA has also restructured staff duties and responsibilities to provide additional resources to administering the organic program. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** This finding remains outstanding because it was not fully implemented. Four operations with no inspection conducted in 2011; acceptance of a livestock organic system plan for not granting access to the outdoors based on production practices; and labels and markings for egg cartons which were misleading, approved by UDA. A review of files verified none of these operations had been issued a notification of noncompliance.

(a) Concerning the operations: Records reviewed verified there were four operations which had not been inspected in 2011 with no further action taken by UDA. UDA stated two of the operations had verbally informed them they would surrender their certification. However, there was nothing in the files to indicate they had surrendered certification.

(b) Concerning access to outdoors:

1. The pullet house where the chicks are kept until they are 16 – 17 weeks old, did not have access to the outdoors.
2. The livestock operation’s organic management guide states, “Laying Barn – ...Also, upon reaching peak production, the covered, screened area along the outside of the barn will be opened and accessible to the hens every day that the weather is reasonable for the hens to go outside (typically above freezing temperatures). The access doors to this outside area will be open for a minimum of four hours daily” and “Outdoor Run Procedures – When the hens reach 90 percent production, the outdoor run will be made available.”

(c) Concerning labels:

1. Stencil on the underside of a dozen egg carton lid approved which stated, "Cage-Free 100% Organic Brown Eggs." The eggs were labeled on the outside of the lid as "organic" which is the category they qualified for because of the non-organic processing aid used during production.
2. Two of the three approved labels included the locations of three "Production Ranches" in Idaho, Utah, and Washington which were utilized by the egg producer. The locations were listed under the name of the processor on one label and adjacent to it on the other. Under the locations was the "Certified Organic by..." statement; one label included the USDA seal and the ACA logo. Only the Utah location was certified by UDA and the other two were not certified at all.

Corrective action (April 2013): UDA will use its applicant processing tracking system and checklist to conduct NOP compliance reviews of new applicants, and of annual updates for operations continuing with NOP certification. UDA's 2012 applicant processing checklist shows non-compliant operations were issued Notices of Noncompliance and Notices of Noncompliance Resolution after corrective actions were determined to resolve noncompliances. To prevent this noncompliance, UDA will establish an annual applicant processing tracking checklist to monitor certification activities including OSP reviews, inspections, Notices of Noncompliance and any adverse action events. **Compliance Assessment Verification (April 2014):** A review of the 'Applicant Processing Tracking' Spreadsheet, the 'Applicant Processing Checklist', four client files and interviews conducted verified that all 2012 and 2013 inspections have been conducted. The Organic Coordinator and Program Manager are keeping track of all inspections and assuring they are being performed annually and notices issued, when applicable.

AIA082211RLP.NC6 - Cleared - NOP 205.501(a)(5) states that certifiers ensure that certification staff have sufficient expertise in organic production or handling to successfully perform their duties. NOP 205.501(a)(1) states that certifiers must have sufficient expertise in organic production or handling to fully comply and implement the terms and conditions of the certification program established by the regulations.

- a) *UDA Personnel records were incomplete. Records for inspectors and reviewers were out-of-date and did not indicate any training on organic systems for several years. Inspection evaluations have not been conducted since 2008. Some files contained records on organic training, while other files did not have any records on organic training. A record of 2011 IOIA processor training was found that indicated UDA organic staff attending or completing the course.*
- b) *One inspector did not indicate that failure to provide outdoor access for a poultry operation was a violation of the organic regulations. One inspector failed to conduct an inspection of all of the organic facilities. Some inspection reports indicated short inspection time (1-2 hours) for large acreage farms. The crop inspection report template does not have a checkpoint for evaluating whether seeds are treated with prohibited substances.*

Corrective Action (11/30/11 & 03/07/12): The corrective actions adequately address the noncompliance. UDA corrective actions for (a) state that the Organic Program Manager will maintain program personnel records on qualifications, conflicts of interest, performance evaluations, and training. UDA established a personnel file checklist to monitor the status of program personnel records. UDA corrections actions for (b) state that annual training on NOP

requirements, including conducting thorough and complete inspections, will be provided to program staff, including inspectors. A copy of the UDA 2012 training agenda was included in the corrective actions. UDA's amended quality manual describes Inspector qualifications and responsibilities. In addition, UDA modified its organic crop inspection report template, section 3, to assess NOP regulation requirements for seeds. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** This finding remains outstanding because it has not been properly implemented. The livestock inspector for the witness inspection had no other training than that received by IOIA in 2001 and in house training conducted March 2012. The in house training covered the findings from the NOP August 2011 Compliance Assessment and inspection activities in general. Based on the livestock witness inspection results, this was inadequate for an inspector which only conducts one or two livestock inspections annually. **Corrective action (April 2013):** UDA has developed an organic staff file checklist to monitor conflicts of interest statements, staff evaluations, and training. A copy of the checklist was provided. In addition, copies of signed forms for organic program staff on 2013 conflict of interest statements, and 2012 staff performance evaluations were included in UDA's corrective actions. To prevent this noncompliance, under UDA's quality management system the organic program manager is assigned the responsibility of maintenance of organic program staff files. The manager will implement the staff file checklist to monitor conflicts of interest, staff evaluations and staff training. **Compliance Assessment Verification (April 2014):** A review of the staff file checklist from 2012 to 2014 and interview conducted with the Program Manager verified that the checklist is being utilized and annual training has been conducted. Additionally, interviews conducted with inspection staff verified that annual training is being conducted, including livestock training for qualified staff.

NP2226MMA.NC1 – Cleared - NOP §205.403(b)(2) states, “All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed...” *A review of files verified that the inspection for a crop and livestock operation was conducted in December when the crops could not be observed.*

Corrective action (April 2013): UDA's 2012 applicant processing checklist processing checklist indicates 2012 inspections were conducted when an operation's land, facilities, and practices would demonstrate compliance with the NOP regulations. UDA conducted its last 2012 crop inspection during the first week of October 2012. To prevent this noncompliance, UDA's Organic Program Manager will implement the applicant processing checklist to assign reviews and inspections in a timely manner. **Compliance Assessment Verification (April 2014):** A review of the 'Applicant Processing' checklist, four client files and interviews conducted verified that all 2012 and 2013 inspections had been conducted, and the 2014 inspections had been assigned and are in the process of being scheduled. Interviews conducted verified that the Organic Coordinator and Program Manager are keeping track of all inspections and assuring they are being performed annually as required.

NP2226MMA.NC2 – Cleared - NOP §205.403(d) states, “The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and

information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.” *There was no exit interview conducted after the livestock witness inspection. The inspector completed the exit interview form and the client signed the form; however, an exit interview was not conducted.* **Corrective action (April 2013):** In 2013, UDA will select new inspectors for use in conducting livestock inspections. The new inspectors will receive external training on conducting livestock inspections. In May 2013, UDA provided internal training to staff inspectors. Procedures for conducting exit interviews were provided at this training. To prevent this noncompliance, beginning in 2014, UDA will include field observations as part of inspector performance evaluations. **Compliance Assessment Verification (April 2014):** UDA has trained four new inspectors for the organic program. One inspector is in their second year and the other three are in the process of performing inspection shadow observations and thus are not qualified yet. Training documentation for May 22, 2013 and February 26, 2014 were reviewed. Interviews conducted with various inspection staff verified the training scope provided and the NOP regulations are understood.

NP2226MMA.NC3 – Cleared - NOP §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.” *There was no annual performance evaluation conducted for the Director of Plant Industry since 2010.* **Corrective action (April 2013):** UDA provided copies of 2012 performance evaluations of program reviewers and inspectors. To prevent this noncompliance, under UDA’s quality management system the organic program manager is assigned the responsibility of maintenance of organic program staff files. The manager will implement the staff file checklist to monitor conflicts of interest, staff evaluations and staff training. **Compliance Assessment Verification (April 2014):** A review of the staff file checklist for 2013 and 2014 and an interview conducted with the Program Manager verified that the checklist is being utilized and annual performance evaluations have been conducted, including the Director of Plant Industry.

NP2226MMA.NC4 – Cleared - NOP §205.501(a)(18) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliances.” *Interviews conducted verified inspectors were not being notified of UDA’s decision regarding certification of the operation inspected by the inspector and any requirements for the correction of minor noncompliances.* **Corrective action (April 2013):** In 2012, UDA implemented procedures to provide notice to staff inspectors on certification decisions, noncompliance resolutions and adverse action notifications. UDA provided copies of notice amended notice templates which require inspectors to receive copy of notices. To prevent this noncompliance, UDA will implement its quality manual instruction to provide notice to inspectors on certification decisions, noncompliance resolutions and adverse action notifications. **Compliance Assessment Verification (April 2014):** A review of the UDA Quality Manual verified that page 41, section

4.1, Process Enforcement Action states that the inspector will be informed of all notices and certification decisions. A review of notices, certification decisions, as well as, interviews conducted with inspectors verified that the inspectors are being cc'd on notifications and decisions.

NP2226MMA.NC5 – Cleared - NOP §205.662(c)(3)- (4) states, “The notification of proposed suspension or revocation of certification shall state: (3) The impact of a suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.” *Records reviewed verified that none of the four notifications of proposed suspension, which were issued, contained the impact of suspension or the right to request mediation or file an appeal. Additionally, the one notice of proposed revocation issued, did not contain the impact of revocation.* **Corrective action (April 2013):** UDA amended its adverse action notice templates based upon NOP training examples. UDA provided a copy of the amended Notice of Proposed Suspension. The amended notice template includes the required information. To prevent this noncompliance, UDA will use NOP model templates when issuing notices of noncompliances or adverse actions. **Compliance Assessment Verification (April 2014):** A review of the 2012 and 2013 Notice of Proposed Suspensions verified that the letters and template are in the correct format and include the impact of a suspension or revocation, as well as, the right to mediation.

Non-compliances Identified during the Current Assessment

NP4112ADA.NC1 – NOP §205.403(e)(1) states “At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector.” *A review of the 3 samples taken in 2013 found that no receipts were provided to the operation’s representatives at the time of sampling.*

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

A renewal assessment of the UDA organic program was conducted in August 2012, and as part of the terms of accreditation, UDA agreed to an additional audit to be conducted prior to the on-site mid-term assessment scheduled for 2014 or 2015. The NOP reviewed the auditor's report to assess UDA's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name:	Utah Department of Agriculture (UDA)
Physical Address:	350 North Redwood Rd., P.O. Box 146500, Salt Lake City, UT 84114
Mailing Address:	Same
Contact & Title:	Ron Larsen, Organic Program Manager
E-mail Address:	rlarsen@utah.gov
Phone Number:	801-538-7187
Auditor(s) and Reviewer(s):	Meg Kuhn, NOP Reviewer; Nikki Adams, On-site Auditor(s).
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	On-site assessment date: April 22, 2014 NOP Review date: May 19, 2014
Audit Identifier:	NP4112ADA
Action Required:	Yes
Audit and Review Type:	Compliance Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of UDA's certification system.
Audit and Determination Criteria:	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit and Review Scope:	Compliance assessment to review UDA's certification services in carrying out the audit criteria

ORGANIZATIONAL STRUCTURE:

The Utah Department of Agriculture and Food (UDAF) were accredited as a USDA National Organic Program (NOP) as a certifying agent on April 29, 2002 for crops, wild crops, livestock, and handling operations. The UDAF list of certified operations includes 52 certified operations, consisting of 25 crop operations, 0 wild crops, 3 livestock operation, and 24 handlers of which are 14 processors, 8 retailers, 3 distributor/retailer and 3 traders. There are no grower groups certified by UDAF. UDAF has certified operations in the state of Utah only.

The UDAF office is located in Salt Lake City, Utah, and all certification activities are finalized in this office. All staff are full-time employees based out of the Salt lake City office, and all also conduct other duties for UDAF in addition to their work for the organic certification program. The UDAF organic certification staff consists of: the Director of Plant Industry, the Organic Program Manager; the Organic Coordinator, a Financial Analyst/ Internal Auditor and 8 staff Organic Inspectors (5 are currently performing inspections and 3 are newly trained inspectors who have not yet performed inspections independently). There is one Deputy Commissioner; however, he only participates in the UDAF Organic Program to help in mediation requests (of which there have been none). The Program Manager and the Organic Coordinator also act as the Reviewers. There is no subcontracted staff.

GENERAL INFORMATION;

A renewal assessment of the UDAF organic program was conducted in August 2012, and found that the previous outstanding non-compliance corrective actions were not effectively implemented within the prescribed timeframe to demonstrate compliance to the USDA NOP Regulations. Subsequently, a Notice of Proposed Suspension was issued on April 1, 2013. UDAF filed an appeal the suspension to the AMS Administrator and submitted corrective actions on April 26, 2013. The NOP reviewed the corrective actions on May 6-14 and July 12-26, 2013. The corrective actions appeared to be adequate; therefore, the NOP withdrew the Proposed Suspension and UDAF subsequently withdrew their appeal. A Settlement Agreement was reached and signed on September 12, 2013, which stipulated that UDAF agree to an on-site assessment in 2013 or 2014 at UDAF's expense for one auditor for one day to determine if UDAF has effectively implemented the submitted corrective actions.

PERSONNEL/ TRAINING:

Staff qualifications are based on a combination of an education degree in agriculture, job duties or expertise in agriculture and/ or organic training. A review of staff, and interviews conducted, verified that all UDAF staff has adequate qualifications and has had recent organic training thru IOIA, NOP ACA and / or in-house trainings.

ADMINISTRATIVE RECORDS & PROCESSES:

UDAF has developed a Program Applicant Processing Tracking Sheet UDAF has developed a staff file checklist to track training of all staff. A review of the tracking form for 2013-2014, training documentation and interviews conducted, verified that annual training is being conducted and the NOP regulations are understood.

NOP DETERMINATION

NOP's review of UDA's onsite audit report was conducted. NOP has determined the following status of the prior noncompliance correction actions and the current identified noncompliances:

Non-compliances from Prior Assessments

NP9222BBA.NC4 – Cleared - NOP § 205.403(a)(1) states, “A certifying agent must conduct an initial on-site inspection of each... An on-site inspection shall be conducted annually thereafter for each certified operation...” *Two of the nine files reviewed showed that the certified operations did not have the inspections completed annually. The processor observed for the on-site inspection during the audit showed that the initial inspection was completed on April 10, 2007 and the next inspection was not conducted until the observation inspection for the on-site audit on August 13, 2009 (16 months past the annual inspection date). The file for one crop operation showed that the last inspection was completed on November 21, 2007 and the next annual inspection had not been completed as of August 13, 2009 (so far 8 ½ months past the annual inspection date).* **Corrective Action (10/2/09 & 12/02/09):** UDA has stated that an Excel spreadsheet will be used to track and ensure that operations have submitted applications and that the required audits are completed. An Excel Spreadsheet was submitted that showed the completion of the 2009 organic inspections by UDA. **Verification ((08/22 - 24/11)):** *UDA’s internal audit report shows that as many as eleven operations continuing with NOP certification in 2010 were not inspected. In addition, UDA’s 2011 inspection records were not available at the time of the assessment. Records showing inspection reports being reviewed and approved in 2010 and 2011 were missing from client files.* **Corrective Action (11/30/11 & 03/07/12):** The corrective actions adequately address the noncompliance. UDA’s corrective action indicated that all operations would be inspected before the end of 2011 or a notice of noncompliance would be sent to the operations. After the August 22 – 24, 2011 compliance assessment, UDA conducted annual inspections on the operations that had not been inspected in 2011. Two of the eleven operations voluntarily surrendered NOP certification. UDA’s new program manager will be responsible for ensuring all required inspections are conducted. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** *This finding remains outstanding because it has not been adequately implemented. Records reviewed verified there were four operations which had not been inspected in 2011 and no further action had been taken on the files. UDA stated two of the operations had verbally informed them they would surrender their certification. However, there was nothing in the files to indicate they had surrendered.* **Corrective action (April 2013):** UDA established and submitted its 2012 program applicant (annual update) processing tracking spreadsheet which showed that required 2012 inspections were conducted. Operations receiving suspensions, surrendering certification or withdrawing applications are also recorded on the spreadsheet. To prevent this non-compliance, staff will use the tracking spreadsheet to monitor progress on completing OSP reviews, assigning inspections and reviewing inspection reports. **Compliance Assessment Verification (April 2014):** A review of the Excel Spreadsheet, four client files and interviews conducted verified that all 2012 and 2013 inspections had been conducted. Interviews conducted verified that the Organic Coordinator and Program Manager are keeping track of all inspections and assuring they are being performed annually, as required.

NP9222BBA.NC5 – Cleared - NOP §205.403(c) Verification of information states, “The on-site inspection of an operation must verify: (1) The operation’s compliance or capability to comply with the Act and the regulations in this part; and (2) That the information, including the organic production or handling system plan... accurately reflects the practices used or to be used by the

applicant for certification or by the certified operation.” *Some of the records and portions of the operation were not reviewed during two of the inspection observations.*

- *The inspector did not review some of the records applicable to the operation during the crop inspection including the production, planting, and harvesting records.*
- *The inspector did not review some of the records during the livestock inspection including the purchase records for the baby chicks and the laying hen chicken mash feed. In addition, the inspector did not observe the beef slaughter stock animals or the pasture where they were located.*

Corrective Action (10/02/09 & 12/09/09): UDA submitted a letter to the auditors listing the deficient areas during the USDA Audit. UDA has a mandatory training/update meeting scheduled for March 4, 2010 to discuss these issues. **Verification (08/22 – 24/11):** *During the poultry operation on-site evaluation, the UDA inspector reported that the operation’s feed mill and the egg handling facility were not inspected during the 2011 organic inspection of the operation.* **Corrective Action (11/30/11):** The corrective actions adequately address the noncompliance. UDA scheduled training on March 22, 2012 for the purpose of updating inspection staff on NOP inspection requirements, including the inspection of all facilities and equipment used for implementing an operation’s OSP. A copy of the training agenda and a list of staff attending the training were included in the corrective actions. UDA’s OSP review report includes recording issues identified during inspection into the report for consideration during the certification decision. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** Based on the livestock witness inspection and all areas which were not reviewed and/or verified, this finding remains outstanding. During the livestock witness inspection, the inspector did not:

- Identify that paper used in pullet houses was not removed as indicated in the organic system plan (OSP). The OSP stated for the pullet house, paper is placed on plastic slats for 2-3 weeks until chicks are big enough to walk on the slats at which point the paper is removed. At the time of the witness inspection, the pullets were 3 ½ weeks old and there was still paper in place although very little was left. An interview with the farm manager verified that it was typical for the paper to remain 3 ½ weeks as was the case during the inspection and that he would have to update the OSP.
- Verify the source of the paper used in the pullet house.
- Verify the source of the wood shavings.
- Review the invoice for purchased chicks.
- Identify an issue with the operation not providing outdoor access until 16 weeks with a sound reasoning as opposed to basing outdoor access on production practices (see details under AIA082211RLP.NC2).
- Review records maintained concerning the times outdoor access is not provided to the birds; or identify an issue with no records maintained to verify the birds are given outdoor access for a minimum of four hours when they are provided access as stated in the OSP.
- Identify an issue with the operation not providing clean dry bedding to all birds, at all times, in all houses. Of the three laying houses visited, only one (the youngest birds) had sufficient clean dry bedding.

Corrective action (April 2013): UDA plans to select and train new inspectors on organic livestock inspections. UDA will submit these training records in their annual report to NOP. The livestock operations certified by UDA will be inspected during August/ September 2013.

UDA will require staff inspectors, including livestock inspectors, to attend annual organic inspection training. **Compliance Assessment Verification (April 2014):** A review of the 'Program Applicant Processing Tracking Sheet', two of three livestock client files and interviews conducted with the livestock inspectors verified that all areas are being reviewed during inspections. Training documentation for training conducted on May 22, 2013 and February 26, 2014 were reviewed.

NP9222BBA.NC9 – Cleared - NOP §205.501 (a)(7) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Have an annual program review of its certification activities conducted by the certifying agent’s staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any non-compliances with the Act and the regulations in this part that are identified in the evaluation.” The UDA Organic Program requires a management review by the Program Manager, Commissioner, and the Division Directors in which the internal audit report is reviewed. *The internal audit was started in April 2009 but not completed. The management review was not conducted or documented for 2008 or 2009.* **Corrective Action (10/02/09 & 12/02/09):** The completed internal audit report for 2009 was submitted. The review with UDA Management is scheduled to occur in January 2010. **Verification (08/22 -24/11):** *UDA conducted internal audits in 2009 and 2010. Results of the internal audits indicated that one exit interview was not conducted, inspection reports were sent to less than 50% of the certified operations, and that inspections did not occur for eleven certified operations in 2010. There was no record of a management review of the internal audit findings or corrective actions to address the noncompliances that were identified by the internal audits.* **Corrective Action (11/30/11):** The corrective actions adequately address the noncompliance. UDA has amended its procedures for management reporting. The agency’s internal auditor and organic program manager will develop internal audit reports for consideration by the UDA Plant Industry Division Director. Based upon findings described within these reports, corrective actions for nonconformities will be developed and implemented. The agency will also monitor implementation of the internal audit corrective actions. Verification of these corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** This finding remains outstanding. The internal audit which was conducted was based on forms required to be completed, being in the file; that appropriate fees were assessed and paid; and interviews with a director and an inspector to see if they understood their responsibilities within the program. One interview was conducted with the Director of Regulatory Services instead of the Director of Division of Plant Industry (DPI) who oversees the program. An interview with the internal auditor verified that he was not familiar with the Final Rule and had never reviewed it. No technical review was conducted on certification files and the scope of the audit did not include the certification activities of UDA. Also in an interview with the Director of DPI, he stated that the management review had been conducted and he may have recorded the date and time it took place in his planner and he would check. However, there was no objective evidence presented by the end of closing meeting to verify the management review had occurred. **Corrective actions (April 2013):** UDA provided a copy of the 2012 internal audit report on the organic program, which included more technical review of the organic program. Results from this report were presented at inspector training held in May 2013. A copy of a list of training items was provided. To prevent this noncompliance, UDA will continue increasing the internal audit scope to include more technical review and they will add more auditors to the internal audit

review. **Compliance Assessment Verification (April 2014):** The latest internal audit conducted January 22, 2014 was reviewed. The scope of the internal audit covered the certification process, training, and a review of client files. The internal audit results were found to be adequate. Training records were reviewed and there has been one new associate trained to the NOP requirements to perform internal audits. The internal audit will be now performed between the new internal auditor, Program Manager and the Organic Certifier. Interviews and the review of the latest internal audit, verified that no one is auditing their own work.

AIA082211RLP.NC1 - Cleared - NOP 205.501(a)(4) states, A private or governmental entity accredited as a certifying agent under this subpart must use a sufficient number of adequately trained personnel, including inspectors and certification review personnel, to comply with and implement the organic certification program established under the Act and the regulations in subpart E of this part. *UDA does not appear to have a sufficient number of trained personnel to comply with, and implement the organic certification program. Nine of thirteen UDA corrective actions submitted in response to noncompliances identified in audit report NP9222BBA were not effectively implemented. The OSP review and the inspection review process are not documented. Notices of noncompliance are not copied to the Administrator as required. Follow up on notices of noncompliance is not conducted or not conducted in a timely manner. Notices of Surrender are not issued when certified operations surrender their certification. Notices of Resolution are not issued when certified operations correct their noncompliances.* **Corrective Action (11/30/11 & 03/07/12):** The corrective actions adequately address the noncompliance. A new program manager has been hired to administer the organic program. UDA amended its program quality manual to include procedures on how UDA will ensure OSP reviews and inspection are effectively implemented, and how UDA will monitor and administer noncompliances identified during NOP certification activities. UDA established an organic program documentation checklist to monitor OSP reviews and inspection activities. Noncompliances or issues of concern resulting from OSP review or inspections will be recorded onto an excel spreadsheet. UDA's amended noncompliance procedures for certified operations include procedures on: submitting noncompliance notices to the administrator; monitoring noncompliances and assessing an operation's corrective actions on noncompliances; and providing notices of surrender or notices of noncompliance resolution. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** This finding remains outstanding. There was objective evidence to verify that notices of noncompliance along with other notifications of adverse actions and of noncompliance resolution were being submitted to the Administrator via emails; and that follow-up was being conducted by UDA. However, the finding remains outstanding because, of the 24 inspection reports returned to UDA, only 6 had been reviewed and had gone through the full certification process for 2012 (with 14 of the 24 returned the week of the renewal assessment). Since these corrective actions were approved as adequately addressed in March and April 2012; there is insufficient data to access implementation and effectiveness. The on-site audit indicates there may still be a problem for the staff assigned to review files, pre and post inspection because of other assignment responsibilities. **Corrective action (April 2013):** UDA provided a copy of its 2012 program applicant processing tracking sheet which indicated OSP reviews and inspections were conducted on 64 operations. Staff used the database to record when OSP reviews and inspections are conducted, when notices of noncompliance are issued, and when an operation's corrective actions were adequate and a Notice of Noncompliance Resolution was issued. In

2013, UDA will expand its applicant tracking system to include more information on inspection activities to reduce the time period committed to inspections. **Compliance Assessment Verification (April 2014):** A review of the 2012 and 2013 'Program Applicant Tracking Form', adverse action notices, and resolution notices verified that inspections are being performed annually and follow up, including adverse action notices, are being issued and copied to the Administrator as required. The tracking form is being utilized to track when inspections are being submitted for review, when adverse actions are taken, resolved, and when the certification process is complete. UDA has trained and is in the process of training additional staff, including inspectors, to have sufficient staff to effectively handle the client load.

AIA082211RLP.NC2 - Cleared - NOP 205.662(a) – when an inspection, review, or investigation of a certified operation by a certifying agent reveals any noncompliance with the Act or regulations, a written notification of noncompliance shall be sent to the certified operation. *UDA did not issue a notice of noncompliance to an organic operation for failure to provide outdoor access. UDA did not issue notices of noncompliance to organic operations for failure to submit 2010 annual OSP updates. A file of handling operation showed that it repeatedly violated the NOP regulations by not complying with the requirements for the availability of records (§ 205.103).* **Corrective Action (11/30/11 & 03/07/12):** The corrective actions adequately address the noncompliance. UDA amended its quality manual to indicate that UDA will implement noncompliance procedures described in NOP instruction (NOP 4002) published in the Program Handbook when noncompliances are identified during NOP certification activities. Section 4 of the amended UDA quality manual includes instruction on issuing notices of noncompliance when noncompliances are identified during NOP certification activities. UDA recently hired a new program manager to administer the UDA organic program. UDA has also restructured staff duties and responsibilities to provide additional resources to administering the organic program. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** This finding remains outstanding because it was not fully implemented. Four operations with no inspection conducted in 2011; acceptance of a livestock organic system plan for not granting access to the outdoors based on production practices; and labels and markings for egg cartons which were misleading, approved by UDA. A review of files verified none of these operations had been issued a notification of noncompliance.

(a) Concerning the operations: Records reviewed verified there were four operations which had not been inspected in 2011 with no further action taken by UDA. UDA stated two of the operations had verbally informed them they would surrender their certification. However, there was nothing in the files to indicate they had surrendered certification.

(b) Concerning access to outdoors:

1. The pullet house where the chicks are kept until they are 16 – 17 weeks old, did not have access to the outdoors.
2. The livestock operation's organic management guide states, "Laying Barn – ...Also, upon reaching peak production, the covered, screened area along the outside of the barn will be opened and accessible to the hens every day that the weather is reasonable for the hens to go outside (typically above freezing temperatures). The access doors to this outside area will be open for a minimum of four hours daily" and "Outdoor Run Procedures – When the hens reach 90 percent production, the outdoor run will be made available."

(c) Concerning labels:

1. Stencil on the underside of a dozen egg carton lid approved which stated, “Cage-Free 100% Organic Brown Eggs.” The eggs were labeled on the outside of the lid as “organic” which is the category they qualified for because of the non-organic processing aid used during production.
2. Two of the three approved labels included the locations of three “Production Ranches” in Idaho, Utah, and Washington which were utilized by the egg producer. The locations were listed under the name of the processor on one label and adjacent to it on the other. Under the locations was the “Certified Organic by...” statement; one label included the USDA seal and the ACA logo. Only the Utah location was certified by UDA and the other two were not certified at all.

Corrective action (April 2013): UDA will use its applicant processing tracking system and checklist to conduct NOP compliance reviews of new applicants, and of annual updates for operations continuing with NOP certification. UDA’s 2012 applicant processing checklist shows non-compliant operations were issued Notices of Noncompliance and Notices of Noncompliance Resolution after corrective actions were determined to resolve noncompliances. To prevent this noncompliance, UDA will establish an annual applicant processing tracking checklist to monitor certification activities including OSP reviews, inspections, Notices of Noncompliance and any adverse action events. **Compliance Assessment Verification (April 2014):** A review of the ‘*Applicant Processing Tracking*’ Spreadsheet, the ‘*Applicant Processing Checklist*’, four client files and interviews conducted verified that all 2012 and 2013 inspections have been conducted. The Organic Coordinator and Program Manager are keeping track of all inspections and assuring they are being performed annually and notices issued, when applicable.

AIA082211RLP.NC6 - Cleared - NOP 205.501(a)(5) states that certifiers ensure that certification staff have sufficient expertise in organic production or handling to successfully perform their duties. NOP 205.501(a)(1) states that certifiers must have sufficient expertise in organic production or handling to fully comply and implement the terms and conditions of the certification program established by the regulations.

- a) *UDA Personnel records were incomplete. Records for inspectors and reviewers were out-of-date and did not indicate any training on organic systems for several years. Inspection evaluations have not been conducted since 2008. Some files contained records on organic training, while other files did not have any records on organic training. A record of 2011 IOIA processor training was found that indicated UDA organic staff attending or completing the course.*
- b) *One inspector did not indicate that failure to provide outdoor access for a poultry operation was a violation of the organic regulations. One inspector failed to conduct an inspection of all of the organic facilities. Some inspection reports indicated short inspection time (1-2 hours) for large acreage farms. The crop inspection report template does not have a checkpoint for evaluating whether seeds are treated with prohibited substances.*

Corrective Action (11/30/11 & 03/07/12): The corrective actions adequately address the noncompliance. UDA corrective actions for (a) state that the Organic Program Manager will maintain program personnel records on qualifications, conflicts of interest, performance evaluations, and training. UDA established a personnel file checklist to monitor the status of program personnel records. UDA corrections actions for (b) state that annual training on NOP

requirements, including conducting thorough and complete inspections, will be provided to program staff, including inspectors. A copy of the UDA 2012 training agenda was included in the corrective actions. UDA's amended quality manual describes Inspector qualifications and responsibilities. In addition, UDA modified its organic crop inspection report template, section 3, to assess NOP regulation requirements for seeds. Verification of the corrective actions will be determined at the next on-site NOP accreditation assessment. **Renewal Assessment Finding (August 2012):** This finding remains outstanding because it has not been properly implemented. The livestock inspector for the witness inspection had no other training than that received by IOIA in 2001 and in house training conducted March 2012. The in house training covered the findings from the NOP August 2011 Compliance Assessment and inspection activities in general. Based on the livestock witness inspection results, this was inadequate for an inspector which only conducts one or two livestock inspections annually. **Corrective action (April 2013):** UDA has developed an organic staff file checklist to monitor conflicts of interest statements, staff evaluations, and training. A copy of the checklist was provided. In addition, copies of signed forms for organic program staff on 2013 conflict of interest statements, and 2012 staff performance evaluations were included in UDA's corrective actions. To prevent this noncompliance, under UDA's quality management system the organic program manager is assigned the responsibility of maintenance of organic program staff files. The manager will implement the staff file checklist to monitor conflicts of interest, staff evaluations and staff training. **Compliance Assessment Verification (April 2014):** A review of the staff file checklist from 2012 to 2014 and interview conducted with the Program Manager verified that the checklist is being utilized and annual training has been conducted. Additionally, interviews conducted with inspection staff verified that annual training is being conducted, including livestock training for qualified staff.

NP2226MMA.NC1 – Cleared - NOP §205.403(b)(2) states, “All on-site inspections must be conducted when an authorized representative of the operation who is knowledgeable about the operation is present and at a time when land, facilities, and activities that demonstrate the operation's compliance with or capability to comply with the applicable provisions of subpart C of this part can be observed...” *A review of files verified that the inspection for a crop and livestock operation was conducted in December when the crops could not be observed.*

Corrective action (April 2013): UDA's 2012 applicant processing checklist processing checklist indicates 2012 inspections were conducted when an operation's land, facilities, and practices would demonstrate compliance with the NOP regulations. UDA conducted its last 2012 crop inspection during the first week of October 2012. To prevent this noncompliance, UDA's Organic Program Manager will implement the applicant processing checklist to assign reviews and inspections in a timely manner. **Compliance Assessment Verification (April 2014):** A review of the 'Applicant Processing' checklist, four client files and interviews conducted verified that all 2012 and 2013 inspections had been conducted, and the 2014 inspections had been assigned and are in the process of being scheduled. Interviews conducted verified that the Organic Coordinator and Program Manager are keeping track of all inspections and assuring they are being performed annually as required.

NP2226MMA.NC2 – Cleared - NOP §205.403(d) states, “The inspector must conduct an exit interview with an authorized representative of the operation who is knowledgeable about the inspected operation to confirm the accuracy and completeness of inspection observations and

information gathered during the on-site inspection. The inspector must also address the need for any additional information as well as any issues of concern.” *There was no exit interview conducted after the livestock witness inspection. The inspector completed the exit interview form and the client signed the form; however, an exit interview was not conducted.* **Corrective action (April 2013):** In 2013, UDA will select new inspectors for use in conducting livestock inspections. The new inspectors will receive external training on conducting livestock inspections. In May 2013, UDA provided internal training to staff inspectors. Procedures for conducting exit interviews were provided at this training. To prevent this noncompliance, beginning in 2014, UDA will include field observations as part of inspector performance evaluations. **Compliance Assessment Verification (April 2014):** UDA has trained four new inspectors for the organic program. One inspector is in their second year and the other three are in the process of performing inspection shadow observations and thus are not qualified yet. Training documentation for May 22, 2013 and February 26, 2014 were reviewed. Interviews conducted with various inspection staff verified the training scope provided and the NOP regulations are understood.

NP2226MMA.NC3 – Cleared - NOP §205.501(a)(6) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services.” *There was no annual performance evaluation conducted for the Director of Plant Industry since 2010.* **Corrective action (April 2013):** UDA provided copies of 2012 performance evaluations of program reviewers and inspectors. To prevent this noncompliance, under UDA’s quality management system the organic program manager is assigned the responsibility of maintenance of organic program staff files. The manager will implement the staff file checklist to monitor conflicts of interest, staff evaluations and staff training. **Compliance Assessment Verification (April 2014):** A review of the staff file checklist for 2013 and 2014 and an interview conducted with the Program Manager verified that the checklist is being utilized and annual performance evaluations have been conducted, including the Director of Plant Industry.

NP2226MMA.NC4 – Cleared - NOP §205.501(a)(18) states, “A private or governmental entity accredited as a certifying agent under this subpart must: Provide the inspector, prior to each on-site inspection, with previous on-site inspection reports and notify the inspector of its decision regarding certification of the production or handling operation site inspected by the inspector and of any requirements for the correction of minor noncompliances.” *Interviews conducted verified inspectors were not being notified of UDA’s decision regarding certification of the operation inspected by the inspector and any requirements for the correction of minor noncompliances.* **Corrective action (April 2013):** In 2012, UDA implemented procedures to provide notice to staff inspectors on certification decisions, noncompliance resolutions and adverse action notifications. UDA provided copies of notice amended notice templates which require inspectors to receive copy of notices. To prevent this noncompliance, UDA will implement its quality manual instruction to provide notice to inspectors on certification decisions, noncompliance resolutions and adverse action notifications. **Compliance Assessment Verification (April 2014):** A review of the UDA Quality Manual verified that page 41, section

4.1, Process Enforcement Action states that the inspector will be informed of all notices and certification decisions. A review of notices, certification decisions, as well as, interviews conducted with inspectors verified that the inspectors are being cc'd on notifications and decisions.

NP2226MMA.NC5 – Cleared - NOP §205.662(c)(3)- (4) states, “The notification of proposed suspension or revocation of certification shall state: (3) The impact of a suspension or revocation on future eligibility for certification; and (4) The right to request mediation pursuant to §205.663 or to file an appeal pursuant to §205.681.” *Records reviewed verified that none of the four notifications of proposed suspension, which were issued, contained the impact of suspension or the right to request mediation or file an appeal. Additionally, the one notice of proposed revocation issued, did not contain the impact of revocation.* **Corrective action (April 2013):** UDA amended its adverse action notice templates based upon NOP training examples. UDA provided a copy of the amended Notice of Proposed Suspension. The amended notice template includes the required information. To prevent this noncompliance, UDA will use NOP model templates when issuing notices of noncompliances or adverse actions. **Compliance Assessment Verification (April 2014):** A review of the 2012 and 2013 Notice of Proposed Suspensions verified that the letters and template are in the correct format and include the impact of a suspension or revocation, as well as, the right to mediation.

Non-compliances Identified during the Current Assessment

NP4112ADA.NC1 – NOP §205.403(e)(1) states “At the time of the inspection, the inspector shall provide the operation’s authorized representative with a receipt for any samples taken by the inspector.” *A review of the 3 samples taken in 2013 found that no receipts were provided to the operation’s representatives at the time of sampling.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Ron Larsen
Utah Department of Agriculture
350 N. Redwood Rd.
P.O. Box 146500
Salt Lake City, UT 84114

Dear Mr. Larsen:

On April 22, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a Compliance Assessment of the Utah Department of Agriculture (UDA) organic certification program. The objective of the assessment was to determine UDA's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4112ADA, is enclosed for your reference.

As the report indicates, eleven (11) noncompliances, NP9222BBA.NC4, NC5, NC9; AIA082211RLP.NC1, NC2, NC6; and NP2226MMA.NC1 through NC5, were cleared from your previous audits. One new noncompliance, NP4112ADA.NC1 was identified during the assessment. Please submit proposed corrective actions for the noncompliance cited to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the UDA's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Renee Mann, at (202) 260-8635 or Renee.Mann@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

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JUN 19 2014

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As the report indicates, eleven (11) noncompliances, NP9222BBA.NC4, NC5, NC9; AIA082211RLP.NC1, NC2, NC6; and NP2226MMA.NC1 through NC5, were cleared from your previous audits. One new noncompliance, NP4112ADA.NC1 was identified during the assessment. Please submit proposed corrective actions for the noncompliance cited to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the UDA's management system will be modified to prevent future noncompliances.

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If you have questions regarding this notice, please contact your Accreditation Manager, Renee Mann, at (202) 260-8635 or Renee.Mann@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Utah Department of Agriculture and Food (UDAF) organic program was conducted on October 6-10, 2014. The National Organic Program (NOP) reviewed the auditor's report to assess UDAF's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Utah Department of Agriculture and Food (UDAF)
Physical Address	350 N Redwood Road, Salt Lake City, UT 84114-6500
Mailing Address	P.O. Box 146500, Salt Lake City, UT 84114-6500
Contact & Title	Robert Hougaard, Director Plant Industry Ronald Larsen, Organic Program Manager
E-mail Address	rhougaard@utah.gov rlarsen@utah.gov
Phone Number	801-538-7180 801-538-7187
Reviewer & Auditor	Penny Zuck, NOP Reviewer Corey Gilbert, Onsite Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action review: May 27, 2015 NOP assessment review: April 6, 2015 Onsite audit: October 6-10, 2014
Audit Identifier	NP4279ZZA
Action Required	None
Audit & Review Type	Mid-Term (12.5 year) Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of UDAF's certification system.
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	UDAF's certification services in carrying out the audit criteria.

The Utah Department of Agriculture and Food (UDAF) is a non-profit department within the Utah State government and was accredited as a certifier for the U.S. organic regulations on April 29, 2002 for the scopes of crop, wild crop, livestock, and handling. The UDAF list of certified operations had 51 certified operations including 25 crop, 0 wild crop, 3 livestock, and 24 handlers (14 processors, 3 distributors, 3 traders, and 8 retailers). All certified operations are located in Utah. UDAF does not certify grower groups. The UDAF main office is in Salt Lake

City, Utah, and all certification activities are finalized in this office.

The UDAF organic certification program is located with the Division of Plant Industry and Conservation. The Commissioner oversees the entire department and a Deputy Commissioner oversees the Division; however, the Commissioner is not directly involved in organic certification and the Deputy Commissioner is only involved if there is a mediation request. The UDAF organic certification staff consists of the Director of Plant Industry and Conservation, the Deputy Director, the Organic Program Manager, the Organic Program Coordinator, a financial analyst/internal auditor, and 5 Organic Inspectors. The organic inspectors conduct state inspections for a variety of programs other than organic. UDAF does not use any subcontracted employees.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether UDAF's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP4112ADA.NC1 – Cleared

Non-compliances Identified during the Current Assessment

Any noncompliance labeled as "**Accepted**," indicates that the corrective actions for the noncompliance are accepted by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4279ZZA.NC1 – Accepted - 7 CFR §205.406(c) states, "If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662. 7 CFR §205.105(d) states, "To be sold or labeled as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))," the product must be produced and handled without the use of (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in §205.606." 7 CFR §205.606 does not list stevia; therefore, as an agricultural product stevia must be certified organic.

Comments: *UDAF approved an organic product profile and organic label and added the product to the operation's certificate addendum in July 2014 for a protein mix containing non-*

organic stevia (0.03%). All the remaining agricultural products were certified organic. The annual certification process had not yet been completed for the operation and UDAF did not believe the product had been produced.

Corrective Action: UDAF submitted copies of the Notice of Noncompliance issued to the client for the use of non-organic ingredients in an organic product and a copy of the Noncompliance Resolution letter verifying the client corrected the noncompliance. UDAF also submitted their revised Quality Manual with the addition of a product formulation and label review section, a label review worksheet for the reviewer to follow, and stamps that will be used to stamp “approved” or “denied” on product profiles and labels along with the date and initials of the reviewer. UDAF will include this topic in a future training for the field staff.

NP4279ZZA.NC2 – Accepted - 7 CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.” 7 CFR §205.504(b)(1) states a certifying agent must submit, “A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates.”

Comments: *Utah Department of Agriculture and Foods’ label review procedure is inadequate and does not address the identification of the label approval status (approved/unapproved, date of decision, name of decision maker).*

Corrective Action: UDAF submitted their revised Quality Manual with the addition of a product formulation and label review section, a label review worksheet, and stamps that will be used to stamp “approved” or “denied” on product profiles and labels along with the date and initials of the reviewer.

NP4279ZZA.NC3 – Accepted - 7 CFR §205.662(c)(2)(3) requires the notification of proposed suspension to state, “(2) The proposed effective date of such suspension and (3) The impact of a suspension on future eligibility for certification” (see §205.662(f)).

Comments: *UDAF issued a notice of proposed suspension on October 10, 2014, which did not state the effective date of the suspension and did not include the impact of proposed suspension on future eligibility. Instead of identifying the effective date of suspension, the notification stated, “if we do not receive your written response to this matter by November 10, 2014 (30 days) we will propose to the NOP that your certification be suspended.”*

Corrective Action: UDAF submitted the template that will be used for future Notices of Proposed Suspension. The template includes the proposed effective date of suspension and the impact of suspension on future eligibility for certification.



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NOTICE OF NONCOMPLIANCE

Mr. Robert Hougaard
Utah Department of Agriculture and Food
P.O. Box 146500
Salt Lake City, UT 84114-6500

Dear Mr. Hougaard:

On October 6-10, 2014 a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Utah Department of Agriculture and Food (UDAF) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On April 6, 2015, the NOP reviewed the results of the onsite audit to determine UDAF's compliance to the USDA organic regulations. A copy of the assessment report, NP4279ZZA is enclosed for your reference.

As the report indicates, one corrective action for prior noncompliance NP4122ADA.NC1 was cleared and determined to be implemented and effective. There are no outstanding noncompliances from your previous audit. Three new noncompliances, NP4279ZZA.NC1 through NP4279ZZA.NC3, were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the UDAF's management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renee Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

APR 14 2015

Mr. Robert Hougaard
Utah Department of Agriculture and Food
P.O. Box 146500
Salt Lake City, UT 84114-6500

Dear Mr. Hougaard:

On October 6-10, 2014 a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Utah Department of Agriculture and Food (UDAF) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On April 6, 2015, the NOP reviewed the results of the onsite audit to determine UDAF's compliance to the USDA organic regulations. A copy of the assessment report, NP4279ZZA is enclosed for your reference.

As the report indicates, one corrective action for prior noncompliance NP4122ADA.NC1 was cleared and determined to be implemented and effective. There are no outstanding noncompliances from your previous audit. Three new noncompliances, NP4279ZZA.NC1 through NP4279ZZA.NC3, were findings identified during the onsite audit and determined to be noncompliances. Please submit proposed corrective actions for all noncompliances to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the UDAF's management system will be modified to prevent future noncompliances.

Please refer to NOP 2608, Responding to Noncompliances, for further instructions on how to respond to noncompliances. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation.

If you have questions regarding this notice, please contact your Accreditation Manager, Renee Gebault King, at (202) 690-1312 or ReneeA.GebaultKing@ams.usda.gov.

Sincerely,

A handwritten signature in cursive script that reads "Cheri Courtney".

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: AIA Inbox

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Utah Department of Agriculture and Food (UDAF) organic program was conducted on October 6-10, 2014. The National Organic Program (NOP) reviewed the auditor's report to assess UDAF's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Utah Department of Agriculture and Food (UDAF)
Physical Address	350 N Redwood Road, Salt Lake City, UT 84114-6500
Mailing Address	P.O. Box 146500, Salt Lake City, UT 84114-6500
Contact & Title	Robert Hougaard, Director Plant Industry Ronald Larsen, Organic Program Manager
E-mail Address	rhougaard@utah.gov rlarsen@utah.gov
Phone Number	801-538-7180; 801-538-7187
Reviewer(s) & Auditor(s)	Penny Zuck, NOP Reviewer; Corey Gilbert, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: April 6, 2015 Onsite audit: October 6-10, 2014
Audit Identifier	NP4279ZZA
Action Required	Yes
Audit & Review Type	Mid-Term (12.5 year) Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of UDAF's certification
Audit & Determination Criteria	<i>7 CFR Part 205, National Organic Program as amended</i>
Audit & Review Scope	Assessment of UDAF's certification services in carrying out the audit criteria.

ORGANIZATIONAL STRUCTURE:

The Utah Department of Agriculture and Food (UDAF) is a non-profit department within the Utah State government and was accredited as a certifier for the U.S. organic regulations on April 29, 2002 for the scopes of crop, wild crop, livestock, and handling. The UDAF list of certified operations had 51 certified operations including 25 crop, 0 wild crop, 3 livestock, and 24 handlers (14 processors, 3 distributors, 3 traders, and 8 retailers). All certified operations are located in Utah. UDAF does not certify grower groups. The UDAF main office is in Salt Lake City, Utah, and all certification activities are finalized in this office.

The UDAF organic certification program is located with the Division of Plant Industry and Conservation. The Commissioner oversees the entire department and a Deputy Commissioner oversees the Division; however, the Commissioner is not directly involved in organic certification and the Deputy Commissioner is only involved if there is a mediation request (none to-date). The UDAF organic certification staff consists of the Director of Plant Industry and Conservation, the Deputy Director, the Organic Program Manager, the Organic Program Coordinator, a financial analyst/internal auditor, and 5 Organic Inspectors. Three additional staff members are undergoing training as organic inspectors, but they have not completed their training and none had conducted any inspections. The Organic Program Manager and Organic Program Coordinator are dedicated primarily to organic certification. The organic inspectors conduct state inspections for a variety of programs other than organic. UDAF does not use any subcontracted employees. A review of personnel files and interviews conducted verified the organic certification staff had sufficient experience, training, and education in agriculture, organic production (crop and livestock) and handling. UDAF conducts annual performance evaluations of all staff and all were satisfactory. A review of training records indicated the organic certification staff had received current training on the U.S. organic regulations.

CERTIFICATION PROCESS:

Requests for certification are received by phone and email and initial correspondence is handled by the Organic Coordinator or Organic Program Manager. Interested applicants are emailed or mailed an organic application packet containing the fee schedule, scope specific application form, scope specific OSP template, and links to the U.S. organic regulations, NOP website, and NOP Program Handbook. After all required information is submitted, the Organic Coordinator or an assigned reviewer determines if the applicant appears to comply and is ready for inspection. The Organic Coordinator assigns the inspector based on qualifications, location, and availability. The inspector is provided the complete organic system/handling plan, conducts the inspection, and submits a completed inspection checklist/report and exit interview document. The final review and certification decision is made by the Organic Program Manager. In all cases, the person making the certification decision is different than the inspector. The operation is issued the approved inspection report, notification of minor issues or notice of noncompliance, notification of noncompliance resolution, and a certificate as applicable.

An annual update reminder is sent to all certified operations sixty days prior to their annual renewal date, and they are all required to submit an annual update form along with any changes to their organic system/handling plan and supporting documentation. The Organic Coordinator conducts the annual update review or assigns it to qualified reviewer/inspector. The inspection is completed by the assigned inspector, report submitted, and the final review and certification decision made by the Organic Program Manager. The approved inspection report and updated certificate are issued to the certified operation.

The Organic Coordinator is the primary person conducting material reviews with the Organic Program Manager assisting when necessary. The applicant or certified operation must submit a product profile, description of intended use, and all supporting documentation for review and approval prior to use. UDAF utilizes U.S. organic regulations, the OMRI list, and WSDA list to determine the acceptance of materials.

The Organic Coordinator reviews the labels and product profile forms submitted by the applicant or certified operation to determine compliance.

UDAF is operating in compliance to the U.S.-Canada Organic Equivalency Arrangement. UDAF has not conducted any activities relevant to the other international agreements.

ADMINISTRATIVE RECORDS AND PROCESSES:

UDAF has an Organic Certification Quality Manual, application forms, template OSPs, inspection checklists, review and certification decision checklists, annual update form, and numerous templates for notifications to applicants and certified operations.

UDAF conducts an annual internal audit/program review and implements corrective actions based on the findings. UDAF conducts annual organic training for all staff and the Organic Program Manager and/or Organic Coordinator attend annual external training on the U.S. organic regulations.

UDAF conducted sample testing on three operations in 2013 and 2014 which met the minimum of 5% of their certified operations for these years.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED:

The assessment included a witness audit of the annual inspection of certified crop and livestock operation located in Mendon, UT. The operation was a dairy with a small flock of chickens for egg production. The operation had adequate pasture to meet the Pasture Practice Standard with a six month grazing season. They also produced grains and peas. The inspection was conducted by a UDAF staff inspector. The inspector was knowledgeable and qualified. The inspection covered all required areas including an exit interview.

The assessment also included a review audit at a certified crop operation in Kaysville, UT. The operation included a small orchard and designated fields for vegetable and grain production. The OSP accurately reflected the operation's activities. A review of the previous inspection report verified the inspector had thoroughly reviewed all areas. The review audit verified compliance to the U.S. organic regulations.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether UDAF's corrective actions adequately addressed previous noncompliances. The NOP also reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to UDAF.

Noncompliances from Prior Assessments – Cleared

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

NP4112ADA.NC1 – Cleared – 7 CFR 205.403(e)(1) states “At the time of the inspection, the inspector shall provide the operation's authorized representative with a receipt for any samples taken by the inspector.” *A review of the 3 samples taken in 2013 found that no receipts were provided to the operation's representatives at the time of sampling.*

Corrective Action: The UDAF submitted an updated Quality Manual describing their new procedure that states a receipt, signed by both the client and the inspector, shall be issued at the time of sample collection, with a receipt copy provided to the client. An updated receipt form was also provided, illustrating the two signatories required on the form.

Verification of Corrective Action (October 2014): The records reviewed for samples taken at three different certified operations verified a copy of the Receipt of Sample form signed by the inspector and operation representative was provided to the client.

There are no **Outstanding** noncompliances from previous audits.

Noncompliances Identified during the Current Assessment

NP4279ZZA.NC1 – 7 CFR §205.406(c) states, “If the certifying agent has reason to believe, based on the on-site inspection and a review of the information specified in §205.404, that a certified operation is not complying with the requirements of the Act and the regulations in this part, the certifying agent shall provide a written notification of noncompliance to the operation in accordance with §205.662. 7 CFR §205.105(d) states, “To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in §205.606.” 7 CFR §205.606 does not list stevia; therefore, as an agricultural product stevia must be certified organic.

Comments: *UDAF approved an organic product profile and organic label and added the product to the operation’s certificate addendum in July 2014 for a protein mix containing non-organic stevia (0.03%). All the remaining agricultural products were certified organic. The annual certification process had not yet been completed for the operation and UDAF did not believe the product had been produced.*

NP4279ZZA.NC2 – 7 CFR §205.501(a)(3) states, “A private or governmental entity accredited as a certifying agent under this subpart must: carry out the provisions of the Act and the regulations in this part, including the provisions of §§205.402 through 205.406 and §205.670.” 7 CFR §205.504(b)(1) states a certifying agent must submit, “A copy of the procedures to be used to evaluate certification applicants, make certification decisions, and issue certification certificates.”

Comments: *Utah Department of Agriculture and Foods’ label review procedure is inadequate and does not address the identification of the label approval status (approved/unapproved, date of decision, name of decision maker).*

NP4279ZZA.NC3 – 7 CFR §205.662(c)(2)(3) requires the notification of proposed suspension to state, “(2) The proposed effective date of such suspension and (3) The impact of a suspension on future eligibility for certification” (see §205.662(f)).

Comments: *UDAF issued a notice of proposed suspension on October 10, 2014, which did not state the effective date of the suspension and did not include the impact of proposed suspension on future eligibility. Instead of identifying the effective date of suspension, the notification stated, “if we do not receive your written response to this matter by November 10, 2014 (30 days) we will propose to the NOP that your certification be suspended.”*

Audit Report Review Chronology Log

Audit Identifier: NP4279ZZA

Audit Type: Mid-Term (12.5 year) Assessment

Accredited Certifying Agent Name: Utah Department of Agriculture and Food (UDAF)

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
4/3/15	RM assigned audit assessment review to PZ
4/6/15	<p>PZ reviewed audit assessment checklist, witness audit checklists, and previous CA report.</p> <ol style="list-style-type: none"> 1. UDA was the acronym assigned by NOP in the case that TM-11s were issued for export but this has not occurred. Discussed with RM how to go about changing the acronym in the NOP system to UDAF. Discovered it was already changed on the list of certifiers on the website and in the AIA database. It just wasn't changed in the P drive. I changed the folder name to UDAF on the P drive. 2. Finding 1 - 205.662(a): non-organic stevia is used in an organic product. Agricultural products must be organic. This was not identified as a non-compliance on client's certification review and a NoNC was not issued to the operation. 3. UDAF capped the maximum number of certified producers at 52 – 205.501(a)(19) "certify all qualified applicants, to the extent of its administrative capacity". Discussed with RM about whether this is an acceptable practice. She recommended discussing it with other AMs to see if they have come across this with other certifiers. It's believed to be compliant. 4. Finding 2 – 205.501(a)(3): label review procedure inadequate because it does not address the identification of the label approval status (approved/unapproved, date of decision, name of decision maker). 5. Finding 3 – 205.662(c)(1): NOPS did not include the proposed effective date of suspension nor the impact of a suspension on the future eligibility for certification. <p>All (one) previous noncompliance was corrected and verified at the audit – Cleared.</p> <p>Processed NoNC Report with 3 noncompliances as a result of 3 verified findings in the audit report.</p>
4/7/15	Processed NoNC letter
5/8/15	UDAF responded to NoNC with corrective actions

5/21/15	PZ reviewed the corrective actions. 2 out of the 3 corrective actions were accepted. Emailed Ron at UDAF for additional information and documentation in response to NP4279ZZA.NC1
5/27/15	<p>Ron emailed a response with additional documentation in response to NP4279ZZA.NC1.</p> <p>The documentation included copies of the Notice of Noncompliance issued to the client who used non-organic stevia in an organic processed product, and a copy of the notice of noncompliance resolution verifying the client corrected the noncompliance.</p> <p>Processed the Corrective Action Report, and NoNC Resolution letter and emailed to RM for review.</p>
5/29/15	PZ made changes per RM edits. Printed NoNC resolution letter and CA report for CC review and approval.
6/3/15	PZ emailed NoNC resolution letter and CA report to UDAF via Rpost.

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

On August 15, 2013, Vermont Organic Farmers, LLC (VOF) and the United States Department of Agriculture (USDA), Agricultural Marketing Service, National Organic Program NOP signed a settlement agreement to resolve a Notice of Proposed Suspension for allowing organic processing activities to occur at uncertified facilities. The responsible party for one of these facilities had been revoked. The April 10, 2014 onsite compliance audit verified VOF's corrective actions through certification file reviews; a review of VOF's policies relating to NOP 4009, *Who Needs to be Certified*; and a witness audit.

GENERAL INFORMATION

Applicant Name:	Vermont Organic Farmers (VOF)
Physical Address:	14 Pleasant St.
Mailing Address:	14 Pleasant St.
Contact & Title:	Richmond, VT 05477
E-mail Address:	Nicole@nofavt.org
Phone Number:	802-434-3821
Auditor(s) and Reviewer (s):	Betsy Rakola, NOP Reviewer; Betsy Rakola, On-site Auditor; Renee Mann, Observer.
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	June 30, 2014: noncompliances identified
Audit Identifier:	NP4100BJR
Action Required:	Yes: corrective actions requested.
Audit and Review Type:	Compliance Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of VOF's certification system.
Audit and Determination Criteria:	Corrective actions submitted August 15, 2013, as related to <i>7 CFR Part 205, National Organic Program as amended</i> .
Audit and Review Scope:	VOF's certification services in carrying out the audit criteria during the period: August 15, 2013 – April 10, 2014.

VOF is a not for profit, Limited Liability Company, which was first accredited by the NOP on September 24, 2002 for crops, wild crops, livestock, and handling operations. VOF currently has 583 certified clients, which include 235 livestock, 525 crops, and 186 handling operations certified to the USDA organic regulations. 233 operations are certified for both crops and livestock. There were no certified wild crop operations at the time of the audit. The majority of clients are certified in the state of Vermont, with additional clients certified in

Massachusetts, New Hampshire, and New York.

Personnel

The VOF certification staff consists of the certification administrator (coordinator), a certification staff assistant, 3 certification specialists, 16 contract inspectors, and a 6 member review committee.

VOF also has an executive committee which consists of 3 non-certified constituents. The responsibility of the executive committee is to review the budget, review administrative policy changes, oversee personnel and wage issues, and review audit reports, complaint files and quality systems.

Summary of Witness Inspections and Review Audits Conducted:

The NOP conducted a witness audit of a maple syrup processor in Websterville, Vermont. The inspector demonstrated a thorough understanding of the regulations and verified the organic status of all ingredients, the compliance of all labels, and the adequacy of private label agreements. The operation demonstrated compliance with the organic regulations.

NOP DETERMINATION

NOP's review of VOF's onsite audit report was conducted. NOP has determined the following status of the prior noncompliance correction actions, and the current identified noncompliances.

Non-compliances issued prior to this audit – Cleared

Settlement clause 5.b: Cleared. *VOF [must have] policies and procedures, and [must have] conducted associated staff training, to ensure that responsible persons associated with suspended or revoked operations are not certified, in accordance with §205.504(a)(4), §205.402(a)(2), and §205.662(f)(2).*

VOF's Corrective Action: VOF proposed to change the language of its 2014 applications to add a question asking its applicants if a responsibly connected person to an operation had applied for organic certification in the past. The 2014 application will also request more detailed business information (names of responsible parties) from each company. VOF also proposed to add language to the inspection report regarding responsibly connected persons. Both documents were submitted to the NOP for review. On November 19, 2013, VOF issued a memo to its staff regarding these changes. VOF trained its staff on this topic at its staff meeting on December 17, 2013.

2014 onsite verification: VOF provided a copy of their OSP cover page, which asked about the names of the owners or partners of an operation in order to identify responsibly connected parties. The OSP also asks whether any responsibly connected parties have been suspended or revoked. Currently, most VOF clients are located in the state of Vermont, and nearly all Vermont operations are certified by VOF, so VOF has the ability to search its client database for previous revocations and suspensions by both operations and responsible parties. Staff demonstrated good knowledge of the updated policies during interviews.

Non-compliances issued prior to this audit –Remain Outstanding

Settlement clause 5.a: Outstanding (see findings below). *VOF [must have] policies and procedures, and [must have] conducted associated staff training, to ensure that all operations handling product “intended to be sold, labeled, and/or represented as organic” are certified, not just reviewed and inspected, in accordance with § 205.50 (a)(4) and §205.100.*

VOF’s Corrective Action: VOF revised its Certification Guidelines to state that “All specified portions of an operation must be certified. For example, co-packing facilities must apply for certification independent of the brand owner that uses the facility.” VOF submitted a draft of the new guidelines with its corrective actions. VOF also submitted an email with an attached memo, informing its staff of the new policy. VOF discussed the new memo with its staff at its July 29, 2013, staff meeting. VOF identified four uncertified co-packing operations that it had approved to process products for its certified clients and issued letters to these operations, instructing each to become certified if it wished to continue processing organic products. All four operations obtained certification from VOF by September 12, 2013.

2014 onsite verification: All operations which are inspected are now certified independently. The NOP reviewed the files of all the operations identified in the original settlement agreement, as well as two additional files, to ensure that they were certified. VOF had evidence of providing new guidance to its operations and its inspectors on policies related to NOP 4009, “*Who Needs to be Certified.*” However, VOF’s internal policies on processor and handler certification remain unclear and did not demonstrate full compliance with the USDA organic regulations, as described in the findings below.

Non-compliances identified during current audit

NP4100BJR.NC1. §205.501(a)(10) states, “A private or governmental entity accredited as a certifying agent under this subpart must: maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in §205.504(b)(5);” *VOF’s policy on processor and handler certification includes the statement, “If issues arise pertaining to production, batch records, co-mingling, etc., should this be written up to the handler or is a second letter written to the processor?” Staff stated that they had not yet determined whether one or both parties should receive a notice of noncompliance. Sharing noncompliance information with a third party would violate confidentiality requirements.*

NP4100BJR.NC2. §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.” *VOF’s policy on “Who Must Be Certified” does not clearly define their policies for certifying processors who conduct certification for certified brand owners. The policy did not define who the responsible party would be, when an audit would be conducted and/or who would receive a notice of noncompliance. The policy stated that, during the inspection of a processing facility, the inspector would not conduct any type of audit.*

NP4100BJR.NC3. §205.403 (a)(1) states, “A certifying agent must conduct an initial on-site inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested.” *VOF is currently conducting an inspection at the processor’s site, in order to issue an inspection to a handler. VOF does not always conduct an additional inspection at the handler’s site (also known as the brand owner), since the processing activities do not occur there. Instead, they do a desk audit to verify organic ingredients, product profiles, and labels, and they verify processing activities during the onsite inspection of the processing facility.*



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Nicole Dehne
Certification Administrator
Vermont Organic Farmers (VOF)
14 Pleasant St.
Richmond, VT 05477
Nicole@nofavt.org

Dear Ms. Dehne:

On April 10, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a Compliance Assessment of the Vermont Organic Farmers (VOF) organic certification program. The objective of the assessment was to determine VOF's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4100BJR, is enclosed for your reference.

As the report indicates, three noncompliances NP4100BJR.NC1 - NP4100BJR.NC3, were identified during the assessment. One noncompliance, Settlement clause 5.a, remains outstanding from your previous audit. Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the VOF management system will be modified to prevent future noncompliances.

Please refer to [NOP 2608, Responding to Noncompliances](#), for further instructions. Failure to promptly resolve outstanding noncompliances may result in proposed suspension or revocation of your USDA organic accreditation. Your proposed corrective actions and reports of any progress to date in implementing the proposed actions must be submitted electronically to AIAInbox@ams.usda.gov.

If you have questions regarding this notice, please contact your Accreditation Manager, Betsy Rakola, at (202) 260-8209 or Betsy.Rakola@ams.usda.gov.

Sincerely,

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division



1400 Independence Avenue, SW.
Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

JUL 7 2014

Nicole Dehne
Certification Administrator
Vermont Organic Farmers (VOF)
14 Pleasant St.
Richmond, VT 05477
Nicole@nofavt.org

Dear Ms. Dehne:

On April 10, 2014, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a Compliance Assessment of the Vermont Organic Farmers (VOF) organic certification program. The objective of the assessment was to determine VOF's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4100BJR, is enclosed for your reference.

As the report indicates, three noncompliances NP4100BJR.NC1 - NP4100BJR.NC3, were identified during the assessment. One noncompliance, Settlement clause 5.a, remains outstanding from your previous audit. Please submit proposed corrective actions for all noncompliances to AIAInbox@ams.usda.gov within 30 days from the date of this Notice indicating how the noncompliance will be corrected. The proposed corrective actions must also indicate how the VOF management system will be modified to prevent future noncompliances.

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If you have questions regarding this notice, please contact your Accreditation Manager, Betsy Rakola, at (202) 260-8209 or Betsy.Rakola@ams.usda.gov.

Sincerely,

A handwritten signature in blue ink that reads "Betsy Rakola for CC". The signature is written in a cursive style.

Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

On August 15, 2013, Vermont Organic Farmers, LLC (VOF) and the United States Department of Agriculture (USDA), Agricultural Marketing Service, National Organic Program NOP signed a settlement agreement to resolve a Notice of Proposed Suspension for allowing organic processing activities to occur at uncertified facilities. The responsible party for one of these facilities had been revoked. The April 10, 2014 onsite compliance assessment verified VOF's corrective actions through certification file reviews; a review of VOF's policies relating to NOP 4009, *Who Needs to be Certified*; and a witness audit.

GENERAL INFORMATION

Applicant Name	Vermont Organic Farmers (VOF)
Physical Address	14 Pleasant St.
Mailing Address	14 Pleasant St.
Contact & Title	Richmond, VT 05477
E-mail Address	Nicole@nofavt.org
Phone Number	802-434-3821
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Betsy Rakola, Onsite Auditor; Renee Mann, Observer.
Program	USDA National Organic Program (NOP)
Audit & Review Date(s)	June 30, 2014: noncompliances identified
Audit Identifier	NP4100BJR
Action Required	Yes
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of VOF's certification system.
Audit & Determination Criteria	<i>Corrective actions submitted August 15, 2013, as related to 7 CFR Part 205, National Organic Program as amended.</i>
Audit & Review Scope	VOF's certification services in carrying out the audit criteria during the period: August 15, 2013 – April 10, 2014.

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NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether VOF's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as “**Cleared**,” indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as “**Outstanding**” indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

Settlement clause 5.b – Cleared

Non-compliances issued prior to this audit –Remain Outstanding

Settlement clause 5.a: Accepted - *VOF [must have] policies and procedures, and [must have] conducted associated staff training, to ensure that all operations handling product “intended to be sold, labeled, and/or represented as organic” are certified, not just reviewed and inspected, in accordance with § 205.504 (a)(4) and §205.100.*

VOF's initial Corrective Action: VOF revised its Certification Guidelines to state that “All specified portions of an operation must be certified. For example, co-packing facilities must apply for certification independent of the brand owner that uses the facility.” VOF submitted a draft of the new guidelines with its corrective actions. VOF also submitted an email with an attached memo, informing its staff of the new policy. VOF discussed the new memo with its staff at its July 29, 2013, staff meeting. VOF identified four uncertified co-packing operations that it had approved to process products for its certified clients and issued letters to these operations, instructing each to become certified if it wished to continue processing organic products. All four operations obtained certification from VOF by September 12, 2013.

2014 onsite verification: All operations which are inspected are now certified independently. The NOP reviewed the files of all the operations identified in the original settlement agreement, as well as two additional files, to ensure that they were certified. VOF had evidence of providing new guidance to its operations and its inspectors on policies related to NOP 4009, “*Who Needs to be Certified.*” However, VOF's internal policies on processor and handler certification remain unclear and did not demonstrate full compliance with the USDA organic regulations, as described in the findings below.

VOF follow-up Corrective Action (provided via e-mail 08/06/14): VOF developed a new policy to clarify their internal policies on processor and handler certification to comply with USDA organic regulations. The Private Label Certification Policy outlines the steps of certification required for manufacturers independent of those required for private brand owners, including onsite inspections.

Non-compliances identified during the Current Assessment

Any noncompliance labeled as “**Accepted**,” indicates that the corrective actions for the noncompliance were reviewed and accepted as adequate by the NOP and will be verified for implementation and effectiveness during the next onsite audit.

NP4100BJR.NC1 - Accepted. 7 CFR §205.501(a)(10) states, “A private or governmental entity accredited as a certifying agent under this subpart must: maintain strict confidentiality with respect to its clients under the applicable organic certification program and not disclose to third parties (with the exception of the Secretary or the applicable State organic program's governing State official or their authorized representatives) any business-related information concerning any client obtained while implementing the regulations in this part, except as provided for in §205.504(b)(5);” *VOF’s policy on processor and handler certification includes the statement, “If issues arise pertaining to production, batch records, co-mingling, etc., should this be written up to the handler or is a second letter written to the processor?” Staff stated that they had not yet determined whether one or both parties should receive a notice of noncompliance. Sharing noncompliance information with a third party would violate confidentiality requirements.*

Corrective Action: VOF prepared a Private Label Certification Policy that defines the scope of a manufacturer and a private label company, and explains the certification procedures required for each entity. This policy specifies with whom (the responsible party) certification issues should be addressed in order to maintain client confidentiality should they arise in the course of organic product processing and handling.

NP4100BJR.NC2 – Accepted. 7 CFR §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.” *VOF’s policy on “Who Must Be Certified” does not clearly define their policies for certifying processors who conduct certification for certified brand owners. The policy did not define who the responsible party would be, when an audit would be conducted and/or who would receive a notice of noncompliance. The policy stated that, during the inspection of a processing facility, the inspector would not conduct any type of audit.*

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NP4100BJR.NC3 – Accepted. 7 CFR §205.403 (a)(1) states, “A certifying agent must conduct an initial onsite inspection of each production unit, facility, and site that produces or handles organic products and that is included in an operation for which certification is requested.” *VOF is currently conducting an inspection at the processor’s site, in order to issue an inspection to a handler. VOF does not always conduct an additional inspection at the handler’s site (also known as the brand owner), since the processing activities do not occur there. Instead, they do a desk*

audit to verify organic ingredients, product profiles, and labels, and they verify processing activities during the onsite inspection of the processing facility.

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NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

On August 15, 2013, Vermont Organic Farmers, LLC (VOF) and the United States Department of Agriculture (USDA), Agricultural Marketing Service, National Organic Program NOP signed a settlement agreement to resolve a Notice of Proposed Suspension for allowing organic processing activities to occur at uncertified facilities. The responsible party for one of these facilities had been revoked. The April 10, 2014 onsite compliance assessment verified VOF's corrective actions through certification file reviews; a review of VOF's policies relating to NOP 4009, *Who Needs to be Certified*; and a witness audit.

GENERAL INFORMATION

Applicant Name	Vermont Organic Farmers (VOF)
Physical Address	14 Pleasant St.
Mailing Address	14 Pleasant St.
Contact & Title	Richmond, VT 05477
E-mail Address	Nicole@nofavt.org
Phone Number	802-434-3821
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Betsy Rakola, Onsite Auditor; Renee Mann, Observer.
Program	USDA National Organic Program (NOP)
Audit & Review Date(s)	June 30, 2014: noncompliances identified
Audit Identifier	NP4100BJR
Action Required	Yes
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of VOF's certification system.
Audit & Determination Criteria	<i>Corrective actions submitted August 15, 2013, as related to 7 CFR Part 205, National Organic Program as amended.</i>
Audit & Review Scope	VOF's certification services in carrying out the audit criteria during the period: August 15, 2013 – April 10, 2014.

VOF is a not-for-profit, Limited Liability Company, which was first accredited by the NOP on September 24, 2002 for crops, wild crops, livestock, and handling operations. VOF currently has 583 certified clients, which include 235 livestock, 525 crop and 186 handling operations certified to the USDA organic regulations. Of these certified clients, 233 operations are certified for both crops and livestock. There were no certified wild crop operations at the time of the audit. The majority of clients are certified in the state of Vermont, with additional clients certified in Massachusetts, New Hampshire, and New York.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether VOF's corrective actions adequately addressed previous noncompliances. NOP also reviewed any corrective actions submitted as a result of noncompliances issued from Findings identified during the onsite audit.

Non-compliances from Prior Assessments

Any noncompliance labeled as "**Cleared**," indicates that the corrective actions for the noncompliance are determined to be implemented and working effectively. Any noncompliance labeled as "**Outstanding**" indicates that either the auditor could not verify implementation of the corrective actions or that records reviewed and audit observations did not demonstrate compliance.

Settlement clause 5.b – Cleared

Non-compliances issued prior to this audit –Remain Outstanding

Settlement clause 5.a: Outstanding - VOF *[must have] policies and procedures, and [must have] conducted associated staff training, to ensure that all operations handling product "intended to be sold, labeled, and/or represented as organic" are certified, not just reviewed and inspected, in accordance with § 205.504 (a)(4) and §205.100.*

VOF's initial Corrective Action: VOF revised its Certification Guidelines to state that "All specified portions of an operation must be certified. For example, co-packing facilities must apply for certification independent of the brand owner that uses the facility." VOF submitted a draft of the new guidelines with its corrective actions. VOF also submitted an email with an attached memo, informing its staff of the new policy. VOF discussed the new memo with its staff at its July 29, 2013, staff meeting. VOF identified four uncertified co-packing operations that it had approved to process products for its certified clients and issued letters to these operations, instructing each to become certified if it wished to continue processing organic products. All four operations obtained certification from VOF by September 12, 2013.

2014 onsite verification: All operations which are inspected are now certified independently. The NOP reviewed the files of all the operations identified in the original settlement agreement, as well as two additional files, to ensure that they were certified. VOF had evidence of providing new guidance to its operations and its inspectors on policies related to NOP 4009, "*Who Needs to be Certified.*" However, VOF's internal policies on processor and handler certification remain unclear and did not demonstrate full compliance with the USDA organic regulations, as described in the findings below.

VOF follow-up Corrective Action (provided via e-mail 08/06/14): VOF developed a new policy to clarify their internal policies on processor and handler certification to comply with USDA organic regulations. The Private Label Certification Policy outlines the steps of certification required for manufacturers independent of those required for private brand owners, including onsite inspections.

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NP4100BJR.NC2 – Accepted. 7 CFR §205.501(a)(2) states, “A private or governmental entity accredited as a certifying agent under this subpart must: demonstrate the ability to fully comply with the requirements for accreditation set forth in this subpart.” *VOF’s policy on “Who Must Be Certified” does not clearly define their policies for certifying processors who conduct certification for certified brand owners. The policy did not define who the responsible party would be, when an audit would be conducted and/or who would receive a notice of noncompliance. The policy stated that, during the inspection of a processing facility, the inspector would not conduct any type of audit.*

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Contact & Title	Richmond, VT 05477
E-mail Address	Nicole@nofavt.org
Phone Number	802-434-3821
Reviewer(s) & Auditor(s)	Renée Gebault King, NOP Reviewer; Betsy Rakola, Onsite Auditor; Renee Mann, Observer.
Program	USDA National Organic Program (NOP)
Audit & Review Date(s)	June 30, 2014: noncompliances identified
Audit Identifier	NP4100BJR
Action Required	Yes
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of VOF's certification system.
Audit & Determination Criteria	<i>Corrective actions submitted August 15, 2013, as related to 7 CFR Part 205, National Organic Program as amended.</i>
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2013 Annual Report Review Chronology Log

Audit Type: 2013 Annual Report Review

Accredited Certifying Agent Name: Vermont Organic Farmers (VOF)

Accreditation Manager: Renee Mann

Date	Activity
10/4/2013	Annual Report Received by AIA.
10/4/2013	Report assigned to Renee Mann, new Accreditation Manager.
10/23/2013	Mary Lou conducted initial review of documents.
2/21/2014	Renee conducted initial review of documents. Renee requested additional information from VOF via email.
3/6/2014	VOF submitted additional information. VOF noted that it had not previously conducted evaluations of its Review Committee, nor conducted an internal audit in the same year when it received an external audit from the NOP.
4/14/2014	Renee drafted NONC to VOF and submitted to management for review.
4/15/2014	Received signed NONC. Renee sent NONC to VOF via registered email.
5/14/2014	VOF submitted corrective actions.
6/7/2014	Renee reviewed corrective actions, drafted NONC Resolution letter and corrective action review report.
6/9/2014	Renee sent letter/report to management for review.
6/10/2014	Cheri signed.
6/11/2014	Renee stamped and readied for sending.
6/12/2014	Renee sent letter/corrective action report via RPost to VOF.

Applicant Name:	Vermont Organic Farmers
Physical Address:	14 Pleasant St., Richmond, VT 05477
Mailing Address:	P.O. Box 697, Richmond, VT 05477
Contact & Title:	Nicole Dehne, Certification Administrator
E-mail Address:	Nicole@nofavt.org
Phone Number:	802-434-3821
Auditor(s):	Renee Mann, Assistant Director
Program:	USDA National Organic Program (NOP)
Audit Date(s):	June 9, 2014
Audit Identifier:	AIA14104RAM
Action Required:	None
Audit Type:	Corrective Action Review
Audit Objective:	To evaluate the corrective actions submitted by the certifying agent in response to the non-compliances identified during the annual report Assessment.
Audit Criteria:	7 CFR Part 205, National Organic Program; Final Rule, dated December 21, 2000, as revised.
Audit Scope:	VOF's 5/14/2014 corrective action plan, in response to the Notice of Noncompliance issued on 4/15/2014.
Location(s) Audited:	Desk

GENERAL INFORMATION

Vermont Organic Farmers, LLC (VOF) is a not for profit, Limited Liability Company which was first accredited as a certifying agent to perform certification activities on behalf of the USDA under the National Organic Program (NOP) on September 24, 2002 for crops, wild crops, livestock, and handling operations. VOF certifies operations primarily in Vermont and surrounding states, including New Hampshire, New Jersey, New York, and Washington D.C.

BACKGROUND INFORMATION

This report explains Vermont Organic Farmers's (VOF) corrective actions in response to a notice of noncompliance, dated April 15, 2014.

FINDINGS

The findings below describe the NOP's issues of concern and identify the relevant section of the regulation for each issue. We also outline the certifying agent's response to these issues, which describe how they will correct the problem and prevent it from recurring in the future. During the next on-site assessment, the NOP will review the corrective actions below to verify that the certifying agent has effectively addressed all concerns.

Non-Compliances – Certifier Response Accepted

The NOP has reviewed the corrective actions submitted by VOF and determined that they demonstrate sufficient compliance.

AIA14104RAM.NC1 – Accepted - §205.510(a)(6) – General requirements for accreditation.

(a) A private or governmental entity accredited as a certifying agent under this subpart must: ...

(6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services;...

VOF submitted performance evaluations in its annual report on October 4, 2013. VOF demonstrated that it had conducted performance evaluations of inspectors and office staff, but it had not evaluated Review Committee members. The Review Committee members make certification decisions and are required to receive annual performance evaluations. **Corrective Actions:** VOF submitted evaluations for its five Review Committee members. VOF also submitted its Administrative Manual showing where VOF had added a requirement that it will annually evaluate the Review Committee members.

AIA14104RAM.NC2 – Accepted - §205.510(a)(7) – General requirements for accreditation. *(a)*

A private or governmental entity accredited as a certifying agent under this subpart must:... *(7)*

Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation;...

VOF submitted an accreditation renewal audit report generated by the USDA NOP as evidence that VOF had completed an annual program review in 2012. The USDA NOP report did not meet the requirements of an annual program review according to 205.501(a)(7) because it was not conducted by the certifying agent's staff, an outside auditor, or a consultant. The USDA NOP audit of VOF was conducted on behalf of the Administrator of the Agricultural Marketing Service and is not equivalent to an annual program evaluation. **Corrective Actions:** VOF revised its Administrative Manual to state that VOF will conduct an Internal Audit every year. The procedure specifies that audits will even be conducted in the same year that the USDA accreditation audit occurs.

15 APR 2014

NOTICE OF NONCOMPLIANCE

Nicole Dehne
Vermont Organic Farmers
14 Pleasant Street
PO Box 697
Richmond, VT 05477

Dear Ms. Dehne:

On October 4, 2013, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) received Vermont Organic Farmers' (VOF) annual report. This report demonstrated that VOF did not conduct performance evaluations of its Review Committee and did not conduct an annual program review. We have determined that this is a noncompliance of 7 CFR § 205.501(a)(6) & (7).

AIA14104RAM.NC1 - §205.510(a)(6) – General requirements for accreditation.

(a) A private or governmental entity accredited as a certifying agent under this subpart must: ... (6) Conduct an annual performance evaluation of all persons who review applications for certification, perform on-site inspections, review certification documents, evaluate qualifications for certification, make recommendations concerning certification, or make certification decisions and implement measures to correct any deficiencies in certification services; ...

VOF submitted performance evaluations in its annual report on October 4, 2013. VOF demonstrated that it had conducted performance evaluations of inspectors and office staff, but it had not evaluated Review Committee members. The Review Committee members make certification decisions and are required to receive annual performance evaluations.

AIA14104RAM.NC2 - §205.510(a)(7) – General requirements for accreditation. *(a) A private or governmental entity accredited as a certifying agent under this subpart must: ... (7) Have an annual program review of its certification activities conducted by the certifying agent's staff, an outside auditor, or a consultant who has expertise to conduct such reviews and implement measures to correct any noncompliances with the Act and the regulations in this part that are identified in the evaluation; ...*

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Please submit proposed corrective actions to AIAInbox@ams.usda.gov within 30 days from the date of receipt of this letter, indicating how this noncompliance will be corrected. VOF must propose and implement measures that will correct this action. The proposed corrective actions must also indicate how the VOF management system will be modified to prevent a future noncompliance. Please refer to [NOP 2608](#), Responding to Noncompliances, for further instruction. Failure to promptly resolve this noncompliance may result in proposed adverse actions against VOF as an accredited certifying agent for the USDA.

If you have questions regarding this notice, please contact your Accreditation Manager, Renee Mann, at renee.mann@ams.usda.gov or (202) 260-8635.

Sincerely,



Cheri Courtney
Director, Accreditation and International Activities Division
National Organic Program

cc: NOP Appeals
USDA Quality Assessment Division

Compliance Audit Resolution Chronology Log

Audit Identifier: NP4100BJR

Accredited Certifying Agent Name: Vermont Organic Farmers

Accreditation Manager: Janna Howley

Date	Activity
4/10	Betsy Rakola conducted a compliance audit of VOF to verify the terms of the 2013 settlement agreement. Renee Mann accompanied as an observer.
4/11/14	Betsy sent the checklist to QAD
6/17/14	Betsy re-sent the checklist to QAD
6/20/14	QAD submitted reviewed checklists to NOP
6/26/14	Betsy prepared the report and submitted it to management for review
6/30/14	Lars Crail (acting director) provided comments. Betsy edited the report and returned it to management for review.
7/7/14	Betsy (acting director) received the approved report from Miles. Betsy signed the NoNC on Cheri's behalf and sent the report to VOF via RPost registered email.
8/6/14	VOF submitted corrective actions to Betsy and Renee M.
8/12/14	VOF assigned to Renée Gebault King (RGK).
8/26/14	RGK reviewed corrective actions submitted by VOF.
8/29/14	RGK accepted CAs submitted by VOF. RGK prepared NoNC Resolution letter and CA Report. Submitted to Cheri Courtney for review.
9/4/14	Approved by CC and MM.
9/11/14	Sent to VOF electronically by RGK.



1400 Independence Ave. SW
Room 2648 - South, STOP 0268
Washington, D.C. 20250

June 3, 2014

Juan Felipe Ortega Valdez
Certificadora Mexicana de Productos y Procesos Ecologicos SC (CERTIMEX)
Calle 16 de Septiembre No. 204
Ejido Guadalupe Victoria
Oaxaca, C.P. 68026 Mexico
Transmittal by email: calidad@certimexsc.com.

Re: Executed Settlement Agreement, APL-004-14

Dear Mr. Valdez:

Thank you for signing and returning the proposed settlement agreement addressing your appeal of the National Organic Program's (NOP) October 18, 2013 Denial of Livestock Accreditation Expansion. The NOP has countersigned the agreement, and the fully executed settlement agreement is attached for your records.

Because CERTIMEX and NOP have reached a settlement agreement, this appeal proceeding is closed without a Decision by the Administrator of the Agricultural Marketing Service at the United States Department of Agriculture (USDA).

The NOP's Accreditation and International Activities Division will work with you to implement the terms of this agreement. If you have any questions, you can reach me at 202-260-8077 or by email at Jennifer.Tucker@ams.usda.gov.

Sincerely,

A handwritten signature in cursive script that reads "Jennifer Tucker".

Jennifer Tucker, Ph.D.
Associate Deputy Administrator
USDA National Organic Program
1400 Independence Avenue, S.W.
Room 2648-S, STOP 0268
Washington, D.C. 20250

cc: NOP Accreditation Manager

Enclosure: Executed Settlement Agreement



1400 Independence Ave. SW
Room 2648 - South, STOP 0268
Washington, D.C. 20250

June 2, 2014

Juan Felipe Ortega Valdez
Certificadora Mexicana de Productos y Procesos Ecologicos SC (CERTIMEX)
Calle 16 de Septiembre No. 204
Ejido Guadalupe Victoria
Oaxaca, C.P. 68026 Mexico
Transmittal by email: calidad@certimexsc.com.

Re: Proposed Settlement Agreement, APL-010-14

Dear Mr. Valdez:

The Agricultural Marketing Service has evaluated your appeal of the October 18, 2013 Denial of Livestock Accreditation Expansion issued by the National Organic Program (NOP).

As a result of this evaluation, the NOP would like to offer you a settlement agreement that would allow you to complete a review process to enable you to certify honeybee clients. A copy of this settlement is enclosed for your consideration.

You are entitled to consult with an attorney. You may accept or reject this proposed settlement. If you choose to sign and date the settlement agreement, please retain a copy for your files and send the original to the address below within 10 days of receipt of this letter.

Please let me know if you have any questions; you can reach me at 202-260-8077 or by email at Jennifer.Tucker@ams.usda.gov.

Sincerely,

A handwritten signature in cursive script that reads "Jennifer Tucker".

Jennifer Tucker, Ph.D.
Associate Deputy Administrator
USDA National Organic Program
1400 Independence Avenue, S.W.
Room 2648-S, STOP 0268
Washington, D.C. 20250

cc: NOP Accreditation Manager

Enclosure: Proposed Settlement Agreement