USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Bio-Hellas' (BIOH) application to request accreditation to the U.S. Department of Agriculture (USDA) organic regulations. The NOP reviewed the application, conducted a Document Adequacy Review audit, and to determine BIOH's capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Bio-Hellas Institute (BIOH)
Physical Address	27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece
Mailing Address	27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece
Contact & Title	Maria Kornarou, Quality Manager
E-mail Address	ydp@bio-hellas.gr
Phone Number	0030 210 8211940
Reviewer(s) & Auditor(s)	Rebecca Claypool, NOP Reviewer; Lars Crail, Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Review of the corrective actions occurred June 5, 2017
Audit Identifier	NP7058LCA
Action Required	None
Audit & Review Type	Document Adequacy Review
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the completeness of BIOH's certification system.
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BIOH's certification services in carrying out the audit criteria.

Bio-Hellas submitted a request to USDA NOP on November 29, 2016, for accreditation to the scopes of Crops, Wild Crops, and Handling/Processing. Bio-Hellas signed an audit cost estimate on March 13, 2017 agreeing to a Document Adequacy Desk Review.

Bio-Hellas was initially accredited as a USDA National Organic Program certifying agent on February 13, 2009 to the accreditation scopes of crops, wild crops, and handling/processing. In 2010, Bio-Hellas requested and was granted the livestock scope. Bio-Hellas surrendered accreditation on July 31, 2012 when the US/EU Equivalency Arrangement was established.

Bio-Hellas' office is located in Athens, Greece. Their certification staff consists of eight individuals including two contract inspectors.

NOP DETERMINATION:

NOP reviewed corrective actions submitted by BIOH as a result of a noncompliance issued from Findings identified during the document adequacy 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.

NP7058LCA.NC1 - Accepted – 7 C.F.R. §205.504(b)(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; its ability to fully comply with and implement the organic certification 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; and its ability to comply with the requirements for accreditation set forth in §205.501: 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." NOP 2609, Unannounced Inspections, states that 5% of certified operations at a minimum annually are to be unannounced.

Comments: *BioHellas' procedures provide for unannounced inspections; however, there is no stated requirement that a minimum of 5% of the total number of certified operations must receive unannounced inspections.*

Corrective Actions: Bio-Hellas updated and submitted their Inspection and Sampling Procedure document, NOP 300-8, which now aligns with the guidelines in NOP 2609, Unannounced Inspections.

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NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Bio-Hellas' (BIOH) application to request accreditation to the U.S. Department of Agriculture (USDA) organic regulations. The NOP reviewed the application, conducted a Document Adequacy Review audit, and determined BIOH's documented system compliant to operate as a USDA accredited certifier.

ASSESSMENT INFORMATION

National Organic Program Assessment Review	
Reviewer	Rebecca Claypool
Review Date	March 13, 2017 – May 19, 2017
Action Required	Yes
National Organic Program Accreditation Assessment	
Assessment Date	May 22, 2017
Assessment Identifier	NP7058LCA
Assessment Activity (select one)	X Documentation Adequacy Review ☐ Pre-decisional Assessment ☐ Initial Assessment ☐ Mid-Term Assessment ☐ Renewal Assessment ☐ Compliance Assessment ☐ Other
General Information	
Applicant Name	Bio-Hellas Institute (BIOH)
Physical Address	27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece
Mailing Address	27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece
Contact & Title	Maria Kornarou and Andreas Georgakakis, Program Managers
E-mail Address	ydp@bio-hellas.gr and pstandards@bio-hellas.gr
Phone Number	0030 210 8211940
Assessment Team	
Lead Auditor	Lars Crail
Second Auditor	NA
Other (Identify Role)	
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 compliance of BIOH's certification system.

Audit & Review Scope	BIOH's documented certification service system as submitted requesting accreditation.

Bio-Hellas submitted a request to USDA NOP on November 29, 2016, for accreditation to the scopes of Crops, Wild Crops, and Handling/Processing. Bio-Hellas signed an audit cost estimate on March 13, 2017 agreeing to a Document Adequacy Desk Review.

Bio-Hellas was initially accredited as a USDA National Organic Program certifying agent on February 13, 2009 to the accreditation scopes of crops, wild crops, and handling/processing. In 2010, Bio-Hellas requested and was granted the livestock scope. Bio-Hellas surrendered accreditation on July 31, 2012 when the US/EU Equivalency Arrangement was established.

Bio-Hellas' office is located in Athens, Greece. Their certification staff consists of eight individuals including two contract inspectors.

NOP DETERMINATION

The NOP reviewed the audit findings and identified one noncompliance:

NP7058LCA.NC1 – 7 C.F.R. §205.504(b)(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; its ability to fully comply with and implement the organic certification 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; and its ability to comply with the requirements for accreditation set forth in §205.501: 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." NOP 2609, Unannounced Inspections, states that 5% of certified operations at a minimum annually are to be unannounced.

Comments: *BioHellas' procedures provide for unannounced inspections; however, there is no stated requirement that a minimum of 5% of the total number of certified operations must receive unannounced inspections.*

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
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Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Maria Kornarou
Bio-Hellas Institute
27 Omorfokklisias St.
15122 Marousi, Athens, Attica-Greece
GREECE

Dear Ms. Maria Kornarou:

On May 22, 2017, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a documentation adequacy review of the Bio-Hellas (BIOH) organic certification program. On May 22, 2017, the NOP reviewed the results of the onsite audit to determine BIOH's compliance to the USDA organic regulations. A copy of the assessment report, NP7058LCA NC, is enclosed for your reference.

As the report indicates, one noncompliance, NP7058LCA.NC1, was identified during the audit. Please submit corrective actions for all noncompliance to the AIAInbox@ams.usda.gov within 30 days from the date of this Notice. All corrective actions must indicate how the noncompliance will be corrected and how the BIOH management system will be modified to prevent a recurrence of the noncompliance. If you wish to rebut any noncompliance, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov before June 9, 2017.

Please refer to NOP 2608 Responding to Noncompliances for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliance may result in denial of BIOH's request for USDA accreditation.

If you have questions regarding this notice, please contact, Lars Crail, Lead Auditor, at Lars.Crail@ams.usda.gov or (202) 631.2105.

Sincerely,

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

Enclosure: Noncompliance Report

cc: AIA Inbox

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
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Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

June 2, 2017

Maria Kornarou
Bio-Hellas Institute
27 Omorfokklisias St.
15122 Marousi, Athens, Attica-Greece
GREECE

Dear Ms. Maria Kornarou:

On May 22, 2017, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed a documentation adequacy review of the Bio-Hellas (BIOH) organic certification program. On May 22, 2017, the NOP reviewed the results of the onsite audit to determine BIOH's compliance to the USDA organic regulations. A copy of the assessment report, NP7058LCA NC, is enclosed for your reference.

As the report indicates, one noncompliance, NP7058LCA.NC1, was identified during the 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 noncompliance will be corrected and how the BIOH management system will be modified to prevent a recurrence of the noncompliance. If you wish to rebut any noncompliance, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov before July 2, 2017.

Please refer to NOP 2608 Responding to Noncompliances for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliance may result in denial of BIOH's request for USDA accreditation.

If you have questions regarding this notice, please contact, Lars Crail, Lead Auditor, at Lars.Crail@ams.usda.gov or (202) 631.2105.

Sincerely,

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

Enclosure: Noncompliance Report

cc: AIA Inbox

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
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Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Bio-Hellas' (BIOH) application to request accreditation to the U.S. Department of Agriculture (USDA) organic regulations. The NOP conducted a Pre-decisional onsite audit to assess BIOH's capability to operate as a USDA accredited certifier.

ASSESSMENT INFORMATION

National Organic Program Assessment Review	
Reviewer	Rebecca Claypool
Review Date	March 23, 2017
Action Required	Yes
National Organic Program Accreditation Assessment	
Assessment Date	June 12-14, 2017
Assessment Identifier	NP7163LCA
Assessment Activity (select one)	☐ Documentation Adequacy Review X Pre-decisional Assessment ☐ Initial Assessment ☐ Mid-Term Assessment ☐ Renewal Assessment ☐ Compliance Assessment ☐ Other
General Information	
Applicant Name	Bio-Hellas Institute (BIOH)
Physical Address	27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece
Mailing Address	27 Omorfokklisias St., 15122 Marousi, Athens, Attica-Greece
Contact & Title	Maria Kornarou, Quality Manager
E-mail Address	ydp@bio-hellas.gr
Phone Number	0030 210 8211940
Assessment Team	
Lead Auditor	Lars Crail
Second Auditor	NA
Other (Identify Role)	NA
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 compliance of BIOH's certification system.

Audit & Review Scope	Onsite assessment of BIOH's documented certification service system and witness audits of Bio-Hellas' inspection activities.

Bio-Hellas submitted a request to USDA National Organic Program (NOP) on November 29, 2016, for accreditation to the scopes of Crops, Wild Crops, and Handling/Processing. Bio-Hellas completed a Document Adequacy Review on June 2, 2017. From June 12 through June 14, NOP conducted a Pre-Decisional Onsite Audit.

Bio-Hellas was initially accredited as a USDA National Organic Program certifying agent on February 13, 2009 to the accreditation scopes of crops, wild crops, and handling/processing. In 2010, Bio-Hellas requested and was granted the livestock scope. Bio-Hellas surrendered accreditation on July 31, 2012 as the US/EU Equivalency Arrangement was established.

Bio-Hellas office is located in Athens, Greece. Their certification staff consists of eight individuals including two contract inspectors. Bio-Hellas request for NOP accreditation is a result of operations seeking USDA organic certification. These operations produce and process non-food organic products that cannot be certified to the European Union organic standards. European Union (EU) organic standards allow for non-food plant propagation; however, plant processing of non-food products cannot be certified and therefore not traded under the US/EU equivalency arrangement.

During the Pre-Decisional onsite audit, NOP conducted witness audits of Bio-Hellas' inspections of a crop producer and a handler. The inspections were conducted to the USDA organic regulations.

NOP DETERMINATION

Corrective actions submitted for one noncompliance issued as a result of the Document Adequacy Review was verified during the onsite audit:

NP7058LCA.NC1 - Cleared – 7 C.F.R. §205.504(b)(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; its ability to fully comply with and implement the organic certification 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; and its ability to comply with the requirements for accreditation set forth in §205.501: 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." NOP 2609, Unannounced Inspections, states that 5% of certified operations at a minimum annually are to be unannounced.

Comments: *BioHellas' procedures provide for unannounced inspections; however, there is no stated requirement that a minimum of 5% of the total number of certified operations must receive unannounced inspections.*

Corrective Actions: Bio-Hellas updated and submitted their Inspection and Sampling Procedure document, NOP 300-8, which now aligns with the guidelines in NOP 2609, Unannounced Inspections.

Verification of Corrective Actions: Bio-Hellas updated NOP 300-8, Inspection and Sampling Procedure, Section 4.1.2, which states that a minimum of 5% of total operations will receive unannounced inspections. If there are less than 20 certified operations, there shall be at least one unannounced inspection conducted.

Noncompliances Identified during the Current Assessment

NP7163LCA.N1 - 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: *During the witness audit of a producer, the BioHellas' inspector informed the operator of a noncompliance and obtained a corrective action to record in the inspection report. The inspection report gives the perception that the inspector is issuing noncompliances and receiving corrective actions from the operator. An inspector's role is to identify issues of concern and request any additional information, not to issue noncompliances, obtain corrective actions, and assess those corrective actions for adequacy.*

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NOTICE OF NONCOMPLIANCE

June 23, 2017

Maria Kornarou
Bio-Hellas Institute
27 Omorfokklisias St.
15122 Marousi, Athens, Attica-Greece
GREECE

Dear Ms. Maria Kornarou:

On June 11-14, 2017, a representative of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), conducted an on-site Pre-decisional audit of the Bio-Hellas (BIOH) organic certification program. On June 23, 2017, the NOP reviewed the results of the onsite audit to determine BIOH's compliance to the USDA organic regulations. A copy of the assessment report, NP7163LCA NC, is enclosed for your reference.

As the report indicates, one noncompliance, NP7163LCA.NC1, was identified during the 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 noncompliance will be corrected and how the BIOH management system will be modified to prevent a recurrence of the noncompliance. If you wish to rebut any noncompliance, please submit objective evidence that supports your argument to the AIAInbox@ams.usda.gov before July 23, 2017.

Please refer to NOP 2608 Responding to Noncompliances for further instructions on how to respond to noncompliances. Failure to promptly resolve noncompliance may result in denial of BIOH's request for USDA accreditation.

If you have questions regarding this notice, please contact, Lars Crail, Lead Auditor, at Lars.Crail@ams.usda.gov or (202) 631.2105.

Sincerely,

Rebecca Claypool for CC

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

Enclosure: Noncompliance Report

cc: AIA Inbox

USDA Agricultural Marketing Service

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NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

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

GENERAL INFORMATION

Applicant Name	Bio Latina S.A.C. (BIOL)
Physical Address	Jr. Domingo Millan #852, Lima 11, Jesus Maria, Lima, Peru
Mailing Address	Same
Contact & Title	Reynaldo Chapilliquen Abad, General Manager
E-mail Address	central@biolatina.com.pe
Phone Number	0051-1-2031130
Reviewer & Auditor	Janna Howley, NOP Reviewer Mike Lopez, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: April 7, 2015 Onsite audit: October 20-24, 2014
Audit Identifier	NP4293AKA
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 BIOL's certification system.
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BIOL's certification services in carrying out the audit criteria during the period: June 2012 through October 2014.

Bio Latina is a for-profit organization that provides certification services in Latin America. They were originally accredited by NOP on April 29, 2002 for the scopes of crops and handling, which are the same scopes they currently maintain. Bio Latina currently certifies operations to the NOP in Bolivia, Colombia, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, and Peru. As of October 20, 2014, Bio Latina had 235 certified operations with 180 crop (142 of the certified crop operations are grower groups) and 55 handling operations. Six of the handling operations are traders; the rest are processors.

Bio Latina's main office is located in Lima, Peru with four satellite offices in Bolivia, Nicaragua, Venezuela, and Honduras. The main office and each of the local offices have a Local Representative who is responsible for certification activities in that area. Although the

representatives in the satellite offices conduct some key certification activities such as application review, initial technical reviews, inspections, report reviews, and corrective action approvals, all of these activities are done electronically through the Bio Latina website in Peru.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether BIOL'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.

NP1229ZZA.NC1 – Cleared
NP1229ZZA.NC2 – Cleared
NP1229ZZA.NC3 – Cleared
NP1229ZZA.NC4 – Cleared
NP1229ZZA.NC5 – Cleared
NP1229ZZA.NC6 – 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.

NP4293AKA.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: *Bio Latina issued a certificate for an Aloe Vera gel that contains 100% organic aloe vera, citric acid, and potassium sorbate. The certificate identifies the product as 100% organic, which is non-compliant because of the use of citric acid and potassium sorbate in the formulation. The actual labels for the product were correct, identifying the product as "organic"; however, the certificate incorrectly classifies the product as "100% organic."*

Corrective Action: In 2013 Bio Latina issued the operator a new certificate for coffee only; the operator has not since requested the organic certification of aloe vera. A copy of the 2013 certificate was provided to the NOP. In order to avoid mistakes in the classification of products, Bio Latina also instituted two trainings (December 2014 and February 2015) using the 2012 NOP Online Training Module PowerPoint presentation, "Subpart D - Labels, Labeling & Market

Information." Copies of the completed, and signed, training forms, *MC02 PER-IE1-INS-221214* and *MC 02 CEN-IE1-INS-030215*, were provided to the NOP. In addition, Bio Latina designed a new form, *MC03 CL3-240315*, that staff is required to complete for products that contain more than one ingredient and/or utilize processing aids. A copy of the new form was provided to the NOP.

Mid-Term Audit Chronology Log

Audit Identifier: NP4293AKA

Audit Type: Mid-Term Assessment

Accredited Certifying Agent Name: Bio Latina

Accreditation Manager (who is working on the project): Janna Howley

Date	Activity
01/02/15	MLC posts audit documents to 01 Report folder: ~Audit checklist, grower group supplement, witness audit checklist
02/17/15	JH started working on NC report; reviewed checklists.
02/20/15	• Added satellite offices to AIA satellite office Excel spreadsheet; Mike Lopez, who audited Bio Latina, noted in his report: Bio Latina's main office is located in Lima, Peru with four satellite offices in Bolivia, Nicaragua, Venezuela, and Honduras. The main office and each of the local offices have a Local Representative who is responsible for certification activities in that area. Although the representatives in the satellite offices conduct some key certification activities such as application review, initial technical reviews, inspections, report reviews, and corrective action approvals, all of these activities are done electronically through the Bio Latina website in Peru. Therefore, based on the information reviewed, the auditor does not find it necessary to visit any of the satellite offices as part of future NOP assessments. • Question: does AIA need to audit these satellite offices if they conduct the activities as described above? • Emailed draft letter and report to RM for review.
02/25/15	• Rcvd comments and edits from RM. Edited the document. Removed statement about not necessary to audit satellite offices in future, b/c AIA determines whether these offices should be audited, versus auditor. • Emailed Mike Lopez to get clarification on materials review narrative statement.
02/26/15	• Mike responded back, "Hi Janna, no, they are not using the EU material review entity for NOP. BioLatina is also EU accredited, and I guess I was trying to convey that they use the applicable approved material review entity before employing the process of reviewing an input themselves." • Updated the report.
02/27/15	Emailed report and letter to CC for review.
03/03/15	Rcvd ok from Cheri to print.
03/04/15	JH sent docs to RGK to see if she could print them (JH out of country on audit). If not, JH will print and submit on 03/09/15.
03/10/15	NC report and letter sent to Bio Latina.
03/24/15	Bio Latina sends proposed CAs to AIA. Assigned to JH. Added to WTL.
04/07/15	• JH begins document review: letter and supporting documents provided by Bio Latina. • JH emailed draft docs to RM for review.
04/09/15	Approval from RM to print. Printed and gave to CC for review.

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NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

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

GENERAL INFORMATION

Applicant Name	Bio Latina S.A.C. (BIOL)
Physical Address	Jr. Domingo Millan #852, Lima 11, Jesus Maria, Lima, Peru
Mailing Address	Same
Contact & Title	Reynaldo Chapilliquen Abad, General Manager
E-mail Address	central@biolatina.com.pe
Phone Number	0051-1-2031130
Reviewer & Auditor	Janna Howley, NOP Reviewer Mike Lopez, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: February 17, 2015 Onsite audit: October 20-24, 2014
Audit Identifier	NP4293AKA
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 BioL's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BIOL's certification services in carrying out the audit criteria during the period: June 2012 through October 2014.

ORGANIZATIONAL STRUCTURE

Bio Latina is a for-profit organization that provides certification services in Latin America. They were originally accredited by NOP on April 29, 2002 for the scopes of crops and handling, which are the same scopes they currently maintain. Bio Latina currently certifies operations to the NOP in Bolivia, Colombia, El Salvador, Guatemala, Honduras, Mexico, Nicaragua, Panama, Paraguay, and Peru. As of October 20, 2014, Bio Latina had 235 certified operations with 180 crop, 142 of the certified crop operations are grower groups and 55 handling operations. Six of the handling operations are traders; the rest are processors. In addition to its NOP accreditation, Bio Latina maintains accreditations for the European Union (EU), the Peru National Organic Standard, National Organic Standards for Bolivia, Guatemala, Panama, Nicaragua and Honduras, UTZ, Starbucks Coffee, 4C, Stop Climate Change, Bird Friendly, SPP, Bio Commerce, CERES, Bio Suisse, and the Federal Office for Agriculture (FOAG) Swiss Organic Ordinance.

Bio Latina's main office is located in Lima, Peru with four satellite offices in Bolivia, Nicaragua, Venezuela, and Honduras. The main office and each of the local offices have a Local Representative who is responsible for certification activities in that area. Although the representatives in the satellite offices conduct some key certification activities such as application review, initial technical reviews, inspections, report reviews, and corrective action approvals, all of these activities are done electronically through the Bio Latina website in Peru.

The Bio Latina organizational structure begins with a Governing Board, which supervises and defines the quality policies and provides financial management for the organization. Next is the General Manager, who supervises all certification activities and is ultimately in charge of certification decisions. There are 21 technical staff composed of eleven 1st line Reviewers/Inspectors, seven 2nd line Reviewers/Inspectors, and three Reviewers/Decision Makers. And finally, there are 14 Administrative Staff that are not involved in certification decisions. Bio Latina maintains agreements with 15 contract inspectors. Resumes and personnel records were provided for all staff members and inspectors. Records reviewed and interviews conducted verified that personnel had the necessary qualifications to perform assigned certification duties.

CERTIFICATION PROCESS

When an interested party contacts Bio Latina to inquire about NOP certification, they are sent an email with general information and a certification packet. The certification packet includes Bio Latina's quality manual and certification procedures, fee schedule, application forms, applicable OSP, scope specific documents, and the NOP standards. All of this information may be provided in hard copy if requested. When the completed forms are returned to Bio Latina with the application fees, an initial review is completed on the documentation for completeness and ability to comply with the NOP rule. This initial review is conducted by the applicable Local Representative or another 1st Line Reviewer. Once the initial review is completed, an inspector will be assigned based on geography, scope, and competency by the Local Representative. Inspections may be conducted by staff or contracted inspectors. The inspector contacts the client and schedules the initial onsite inspection. When the inspection is completed, the inspector submits the report and supporting documentation to the Peru office for review and decision on certification. A second-line reviewer does the final review on the file with the accompanying inspection report, and then submits the file to one of the Reviewer/Decision Makers for the decision on certification. At this point, if there are non-compliances, a notice of non-compliance will be issued. Once all non-compliances are cleared and the decision is made to grant certification, it is submitted to the General Manager on the certification decision form and a certificate is issued.

The certification renewal/annual update procedure is similar to that of initial applicants. Bio Latina sends out a letter two months prior to the renewal date each year with the application/OSP update form. The applicant will return the application with their intent to continue certification, as well as any changes to the OSP and supporting documentation. Inspections are scheduled according to anniversary dates, but other than that, the review and inspection procedures are the same as for new applicants.

Bio Latina's *Procedure 3-5* dictates that unannounced inspections are to be performed each year based on the risk of the certified operations. This risk is assessed based on many factors including size of production groups, risk of mixing conventional and organic, sanctions received in the past three years, types of inputs used, infestations of pests in the country/region, and location in areas where agro-chemicals are used. In 2013, Bio Latina had 235 certified operations and performed 186 unannounced inspections for a rate of 79%. The unannounced inspection policy is provided to applicants in the application as well as the certification letter. Clients are also made aware of the risk category assigned to them and the reasons they were classified as such.

Bio Latina certifies 142 grower groups throughout Latin America. The policies and requirements for grower groups (*Procedure 3-1B*) are included in the Bio Latina Procedures Manual, which is provided to all applicants. All grower group procedures are in accordance with the NOP Rule, *NOP Policy Memo 11-10*, and the NOSB recommendations. Inspectors are provided with an addendum to the crop OSP checklist that contains all the requirements for grower groups. Files reviewed indicated that Bio Latina is certifying grower groups in accordance with the NOP regulations, *NOP Policy Memo 11-10*, and the NOSB recommendations.

Bio Latina has a documented material review procedure for reviewing inputs used by certified operations. The 1st line reviewer makes the initial review of the input, followed by the 2nd line reviewer and finally the Reviewer/Decision Maker. Initially, inputs are searched on OMRI. If the input is not listed, the client must submit an input application form which must include the material safety data sheet and a statement indicating the area of the National List in which it complies. Product formulations are generally simple and are cross-referenced with the National list. Records reviewed indicated that Bio Latina is adequately reviewing all inputs and there was no evidence that prohibited substances have been applied in certified operations.

Bio Latina requires that clients submit labels for review and approval prior to use upon initial application, or as the need arises for certified operations. The Certification Officers review and approve labels and they are verified during annual onsite inspections. Upon approval, labels are uploaded to the appropriate client file. Each client file has a master list of approved labels that the inspector can reference during onsite inspections. A review of approved labels confirmed that Bio Latina is approving labels bearing the USDA seal in accordance with the NOP Rule.

Bio Latina provides export certification for Canada. Based on the certifications requested on the application, Bio Latina will verify the additional requirements for the applicable country during documentation reviews and onsite inspections. When a client is verified as being eligible to export to the applicable country, it is indicated as such in their file. Prior to issuing the certificate, they will verify in the file that the client is eligible to export to the country requested. All Canadian Attestation Statements were found to be satisfactory. It should be noted that Bio Latina also certifies products for the European Union; however, they maintain accreditation by the EU to certify organic products.

ADMINISTRATIVE RECORDS & PROCESSES

Bio Latina maintains a Quality Manual, an Inspection Manual, and a Procedures Manual. All policies, procedures, work instructions, and quality statements and policies are maintained

electronically. All required documentation was readily accessible to the auditor for review. Document control and identification is well maintained.

An internal audit is conducted annually utilizing the NOP checklist. Results of the internal audit are reviewed during the annual management review of the program. The last internal audit was conducted on April 23, 2014. All opportunities for improvement and non-conformances identified in the 2013 internal audit were addressed and corrected.

Bio Latina provides training for its employees on an ongoing basis from both internal and external sources. Bio Latina conducts annual Certification Program meetings in the Lima office. These meetings provide staff with information on new policies, standards, and other relevant information pertaining to organics. All certification staff are required to attend these meetings. External training is also encouraged for all staff members through webinars and local training sessions. Typical sources for this training include IOIA and Peru Ministry of Agriculture. Bio Latina also sends a representative to the annual NOP ACA training when possible.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED

In conjunction with this onsite assessment, a witness inspection was conducted in the scope of crops at a grower group operation. This was an annual renewal inspection and was announced. A Bio Latina staff inspector was observed. The witness inspection was conducted in Cajamarca, Peru. This operation, certified as a grower group for the scope of crops, is composed of 412 farms with a total of 215.03 hectares certified. Crops certified include aguaymanto, quinoa, maca, yacon, and tarwi.

The inspector was thorough and covered all areas of the operation. A product trace-back audit was performed with satisfactory results. All materials observed were in direct compliance to the National List. Compounds used included calcium compounds, potash, and avian guano. The guano met all requirements for composted manure. The inspector conducted an exit interview in which he reviewed the non-compliances issued after the last inspection and discussed the corrective actions submitted by the operation. All non-compliances were cleared and no new issues of concern were documented. Overall, the inspector conducted himself in a professional manner and displayed excellent knowledge of the NOP standards. This inspector also showed a vast knowledge of internal control systems and grower groups in general. The witness inspection was conducted in an adequate manner and in such a way as to confidently certify the operation to the scope of crops as organic.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether BIOL 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 BIOL.

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.

NP1229ZZA.NC1 – **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.

Comments: *Bio Latina has not submitted any notices of noncompliance or notification of noncompliance correction to the Administrator since the last assessment; although, they have issued them to certified operations. Bio Latina issued three notices of denial of certification in 2011; however, these were not submitted to the Administrator. Bio Latina issued one notice of noncompliance and notice of proposed suspension in July 2011, and these were not submitted to the Administrator. Bio Latina did submit their one notice of suspension to their Regional Accreditation Manager on October 14, 2011; however, it was not submitted to the NOP Appeals e-mail address or physical address as required.*

Corrective Actions: Bio Latina began sending all adverse action notices to the NOP in November 2011. The NOP confirmed receipt of these notices.

Verification of Corrective Action: Bio Latina has updated the non-compliance procedure in the procedures manual and created instructions for sending adverse actions notices to NOP. The auditor verified that notifications are being sent by reviewing copies of emails.

NP1229ZZA.NC2 – **Cleared –** 7 CFR §205.662(c)(3)(4) states, "The notification of proposed suspension or revocation of certification shall state: (3) The impact of 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: *Bio Latina's template form (ME4) for proposed suspension or proposed revocation does not correctly distinguish between the impact of suspension and revocation. Bio Latina proposed suspension (and ultimately enacted suspension) for one certified operation and the Notice of Proposed Suspension did not adequately include the impact of suspension on future eligibility for certification or the rights to request mediation or to file an appeal. The notice of proposed suspension did not correctly distinguish between the impact of suspension and revocation; stated that if the suspension goes into effect and the certified operation does not provide corrective actions within 10 working days then their certification will be revoked; stated the certified operation had 15 working days to file an appeal; and did not provide the address for submitting the appeal.*

Corrective Actions: Bio Latina revised its adverse action procedures in its quality manual and also revised its templates to comply with NOP regulations. Information now states a 30 day period to file an appeal, includes the correct address for NOP Appeals, and explains the

difference between suspension and revocation. Training was held on November 30, 2011 to inform staff of the modifications.

Verification of Corrective Action: The auditor reviewed the revised procedures and templates, and verified that the revised templates are in use as observed in client files.

NP1229ZZA.NC3 – **Cleared –** 7 CFR §205.405(d)(1)-(3) states, "A notice of denial of certification must state… the applicant's right to: (1) Reapply for certification pursuant to §§205.401 and 205.405(e); (2) Request mediation pursuant to §205.663…; or (3) File an appeal of the denial of certification pursuant to §205.681…."

Comments: *Bio Latina issued three notices of denial of certification and none of them contained the required information about the applicant's right to reapply for certification; the information regarding the right to request mediation or appeal was incomplete, and the notice specified they had 15 working days to appeal. Bio Latina's appeal procedure (3-9), which is provided to clients at the time of application, correctly addresses the mediation and appeal process for NOP; however, this information was not included in the notices of denial of certification. In addition, the address provided in the appeal procedure for submitting the appeal to the Administrator was incorrect.*

Corrective Action: Bio Latina modified two documents: its Denial of Certification template to include information on appeals, and its procedure on complaints and appeals to note the unique procedures for NOP Appeals.

Verification of Corrective Action: The auditor verified that the procedure and template were revised. There have been no denials since the previous assessment.

NP1229ZZA.NC4 – **Cleared –** 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…shall send the certified operation a written notification of suspension or revocation."

Comments: *Bio Latina issued a Notice of Suspension which incorrectly states the certified operation may submit an appeal of the suspension to the NOP. According to 7 CFR 205.681(a), certified operations may only appeal a notice of proposed suspension not a notice of suspension. 205.662(f)(1) specifies the request for reinstatement of certification for a certified operation whose certification has been suspended may be submitted to the Secretary.*

Corrective Action: Bio Latina modified its adverse action policies and templates to remove any references to appeal rights for notices of revocation and suspension. The template for the Notice of Proposed Suspension/Revocation still contains language regarding the right to mediation or appeal.

Verification of Corrective Action: The auditor verified that the revised templates are available for use. There have been no suspensions or revocations since the previous assessment.

NP1229ZZA.NC5 – **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 11-10* states, "accredited certifying agents should use the National Organic Standards Board (NOSB) recommendations of October 2002 and November 2008 as the current policies." NOSB Recommendation, November 2008, section III.D requires, "…all new entrants to a production unit must be inspected in their first year with the group…Once the annual sampling percentage rate is determined by the ACA, the highest risk sub-units are identified and inspected. Of the remaining sample to be inspected annually, at least 25% of these the sub-units should be selected at random."

Comments:

1. *Bio Latina's grower group procedure (3-1B, Application of the certification system for collective operators) does not require mandatory inspection of new entrants into the production unit by Bio Latina and interviews with Bio Latina confirmed they do not inspect all new entrants; although, they might select some new entrants based on risk. Bio Latina's procedures do require the Internal Control System (ICS) to be conducting 100% annual inspections on all producers and inspections on new entrants.*
2. *Bio Latina's grower group procedures do not specify the criteria used to determine and select high-risk producers; although, interviews and files reviewed verified it is based on the similar criteria to that listed in the NOSB recommendations.*
3. *Bio Latina's procedures do not specify that "Of the remaining sample to be inspected annually, at least 25% of these the sub-units should be selected at random." Files reviewed and interviews verified the remaining sub-units selected (after high risk chosen) are selected at random and the number is at least 25%.*

Corrective Action: Bio Latina updated its grower group policy to mandate 100% inspections during the first visit, to establish criteria by which to select high-risk producers for inspection, and to include requirement that an additional 25% of producers must be inspected at random, per the NOSB recommendation.

Verification of Corrective Actions: The auditor reviewed revised procedures and verified they are being followed through one witness inspection and review of client files.

NP1229ZZA.NC6 – **Cleared -** Bio Latina's Procedure 3-8 Organic Certification and Other Related Certification, Section 4.3 Certification, specifies the General Manager makes the certification decision.

Comments: *Bio Latina's certification procedure (3-8) and certification decision form (Solicitud de Certicación y Dictamen de certificación, Form DD3, Version 10, 01.05.11) do not accurately reflect their current certification decision process and responsibilities. Based on interviews with the General Manager, Quality Manager, and Technical Manager, it was determined that in May 2011 Bio Latina changed their procedure to have the Technical Managers (Certification Committee Members) make the certification decision instead of the General Manager and for the General Manager to only have responsibility to ensure the certification certificate is issued (administrative function). Bio Latina did not update the certification procedure (3-8) or form (DD3) to reflect this change. The DD3 Form still documents that General Manager makes the certification based on the recommendation of the Technical Manager when in fact the Technical Manager or Technical Sub-Manager make the certification decision and the General Manager is simply documenting that the certificate should be issued.*

Corrective Action: Bio Latina modified its quality manual to reflect the current procedures.

Verification of Corrective Action: The revised procedure was verified as being in effect. Through interviews, review of the written procedures, and review of client files it was verified that these procedures are in place.

Noncompliances Identified during the Current Assessment

NP4293AKA.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."

Comments: *Bio Latina issued a certificate for an Aloe Vera gel that contains 100% organic aloe vera, citric acid, and potassium sorbate. The certificate identifies the product as 100% organic, which is non-compliant because of the use of citric acid and potassium sorbate in the formulation. The actual labels for the product were correct, identifying the product as "organic"; however, the certificate incorrectly classifies the product as "100% organic."*

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

MAR 1 0 2015

Reynaldo Chapilliquen Abad
Bio Latina S.A.C.
Jr. Domingo Millan #852
Lima 11, Jesus Maria, Lima
Peru

Dear Mr. Chapilliquen Abad:

On October 20-24, 2014 a representative of the United States Department of Agriculture (USDA), National Organic Program (NOP), completed an onsite audit of the Bio Latina S.A.C. (BIOL) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On February 20, 2015, the NOP reviewed the results of the onsite audit to determine BIOL's compliance to the USDA organic regulations. A copy of the assessment report, NP4293AKA, is enclosed for your reference.

As the report indicates, six corrective actions for prior noncompliances (NP1229ZZA.NC1-NC6) were cleared and determined to be implemented and effective. Zero noncompliances remain outstanding from your previous audit. One new finding (NP4293AKA.NC1) was 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 BIOL 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,

Cheri Courtney

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

Enclosure

cc: AIA Inbox

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Bio Latina's accreditation renewal application to become a U.S. Department of Agriculture (USDA) accredited certifier on October 28, 2016. The NOP has reviewed Bio Latina's application, conducted an onsite audit, and reviewed the audit report to determine Bio Latina's capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Bio Latina (BIOL)
Physical Address	Jr. Domingo Millán 852, Lima, Jesus Maria, 18 Peru
Mailing Address	Jr. Domingo Millán 852, Lima, Jesus Maria, 18 Peru
Contact & Title	Reynaldo Chapilliquen Abad, General Manager
E-mail Address	central@biolatina.com
Phone Number	00 51 1 2031130
Reviewer & Auditors	Rebecca Claypool, NOP Reviewer; Jason Lopez and Lars Crail, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: March, 3 2017 Onsite audit: Jan 21 – Jan 28, 2017
Audit Identifier	NP7021JZA
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 BIOL's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BIOL's certification services in carrying out the audit criteria.

The National Organic Program (NOP) conducted an accreditation renewal onsite audit of Bio Latina (BIOL) on January 22-28, 2017.

BIOL is a for-profit organization providing certification services in Latin America. BIOL's accreditation to the USDA organic scopes of crops and handling began on April 29, 2002. The current term of accreditation will expire on April 29, 2017. Bio Latina currently maintains a main office in Lima, Peru, and conducts certification activities in Peru, Bolivia, Nicaragua, Honduras, Panama, El Salvador, and Guatemala. Bio Latina has 43 full time employees in various countries of operation. Employees hold several titles that may include Director, Managing Director, Director, Certifier, Inspector, Administrative Assistant, and Representative. As of January 2, 2017, Bio Latina had 223 certified clients and these clients represent 337

certified scopes (193 crops, 99 handling, and 43 trader/broker operations). BIOL certifies 196 Grower Groups.

Auditors conducted witness audits in Peru and Bolivia, of grower group operations certified to crops and handling.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether BIOL 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 BIOL.

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.

NP4293AKA.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: *Bio Latina issued a certificate for an Aloe Vera gel that contains 100% organic aloe vera, citric acid, and potassium sorbate. The certificate identifies the product as 100% organic, which is non-compliant because of the use of citric acid and potassium sorbate in the formulation. The actual labels for the product were correct, identifying the product as "organic"; however, the certificate incorrectly classifies the product as "100% organic."*

2015 Corrective Action: In 2013 Bio Latina issued the operator a new certificate for coffee only; the operator has not since requested the organic certification of aloe vera. A copy of the 2013 certificate was provided to the NOP. In order to avoid mistakes in the classification of products, Bio Latina also instituted two trainings (December 2014 and February 2015) using the 2012 NOP Online Training Module PowerPoint presentation, "Subpart D - Labels, Labeling & Market Information." Copies of the completed, and signed, training forms, *MC02 PER-IE1-INS-221214* and *MC 02 CEN-IE1-INS-030215*, were provided to the NOP. In addition, Bio Latina designed a new form, *MC03 CL3-240315,* that staff is required to complete for products that contain more than one ingredient and/or utilize processing aids. A copy of the new form was provided to the NOP.

2017 Verification of Corrective Actions: The auditor reviewed one operation where Bio Latina utilized the new form, MC03 CL3-240315, for essential oils and correctly identified the product as "organic." Bio Latina has effectively implemented the corrective actions.

AIA16011JZ.NC1 – Cleared. 7 C.F.R §205.501(a)(15)(ii) which states, "(a) A private or governmental entity accredited as a certifying agent under this subpart must: (15) Submit to the Administrator a copy of:…(ii) 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: *The certifier did not publish its list of certified operations to the Organic INTEGRITY Database before the January 8, 2016 deadline.*

2016 Corrective Actions: BIOL published its list of certified operations to the Organic INTEGRITY Database. BIOL developed a procedure for Organic INTEGRITY Database information maintenance and assigned two staff positions to perform these duties. BIOL provided training on the new process on January 27, 2016 to staff. BIOL stated that it will update the Organic INTEGRITY Database throughout the year to insure the information is accurate on January 2 of each year.

2017 Verification of Corrective Action: *Bio Latina submitted updates to the Organic Integrity Database before the annual January 2, 2017 deadline.*

AIA16123JZ.NC1 – Cleared. 7 C.F.R §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…"

Comments: *Bio Latina issued four transaction certificates on October 22 and 29, 2015 allowing Bolivian Shoji to represent product as organic prior to its reinstatement by the NOP. Bio Latina suspended Bolivian Shoji on September 22, 2015. Bio Latina submitted Bolivian Shoji's reinstatement to NOP on November 18, 2015 and was reinstated by the NOP on March 11, 2016.*

2016 Corrective Actions: Bio Latina will not approve or deny certification of a suspended operation without the NOP's written approval, which includes any reinstatement decision by issuing transaction certificates granting an operation permission to act as if it were reinstated. Bio Latina has amended the reinstatement procedure to reference NOP 2605 "*Reinstating Suspended Operations.*" Bio Latina trained applicable personnel on this process change on June 1, 2016.

2017 Verification of Corrective Actions: The auditor reviewed the only reinstatement request processed since Bio Latina's submission of the corrective action. Bio Latina followed the proper reinstatement procedure as stated in their procedure manual (section 4.5.17). Interviews with certifier staff revealed a firm understanding of the reinstatement process.

Noncompliances Identified during the Current Assessment

NP7021JZA.NC1 – 7 C.F.R. §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: *BIOL's organic certificates indicate "Commercialization" as a scope of certification.*

NP7021JZA.NC2 – 7 C.F.R. §205.670(e) states, "…sample integrity must be maintained throughout the chain of custody…"

Comments: *During a witness audit, the inspector allowed a collected sample to be refrigerated at the inspected operation manager's home until the completion of the onsite inspection.*

NP7021JZA.NC3 – 7 C.F.R. §205.670(f) states, "Results of all analyses and tests performed under this section will be available for public access, unless the testing is part of an ongoing compliance investigation."

Comments: *BIOL's policy is not to release the results of residue analysis to the public upon request. Bio-Latina will release residue analysis results only to the operation, another certifier, or with the permission of the operation.*

NP7021JZA.NC4 - 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: *Certified products listed on organic certificates are not in English and identify the products with local names and not commercially know names.*

NP7021JZA.NC5 – 7 C.F.R. §205.405(c)(1)(ii) states, "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: *In one reviewed case of suspension, the applicant was issued a suspension rather than a denial notification. BIOL does not distinguish between the process of suspension and denial of certification.*

NP7021JZA.NC6 – 7 C.F.R. §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."

Comments: *In two cases where BIOL issued proposed suspension, the notifications did not state the effective date of suspension.*

NP7021JZA.NC7 – 7 C.F.R. §205.662(c)(3) states, "The notification of proposed suspension or revocation of certification shall state: The impact of a suspension or revocation on future eligibility for certification;…"

Comments: *In two cases where BIOL issued proposed suspension, the notifications did not state the impact of suspension.*

NP7021JZA.NC8 – 7 C.F.R. § 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: *Two adverse action cases reviewed revealed that the notifications were not issued via a delivery service which provides dated return receipts.*

NP7021JZA.NC9 - 7 C.F.R. §205.501(a)(15)(i) states, "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: *In one of two adverse action cases reviewed, there was no record that the NOP was copied in the notifications.*

NP7021JZA.NC10 – 7 C.F.R. §205.662(a)(3) states, "…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: *Two adverse action cases reviewed revealed that notifications of noncompliance do not state that the operator has the option of rebutting the noncompliance.*

NP7021JZA.NC11 – 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: *Two adverse action cases reviewed revealed that the notification of proposed adverse actions (i.e. proposed suspension or revocation) state that operations may submit corrective actions to address issued noncompliance(s).*

NP7021JZA.NC12 – 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…" §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: *Two adverse action cases reviewed revealed that the certifier issued simultaneously a proposed suspension and the suspension notifications on the same date. There was no period for the operations to request mediation or to file an appeal.*

NP7021JZA.NC13 -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…" §205.307(b) states, "Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable."

Comments: *One approved wholesale label template reviewed did not indicate the use of a lot number.*

USDA Agricultural Marketing Service

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MAR 1 0 2017

NOTICE OF NONCOMPLIANCE

Reynaldo Chapilliquen Abad
Bio Latina
Jr. Domingo Millán 852
Lima, Jesus Maria
18 Peru

Dear Mr. Abad:

On January 21, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Bio Latina (BIOL) organic certification program as part of its USDA Renewal Accreditation Assessment. On March 3, 2017, the NOP reviewed the results of the onsite audit to determine BIOL's compliance to the USDA organic regulations. A copy of the assessment report, NP7021JZA, is enclosed for your reference.

As the report indicates, thirteen new noncompliances (NP7021JZA.NC1 through NC13), 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 BIOL 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 BIOL's USDA accreditation.

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

Enclosure: Noncompliance Report

cc: AIA Inbox

USDA Agricultural Marketing Service

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

MAR 1 0 2017

NOTICE OF NONCOMPLIANCE

Reynaldo Chapilliquen Abad
Bio Latina
Jr. Domingo Millán 852
Lima, Jesus Maria
18 Peru

Dear Mr. Abad:

On January 21, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Bio Latina (BIOL) organic certification program as part of its USDA Renewal Accreditation Assessment. On March 3, 2017, the NOP reviewed the results of the onsite audit to determine BIOL's compliance to the USDA organic regulations. A copy of the assessment report, NP7021JZA, is enclosed for your reference.

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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,

for CC

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

Enclosure: Noncompliance Report

cc: AIA Inbox

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received Bio Latina (BIOL) accreditation renewal application on October 28, 2016. The NOP reviewed BIOL's application, conducted an onsite audit, and reviewed the audit report to determine BIOL's capability to operate as a U.S. Department of Agriculture (USDA) accredited certifier.

GENERAL INFORMATION

Applicant Name	Bio Latina (BIOL)
Physical Address	Jr. Domingo Millán 852, Lima, Jesus Maria, 18 Peru
Mailing Address	Jr. Domingo Millán 852, Lima, Jesus Maria, 18 Peru
Contact & Title	Reynaldo Chapilliquen Abad, General Manager
E-mail Address	central@biolatina.com
Phone Number	00 51 1 2031130
Reviewers & Auditors	Rebecca Claypool, NOP Reviewer; Jason Lopez and Lars Crail, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective action review: April 4, 2017 NOP assessment review: March, 3 2017 Onsite audit: Jan 21 – Jan 28, 2017
Audit Identifier	NP7021JZA
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 BIOL's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BIOL's certification services in carrying out the audit criteria.

The National Organic Program (NOP) conducted an accreditation renewal onsite audit of Bio Latina (BIOL) on January 22-28, 2017.

BIOL is a for-profit organization providing certification services in Latin America. BIOL's accreditation to the USDA organic scopes of crops and handling began on April 29, 2002. The current term of accreditation will expire on April 29, 2017. Bio Latina currently maintains a main office in Lima, Peru, and conducts certification activities in Peru, Bolivia, Nicaragua, Honduras, Panama, El Salvador, and Guatemala. Bio Latina has 43 full time employees in various countries of operation. Employees hold several titles that may include Director,

Managing Director, Director, Certifier, Inspector, Administrative Assistant, and Representative. As of January 2, 2017, Bio Latina had 223 certified clients and these clients represent 337 certified scopes (193 crops, 99 handling, and 43 trader/broker operations). BIOL certifies 196 Grower Groups.

Auditors conducted witness audits in Peru and Bolivia, of grower group operations certified to crops and handling.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether BIOL'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.

NP4293AKA.NC1 – Cleared.
AIA16011JZ.NC1 – Cleared.
AIA16123JZ.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.

NP7021JZA.NC1 – Accepted. 7 C.F.R. §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: *BIOL's organic certificates indicate "Commercialization" as a scope of certification.*

2017 Corrective Action: BIOL issued a newsletter to operators specifying the correct terminology for the scope of certification is handling/processed products rather than commercialization. BIOL submitted a copy of the newsletter ANX01. BIOL also conducted a training for their staff on March 29, 2017 covering the new certificate template. BIOL updated their certification procedure 3-1 section 4.12 of crops or handling/processed products. BIOL submitted an updated certificate (ANX02) a staff training long (ANX03), and their updated procedure (ANX02 Proc 3-1).

NP7021JZA.NC2 – Accepted. 7 C.F.R. §205.670(e) states, "…sample integrity must be maintained throughout the chain of custody…"

Comments: *During a witness audit, the inspector allowed a collected sample to be refrigerated at the inspected operation manager's home until the completion of the onsite inspection.*

2017 Corrective Action: BIOL developed a guide to maintain the integrity of residue test results throughout the chain of custody. The new guide Collection, Preservation and Shipping of Samples explains in section 6 that the person who conducted the sampling must monitor the sample until shipment or it is released to the lab. BIOL updated their certification procedure 3-6 section 4.6.11 to include sampling requirements. BIOL trained their staff on the new policy March 28, 2017 and submitted their training log, the updated procedure (ANX04) and the new guide to sampling (ANX05).

NP7021JZA.NC3 – Accepted. 7 C.F.R. §205.670(f) states, "Results of all analyses and tests performed under this section will be available for public access, unless the testing is part of an ongoing compliance investigation."

Comments: *BIOL's policy is not to release the results of residue analysis to the public upon request. Bio-Latina will release residue analysis results only to the operation, another certifier, or with the permission of the operation.*

2017 Corrective Action: BIOL informed operators and staff the residue test results are available to the public upon request. BIOL updated the Special Aspects of the Certification Scheme section 4.6.10 to include the requirement that test results are available to the public upon request unless the testing is part of an ongoing investigation. BIOL submitted the updated policy (ANEX06). BIOL conducted a staff training on March 29, 2017, and submitted a copy of the training log.

NP7021JZA.NC4 – 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: *Certified products listed on organic certificates are not in English and identify the products with local names and not commercially know names.*

2017 Corrective Action: BIOL informed their operators and staff that products listed on certificates will be listed in English and with names commercially known. BIOL inserted instructional text in the certificate template for products to be listed in English. BIOL conducted a training for staff on March 29, 2017. BIOL submitted the notice sent to operators and staff (ANX06 Circular), a staff training log (ANX03), and the updated certificate template (ANX02 certificate).

NP7021JZA.NC5 – **Accepted.** 7 C.F.R. §205.405(c)(1)(ii) states, "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: *In one reviewed case of suspension, the applicant was issued a suspension rather than a denial notification. BIOL does not distinguish between the process of suspension and denial of certification.*

2017 Corrective Action: BIOL sent a letter to the applicant, explaining that the correct notification should have been a notification of denial. BIOL submitted a copy of the notification of denial (ANX07 PER). BIOL conducted a staff training on March 27, 2017, on the processes leading to the suspension of certified operations and the denial of applicants. BIOL submitted a training log of the March training (ANX09).

NP7021JZA.NC6 – Accepted. 7 C.F.R. §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."

Comments: *In two cases where BIOL issued proposed suspension, the notifications did not state the effective date of suspension.*

2017 Corrective Action: BIOL updated their template of Notice of Proposed Suspension to include a placement of the suspension effective date. BIOL informed their operators and staff of this regulatory requirement and conducted a staff training on March 29, 2017. BIOL submitted the updated template (ANX08 ME4) and the March training log (ANX03).

NP7021JZA.NC7 – Accepted. 7 C.F.R. §205.662(c)(3) states, "The notification of proposed suspension or revocation of certification shall state: The impact of a suspension or revocation on future eligibility for certification;…"

Comments: *In two cases where BIOL issued proposed suspension, the notifications did not state the impact of suspension.*

2017 Corrective Action: BIOL updated the templates for notices of proposed suspension and proposed revocation to include the impact of suspension or revocation. BIOL notified their operators and staff about this regulatory requirement in a newsletter (ANX09 BO). BIOL conducted a staff training on March 29, 2017. BIOL submitted the training log (ANX03) and the updated template (ANX08).

NP7021JZA.NC8 – **Accepted.** 7 C.F.R. § 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: *Two adverse action cases reviewed revealed that the notifications were not issued via a delivery service which provides dated return receipts.*

2017 Corrective Action: BIOL is now using a registered email service for official notices, and a courier service that delivers hard copy documents and provides a receipt of delivery (ANX11 and ANX12). BIOL submitted examples both types of receipts. BIOL trained staff on this procedure change on March 29, 2017 and submitted a training log (ANX03). BIOL also updated their certification procedure 4-2 section 4.3.8 (ANX11 GMP) to include that official notices to operations must be sent with a service that provides dated return receipts.

NP7021JZA.NC9 – Accepted. 7 C.F.R. §205.501(a)(15)(i) states, "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: *In one of two adverse action cases reviewed, there was no record that the NOP was copied in the notifications.*

2017 Corrective Action: BIOL is now sending official notices to the NOP Adverse Action's email inbox as well as to the operation. The email registration service BIOL subscribes to, records the recipients of all email notifications sent. BIOL submitted registered email receipts that included the NOP (ANX13).

NP7021JZA.NC10 – **Accepted.** 7 C.F.R. §205.662(a)(3) states, "…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: *Two adverse action cases reviewed revealed that notifications of noncompliance do not state that the operator has the option of rebutting the noncompliance.*

2017 Corrective Action: BIOL updated their notice of noncompliance to include the option to rebut the noncompliance. BIOL submitted the updated template (ANX12). BIOL trained their staff on March 29, 2017 and submitted the training log (ANX03).

NP7021JZA.NC11 – **Accepted.** 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: *Two adverse action cases reviewed revealed that the notification of proposed adverse actions (i.e. proposed suspension or revocation) state that operations may submit corrective actions to address issued noncompliance(s).*

2017 Corrective Action: BIOL updated their notice of proposed suspension and revocation to only include the options for appeal or to request mediation. BIOL submitted a copy of the updated templates (ANX08). BIOL informed their operators and staff this regulatory requirement, and conducted a staff training on March 27, 2017. BIOL submitted the training log (ANX09).

NP7021JZA.NC12 – Accepted. 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…" §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: *Two adverse action cases reviewed revealed that the certifier issued simultaneously a proposed suspension and the suspension notifications on the same date. There was no period for the operations to request mediation or to file an appeal.*

2017 Corrective Action: BIOL updated their certification procedure 3-7 section 4.5.11/13 to include that notices of proposed suspension/revocation and notices of suspension/revocation may not be sent on the same day (ANX13 proc 3-7). BIOL trained their staff on the updated procedure March 27, 2017 and submitted the training log (ANX09). Operators were also informed about the required change in policy through a newsletter (ANX01 BO).

NP7021JZA.NC13 – Accepted. 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…" §205.307(b) states, "Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable."

Comments: *One approved wholesale label template reviewed did not indicate the use of a lot number.*

2017 Corrective Action: BIOL updated their label checklist to address all of the NOP label requirements including lot numbers on nonretail labels. BIOL trained their staff on the updated checklist on March 29, 2107 and submitted the training log (ANX03). BIOL also submitted the updated label checklist (ANX14)

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

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Contact & Title	Reynaldo Chapilliquen Abad, General Manager
E-mail Address	central@biolatina.com
Phone Number	00 51 1 2031130
Reviewers & Auditors	Rebecca Claypool, NOP Reviewer; Jason Lopez and Lars Crail, On-site Auditors.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective action review: April 4, 2017 NOP assessment review: March, 3 2017 Onsite audit: Jan 21 – Jan 28, 2017
Audit Identifier	NP7021JZA
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 BIOL's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BIOL's certification services in carrying out the audit criteria.

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Comments: *During a witness audit, the inspector allowed a collected sample to be refrigerated at the inspected operation manager's home until the completion of the onsite inspection.*

2017 Corrective Action: BIOL developed a guide to maintain the integrity of residue test results throughout the chain of custody. The new guide Collection, Preservation and Shipping of Samples explains in section 6 that the person who conducted the sampling must monitor the sample until shipment or it is released to the lab. BIOL updated their certification procedure 3-6 section 4.6.11 to include sampling requirements. BIOL trained their staff on the new policy March 28, 2017 and submitted their training log, the updated procedure (ANX04) and the new guide to sampling (ANX05).

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Comments: *BIOL's policy is not to release the results of residue analysis to the public upon request. Bio-Latina will release residue analysis results only to the operation, another certifier, or with the permission of the operation.*

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NP7021JZA.NC4 – 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: *Certified products listed on organic certificates are not in English and identify the products with local names and not commercially know names.*

2017 Corrective Action: BIOL informed their operators and staff that products listed on certificates will be listed in English and with names commercially known. BIOL inserted instructional text in the certificate template for products to be listed in English. BIOL conducted a training for staff on March 29, 2017. BIOL submitted the notice sent to operators and staff (ANX06 Circular), a staff training log (ANX03), and the updated certificate template (ANX02 certificate).

NP7021JZA.NC5 – **Accepted.** 7 C.F.R. §205.405(c)(1)(ii) states, "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: *In one reviewed case of suspension, the applicant was issued a suspension rather than a denial notification. BIOL does not distinguish between the process of suspension and denial of certification.*

2017 Corrective Action: BIOL sent a letter to the applicant, explaining that the correct notification should have been a notification of denial. BIOL submitted a copy of the notification of denial (ANX07 PER). BIOL conducted a staff training on March 27, 2017, on the processes leading to the suspension of certified operations and the denial of applicants. BIOL submitted a training log of the March training (ANX09).

NP7021JZA.NC6 – Accepted. 7 C.F.R. §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."

Comments: *In two cases where BIOL issued proposed suspension, the notifications did not state the effective date of suspension.*

2017 Corrective Action: BIOL updated their template of Notice of Proposed Suspension to include a placement of the suspension effective date. BIOL informed their operators and staff of this regulatory requirement and conducted a staff training on March 29, 2017. BIOL submitted the updated template (ANX08 ME4) and the March training log (ANX03).

NP7021JZA.NC7 – Accepted. 7 C.F.R. §205.662(c)(3) states, "The notification of proposed suspension or revocation of certification shall state: The impact of a suspension or revocation on future eligibility for certification;…"

Comments: *In two cases where BIOL issued proposed suspension, the notifications did not state the impact of suspension.*

2017 Corrective Action: BIOL updated the templates for notices of proposed suspension and proposed revocation to include the impact of suspension or revocation. BIOL notified their operators and staff about this regulatory requirement in a newsletter (ANX09 BO). BIOL conducted a staff training on March 29, 2017. BIOL submitted the training log (ANX03) and the updated template (ANX08).

NP7021JZA.NC8 – **Accepted.** 7 C.F.R. § 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: *Two adverse action cases reviewed revealed that the notifications were not issued via a delivery service which provides dated return receipts.*

2017 Corrective Action: BIOL is now using a registered email service for official notices, and a courier service that delivers hard copy documents and provides a receipt of delivery (ANX11 and ANX12). BIOL submitted examples both types of receipts. BIOL trained staff on this procedure change on March 29, 2017 and submitted a training log (ANX03). BIOL also updated their certification procedure 4-2 section 4.3.8 (ANX11 GMP) to include that official notices to operations must be sent with a service that provides dated return receipts.

NP7021JZA.NC9 – Accepted. 7 C.F.R. §205.501(a)(15)(i) states, "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: *In one of two adverse action cases reviewed, there was no record that the NOP was copied in the notifications.*

2017 Corrective Action: BIOL is now sending official notices to the NOP Adverse Action's email inbox as well as to the operation. The email registration service BIOL subscribes to, records the recipients of all email notifications sent. BIOL submitted registered email receipts that included the NOP (ANX13).

NP7021JZA.NC10 – **Accepted.** 7 C.F.R. §205.662(a)(3) states, "…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: *Two adverse action cases reviewed revealed that notifications of noncompliance do not state that the operator has the option of rebutting the noncompliance.*

2017 Corrective Action: BIOL updated their notice of noncompliance to include the option to rebut the noncompliance. BIOL submitted the updated template (ANX12). BIOL trained their staff on March 29, 2017 and submitted the training log (ANX03).

NP7021JZA.NC11 – **Accepted.** 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: *Two adverse action cases reviewed revealed that the notification of proposed adverse actions (i.e. proposed suspension or revocation) state that operations may submit corrective actions to address issued noncompliance(s).*

2017 Corrective Action: BIOL updated their notice of proposed suspension and revocation to only include the options for appeal or to request mediation. BIOL submitted a copy of the updated templates (ANX08). BIOL informed their operators and staff this regulatory requirement, and conducted a staff training on March 27, 2017. BIOL submitted the training log (ANX09).

NP7021JZA.NC12 – Accepted. 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…" §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: *Two adverse action cases reviewed revealed that the certifier issued simultaneously a proposed suspension and the suspension notifications on the same date. There was no period for the operations to request mediation or to file an appeal.*

2017 Corrective Action: BIOL updated their certification procedure 3-7 section 4.5.11/13 to include that notices of proposed suspension/revocation and notices of suspension/revocation may not be sent on the same day (ANX13 proc 3-7). BIOL trained their staff on the updated procedure March 27, 2017 and submitted the training log (ANX09). Operators were also informed about the required change in policy through a newsletter (ANX01 BO).

NP7021JZA.NC13 – Accepted. 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…" §205.307(b) states, "Nonretail containers used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display the production lot number of the product if applicable."

Comments: *One approved wholesale label template reviewed did not indicate the use of a lot number.*

2017 Corrective Action: BIOL updated their label checklist to address all of the NOP label requirements including lot numbers on nonretail labels. BIOL trained their staff on the updated checklist on March 29, 2107 and submitted the training log (ANX03). BIOL also submitted the updated label checklist (ANX14)

Audit Chronology Log

Audit Identifier (if any): NP7021JZA

Audit Type: Renewal Assessment

Accredited Certifying Agent Name: Bio Latina (BIOL)

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

Date	Activity
3/2/17	NC Report was assigned to RC.
3/3/17	RC began drafting the NC Report.
3/6/17	RC finished making minor edits to the NC Report and drafted a Notice of Noncompliance. Sent RM and CC an email DocRouter to review the NC Report and NoNC.
3/9/17	RC received approval, and printed the documents for final review and signature.
3/10/17	JR process and issued NoNC to Certifier via RPost
4/3/17	Corrective action report assigned to Rebecca Claypool (RC)
4/4/17	RC began reviewing the CAs and drafted the CA report.
4/5/17	RC finished reviewing CAs and emailed BIOL for more information. Many docs were not translated and most CAs were incomplete. The information is due in 1 week 4/12/17
4/10/17	RC received a response from BIOL
4/13/17	RC began reviewing the additional response and updating the CA Report.
4/14/17	RC completed the CA Report. All CAs are acceptable. RC drafted a Notice of Accreditation Renewal, doc router, and sent an email DocRouter to CC for review.
4/20/17	AC met to discuss the renewal of BIOL. AC recommended renewal. Sent docs to Jason Lopez to print for final review.
5/3/17	JR received signed Terms of Accred; and sent Accred Certificate to Certifier

Non-compliances from prior Assessments - cleared

number	non-conformity	verification of corrective action (Sept 2014)	responsible person	status	annex
NP6254EEA.NC1	7 CFR §205.501 11 (v) Conflict of interest were not completely available	Conflict of interest disclosure reports were on file for staff and inspectors, in addition to six administrative board members and seven executive board (management team) members.	-	cleared	-
NP9173ACA.NC2	7 CFR §205.501 (a)(6) Annual performance evaluation	The review of performance evaluation records indicated that evaluations are being conducted for certification staff and inspectors.	-	cleared	-
NP9173ACA.NC7	7 CFR §205.662(a)(3) & (b) Written notification of non-compliance	A review of certification files confirmed that BioI issues a Notice of Noncompliance Resolution to the certified operation when corrective action is accepted as adequate.	-	cleared	-
NP1234NNA.NC1	7 CFR §205.402 (a)(1) incomplete OSP	BioI is currently using the amended handler OSP and livestock inspection form. The audit confirmed that inspections are scheduled only if the information on the OSP is complete and the applicant appears to comply.	-	cleared	-
NP1234NNA.NC2	7 CFR §205.402 (a)(2) procedure for label approval	BioI uses a checklist to ensure that all information on the OSP is reviewed by the certifier. Inspectors only propose noncompliances, and the final decision is made by the certifier upon review of the inspection report. The review of product labels approved by BioI and its materials review process indicated that corrective actions have been properly implemented.	-	cleared	-
NP1234NNA.NC3	7 CFR §205.406 (b) Update OSP	BioI requires its certified operators to complete a new OSP annually. The OSP includes a section for the operator to report whether there are any changes from the previous year.	-	cleared	-
NP1234NNA.NC4	7 CFR §205.501 (a)(7) Annual program review	Review of BioI's 2013 and 2014 program review documents indicated that the internal audit checklist	-	cleared	-

		now includes NOP specific checkpoints.			
NP1234NNA.NC6	7 CFR §205.501 (a)(11)(iv) BioI is outlining corrective actions	The auditor verified that BioI's Notice of Noncompliance form states the noncompliance, and requires the client to respond with corrective action plans. The auditors also reviewed Notices of Noncompliance issued to BioI's clients and found these to be compliant.	-	cleared	-
NP1234NNA.NC11	7 CFR §205.670 (d)(1) results of test samples were not sent to the Administrator	BioI follows the instructions in NOP 2613 Responding to Results from Pesticide Residue Testing, which only requires that the certifier keep the results on file for review during accreditation audits.	-	cleared	-

Non-compliances from prior Assessments - outstanding

number	non-conformity	verification of corrective action (Sept 2014)	measures	responsible person	status	annex
NP1234NNA.NC5	7 CFR §205.501 (a)(8) BioI has not addressed the pasture practice standard under 7 CFR §205.240 and dry matter intake requirements under 7 CFR §205.237 with applicants or certified operations. BioI applies the Bio Suisse rules for requirements of pasture of 156 days with 25% dry matter from pasture. They feel this is a stricter	BioI does not currently certify any ruminant livestock operations or have any applicants seeking livestock certification. However, the current livestock OSP still does not address the requirements of the pasture plan standard under 7 CFR §205.240 and the inspection report does not include the verification of the operation's grazing period. Also, inspectors have not yet been instructed on which requirements need to be	The OSP 25_134EN was updated in section 2, 9, 11 and 12. The annex 9.1 (25_135EN) was updated, too. A new checklist for livestock inspections was created. The templates you find in the annex.	Armelle	done	25_134EN 25_135EN NP1234NNA.NC5

	standard and meets the NOP pasture standard.	verified during the onsite inspection with regard to dry matter intake and pasture access.				
NP1234NNA.NC7	7 CFR §205.501 (a)(18) BioI does not notify the inspector of the certification decision for all sites. The current practice is to only notify the inspector if there have been changes in the decisions from the inspection report.	The auditor noted that BioI notifies the inspector of its certification decision only when the inspection review results in the operation receiving a Notice of Noncompliance.	In future BioI sends the decision of the Certification Body via mail to the operator when no noncompliances were found. You find the template in the annex. The yellow text has to be changed individually from the certifier. The certifier sends the notification of certification decision via mail to the operator and inspector, see 25_154EN, point 24	Julia	done	NP1234NNA.NC7 25_154EN
NP1234NNA.NC8	7 CFR §205.504 (a)(1) BioI does not have a documented training program for staff who review applications for completeness and compliance. Furthermore, BioI has hired new staff to serve in this capacity since the 2009 NOP	The review of training records indicated that BioI has implemented its corrective actions for training certifiers. However, BioI has not implemented a training program for new inspectors, which requires that new inspectors accompany experienced inspectors on inspections until sufficient	The training concept 25_108EN was changed in point 6.1.	Julia	done	25_108EN

	assessment. This is a concern as indicated by the findings outlined under noncompliances for 7 CFR §205.402 (a) (1) and (2). In addition the training program for new inspectors does not include the requirement that they participate in two acceptable shadow inspections before conducting inspections on their own.	experience is obtained.				
NP1234NNA.NC9	NOP §205.642 BioI forwarded a copy of the fee schedule for international clients to the Administrator. However, the price list for domestic clients was not submitted. It is not clear what portion of the fees is nonrefundable.	The review of BioI's fee schedules indicated that though its nonrefundable policies are stated on the Domestic Processing, Domestic Agriculture, and International fee schedules, it is not stated on the fee schedule for Turkey.	The nonrefundable policies were added in the fee schedule for Turkey.	Armelle	done	NP1234NNA.NC9
NP1234NNA.NC10	NOP §205.662 (a) BioI sent a notice of suspension to a certified operation without first issuing a Notice of	BioI follows the instructions of NOP 2605 Reinstating Suspended Organic Operations when suspended operations apply for certification. However, BioI	The procedure will be explained again in the certifier training in March 2015. More information was added in the document	Julia	done	25_154EN

	Noncompliance, and a Notice of Proposed Suspension. The inspection report noted several noncompliances; however, the operation was not given the opportunity to correct or rebut the noncompliances. Additionally, BioI allowed the operation to reapply for certification as a new applicant directly through BioI without the operation first requesting to be reinstated through the Secretary of Agriculture as required by 7 CFR §205.662(f).	issued a certified operation a termination of certification notice without following the noncompliance and adverse actions process as required by the USDA organic regulations.	25_154EN. All changes are marked yellow. Within the evaluation of the certifier the compliance of the procedure will be better approved.			

Non-compliances identified during the current Assessment

number	non-conformity	measure	responsible person	status	annex
NP4252LCA.NC1	7 CFR §205.660(d) Notifications of noncompliance resolution are not issued by BioI via a delivery service which provides dated return receipts.	The process 25_154EN has changed in point 34. In future all notification of noncompliances resolution will be send via registered letter, too.	Julia	done	25_154EN
NP4252LCA.NC2	7 CFR §205.642 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. In general, BioI provides new applicants and operations for continuing certification its published fee schedule that allows them to estimate their certification costs. International operations and operations that request an estimate of certification expenses are provided one. However, BioI is not providing all new applicants and all continuing operations a cost estimate of initial or continuing certification.	From year 2015 on bio.inspecta will provide all applicants and all continuing operations a cost estimate. The template for the applicants is in annex NP4252LCA.NC2.1, the template for all continuing operations is in annex NP4252LCA.NC2.2. The yellow text has to be changed individually from the person who makes the cost estimate.	Julia/ Armelle	done	NP4252LCA.NC2.1 NP4252LCA.NC2.2
NP4252LCA.NC3	7 CFR §205.501(a)(1) BioI issued a certified operation a Notice of Certification Termination without following the noncompliance and adverse actions processes as required by the USDA organic	The procedure will be explained again in the certifier's training in March 2015. More information was added in the document 25_154EN. Within the internal audit the compliance of the procedure will be checked at random.	Julia	done	25_154EN

	regulations.				
NP4252LCA.NC4	7 CFR §205.501(a)(1) Several noncompliances were reviewed for content and applicability during the audit. Noncompliances did not correctly match the regulatory citation to the evidence or the inspector's description. Several noncompliances cited a general regulatory reference without specifically identifying the applicable subsection of the regulation. Inspectors are not required to reference the organic regulation when identifying issues of concern in their reports or during the exit interview. During one of the witness audits, the inspector identified an issue of concern relating to record keeping (7 CFR §201.103(b)(4)), but indicated to the auditor that it was a label violation (7 CFR §205.300-311). When the auditor questioned the inspector for more specifics about the reference, the inspector showed the auditor BioI handouts from a recent training as supporting evidence of the noncompliance.	The correct reference to the regulatory will be trained in March 2015. BioI will make a test after the training to check if the knowledge is available. The training materials will be sent to USDA until March 9, 2015.	Julia	done	
NP4252LCA.NC5	7 CFR §205.501(a)(21) There are several grower group certified operations located in Turkey and on the January 2, 2014 list submitted to the NOP. A review of those operations revealed that they do not meet the definition of a grower	see annex	Armelle	done	NP4252LCA.NC5

	group because there is no Internal Control System (ICS) and the groups are not responsible for their own certification. Instead these operations are a group of uncertified, independent farmers that are contracted by a trader or exporter to provide product; the trader or exporter is the named party on the organic certificate.				
NP4252LCA.NC6	7 CFR §205.501(a)(21) In addition to the uncertified groups of producers listed as certified by BioI, there appear to be several uncertified processing facilities involved in the handling (drying, sorting, storing, and packing) of crops supplied by these groups that are being labeled as organic.	Up to now bio.inspecta insists an own NOP certification of each third contracting company. The companies will be informed with the letter in the annex. This issue will be trained in March 2015. We want to remark that we worry that all certifying agents have this practice. We hope that we don't have a disadvantage if we enforce this requirement.	Armelle	done	NP4252LCA.NC6
NP4252LCA.NC7	7 CFR §205.403(e)(2) Pesticide residue results obtained by BioI are not consistently issued to the operations that provided the sample.	In the "Procedure Sample collection and analysis of residues" 25_255EN the point, that the results of analysis are forwarded to the client, was added, section "Analysis".	Julia/ Armelle	done	25_255EN
NP4252LCA.NC8	7 CFR § 205.403 (c)(1) During the witness inspection of a handler operation, the inspector did not verify transportation clean-out documentation even though it was clear that the operation was responsible for procuring transportation of the organic wheat from the crop operations to the storage facility.	In the checklist a note was added that the cleaning documents are available. This issue will be part of the auditor training in March 2015.	Julia	done	NP4252LCA.NC8
NP4252LCA.NC9	7 CFR § 205.403 (e)(2)	All national processors get the inspection report	Julia/	done	25_154EN

	During the witness inspection of a handler operation, it was confirmed that the operator was not provided with a copy of its inspection report in 2013.	from the auditor after the audit via mail. All national farmers and international farmers and processors get the inspection report from the Admin/secretariat INT with other documents like certificate, invoice etc. See point 41 of the document 25_154EN.	Armelle		
NP4252LCA.NC10	7 CFR § 205.404 (b) The categories on organic certificates issued by BioI are production, preparation, storage, and trade, which do not comply with the categories required by the USDA NOP. The anniversary date is not listed on organic certificates.	The certificate has changed. You find the templates in the annex. NP4252LCA.NC10.1 together with NP4252LCA.NC10.2 is an example for a processing client. NP4252LCA.NC10.3 is an example for a crop and wild crop client.	Julia	done	NP4252LCA.NC10.1 NP4252LCA.NC10.2 NP4252LCA.NC10.3

USDA Agricultural Marketing Service

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Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM REPORT: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Bio.inspecta AG organic program was conducted on September 9-10, 2014. The National Organic Program (NOP) reviewed the auditor's report to assess Bio.inspecta's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name:	Bio.inspecta AG (BioI)
Physical Address:	Ackerstrasse, CH-5070, Frick, Switzerland
Mailing Address:	Ackerstrasse, CH-5070, Frick, Switzerland
Contact & Title:	Julia Winter, Program Manager
E-mail Address:	julia.winter@bio-inspecta.ch
Phone Number:	+41 (0) 62 865 63 24
Reviewer (s) and Auditor(s):	Renée Gebault King, NOP Reviewer; Lars Crail, Onsite Lead Auditor; Robert Yang, Audit Trainee.
Program:	USDA National Organic Program (NOP)
Review and Audit Date(s):	NOP Review date: November 30, 2014 Onsite assessment date: September 10-12, 2014
Audit Identifier:	NP4252LCA
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:	*7 CFR Part 205, National Organic Program as amended*
Audit and Review Scope:	Assessment of BioI's certification services in carrying out the audit criteria April 5, 2014 through September 12, 2014.

GENERAL INFORMATION

Bio.inspecta (BioI) currently has 75 clients certified to the USDA NOP that includes 6 crop, 1 wild crop, 17 livestock and 51 processing/handling operations; it has also certified 7 traders and 1 grower group. BioI is currently certifying operations to the USDA NOP in Switzerland, Albania, Tanzania, India, Lebanon, Indonesia, and Romania. The main office is located in Frick, Switzerland, with staff housed in a complex that includes an organic research and development division. While BioI is housed in the same complex, there is no affiliation with the research and development division. BioI is also accredited to administer private labels to Bio Suisse, M-Bio, Manor, Naur Plus, Demeter and GlobalGap. BioI has four COR (Canadian Organic Regime) clients, of which three are also certified to the USDA NOP.

FEES

The BioI fee schedule is available to clients via the company website or it is sent as part of the application packet for any client who requests information. Fees include an inspection fee, review fee and certification fee. The fees appear to be reasonable and the fee schedule is clear in the amount charged. BioI provides an estimate of costs for certification in a pre-inspection letter to each new client. If there are no changes to the fee schedule, clients are notified through the annual company newsletter.

PERSONNEL

The list of personnel identified 15 staff members with personnel performing more than one role in the certification process. The BioI certification program is broken down into three sections: the Agriculture section; Processing and Handling section; and the International Services section. The positions filled by the 15 personnel include the following: two section heads (same section head for Agriculture and International Services section), with the Processing and Handling section head also listed as a certifier and inspector; three product managers with all listed as certifiers and two also listed as inspectors; nine certifiers with six also listed as inspectors; and one staff inspector. In addition to the staff, there were approximately 17 subcontracted inspectors; five members on an administrative board of directors; and a five member executive board of directors.

Job descriptions for the section heads, product managers, and certifiers are contained in the Quality Management Handbook. Certifiers conduct the initial review for completeness and compliance, review material inputs, review labels, and make the certification decision. In some situations the certifiers send the file to the certification committee for a decision. The certification committee consists of the two program managers and the section head. The case is discussed, with the final determination made by the section head.

Interviews conducted during the audit verified that during some inspections inspectors are reviewing, approving and/or obtaining labels, material inputs, and updated organic system plans. In addition, files reviewed during the audit indicate that the BioI training program needs to be improved and a training program for certifiers developed. There were no conflict of interest issues with any personnel identified during the assessment process other than missing or outdated reports.

CERTIFICATION PROCESS

When requests for certification are received an information packet specific to the scope of a client's request is sent out to the client and the USDA organic standard is provided to the applicants through the BioI website. Materials can be sent to clients either electronically or in hard copy.

Initial applications and organic system plans (OSPs) are reviewed for completeness and ability to comply by staff certifiers. Labels and materials/inputs can be reviewed as part of this process. Program managers assign an inspector to complete the inspection after review of the application materials. Inspectors are assigned on the basis of expertise, location and scope of inspection. Upon assignment, inspectors receive the complete client file that includes the OSP, all annexes and, when applicable, the previous inspection report.

After the completion of the inspection, inspection materials are reviewed for completeness and compliance by a certifier or program manager. BioI also contracts with CERES to conduct material reviews on its behalf, though this service has not been used to date.

The certifier makes the decision to certify an operation and also to issue non-compliances if necessary. Records showed that in all cases the certification decision was made by someone different from the one that conducted the initial review, secondary review, and/or the inspection.

ADMINISTRATIVE PROCEDURES

BioI has written procedures to address issuance of noncompliances, adverse actions and mediation and appeals. All notices of noncompliance issued thus far were also provided to the NOP Appeals Team. There have been no denials of certification, no requests for mediation or any appeals. One letter of suspension was issued to an operation, but the auditor noted the required procedure for issuing the suspension was not followed.

BioI has conducted an annual program review and annual updates have been submitted to the USDA NOP Administrator as required. However, the annual program review is not specific to the NOP and is general in scope.

WITNESS INSPECTIONS

As part of the assessment a witness inspection was conducted on a handling operation. The handling operation was a small processor of spices and herbs, and trader of essential oils. The operator cuts, grinds, and mixes the spices and herbs in small quantities. If larger orders need to be processed, they are sent to a subcontracted processor that is also certified by BioI. The inspection was conducted by a BioI certifier who was also qualified as an inspector. All areas were verified as required and an exit interview was conducted.

A witness inspection was also conducted at a crop and livestock operation. This NOP inspection was conducted in conjunction with an inspection for Bio Suisse certification. The operation included a milking herd of cows and organic crop land for production of hay, corn silage, carrots and wheat. The inspector verified several elements of the OSP such as fertilizers, materials, machinery, and crop rotations, but did not confirm compliance with the NOP Pasture Rule. BioI considers the requirements for Bio Suisse forage intake to exceed the requirements for dry matter intake from pasture as stated in the NOP Rule, and therefore, does not make any additional considerations or calculations for 30% dry matter intake during the grazing season. An exit interview was conducted with the knowledgeable representative of the operation.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether BioI'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 BioI.

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.

NP6254EEA.NC1 – Cleared- 7 CFR §205.501 11 (v) - General Requirements for Accreditation states, "Prevent conflicts of interest by: requiring all persons who review applications for certification, perform onsite inspection, 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." *The board of directors and two employees did not have current (annual) conflict of interest statements on file since their "Contract Agreement" uses different terminology, and does not contain the conflict of interest clause that all other personnel contracts contain.*

Corrective Action (2006): No corrective action submitted.

Corrective Action (August 27, 2007): BioI stated in the corrective actions that they submitted Conflict of Interest disclosure reports; however, there were no conflict of interest disclosure reports attached to the corrective actions.

Corrective Action (December 5, 2007): Conflict of Interest disclosure reports were submitted for all 12 principles and inspectors of the society. This adequately addresses the finding.

Verification of Corrective Action (June 2009): Conflict of Interest disclosure reports were reviewed for the previous and current personnel involved in inspections, document review and certification of operations; most were found to be in compliance. However, the BioI division managers, one division quality manager, and one inspector had not completed the conflict of interest disclosure report.

Corrective Action (2009): Conflict of interest disclosure reports for the Division Managers, Quality Manager, and inspector was submitted and reviewed.

2011 Mid-Term Assessment Finding: There were no conflict of interest disclosure reports on file for one of the five members on the administrative board of directors and one of the five members on the executive board of directors. Also, there were no current conflict of interest disclosure reports on file for three of the subcontracted inspectors. Based upon this finding, the noncompliance, accepted as adequately addressed in 2009, was reverted to outstanding.

Corrective Actions (2011): The corrective actions adequately address the noncompliance. BioI submitted the missing conflict of interest disclosure reports as part of its corrective actions. BioI modified its quality system procedures to indicate that conflict of interest reports will be compiled annually at the end of February. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): Conflict of interest disclosure reports were on file for staff and inspectors, in addition to six administrative board members and seven executive board (management team) members.

NP9173ACA.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 onsite 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." *One member of the certification committee had no current performance evaluation. Also, the contract inspectors did not have current performance evaluations.*
Corrective Action (2009): BioI submitted a statement indicating that all inspectors and certifying staff will have a performance evaluation at least once a year.
2011 Mid-Term Assessment Finding: One staff and one subcontracted inspector's most recent performance evaluation was dated in 2009, and two subcontracted inspectors did not have a performance evaluation in their file at all. Based upon this finding, the noncompliance, accepted as adequately addressed in 2009, was reverted to outstanding.
Corrective Actions (2011): BioI's corrective actions submitted in November 2011 were the same corrective actions submitted in 2009. The 2011 Mid-Term Assessment determined that this corrective action was not effectively implemented. The NOP reviewer requested additional information about the performance evaluation schedule for BioI staff.
Corrective Actions (January 2012): BioI's response indicated that inspector reports are assessed by certification staff. Furthermore, these assessments are part of the performance evaluation given at BioI's annual staff training in February and March 2012. Certification staff will also receive their performance evaluations at the annual training. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): The review of performance evaluation records indicated that evaluations are being conducted for certification staff and inspectors.

NP9173ACA.NC7 – Cleared – 7 CFR §205.662(a)(3) & (b) 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. Such notification shall provide: (3) the date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation… (b) When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent… shall send the certified operation a written notification of noncompliance resolution." *BioI had a client that had a noncompliance identified during the onsite inspection but the client submitted corrective actions before the report was sent out. BioI did not send a written notification of noncompliance resolution.* **Corrective Action:** BioI has modified and added a new check point on form 24_154 to ensure that a noncompliance resolution is sent to the client. BioI stated they did inform the client that the corrective actions submitted were adequate.
2011 Mid-Term Assessment Finding: While BioI has been issuing notices of noncompliance in the required manner, notices of resolution have not been sent to certified operations when corrective action is accepted as adequate. Based upon this finding, the noncompliance, accepted as adequately addressed in 2009, was reverted to outstanding. **Corrective Actions:** The corrective actions adequately address the noncompliance. BioI submitted a Notice of Noncompliance Resolution template as part of its corrective actions for this noncompliance. BioI has modified its quality system procedures to indicate that noncompliance resolution letters will be sent to operations when noncompliances are resolved. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): A review of certification files confirmed that BioI issues a Notice of Noncompliance Resolution to the certified operation when corrective action is accepted as adequate.

NP1234NNA.NC1 – Cleared. 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." *The audit reviewed certification files and verified that inspections are assigned even when applications with incomplete OSPs received. The OSP for the livestock witness audit did not contain or identify homeopathic materials used on the livestock operation. The OSP for the handler witness audit did not contain:*

- *Cleaning procedures for all equipment, including the equipment used for oil distillation. The witness audit revealed that sometimes alcohol is used to clean the equipment, but this information was not included in the OSP. The OSP indicated that only water and vinegar were used for cleaning;*
- *A list or general information on all equipment utilized;*
- *Procedures for verifying the organic status of raw materials upon receipt;*
- *Procedures for and the frequency of monitoring activities for receiving, production, and shipping practices to ensure the OSP is effectively implemented;*
- *Current labels utilized by the operation; and*
- *The process for product treated with carbon dioxide.*

Corrective Actions: BioI's handling OSP forms have been amended to include requests for information on equipment utilized and cleaning procedures used during processing. The amended handling OSP also requires the operation provide:

- A complete list of products, ingredients, additives, processing aids, and suppliers.
- A description of monitoring and internal quality control practices, including practices used for monitoring receipt of and use of ingredients.
- Labels used on organic products.

BioI's inspection form for organic livestock production has been amended to include an assessment of medications, including homeopathic materials, which may be used during livestock health care practices. Certifiers will review this information for NOP compliance before scheduling inspections. If the OSP is not compliant or is incomplete, the inspection will not be scheduled. To prevent this noncompliance from reoccurring, BioI modified its quality system by amending the OSP forms to require more detailed descriptions and amended its OSP review procedures to assess OSP's for NOP compliance before inspections are scheduled. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): BioI is currently using the amended handler OSP and livestock inspection form. The audit confirmed that inspections are scheduled only if the information on the OSP is complete and the applicant appears to comply.

NP1234NNA.NC2 – 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 an applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part." *The files reviewed and interviews conducted by the auditor verified that inspectors are making approval decisions for labels, materials, and inputs during inspections. Additionally, there is no procedure or process for*

the certifier to review and approve labels prior to inspection to enable inspectors to verify the use of approved labels. Of three labels reviewed for one handler, all had the "Certified by" statement above the information identifying the distributor as opposed to below it. The review of livestock files showed that BioI approved the use of levamasole and the antibiotic tetracycline in cattle, but neither substance is on the National List of approved substances.
Corrective Actions: BioI amended its procedures for reviewing OSPs or amendments to specify that production practices, materials, labels, and other plan information are reviewed for compliance by a staff certifier prior to scheduling an inspection. The amended procedures also indicate that OSPs or amended OSPs will be verified during the inspection. The inspector will only verify the OSP and will not be making certification decisions. If the OSP is not complete or is not compliant with the NOP regulations, the certifier will not schedule the inspection. When reviewing labels, the certifiers will not approve labels unless the term "certified by" appears below the information identifying the distributor. Also, certifiers will review livestock medications for NOP compliance and will only approve materials that comply with the NOP regulations. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): BioI uses a checklist to ensure that all information on the OSP is reviewed by the certifier. Inspectors only propose noncompliances, and the final decision is made by the certifier upon review of the inspection report. The review of product labels approved by BioI and its materials review process indicated that corrective actions have been properly implemented.

NP1234NNA.NC3 – Cleared. 7 CFR §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 onsite inspection of the certified operation pursuant to §205.403." *BioI has not required operators to submit updates to the OSP if there are no changes to the plan, but updates are collected at the time of inspection.*
Corrective Actions: BioI changed its certification review checklist to specify that certifiers will review annual OSP updates for compliance before scheduling inspections. The change in the checklist has been incorporated into the quality manual procedures. In March 2012, BioI will train staff involved with NOP certification on the amended procedures. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): BioI requires its certified operators to complete a new OSP annually. The OSP includes a section for the operator to report whether there are any changes from the previous year.

NP1234NNA.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…" *BioI conducts annual program reviews. The program reviews, however, generally focus on BioI's quality management system as it pertains to the requirements of ISO accreditation in general and not specific to the NOP Final Rule requirements.*
Corrective Actions: BioI will include NOP regulatory requirements within the scope of its next annual review in March 2012. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): Review of BioI's 2013 and 2014 program review documents indicated that the internal audit checklist now includes NOP specific checkpoints.

NP1234NNA.NC6 – C**leared.** 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." *The review of Notices of Noncompliance sent to operators indicated that BioI is outlining corrective actions for the operator to implement to resolve noncompliances.*
Corrective Actions: Certifiers will issue Notices of Noncompliance to certified operations or new applicants. The operation receiving the notice will be required to propose and implement corrective actions to resolve noncompliances. BioI has modified its quality system procedures to implement these changes when noncompliances are identified during NOP certification activities. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): The auditor verified that BioI's Notice of Noncompliance form states the noncompliance, and requires the client to respond with corrective action plans. The auditors also reviewed Notices of Noncompliance issued to BioI's clients and found these to be compliant.

NP1234NNA.NC11 – **Cleared.** 7 CFR §205.670 (d)(1) states, "Results of all analyses and tests performed under this section: Must be promptly provided to the Administrator..." *BioI has collected and tested samples from NOP clients; however, the results of these tests have not been forwarded to the Administrator.*
Corrective Actions: BioI provided analytical results to the NOP on October 20, 2011. BioI's instructions on sample collection, procedures for analysis of residues, and the sampling record template have been established. The quality system procedures have been modified to include instructions for sending analysis results to NOP on a regular schedule. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): BioI follows the instructions in NOP 2613 Responding to Results from Pesticide Residue Testing, which only requires that the certifier keep the results on file for review during accreditation audits.

NP1234NNA.NC5 – **Outstanding.** 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." *BioI has not addressed the pasture practice standard under 7 CFR §205.240 and dry matter intake requirements under 7 CFR §205.237 with applicants or certified operations. BioI applies the Bio Suisse rules for requirements of pasture of 156 days with 25% dry matter from pasture. They feel this is a stricter standard and meets the NOP pasture standard.*
Corrective Actions: Beginning in January 2012, BioI will provide notice to clients on the pasture practice standard under 7 CFR § 205.240 and dry matter requirements under 7 CFR § 205.237. BioI has amended its quality system by modifying the livestock OSP form to request information relevant to the NOP pasture practice standard and pasture dry matter feeding requirements. During inspections, the inspector must also assess whether an operation is

complying with the NOP requirement for 30% dry matter intake from pasture grazed during the grazing season, and determine if ruminants have had access to pasture for at least 120 days during the grazing season. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): BioI does not currently certify any ruminant livestock operations or have any applicants seeking livestock certification. However, the current livestock OSP still does not address the requirements of the pasture plan standard under 7 CFR §205.240 and the inspection report does not include the verification of the operation's grazing period. Also, inspectors have not yet been instructed on which requirements need to be verified during the onsite inspection with regard to dry matter intake and pasture access.

NP1234NNA.NC7 – **Outstanding.** 7 CFR §205.501 (a)(18) states, "A private or governmental entity accredited as a certifying agent under this subpart must:…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 non compliances." *BioI does not notify the inspector of the certification decision for all sites. The current practice is to only notify the inspector if there have been changes in the decisions from the inspection report.*
Corrective Actions: BioI has modified its procedures to indicate that an inspector will receive a copy of the certification decision when notification is provided to the operation. BioI has established letter and checklist templates for providing notifications on NOP certification decisions to clients and inspectors. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): The auditor noted that BioI notifies the inspector of its certification decision only when the inspection review results in the operation receiving a Notice of Noncompliance.

NP1234NNA.NC8 – **Outstanding.** 7 CFR §205.504 (a)(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… (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel." *BioI does not have a documented training program for staff who review applications for completeness and compliance. Furthermore, BioI has hired new staff to serve in this capacity since the 2009 NOP assessment. This is a concern as indicated by the findings outlined under noncompliances for 7 CFR §205.402 (a) (1) and (2). In addition the training program for new inspectors does not include the requirement that they participate in two acceptable shadow inspections before conducting inspections on their own.*
Corrective Actions: BioI revised its training programs for new inspectors and certifiers. The training program covers procedures for initially reviewing OSPs for completeness and compliance with the NOP regulations. BioI also modified its quality system procedures to indicate that new inspectors without experience must accompany experienced inspectors on inspections until sufficient experience is obtained. When the experience training is complete, the trained inspectors will be independently assigned to carry out inspections. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): The review of training records indicated that BioI has implemented its corrective actions for training certifiers. However, BioI

has not implemented a training program for new inspectors, which requires that new inspectors accompany experienced inspectors on inspections until sufficient experience is obtained.

NP1234NNA.NC9 – **Outstanding.** NOP §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 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." *BioI forwarded a copy of the fee schedule for international clients to the Administrator. However, the price list for domestic clients was not submitted. It is not clear what portion of the fees is nonrefundable.*
Corrective Actions: BioI provided a 2012 fee schedule which describes NOP certification fees for both international and domestic clients. The disclaimer, "all fees are nonrefundable," is noted on the fee schedule.
Verification of Corrective Action (September 2014): The review of BioI's fee schedules indicated that though its nonrefundable policies are stated on the Domestic Processing, Domestic Agriculture, and International fee schedules, it is not stated on the fee schedule for Turkey.

NP1234NNA.NC10 – **Outstanding.** 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 notice of noncompliance shall be sent to the certified operation." *BioI sent a notice of suspension to a certified operation without first issuing a Notice of Noncompliance, and a Notice of Proposed Suspension. The inspection report noted several noncompliances; however, the operation was not given the opportunity to correct or rebut the noncompliances. Additionally, BioI allowed the operation to reapply for certification as a new applicant directly through BioI without the operation first requesting to be reinstated through the Secretary of Agriculture as required by 7 CFR §205.662(f).*
Corrective Actions: BioI modified its procedures to implement noncompliance procedures for certified operations described in 7 CFR §205.662 when noncompliances are identified during certification activities. Adverse actions will be issued to operations when noncompliances cannot be resolved. On October 10, 2011, BioI issued a combined Notice of Noncompliance and Denial of Certification to the operation cited in the noncompliance description. BioI's November 2011 submission of corrective actions did not address requirements for reinstating suspended operations. The NOP reviewer requested additional information on BioI's procedures for reinstating suspended operations. BioI's response indicated that, in 2012, it will implement NOP reinstatement procedures described in the NOP Program Handbook when suspended operations request NOP reinstatement. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): BioI follows the instructions of NOP 2605 Reinstating Suspended Organic Operations when suspended operations apply for certification. However, BioI issued a certified operation a termination of certification notice without following the noncompliance and adverse actions process as required by the USDA organic regulations.

Non-compliances Identified during the Current Assessment

NP4252LCA.NC1 - 7 CFR §205.660(d) states that "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 of noncompliance resolution are not issued by BioI via a delivery service which provides dated return receipts.*

NP4252LCA.NC2 - 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."
Comments: *In general, BioI provides new applicants and operations for continuing certification its published fee schedule that allows them to estimate their certification costs. International operations and operations that request an estimate of certification expenses are provided one. However, BioI is not providing all new applicants and all continuing operations a cost estimate of initial or continuing certification.*

NP4252LCA.NC3 – 7 CFR §205.501(a)(1) states that certifiers must "Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part."

- 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."
- 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.
- 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…shall send the certified operation a written notification of suspension or revocation."

Comments: *BioI issued a certified operation a Notice of Certification Termination without following the noncompliance and adverse actions processes as required by the USDA organic regulations.*

NP4252LCA.NC4 – 7 CFR §205.501(a)(1) states that certifiers must "Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part."

- 7 CFR §205.662(a)(1) states that, "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: A description of each noncompliance."

Comments: *Several noncompliances were reviewed for content and applicability during the audit. Noncompliances did not correctly match the regulatory citation to the evidence or the inspector's description. Several noncompliances cited a general regulatory reference without specifically identifying the applicable subsection of the regulation. Inspectors are not required to reference the organic regulation when identifying issues of concern in their reports or during the exit interview. During one of the witness audits, the inspector identified an issue of concern relating to record keeping (7 CFR §201.103(b)(4)), but indicated to the auditor that it was a label violation (7 CFR §205.300-311). When the auditor questioned the inspector for more specifics about the reference, the inspector showed the auditor BioI handouts from a recent training as supporting evidence of the noncompliance.*

NP4252LCA.NC5 – 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." Furthermore,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: *There are several grower group certified operations located in Turkey and on the January 2, 2014 list submitted to the NOP. A review of those operations revealed that they do not meet the definition of a grower group because there is no Internal Control System (ICS) and the groups are not responsible for their own certification. Instead these operations are a group of uncertified, independent farmers that are contracted by a trader or exporter to provide product; the trader or exporter is the named party on the organic certificate.*

NP4252LCA.NC6– 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." Furthermore, NOP 4009 "Who Needs to be Certified?" in the program handbook 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: *In addition to the uncertified groups of producers listed as certified by BioI, there appear to be several uncertified processing facilities involved in the handling (drying, sorting, storing, and packing) of crops supplied by these groups that are being labeled as organic.*

NP4252LCA.NC7 - 7 CFR §205.403(e)(2) states, "A copy of the onsite inspection report and any test results will be sent to the inspected operation by the certifying agent."
Comments: *Pesticide residue results obtained by BioI are not consistently issued to the operations that provided the sample.*

NP4252LCA.NC8 - 7 CFR § 205.403 (c)(1) states, "The onsite inspection of an operation must verify: the operation's comply with the Act and the regulations in this part."
Comments: *During the witness inspection of a handler operation, the inspector did not verify transportation clean-out documentation even though it was clear that the operation was responsible for procuring transportation of the organic wheat from the crop operations to the storage facility.*

NP4252LCA.NC9 – 7 CFR § 205.403 (e)(2) states, "A copy of the onsite inspection report … will be sent to the inspected operation by the certifying agent."
Comments: *During the witness inspection of a handler operation, it was confirmed that the operator was not provided with a copy of its inspection report in 2013.*

NP4252LCA.NC10 – 7 CFR § 205.404 (b) states, "The certifying agent must issue a certificate of organic operation…." NOP 2603 Organic Certificates indicates that "Organic certificates should … include the following:

- Categories of organic operation (crops, wild crops, livestock, and handling/processing)
- Anniversary date (when the certified operation must submit its annual update)

Comments: *The categories on organic certificates issued by BioI are production, preparation, storage, and trade, which do not comply with the categories required by the USDA NOP. The anniversary date is not listed on organic certificates.*

USDA Agricultural Marketing Service

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NATIONAL ORGANIC PROGRAM REPORT: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Bio.inspecta AG organic program was conducted on September 9-10, 2014. The National Organic Program (NOP) reviewed the auditor's report to assess Bio.inspecta's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name:	Bio.inspecta AG (BioI)
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Reviewer (s) and Auditor(s):	Renée Gebault King, NOP Reviewer; Lars Crail, Onsite Lead Auditor; Robert Yang, Audit Trainee.
Program:	USDA National Organic Program (NOP)
Review and Audit Date(s):	NOP Review date: November 30, 2014 Onsite assessment date: September 10-12, 2014
Audit Identifier:	NP4252LCA
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:	*7 CFR Part 205, National Organic Program as amended*
Audit and Review Scope:	Assessment of BioI's certification services in carrying out the audit criteria April 5, 2014 through September 12, 2014.

GENERAL INFORMATION

Bio.inspecta (BioI) currently has 75 clients certified to the USDA NOP that includes 6 crop, 1 wild crop, 17 livestock and 51 processing/handling operations; it has also certified 7 traders and 1 grower group. BioI is currently certifying operations to the USDA NOP in Switzerland, Albania, Tanzania, India, Lebanon, Indonesia, and Romania. The main office is located in Frick, Switzerland, with staff housed in a complex that includes an organic research and development division. While BioI is housed in the same complex, there is no affiliation with the research and development division. BioI is also accredited to administer private labels to Bio Suisse, M-Bio, Manor, Naur Plus, Demeter and GlobalGap. BioI has four COR (Canadian Organic Regime) clients, of which three are also certified to the USDA NOP.

FEES

The BioI fee schedule is available to clients via the company website or it is sent as part of the application packet for any client who requests information. Fees include an inspection fee, review fee and certification fee. The fees appear to be reasonable and the fee schedule is clear in the amount charged. BioI provides an estimate of costs for certification in a pre-inspection letter to each new client. If there are no changes to the fee schedule, clients are notified through the annual company newsletter.

PERSONNEL

The list of personnel identified 15 staff members with personnel performing more than one role in the certification process. The BioI certification program is broken down into three sections: the Agriculture section; Processing and Handling section; and the International Services section. The positions filled by the 15 personnel include the following: two section heads (same section head for Agriculture and International Services section), with the Processing and Handling section head also listed as a certifier and inspector; three product managers with all listed as certifiers and two also listed as inspectors; nine certifiers with six also listed as inspectors; and one staff inspector. In addition to the staff, there were approximately 17 subcontracted inspectors; five members on an administrative board of directors; and a five member executive board of directors.

Job descriptions for the section heads, product managers, and certifiers are contained in the Quality Management Handbook. Certifiers conduct the initial review for completeness and compliance, review material inputs, review labels, and make the certification decision. In some situations the certifiers send the file to the certification committee for a decision. The certification committee consists of the two program managers and the section head. The case is discussed, with the final determination made by the section head.

Interviews conducted during the audit verified that during some inspections inspectors are reviewing, approving and/or obtaining labels, material inputs, and updated organic system plans. In addition, files reviewed during the audit indicate that the BioI training program needs to be improved and a training program for certifiers developed. There were no conflict of interest issues with any personnel identified during the assessment process other than missing or outdated reports.

CERTIFICATION PROCESS

When requests for certification are received an information packet specific to the scope of a client's request is sent out to the client and the USDA organic standard is provided to the applicants through the BioI website. Materials can be sent to clients either electronically or in hard copy.

Initial applications and organic system plans (OSPs) are reviewed for completeness and ability to comply by staff certifiers. Labels and materials/inputs can be reviewed as part of this process. Program managers assign an inspector to complete the inspection after review of the application materials. Inspectors are assigned on the basis of expertise, location and scope of inspection. Upon assignment, inspectors receive the complete client file that includes the OSP, all annexes and, when applicable, the previous inspection report.

After the completion of the inspection, inspection materials are reviewed for completeness and compliance by a certifier or program manager. BioI also contracts with CERES to conduct material reviews on its behalf, though this service has not been used to date.

The certifier makes the decision to certify an operation and also to issue non-compliances if necessary. Records showed that in all cases the certification decision was made by someone different from the one that conducted the initial review, secondary review, and/or the inspection.

ADMINISTRATIVE PROCEDURES

BioI has written procedures to address issuance of noncompliances, adverse actions and mediation and appeals. All notices of noncompliance issued thus far were also provided to the NOP Appeals Team. There have been no denials of certification, no requests for mediation or any appeals. One letter of suspension was issued to an operation, but the auditor noted the required procedure for issuing the suspension was not followed.

BioI has conducted an annual program review and annual updates have been submitted to the USDA NOP Administrator as required. However, the annual program review is not specific to the NOP and is general in scope.

WITNESS INSPECTIONS

As part of the assessment a witness inspection was conducted on a handling operation. The handling operation was a small processor of spices and herbs, and trader of essential oils. The operator cuts, grinds, and mixes the spices and herbs in small quantities. If larger orders need to be processed, they are sent to a subcontracted processor that is also certified by BioI. The inspection was conducted by a BioI certifier who was also qualified as an inspector. All areas were verified as required and an exit interview was conducted.

A witness inspection was also conducted at a crop and livestock operation. This NOP inspection was conducted in conjunction with an inspection for Bio Suisse certification. The operation included a milking herd of cows and organic crop land for production of hay, corn silage, carrots and wheat. The inspector verified several elements of the OSP such as fertilizers, materials, machinery, and crop rotations, but did not confirm compliance with the NOP Pasture Rule. BioI considers the requirements for Bio Suisse forage intake to exceed the requirements for dry matter intake from pasture as stated in the NOP Rule, and therefore, does not make any additional considerations or calculations for 30% dry matter intake during the grazing season. An exit interview was conducted with the knowledgeable representative of the operation.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether BioI'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 BioI.

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.

NP6254EEA.NC1 – Cleared- 7 CFR §205.501 11 (v) - General Requirements for Accreditation states, "Prevent conflicts of interest by: requiring all persons who review applications for certification, perform onsite inspection, 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." *The board of directors and two employees did not have current (annual) conflict of interest statements on file since their "Contract Agreement" uses different terminology, and does not contain the conflict of interest clause that all other personnel contracts contain.*

Corrective Action (2006): No corrective action submitted.

Corrective Action (August 27, 2007): BioI stated in the corrective actions that they submitted Conflict of Interest disclosure reports; however, there were no conflict of interest disclosure reports attached to the corrective actions.

Corrective Action (December 5, 2007): Conflict of Interest disclosure reports were submitted for all 12 principles and inspectors of the society. This adequately addresses the finding.

Verification of Corrective Action (June 2009): Conflict of Interest disclosure reports were reviewed for the previous and current personnel involved in inspections, document review and certification of operations; most were found to be in compliance. However, the BioI division managers, one division quality manager, and one inspector had not completed the conflict of interest disclosure report.

Corrective Action (2009): Conflict of interest disclosure reports for the Division Managers, Quality Manager, and inspector was submitted and reviewed.

2011 Mid-Term Assessment Finding: There were no conflict of interest disclosure reports on file for one of the five members on the administrative board of directors and one of the five members on the executive board of directors. Also, there were no current conflict of interest disclosure reports on file for three of the subcontracted inspectors. Based upon this finding, the noncompliance, accepted as adequately addressed in 2009, was reverted to outstanding.

Corrective Actions (2011): The corrective actions adequately address the noncompliance. BioI submitted the missing conflict of interest disclosure reports as part of its corrective actions. BioI modified its quality system procedures to indicate that conflict of interest reports will be compiled annually at the end of February. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): Conflict of interest disclosure reports were on file for staff and inspectors, in addition to six administrative board members and seven executive board (management team) members.

NP9173ACA.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 onsite 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." *One member of the certification committee had no current performance evaluation. Also, the contract inspectors did not have current performance evaluations.*
Corrective Action (2009): BioI submitted a statement indicating that all inspectors and certifying staff will have a performance evaluation at least once a year.
2011 Mid-Term Assessment Finding: One staff and one subcontracted inspector's most recent performance evaluation was dated in 2009, and two subcontracted inspectors did not have a performance evaluation in their file at all. Based upon this finding, the noncompliance, accepted as adequately addressed in 2009, was reverted to outstanding.
Corrective Actions (2011): BioI's corrective actions submitted in November 2011 were the same corrective actions submitted in 2009. The 2011 Mid-Term Assessment determined that this corrective action was not effectively implemented. The NOP reviewer requested additional information about the performance evaluation schedule for BioI staff.
Corrective Actions (January 2012): BioI's response indicated that inspector reports are assessed by certification staff. Furthermore, these assessments are part of the performance evaluation given at BioI's annual staff training in February and March 2012. Certification staff will also receive their performance evaluations at the annual training. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): The review of performance evaluation records indicated that evaluations are being conducted for certification staff and inspectors.

NP9173ACA.NC7 – Cleared – 7 CFR §205.662(a)(3) & (b) 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. Such notification shall provide: (3) the date by which the certified operation must rebut or correct each noncompliance and submit supporting documentation… (b) When a certified operation demonstrates that each noncompliance has been resolved, the certifying agent… shall send the certified operation a written notification of noncompliance resolution." *BioI had a client that had a noncompliance identified during the onsite inspection but the client submitted corrective actions before the report was sent out. BioI did not send a written notification of noncompliance resolution.* **Corrective Action:** BioI has modified and added a new check point on form 24_154 to ensure that a noncompliance resolution is sent to the client. BioI stated they did inform the client that the corrective actions submitted were adequate.
2011 Mid-Term Assessment Finding: While BioI has been issuing notices of noncompliance in the required manner, notices of resolution have not been sent to certified operations when corrective action is accepted as adequate. Based upon this finding, the noncompliance, accepted as adequately addressed in 2009, was reverted to outstanding. **Corrective Actions:** The corrective actions adequately address the noncompliance. BioI submitted a Notice of Noncompliance Resolution template as part of its corrective actions for this noncompliance. BioI has modified its quality system procedures to indicate that noncompliance resolution letters will be sent to operations when noncompliances are resolved. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): A review of certification files confirmed that BioI issues a Notice of Noncompliance Resolution to the certified operation when corrective action is accepted as adequate.

NP1234NNA.NC1 – Cleared. 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." *The audit reviewed certification files and verified that inspections are assigned even when applications with incomplete OSPs received. The OSP for the livestock witness audit did not contain or identify homeopathic materials used on the livestock operation. The OSP for the handler witness audit did not contain:*

- *Cleaning procedures for all equipment, including the equipment used for oil distillation. The witness audit revealed that sometimes alcohol is used to clean the equipment, but this information was not included in the OSP. The OSP indicated that only water and vinegar were used for cleaning;*
- *A list or general information on all equipment utilized;*
- *Procedures for verifying the organic status of raw materials upon receipt;*
- *Procedures for and the frequency of monitoring activities for receiving, production, and shipping practices to ensure the OSP is effectively implemented;*
- *Current labels utilized by the operation; and*
- *The process for product treated with carbon dioxide.*

Corrective Actions: BioI's handling OSP forms have been amended to include requests for information on equipment utilized and cleaning procedures used during processing. The amended handling OSP also requires the operation provide:

- A complete list of products, ingredients, additives, processing aids, and suppliers.
- A description of monitoring and internal quality control practices, including practices used for monitoring receipt of and use of ingredients.
- Labels used on organic products.

BioI's inspection form for organic livestock production has been amended to include an assessment of medications, including homeopathic materials, which may be used during livestock health care practices. Certifiers will review this information for NOP compliance before scheduling inspections. If the OSP is not compliant or is incomplete, the inspection will not be scheduled. To prevent this noncompliance from reoccurring, BioI modified its quality system by amending the OSP forms to require more detailed descriptions and amended its OSP review procedures to assess OSP's for NOP compliance before inspections are scheduled. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): BioI is currently using the amended handler OSP and livestock inspection form. The audit confirmed that inspections are scheduled only if the information on the OSP is complete and the applicant appears to comply.

NP1234NNA.NC2 – 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 an applicant appears to comply or may be able to comply with the applicable requirements of subpart C of this part." *The files reviewed and interviews conducted by the auditor verified that inspectors are making approval decisions for labels, materials, and inputs during inspections. Additionally, there is no procedure or process for*

the certifier to review and approve labels prior to inspection to enable inspectors to verify the use of approved labels. Of three labels reviewed for one handler, all had the "Certified by" statement above the information identifying the distributor as opposed to below it. The review of livestock files showed that BioI approved the use of levamasole and the antibiotic tetracycline in cattle, but neither substance is on the National List of approved substances.
Corrective Actions: BioI amended its procedures for reviewing OSPs or amendments to specify that production practices, materials, labels, and other plan information are reviewed for compliance by a staff certifier prior to scheduling an inspection. The amended procedures also indicate that OSPs or amended OSPs will be verified during the inspection. The inspector will only verify the OSP and will not be making certification decisions. If the OSP is not complete or is not compliant with the NOP regulations, the certifier will not schedule the inspection. When reviewing labels, the certifiers will not approve labels unless the term "certified by" appears below the information identifying the distributor. Also, certifiers will review livestock medications for NOP compliance and will only approve materials that comply with the NOP regulations. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): BioI uses a checklist to ensure that all information on the OSP is reviewed by the certifier. Inspectors only propose noncompliances, and the final decision is made by the certifier upon review of the inspection report. The review of product labels approved by BioI and its materials review process indicated that corrective actions have been properly implemented.

NP1234NNA.NC3 – **Cleared.** 7 CFR §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 onsite inspection of the certified operation pursuant to §205.403." *BioI has not required operators to submit updates to the OSP if there are no changes to the plan, but updates are collected at the time of inspection.*
Corrective Actions: BioI changed its certification review checklist to specify that certifiers will review annual OSP updates for compliance before scheduling inspections. The change in the checklist has been incorporated into the quality manual procedures. In March 2012, BioI will train staff involved with NOP certification on the amended procedures. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): BioI requires its certified operators to complete a new OSP annually. The OSP includes a section for the operator to report whether there are any changes from the previous year.

NP1234NNA.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…" *BioI conducts annual program reviews. The program reviews, however, generally focus on BioI's quality management system as it pertains to the requirements of ISO accreditation in general and not specific to the NOP Final Rule requirements.*
Corrective Actions: BioI will include NOP regulatory requirements within the scope of its next annual review in March 2012. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): Review of BioI's 2013 and 2014 program review documents indicated that the internal audit checklist now includes NOP specific checkpoints.

NP1234NNA.NC6 – C**leared.** 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." *The review of Notices of Noncompliance sent to operators indicated that BioI is outlining corrective actions for the operator to implement to resolve noncompliances.*
Corrective Actions: Certifiers will issue Notices of Noncompliance to certified operations or new applicants. The operation receiving the notice will be required to propose and implement corrective actions to resolve noncompliances. BioI has modified its quality system procedures to implement these changes when noncompliances are identified during NOP certification activities. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): The auditor verified that BioI's Notice of Noncompliance form states the noncompliance, and requires the client to respond with corrective action plans. The auditors also reviewed Notices of Noncompliance issued to BioI's clients and found these to be compliant.

NP1234NNA.NC11 – **Cleared.** 7 CFR §205.670 (d)(1) states, "Results of all analyses and tests performed under this section: Must be promptly provided to the Administrator..." *BioI has collected and tested samples from NOP clients; however, the results of these tests have not been forwarded to the Administrator.*
Corrective Actions: BioI provided analytical results to the NOP on October 20, 2011. BioI's instructions on sample collection, procedures for analysis of residues, and the sampling record template have been established. The quality system procedures have been modified to include instructions for sending analysis results to NOP on a regular schedule. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): BioI follows the instructions in NOP 2613 Responding to Results from Pesticide Residue Testing, which only requires that the certifier keep the results on file for review during accreditation audits.

NP1234NNA.NC5 – **Outstanding.** 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." *BioI has not addressed the pasture practice standard under 7 CFR §205.240 and dry matter intake requirements under 7 CFR §205.237 with applicants or certified operations. BioI applies the Bio Suisse rules for requirements of pasture of 156 days with 25% dry matter from pasture. They feel this is a stricter standard and meets the NOP pasture standard*.
Corrective Actions: Beginning in January 2012, BioI will provide notice to clients on the pasture practice standard under 7 CFR § 205.240 and dry matter requirements under 7 CFR § 205.237. BioI has amended its quality system by modifying the livestock OSP form to request information relevant to the NOP pasture practice standard and pasture dry matter feeding requirements. During inspections, the inspector must also assess whether an operation is

complying with the NOP requirement for 30% dry matter intake from pasture grazed during the grazing season, and determine if ruminants have had access to pasture for at least 120 days during the grazing season. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): BioI does not currently certify any ruminant livestock operations or have any applicants seeking livestock certification. However, the current livestock OSP still does not address the requirements of the pasture plan standard under 7 CFR §205.240 and the inspection report does not include the verification of the operation's grazing period. Also, inspectors have not yet been instructed on which requirements need to be verified during the onsite inspection with regard to dry matter intake and pasture access.

NP1234NNA.NC7 – **Outstanding.** 7 CFR §205.501 (a)(18) states, "A private or governmental entity accredited as a certifying agent under this subpart must:…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 non compliances." *BioI does not notify the inspector of the certification decision for all sites. The current practice is to only notify the inspector if there have been changes in the decisions from the inspection report.*
Corrective Actions: BioI has modified its procedures to indicate that an inspector will receive a copy of the certification decision when notification is provided to the operation. BioI has established letter and checklist templates for providing notifications on NOP certification decisions to clients and inspectors. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): The auditor noted that BioI notifies the inspector of its certification decision only when the inspection review results in the operation receiving a Notice of Noncompliance.

NP1234NNA.NC8 – **Outstanding.** 7 CFR §205.504 (a)(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… (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel." *BioI does not have a documented training program for staff who review applications for completeness and compliance. Furthermore, BioI has hired new staff to serve in this capacity since the 2009 NOP assessment. This is a concern as indicated by the findings outlined under noncompliances for 7 CFR §205.402 (a) (1) and (2). In addition the training program for new inspectors does not include the requirement that they participate in two acceptable shadow inspections before conducting inspections on their own.*
Corrective Actions: BioI revised its training programs for new inspectors and certifiers. The training program covers procedures for initially reviewing OSPs for completeness and compliance with the NOP regulations. BioI also modified its quality system procedures to indicate that new inspectors without experience must accompany experienced inspectors on inspections until sufficient experience is obtained. When the experience training is complete, the trained inspectors will be independently assigned to carry out inspections. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.
Verification of Corrective Action (September 2014): The review of training records indicated that BioI has implemented its corrective actions for training certifiers. However, BioI

has not implemented a training program for new inspectors, which requires that new inspectors accompany experienced inspectors on inspections until sufficient experience is obtained.

NP1234NNA.NC9 – **Outstanding.** NOP §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 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." *BioI forwarded a copy of the fee schedule for international clients to the Administrator. However, the price list for domestic clients was not submitted. It is not clear what portion of the fees is nonrefundable.*
Corrective Actions: BioI provided a 2012 fee schedule which describes NOP certification fees for both international and domestic clients. The disclaimer, "all fees are nonrefundable," is noted on the fee schedule.
Verification of Corrective Action (September 2014): The review of BioI's fee schedules indicated that though its nonrefundable policies are stated on the Domestic Processing, Domestic Agriculture, and International fee schedules, it is not stated on the fee schedule for Turkey.

NP1234NNA.NC10 – **Outstanding.** 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 notice of noncompliance shall be sent to the certified operation." *BioI sent a notice of suspension to a certified operation without first issuing a Notice of Noncompliance, and a Notice of Proposed Suspension. The inspection report noted several noncompliances; however, the operation was not given the opportunity to correct or rebut the noncompliances. Additionally, BioI allowed the operation to reapply for certification as a new applicant directly through BioI without the operation first requesting to be reinstated through the Secretary of Agriculture as required by 7 CFR §205.662(f).*
Corrective Actions: BioI modified its procedures to implement noncompliance procedures for certified operations described in 7 CFR §205.662 when noncompliances are identified during certification activities. Adverse actions will be issued to operations when noncompliances cannot be resolved. On October 10, 2011, BioI issued a combined Notice of Noncompliance and Denial of Certification to the operation cited in the noncompliance description. BioI's November 2011 submission of corrective actions did not address requirements for reinstating suspended operations. The NOP reviewer requested additional information on BioI's procedures for reinstating suspended operations. BioI's response indicated that, in 2012, it will implement NOP reinstatement procedures described in the NOP Program Handbook when suspended operations request NOP reinstatement. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

Verification of Corrective Action (September 2014): BioI follows the instructions of NOP 2605 Reinstating Suspended Organic Operations when suspended operations apply for certification. However, BioI issued a certified operation a termination of certification notice without following the noncompliance and adverse actions process as required by the USDA organic regulations.

Non-compliances Identified during the Current Assessment

NP4252LCA.NC1 - 7 CFR §205.660(d) states that "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 of noncompliance resolution are not issued by BioI via a delivery service which provides dated return receipts.*

NP4252LCA.NC2 - 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."
Comments: *In general, BioI provides new applicants and operations for continuing certification its published fee schedule that allows them to estimate their certification costs. International operations and operations that request an estimate of certification expenses are provided one. However, BioI is not providing all new applicants and all continuing operations a cost estimate of initial or continuing certification.*

NP4252LCA.NC3 – 7 CFR §205.501(a)(1) states that certifiers must "Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part."

- 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."
- 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.
- 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…shall send the certified operation a written notification of suspension or revocation."

Comments: *BioI issued a certified operation a Notice of Certification Termination without following the noncompliance and adverse actions processes as required by the USDA organic regulations.*

NP4252LCA.NC4 – 7 CFR §205.501(a)(1) states that certifiers must "Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part."

- 7 CFR §205.662(a)(1) states that, "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: A description of each noncompliance."

Comments: *Several noncompliances were reviewed for content and applicability during the audit. Noncompliances did not correctly match the regulatory citation to the evidence or the inspector's description. Several noncompliances cited a general regulatory reference without specifically identifying the applicable subsection of the regulation. Inspectors are not required to reference the organic regulation when identifying issues of concern in their reports or during the exit interview. During one of the witness audits, the inspector identified an issue of concern relating to record keeping (7 CFR §201.103(b)(4)), but indicated to the auditor that it was a label violation (7 CFR §205.300-311). When the auditor questioned the inspector for more specifics about the reference, the inspector showed the auditor BioI handouts from a recent training as supporting evidence of the noncompliance.*

NP4252LCA.NC5 – 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." Furthermore,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: *There are several grower group certified operations located in Turkey and on the January 2, 2014 list submitted to the NOP. A review of those operations revealed that they do not meet the definition of a grower group because there is no Internal Control System (ICS) and the groups are not responsible for their own certification. Instead these operations are a group of uncertified, independent farmers that are contracted by a trader or exporter to provide product; the trader or exporter is the named party on the organic certificate.*

NP4252LCA.NC6– 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." Furthermore, NOP 4009 "Who Needs to be Certified?" in the program handbook 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: *In addition to the uncertified groups of producers listed as certified by BioI, there appear to be several uncertified processing facilities involved in the handling (drying, sorting, storing, and packing) of crops supplied by these groups that are being labeled as organic.*

NP4252LCA.NC7 - 7 CFR §205.403(e)(2) states, "A copy of the onsite inspection report and any test results will be sent to the inspected operation by the certifying agent."
Comments: *Pesticide residue results obtained by BioI are not consistently issued to the operations that provided the sample.*

NP4252LCA.NC8 - 7 CFR § 205.403 (c)(1) states, "The onsite inspection of an operation must verify: the operation's comply with the Act and the regulations in this part."
Comments: *During the witness inspection of a handler operation, the inspector did not verify transportation clean-out documentation even though it was clear that the operation was responsible for procuring transportation of the organic wheat from the crop operations to the storage facility.*

NP4252LCA.NC9 – 7 CFR § 205.403 (e)(2) states, "A copy of the onsite inspection report … will be sent to the inspected operation by the certifying agent."
Comments: *During the witness inspection of a handler operation, it was confirmed that the operator was not provided with a copy of its inspection report in 2013.*

NP4252LCA.NC10 – 7 CFR § 205.404 (b) states, "The certifying agent must issue a certificate of organic operation…." NOP 2603 Organic Certificates indicates that "Organic certificates should … include the following:

- Categories of organic operation (crops, wild crops, livestock, and handling/processing)
- Anniversary date (when the certified operation must submit its annual update)

Comments: *The categories on organic certificates issued by BioI are production, preparation, storage, and trade, which do not comply with the categories required by the USDA NOP. The anniversary date is not listed on organic certificates.*

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Julia Winter
Bio.inspecta AG
Ackerstrasse
Ch-5070
Frick, Switzerland

Dear Ms. Winter:

On September 10-12, 2014, representatives of the United States Department of Agriculture (USDA), National Organic Program (NOP), completed an onsite audit of the Bio.inspecta AG (Bio.inspecta) organic certification program as part of its USDA Renewal Accreditation Assessment. On November 30, 2014, the NOP reviewed the results of the onsite audit to determine Bio.inspecta's compliance to the USDA organic regulations. A copy of the assessment report, NP4252LCA, is enclosed for your reference.

As the report indicates, nine corrective action(s) for prior noncompliance(s), NP6254EEA.NC1, NP9173ACA.NC2, NC7, NP1234NNA.NC1 through NC4, NC6 and NC11, were cleared and determined to be implemented and effective. Five noncompliances, NP1234NNA.NC5, NC7 through NC10, remain outstanding from your previous audit. Ten new noncompliances, NP4252LCA.NC1 through NC10, 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 Bio-inspecta 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

Enclosure

cc: AIA Inbox

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

DEC 18 2014

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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

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

Enclosure

cc: AIA Inbox

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

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

GENERAL INFORMATION

Applicant Name:	Bio.inspecta AG (BioI)
Physical Address:	Ackerstrasse, CH-5070, Frick, Switzerland
Mailing Address:	Ackerstrasse, CH-5070, Frick, Switzerland
Contact & Title:	Julia Winter, Program Manager
E-mail Address:	julia.winter@bio-inspecta.ch
Phone Number:	+41 (0) 62 865 63 24
Reviewer (s) and Auditor(s):	Penny Zuck, NOP Reviewer; Lars Crail, Onsite Lead Auditor; Robert Yang, Audit Trainee.
Program:	USDA National Organic Program (NOP)
Review and Audit Date(s):	Corrective Action review: May 29, 2015 NOP Review date: November 30, 2014 Onsite assessment date: September 10-12, 2014
Audit Identifier:	NP4252LCA
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 BioI's certification system.
Audit and Determination Criteria:	*7 CFR Part 205, National Organic Program as amended*
Audit and Review Scope:	Assessment of BioI's certification services in carrying out the audit criteria.

Bio.inspecta (BioI) currently has 75 clients certified to the USDA NOP that includes 6 crop, 1 wild crop, 17 livestock and 51 processing/handling operations; it has also certified 7 traders and 1 grower group. BioI is currently certifying operations to the USDA NOP in Switzerland, Albania, Tanzania, India, Lebanon, Indonesia, and Romania. The main office is located in Frick, Switzerland, with staff housed in a complex that includes an organic research and development division.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether BioI'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 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.

NP6254EEA.NC1 – **Cleared**
NP9173ACA.NC2 – Cleared
NP9173ACA.NC7 – Cleared
NP1234NNA.NC1 – Cleared
NP1234NNA.NC2 – Cleared
NP1234NNA.NC3 – **Cleared**
NP1234NNA.NC4 – **Cleared**
NP1234NNA.NC6 – C**leared**
NP1234NNA.NC11 – **Cleared**

NP1234NNA.NC5 – **Accepted.** 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." *BioI has not addressed the pasture practice standard under 7 CFR §205.240 and dry matter intake requirements under 7 CFR §205.237 with applicants or certified operations. BioI applies the Bio Suisse rules for requirements of pasture of 156 days with 25% dry matter from pasture. They feel this is a stricter standard and meets the NOP pasture standard*.

Corrective Actions: Beginning in January 2012, BioI will provide notice to clients on the pasture practice standard under 7 CFR § 205.240 and dry matter requirements under 7 CFR § 205.237. BioI has amended its quality system by modifying the livestock OSP form to request information relevant to the NOP pasture practice standard and pasture dry matter feeding requirements. During inspections, the inspector must also assess whether an operation is complying with the NOP requirement for 30% dry matter intake from pasture grazed during the grazing season, and determine if ruminants have had access to pasture for at least 120 days during the grazing season. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

2014 Verification of Corrective Action: BioI does not currently certify any ruminant livestock operations or have any applicants seeking livestock certification. However, the current livestock OSP still does not address the requirements of the pasture plan standard under 7 CFR §205.240 and the inspection report does not include the verification of the

operation's grazing period. Also, inspectors have not yet been instructed on which requirements need to be verified during the onsite inspection with regard to dry matter intake and pasture access.

2015 Corrective Actions: BioI submitted the OSP and inspection checklist templates with the USDA-NOP organic pasture requirements included.

NP1234NNA.NC7 – **Accepted.** 7 CFR §205.501 (a)(18) states, "A private or governmental entity accredited as a certifying agent under this subpart must:…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 non compliances." *BioI does not notify the inspector of the certification decision for all sites. The current practice is to only notify the inspector if there have been changes in the decisions from the inspection report.*

Corrective Actions: BioI has modified its procedures to indicate that an inspector will receive a copy of the certification decision when notification is provided to the operation. BioI has established letter and checklist templates for providing notifications on NOP certification decisions to clients and inspectors. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

2014 Verification of Corrective Action: The auditor noted that BioI notifies the inspector of its certification decision only when the inspection review results in the operation receiving a Notice of Noncompliance.

2015 Corrective Action: BioI submitted the checklist template that is used when operations are notified of their certification decision. The checklist notes that a copy of the certification decision is sent to the inspector.

NP1234NNA.NC8 – **Accepted.** 7 CFR §205.504 (a)(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… (1) A copy of the applicant's policies and procedures for training, evaluating, and supervising personnel." *BioI does not have a documented training program for staff who review applications for completeness and compliance. Furthermore, BioI has hired new staff to serve in this capacity since the 2009 NOP assessment. This is a concern as indicated by the findings outlined under noncompliances for 7 CFR §205.402 (a) (1) and (2). In addition the training program for new inspectors does not include the requirement that they participate in two acceptable shadow inspections before conducting inspections on their own.*

Corrective Actions: BioI revised its training programs for new inspectors and certifiers. The training program covers procedures for initially reviewing OSPs for completeness and compliance with the NOP regulations. BioI also modified its quality system procedures to indicate that new inspectors without experience must accompany experienced inspectors on inspections until sufficient experience is obtained. When the experience training is complete, the trained inspectors will be independently assigned to carry out inspections. Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

2014 Verification of Corrective Action: The review of training records indicated that BioI has implemented its corrective actions for training certifiers. However, BioI has not implemented a training program for new inspectors, which requires that new inspectors accompany experienced inspectors on inspections until sufficient experience is obtained.

2015 Corrective Action: BioI submitted the NOP Training Concept document which includes a section for inspectors requiring new inspectors to accompany experienced inspectors. The inspectors are assessed and shadow inspections are repeated until sufficient experience is obtained.

NP1234NNA.NC9 – **Accepted.** NOP §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 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." *BioI forwarded a copy of the fee schedule for international clients to the Administrator. However, the price list for domestic clients was not submitted. It is not clear what portion of the fees is nonrefundable.*

Corrective Actions: BioI provided a 2012 fee schedule which describes NOP certification fees for both international and domestic clients. The disclaimer, "all fees are nonrefundable," is noted on the fee schedule.

2014 Verification of Corrective Action: The review of BioI's fee schedules indicated that though its nonrefundable policies are stated on the Domestic Processing, Domestic Agriculture, and International fee schedules, it is not stated on the fee schedule for Turkey.

2015 Corrective Action: BioI submitted the revised fee schedule for Turkey and it includes a non-refundable statement in reference to NOP fees.

NP1234NNA.NC10 – **Accepted.** 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 notice of noncompliance shall be sent to the certified operation." *BioI sent a notice of suspension to a certified operation without first issuing a Notice of Noncompliance, and a Notice of Proposed Suspension. The inspection report noted several noncompliances; however, the operation was not given the opportunity to correct or rebut the noncompliances. Additionally, BioI allowed the operation to reapply for certification as a new applicant directly through BioI without the operation first requesting to be reinstated through the Secretary of Agriculture as required by 7 CFR §205.662(f).*

Corrective Actions: BioI modified its procedures to implement noncompliance procedures for certified operations described in 7 CFR §205.662 when noncompliances are identified during certification activities. Adverse actions will be issued to operations when noncompliances cannot be resolved. On October 10, 2011, BioI issued a combined Notice of Noncompliance and Denial of Certification to the operation cited in the noncompliance description. BioI's November 2011 submission of corrective actions did not address requirements for reinstating suspended operations. The NOP reviewer requested additional information on BioI's procedures for reinstating suspended operations. BioI's response indicated that, in 2012, it will implement NOP reinstatement procedures described in the NOP Program Handbook when suspended operations request NOP reinstatement.

Verification of these corrective actions will be determined at the next onsite NOP accreditation assessment.

2014 Verification of Corrective Action: BioI follows the instructions of NOP 2605 Reinstating Suspended Organic Operations when suspended operations apply for certification. However, BioI issued a certified operation a termination of certification notice without following the noncompliance and adverse actions process as required by the USDA organic regulations.

2015 Corrective Action: The procedure was revised in the Inspection and Certification checklist (document 25_154EN) to show proper process of adverse actions according to the regulations. Revised document 25_154EN was submitted to the NOP. BioI provided training to the staff and submitted the power point presentation that was used, which included these revised procedures.

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.

NP4252LCA.NC1 – Accepted. 7 CFR §205.660(d) states that "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 of noncompliance resolution are not issued by BioI via a delivery service which provides dated return receipts.*

2015 Corrective Action: BioI submitted an updated Inspection and Certification checklist with the procedure to send all notification of noncompliance resolutions via registered letter.

NP4252LCA.NC2 – Accepted. 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."

Comments: *In general, BioI provides new applicants and operations for continuing certification its published fee schedule that allows them to estimate their certification costs. International operations and operations that request an estimate of certification expenses are provided one. However, BioI is not providing all new applicants and all continuing operations a cost estimate of initial or continuing certification.*

2015 Corrective Action: BioI will provide all applicants and all continuing operations a cost estimate. The templates for the estimates were submitted. One is for new applicants and one is for continuing operations. BioI also submitted the procedure for NOP Inspection and Certification. Chapter 2 of the procedure was updated to clarify that BioI staff would use the new templates for both new applicants and continuing operations. The term "Offer" was added to the documents 22_001, 23_001 and 25_1001, referring to the estimate of certification costs. Additionally, the procedure was added to the document NOP concept 25_422EN. The certification staff and inspectors were trained on the new procedure.

NP4252LCA.NC3 – Accepted. 7 CFR §205.501(a)(1) states that certifiers must "Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part."

- 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."
- 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.
- 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…shall send the certified operation a written notification of suspension or revocation."

Comments: *BioI issued a certified operation a Notice of Certification Termination without following the noncompliance and adverse actions processes as required by the USDA organic regulations.*

2015 Corrective Action: The procedure was updated in the Inspection and Certification checklist to show proper process of adverse actions according to the regulations. BioI plans to check the compliance of the procedure as part of the internal audit. BioI provided training to the staff and submitted the power point presentation that was used, which included this procedure.

NP4252LCA.NC4 – Accepted. 7 CFR §205.501(a)(1) states that certifiers must "Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part."

- 7 CFR §205.662(a)(1) states that, "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: A description of each noncompliance."

Comments: *Several noncompliances were reviewed for content and applicability during the audit. Noncompliances did not correctly match the regulatory citation to the evidence or the inspector's description. Several noncompliances cited a general regulatory reference without specifically identifying the applicable subsection of the regulation. Inspectors are not required to reference the organic regulation when identifying issues of concern in their reports or during the exit interview. During one of the witness audits, the inspector identified an issue of concern relating to record keeping (7 CFR §201.103(b)(4)), but indicated to the auditor that it was a label violation (7 CFR §205.300-311). When the auditor questioned the inspector for more specifics about the reference, the inspector showed the auditor BioI handouts from a recent training as supporting evidence of the noncompliance.*

2015 Corrective Action: BioI provided training to the inspectors and submitted the power point presentation that was used, which included this topic.

NP4252LCA.NC5 – 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 or conditions determined by the Administrator to be necessary." Furthermore, 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: *There are several grower group certified operations located in Turkey and on the January 2, 2014 list submitted to the NOP. A review of those operations revealed that they do not meet the definition of a grower group because there is no Internal Control System (ICS) and the groups are not responsible for their own certification. Instead these operations are a group of independent farmers that are contracted by a trader or exporter to provide product; the trader or exporter is the named party on the organic certificate.*
2015 Corrective Action: BioI submitted a plan that will be implemented over the next two years as follows and will require the operations in Turkey to either 1) obtain individual certification or 2) develop an Internal Control System to be certified as a grower group:

- Phase 1 (2015) – inform clients regarding options (1 & 2 above) and costs, BioI and clients consider and decide suitable option for each client situation, BioI prepares training sessions for ICS, and BioI trains staff regarding ICS in Turkey.
- Phase 2 (2016) – Implementation and complete inspections and certification of those clients who choose option 1) to obtain individual certification.
- Phase 2 (2016) – BioI trains farmer groups regarding requirements for ICS in Turkey, farmer groups develop and start introduction of ICS, BioI conducts pre-audits at pilot farmer groups, and BioI approved inspectors for ICS in Turkey.
- Phase 3 (2017) – Implementation and complete inspections and certifications of option 2) ICS farmer groups.

BioI is required to submit progress reports to the NOP on a regular basis during each Phase of the plan.

NP4252LCA.NC6– 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 or conditions determined by the Administrator to be necessary." Furthermore, NOP 4009 "Who Needs to be Certified?" in the program handbook 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: *In addition to the groups of producers listed as certified by BioI, there appear to be several contracted processing facilities involved in the handling (drying, sorting, storing, and packing) of crops supplied by these groups that are being labeled as organic.*
2015 Corrective Action: BioI provided training to the inspectors and staff and submitted the power point presentations that were used, which included this topic. A letter was sent out to all applicable clients via email February 24, 2015 informing them of the requirement that all

operations must obtain their own organic certification and cannot be subcontracted within the certification of another operation and referring to NOP 4009. A copy of the letter was submitted to NOP. BioI is currently conducting inspections and processing certifications of these operations. They expect certifications to be carried out until December 2015.

NP4252LCA.NC7 – **Accepted.** 7 CFR §205.403(e)(2) states, "A copy of the onsite inspection report and any test results will be sent to the inspected operation by the certifying agent."

Comments: *Pesticide residue results obtained by BioI are not consistently issued to the operations.*

2015 Corrective Action: BioI submitted the revised Sample Collection and Analysis of Residues procedure to include sending the results of analysis to the client. BioI provided training to the inspectors and staff and submitted the power point presentations that were used, which included this topic.

NP4252LCA.NC8 – **Accepted.** 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."

Comments: *During the witness inspection of a handler operation, the inspector did not verify transportation clean-out documentation even though it was clear that the operation was responsible for procuring transportation of the organic wheat from the crop operations to the storage facility.*

2015 Corrective Action: BioI submitted a revised checklist with the added note for inspectors to check that cleaning documentation is available. BioI provided training to the inspectors and submitted the power point presentation that was used, which included this topic

NP4252LCA.NC9 – **Accepted.** 7 CFR § 205.403 (e)(2) states, "A copy of the onsite inspection report … will be sent to the inspected operation by the certifying agent."

Comments: *During the witness inspection of a handler operation, it was confirmed that the operator was not provided with a copy of its inspection report in 2013.*

2015 Corrective Action: BioI submitted the revised Inspection and Certification checklist that requires a copy of the inspection report to be sent to all national and international operations.

NP4252LCA.NC10 – **Accepted.** 7 CFR § 205.404 (b) states, "The certifying agent must issue a certificate of organic operation…." NOP 2603 Organic Certificates indicates that "Organic certificates should … include the following:

- Categories of organic operation (crops, wild crops, livestock, and handling/processing)
- Anniversary date (when the certified operation must submit its annual update)

Comments: *The categories on organic certificates issued by BioI are production, preparation, storage, and trade, which do not comply with the categories required by the USDA NOP. The anniversary date is not listed on organic certificates.*

2015 Corrective Action: BioI submitted certificates to show the categories of operation, according to the NOP regulations, and the anniversary date have been added.

Renewal Audit Corrective Actions Chronology Log

Audit Identifier: NP4252LCA

Audit Type: Renewal

Accredited Certifying Agent Name: BioInspecta (BioI)

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
4/10/15	RM assigned to PZ
4/20/15	PZ reviewed corrective actions. BioI submitted a rebuttal for NP4252LCA. NC5 regarding grower groups. This was not accepted by NOP. All other corrective actions were verified and noted in report as being accepted.
5/29/15	BioI submitted corrective actions for NP4252LCA and were accepted by NOP.
6/1/15	Processed CA Report, terms, certificate, and renewal of accreditation letter – emailed to RM for review. Also sent an email to BioInspecta asking for the training materials they indicated would be sent to NOP following training to correct the noncompliance NP4252LCA.NC4.
6/2/15	Drafted email to send to BioI requesting additional documentation for CAs that are not accepted per RM notes on report. Need to discuss noncompliance regarding non-certified handlers with RM (NP4252LCA.NC.6) Also awaiting review of the corrective action for noncompliance regarding grower groups (NP4252LCA.NC5)
6/9/15	Discussed above with RM and emailed Judith at BioI for additional information to verify corrective actions.
6/18/15	Rec'd additional documentation and clarification of outstanding noncompliances.
6/22/15	PZ reviewed the corrective actions and supporting documentation. Completed the CA Report (left in track change mode) and NoNC resolution, terms, and certificate. Emailed to RM for review.
6/25/15	Revised letter and CA report with RM comments/edits. Emailed BioI for more information regarding the date by which they expect to resolve the noncompliance involving the subcontracted operations obtaining certification.
7/10/15	Rec'd email from Julia with the following information regarding the timeline for resolving noncompliance of subcontracted operations.

Renewal Audit Corrective Actions Chronology Log

Audit Identifier: NP4252LCA

Audit Type: Renewal

Accredited Certifying Agent Name: BioInspecta (BioI)

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
	"The inspections and certification of the subcontracted operations are still in progress. Certification would be carried out till December."
7/13/15	Processed file for Cheri's review.
7/15/15	Edited CA Report and letter to require progress reports for NP4252LCA.NC5 grower group corrective actions.
7/29/15	Accreditation Committee Meeting
7/31/15	Revised CA report and terms with recommendations from the Accreditation Committee. Emailed to RM for review and approval.
8/6/15	Printed documents for final review and signature.
	Miles out of the office until 8/14/15. Hold for signature.
8/19/15	PZ Emailed notice of accreditation renewal, terms, and CA report to BioI.
10/19/15	PZ emailed a reminder to Daniel that we have not received the signed terms of accreditation.

NC Report Chronology Log

Audit Identifier (if any): NP4252LCA

Audit Type: Renewal

Accredited Certifying Agent Name: Bio.inspecta (BioI)

Accreditation Manager (who is working on the project): Renée Gebault King (RGK)

Date	Activity
11/7/14	NC Report assigned to RGK.
11/30/14	RGK reviewed report.
12/01/14	RGK drafted NoNC letter and NC report.
12/02/14	RGK submitted NC Report and NoNC electronically to R Mann (RM) for review.
12/08/14	RGK received edits from RM; use "bio.inspecta" in report, not BioI or Bio.inspecta per plain language policies.
12/09-10/14	RGK updated NC Report and NoNC letter. Asked for clarification with R. Yang on some findings identified in the report.
12/11/14	RGK submitted NC Report and NoNC electronically to C Courtney (CC) for review. CC met with RGK and requested that report reference "Bio.inspecta" or BioI acronym.
12/15/14	RGK updated report to reflect Bio.inspecta or BioI, and separated NC5 into two separate NCs (NC5, NC6), making a total of 10 NCs. Resubmitted in hard copy for review to CC.
1/30/15	Rec'd CA response
4/10/15	Assigned to PZ for CA Report

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a compliance assessment of Bio.inspecta AG (BIOI) in accordance with the agreement signed June 6, 2017. An onsite audit was conducted, and the audit report reviewed to determine BIOI's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Bio.inspecta AG (BIOI)
Physical Address	Ackerstrasse, CH-5070, Frick, Switzerland
Mailing Address	Ackerstrasse, CH-5070, Frick, Switzerland
Contact & Title	Julia Winter, NOP Managere
E-mail Address	Julia.winter@bio-inspecta.ch
Phone Number	0041 62 865 63 15
Reviewer & Auditor	Rebecca Claypool, NOP Reviewer; Miles McEvoy, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: August 2, 2017 Onsite audit: June 19-20, 2017
Audit Identifier	NP7173MMA
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 BIOI's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BIOI's certification services in carrying out the audit criteria during the period: June 2016 through June 2017

NOP conducted an onsite compliance audit of Bio.inspecta AG (BIOI) on June 19 - 20, 2017 at BIOI's main office in Frick, Switzerland. The purpose of the audit is to review BIOI certification of organic corn and soy production and handling in Eastern Europe and Central Asia. BIOI agreed to an additional onsite audit for NOP to assess the certification of organic corn and soy production of BIOI's operations. The compliance audit did not address the corrective actions submitted for BIOI's 2016 Midterm Assessment.

Bio.inspecta AG is a private for-profit corporation, which was initially accredited as a USDA National Organic Program (NOP) certifying agent on April 15, 2004 for the scopes of crops, wild crops, livestock and handling. The main office is in Frick, Switzerland (Bio.inspecta AG) and a satellite office is located in Izmir, Turkey (Bio.inspecta Ltd). BIOI certifies operations in

Switzerland, Albania, Bulgaria, Germany, Hungary, Iran, Kazakhstan, Romania, Russian Federation, Tanzania, Turkey, Ukraine, and United Arab Emirates.

NOP DETERMINATION

The NOP reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to BIOI.

Noncompliances from Prior Assessments - *Not reviewed during the compliance audit.*

Noncompliances Identified during the Current Assessment

NP7173MVA.NC1 – 7 C.F.R. §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: *BIOI does not inspect all fields or production units of their certified operations each year. The BIOI Inspection Manual (24_003EN) section 3.2 states that for risk countries and large operators (>5000 hectares) the inspector must inspect at least one third of all fields. Two thirds of an operation's fields may not be inspected annually.*

NP7173MVA.NC2 – 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: *BIOI did not issue a Notice of Noncompliance, Notice of Proposed Suspension or a Notice of Suspension when an operator was not available for inspection during normal business hours. BIOI cancelled the operation's certification without providing the operator the right to respond to the noncompliance, or appeal the suspension (cancellation) of certification.*

NP7173MVA.NC3 – 7 C.F.R. §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: *The 2016 evaluation of a certification staff member indicated deficiencies in performance, specifically around the accuracy and completeness of the review and evaluation of certification documents. BIOI did not implemented measures to correct the deficiencies identified in the 2016 evaluation.*

NP7173MVA.NC4 – 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 4009

Who Needs to be Certified? states in section 3, “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: *A file reviewed by the auditor listed four operations in the organic system plan that appear to be separate operations. These operations are not independently certified even though they appear to need organic certification to handle organic products.*

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Julia Winter
Bio.inspecta AG
Ackerstrasse
CH-5070, Frick
Switzerland

Dear Ms. Winter:

On June 19, 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 Bio.inspecta AG (BIOI) organic certification program as part of its USDA Compliance Assessment. On August 2, 2017, the NOP reviewed the results of the onsite audit to determine BIOI's compliance to the USDA organic regulations. A copy of the assessment report, NP7173MMA, is enclosed for your reference.

As the report indicates, four new noncompliances (NP7173MMA.NC1 through NC4), 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 BIOI 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 BIOI's USDA accreditation.

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

Enclosure: Noncompliance Report

cc: AIA Inbox

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment Baystate Organic Certifiers (BOC) organic program was conducted on June 5-8, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess BOC's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Baystate Organic Certifiers (BOC)
Physical Address	1220 Cedarwood Circle North Dighton, MA 02764
Mailing Address	1220 Cedarwood Circle North Dighton, MA 02764
Contact & Title	Don Franczyk, Executive Director
E-mail Address	baystateorganic@earthlink.net
Phone Number	774-872-5544
Reviewer **Auditors**	Jason Lopez, NOP Reviewer; Lars Crail, On-site Auditor; Graham Davis, Technical Expert.
Program	USDA National Organic Program (NOP)
Review **Audit Dates**	NOP assessment review: August 21, 2017 Onsite audit: June 5-8, 2017
Audit Identifier	NP7156GDA
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 BOC's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BOC's certification services in carrying out the audit criteria during the period: June 2014 through June 2017

The National Organic Program (NOP) conducted an onsite accreditation renewal audit of the Baystate Organic Certifiers (BOC) June 5-8, 2017.

BOC is the certification program name of Massachusetts Independent Certification Inc. which is a 501(c)(3) corporation. BOC was initially accredited as a certifying agent on April 29, 2002 to the following accreditation scopes: crops, wild crops, livestock, and handling. BOC current accreditation period ended on April 29, 2017.

BOC's certifies 394 operations to the following certification scopes: Crops (237), Livestock (46), and Handler/Processor (197).

BOC's office is located in North Dighton, Massachusetts. BOC's staff consists of: Technical Staff (8), Contracted Inspectors (6), and Administrative/support staff (2).

As part of the onsite accreditation audit activities, two witness audits (WA) were conducted on crop production operations (one was a certification applicant) and one witness audit of a handler/processor operation.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether BOC 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 BOC.

Noncompliances Identified during the Current Assessment

NP7156GDA.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 what elements and phrases should be on an organic certificate.

Comments: *The following organic certificate elements are incorrect or missing:*

1. *"Anniversary date" is not stated.*
2. *The statement "Certified to the USDA organic regulations, 7 C.F.R. Part 205." is not stated on certificates.*
3. *The certificate does not have the statement: "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked."*

NP7156GDA.NC2 – 7 C.F.R. §205.403(d) states, "*Exit interview.* … The inspector must also address the need for any additional information as well as any issues of concern."

Comments: *Operations are provided an "Exit Interview" document at the conclusion of each inspection where Issues of Concern are identified and additional information is requested. BOC inspectors do not consistently cite the organic regulations for identified Issues of Concern listed.*

NP7156GDA.NC3 – 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…."

Comments: *BOC is not issuing proposed suspensions or revocations in a timely manner once the time period stated in the notice of noncompliance has passed.*

NP7156GDA.NC4 – 7 C.F.R. §205.662 (e)(1) states, "If the operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension …, the certifying agent ... shall send the certified operation a written notification of suspension …."

Comments: *BOC is not issuing suspensions in a timely manner once the time period stated in the notice of proposed suspension has passed.*

NP7156GDA.NC5 – 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: *BOC allows a grace period of 30 days or more before issuing a noncompliance for failure to submit an annual update by the anniversary date.*

NP7156GDA.NC6 - 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 2025 Instruction Internal Program Review states, "Internal program reviews are conducted by personnel different from those who perform certification activities.

Comments: *A review of BOC's 2016 annual program review revealed that it was conducted by BOC Executive Director and Certification Specialists who performed the certification activities being reviewed.*

NP7156GDA.NC7 - 7 C.F.R §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: *Several BOC approved labels did not identify each organic ingredient in the ingredient statement.*

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Don Franczyk
Baystate Organic Certifiers
1220 Cedarwood Circle
North Dighton, MA 02764

Dear Mr. Franczyk:

On June 5-8, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Baystate Organic Certifiers (BOC) organic certification program as part of its USDA Renewal Accreditation Assessment. On August 21, 2017, the NOP reviewed the results of the onsite audit to determine BOC's compliance to the USDA organic regulations. A copy of the assessment report, NP7156GDA, is enclosed for your reference.

As the report indicates, seven new noncompliances (NP7156GDA.NC1 through 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 BOC 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 BOC's USDA accreditation.

If you have questions regarding this notice, please contact, Jason Lopez, Accreditation Manager, at (202) 640-9445 or JasonJ.Lopez@ams.usda.gov.

Sincerely,

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

Enclosure: NP7156GDA NC Report

cc: AIA Inbox

Settlement & Audit Chronology Log

Audit Identifier (if any): Settlement Agreement & NP7015LCA

Audit Type: Mid-Term audit

Accredited Certifying Agent Name: Bolicert

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
6/16/15	NOP issued NoPS to Bolicert – various noncompliances & not meeting the terms of settlement agreement w/NOP.
2/8/16	NOP issued a second NoPS to Bolicert – no submission of Jan 2 list of operations
	Bolicert appealed both notices
5/26/16	Settlement Agreement executed. Link to settlement agreement: Exec Settlement.Bolicert.APL-026-15.pdf
6/10/16	PZ Review of Settlement Agreement and Summary: **NOP:** Conduct an additional site evaluation, at Bolicert's expense within 12 months (by 5/26/17) See Settlement Agreement for the scope of the assessment. **Bolicert must:** 1. Within 45 days (by 7/10/16) submit corrective and preventative actions for the outstanding noncompliances from the 2014 renewal assessment: • NP4350LCA.NC2, Part 1 • NP4350LCA.NC4 • NP4350LCA.NC7 2. Submit its annual list of certified operations through the OID in accordance with NOP 2026 Instruction no later than January 2 of each year. 3. Update OID with any new clients or changes to existing clients, on a monthly basis, beginning the first day of the month following settlement execution (6/1/16). 4. Notify AM via email on the first day of each month when it has completed its monthly submission OR if there have been no changes this month. 5. Provide a native English speaker who is fluent in Spanish at all future NOP site evaluations to ensure adequate translation needs are met. 6. Within 30 days of agreement (by 6/26/16) have on file and properly distribute to its staff Spanish-language versions of the USDA organic regulations and Program Handbook. 7. Send at least 1 staff member to the NOP's annual training for ACAs and hold training to review material from the NOP annual training with its staff within 30 days of each session (next ACA training is 1/31/17, so must complete by 3/1/17).

Audit Identifier (if any): Settlement Agreement & NP7015LCA

Audit Type: Mid-Term audit

Accredited Certifying Agent Name: Bolicert

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
	8. Undergo additional site evaluation, at Bolicert's expense within 12 months of agreement (by 5/26/17). See Summary of Corrective Actions submitted following the NoPS: ..\..\..\..\..\Appeals\1 CLOSED Appeals\FY 2015\15-026 Bolicert\Summary-Corrective Action.Bolicert.APL-026-15.pdf **Note:** (b) (5) [redacted] **Action Items:** PZ - Reviewer: • Collect and review corrective actions and process CA report. JL – Accreditation Manager: • Follow up w/Bolicert for OID update (according to the data in OID, it has not been updated since February 2016) • Follow up w/Bolicert every month until terms of the agreement are met on the submission of OID information. • Due 6/26/16 – verify Bolicert has on file and properly distributed to its staff Spanish-language versions of the USDA organic regulations and Program Handbook. • Verify staff member attends ACA training in January 2017. • Due 3/1/17 – verify training of staff on material from ACA training. • Follow up with lead auditor to make sure additional audit takes place by 5/26/17 and follows the scope in the settlement agreement. Question: (b) (5) [redacted]
6/13/16	Meeting to discuss the summary of settlement agreement – PZ, RY, JL, LC. Jason will check with those who are receiving emails from the Adverse Action and AIA inboxes to see if Bolicert submitted notification regarding the OID monthly update as required.

Audit Identifier (if any): Settlement Agreement & NP7015LCA

Audit Type: Mid-Term audit

Accredited Certifying Agent Name: Bolicert

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
	Penny will discuss the corrective actions with Meg to make sure there aren't any other outstanding noncompliances other than those listed in the Settlement Agreement.
6/14/16	PZ emailed Meg to ask (b) (5) [redacted] Meg's response - (b) (5) [redacted]
9/2/16	Issued Administrator's Decision to suspend Bolicert for one year.
10/13/16	Bolicert requested Administrative Hearing.
01/20/17	On-site audit by NOP auditor at Bolicert office
3/21/17	Review of audit report assigned to PZ
3/22/17	PZ Review: 1. Bolicert did not attend the ACA training as required by the settlement agreement. 2. 13 Prior outstanding noncompliances were not verified since corrective actions were not accepted prior to the audit. 3. 9 new findings were reported. 4. AIA15119PZ.NC1 was listed as one of the outstanding prior noncompliances: AIA15119PZ.NC1 - NOP §205.510(a)(1-4) requires that the accredited certifying agent must submit annually to the Administrator on or before the anniversary date of the issuance of the notification of accreditation. Comments: *BOLICERT submitted an incomplete annual update for 2015. The report is required to cover March 13, 2014 through March 13, 2015, but only covers through December 2014.* 2016 Annual Report was received and reviewed by NOP and NOP issued an acknowledgement letter that the annual report submission complied with the requirement. 2017 Annual Report has been received by NOP (3/13/17) – not yet reviewed.

Settlement & Audit Chronology Log

Audit Identifier (if any): Settlement Agreement & NP7015LCA

Audit Type: Mid-Term audit

Accredited Certifying Agent Name: Bolicert

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
4/13/17	PZ met with CC and Jenny to discuss the current situation of Bolicert. Decision is to process the last audit report as usual and issue a noncompliance report along with a notification of noncompliance. PZ will also check with Jason to see if Bolicert has been corresponding with him monthly as required by the settlement agreement. PZ will also check the status of the hearing with Kristin. Jason has not heard from Bolicert. Kristin's reply – *"Currently, the draft Bolicert Complaint for Administrative Hearing is with OGC. We submitted the draft on February 22, 2017. The next step will be for assigned attorney Lauren Decker to complete review of the draft and finalize OGC's decision to support the filing of a formal complaint with the AMS Office of Administrative Law judges."* PZ reviewed audit report and drafted the Noncompliance Report and Notice of Noncompliance – to CC for review.
4/18/17	PZ Emailed Lars for clarification on two findings. PZ Separated the settlement agreement noncompliances from the audit report and processed a notice of noncompliance – emailed to CC for review. PZ emailed Notice of Noncompliance for settlement agreement items via Rpost.
5/1/17	PZ received email from Lars with clarifications on the questions about some findings.
5/3/17	PZ revised Noncompliance Report – emailed to CC for review.
5/3/17	LC revised NCs in NC Report for additional clarity.
5/23/17	PZ accepted tracked changes in the NC Report and printed for final approval and signature.
8/31/17	PZ reviewed corrective actions submitted in response to the NoNC and NC report.

USDA Agricultural Marketing Service

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Room 2646-S, STOP 0268
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NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

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

GENERAL INFORMATION

Applicant Name	Boliviana de Certificacion (BOLI)
Physical Address	Colon Street 756, Floor 2, Office 2A Building Valdivia, La Paz, Bolivia
Mailing Address	Colon Street 756, Floor 2, Office 2A, P.O. Box 13030, La Paz, Bolivia
Contact & Title	Carmen Murillo Quiroga
E-mail Address	bolicert@mail.megalink.com
Phone Number	591-2-29-02103
Reviewer & Auditor	Penny Zuck, NOP Reviewer; Lars Crail On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: April 13, 2017 Onsite audit: January 19-20, 2017
Audit Identifier	NP7015LCA
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 BOLI's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	BOLI's certification services in carrying out the audit criteria during the period: December 20, 2014 through January 20, 2017

NOP conducted an onsite mid-term audit of the Boliviana de Certificacion (BOLI) January 19 - 20, 2017. The onsite audit focused on requested and submitted certification materials provided by BOLI. There were no accepted corrective actions of prior outstanding noncompliances to be verified. No witness or review audits were conducted.

BOLI was initially accredited as a USDA certifying agent on March 13, 2003 and maintains the accreditation scopes for crops, wild crops, and handling/processing. BOLI's current accreditation period expired on March 12, 2013. The accreditation renewal assessment occurred in late 2014 and early 2015. NOP issued a proposed suspension in 2015 due to BOLI's inability to adequately address systematic noncompliances and fulfil the terms a settlement agreement established with the NOP in January 2013. BOLI appealed NOP's decision. On February 8,

2016, NOP issued BOLI a proposed suspension for failing to address a noncompliance for updating the Organic Integrity Database on January 2, 2016. BOLI appealed NOP's decision. On May 24, 2016, BOLI entered a settlement agreement with AMS to resolve the two appeal cases. BOLI did not adhere to the settlement agreement terms. Bolicert failed to submit corrective actions and Bolicert failed to provide updates to its Accreditation Manager concerning the list of certified operations. AMS reinitiated its administrative process to suspend BOLI and the Administrator on October 12, 2016 denied BOLI's appeal cases. BOLI has requested an administrative judge hearing and the case is pending resolution.

BOLI's office is located in La Paz, Bolivia and its certification activities occur in Bolivia. BOLI certifies 37 operations: Crops (26), Wild Crops (4), and Handler/Processor/Exporters (15). BOLI certifies 16 grower groups producing and handling quinoa, coconut, and cacao.

BOLI's staff consists of 21 individuals: Administrative Director (1), Certification Officers (4), Reviewer/Inspector (1), Contract Inspectors (13), and Administrative/support staff (2).

NOP DETERMINATION

The NOP reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to BOLI. In addition, the NOP reviewed the Settlement Agreement currently in place between the NOP and BOLI to determine whether the terms are being met.

Noncompliances Identified during the Current Assessment

NP7015LCA.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, describes the elements of an organic certificate that should be included.

Comments: *The following issues were identified on BOLI issued certificates:*

1. *The certification scopes on BOLI certificates are not clearly listed as Crops, Wild Crops, Livestock, and Handling/Processing.*
2. *The effective date is stated on certificates as "Start Date."*
3. *The statement on BOLI certificates identifying the US organic standard does not state: "Certified to the USDA organic regulations, 7 CFR Part 205."*
4. *The statement on BOLI certificates does not state: "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked."*

NP7015LCA.NC2 - 7 C.F.R. §205.501(a)(15)(i) states, "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: *BOLI is not sending copies of notification of noncompliance corrections (i.e noncompliance resolutions) to the NOP.*

NP7015LCA.NC3 – 7 C.F.R. §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: *Email notifications issued by BOLI are not sent via a delivery service which provides dated return receipts.*

NP7015LCA.NC4 - 7 C.F.R. §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."

Comments: *During the review of one certification file where the operation resolved a noncompliance, a notice of noncompliance resolution was issued to the operation, but a record of the notice could not be located by BOLI staff for the auditor to review. The auditor reviewed an email message issued by the BOLI Program Manager to the operation, but there was no attached resolution notification.*

NP7015LCA.NC5 – 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: *Three of the three reviewed operation files where samples were collected by BOLI did not include a record demonstrating that the test results were provided to the operations.*

NP7015LCA.NC6 – 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: *The following evidence indicates that BOLI did not issue notices of noncompliance when issues of concern were identified:*

- *The auditor reviewed an unannounced inspection report with issues of concern identified by the inspector; however, BOLI did not issue the operation noncompliances as a result of the inspection report findings. The auditor determined that the report's issues of concern warranted USDA organic noncompliances.*
- *An operation did not submit an annual update and BOLI did not issue a noncompliance.*
- *During the annual inspection of a grower group, the inspection report identified three major issues where group members had used prohibited inputs or identified evidence of prohibited input use (e.g. plastic herbicide containers); however, BOLI only issued a notification to the grower group for five unrelated minor noncompliances.*
- *The auditor reviewed an inspection report with issues of concern identified during an additional inspection of an operation. The operation was certified to the NOP and to the European Union (EU) organic standards. BOLI issued EU nonconformities associated with the identified issues of concern, but did not issue noncompliances to the operation*

for violations of the USDA organic regulations. The auditor determined that the report's issues of concern warranted BOLI issuing USDA organic noncompliances.

NP7015LCA.NC7 - 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: *For one reviewed additional inspection in 2016, BOLI did not send the operation a copy of the inspection report.*

NP7015LCA.NC8 – 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: *Inspectors are not referencing the organic regulations on the exit interview forms for identified Issues of Concern.*

NP7015LCA.NC9 – 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… 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: *BOLI is not issuing operations proposed adverse actions if the operations fail to meet noncompliance notification deadlines for submitting corrective actions or rebuttals. In the one case reviewed, BOLI de-certified an operation for not providing an annual update and payment of fees.*

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NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

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

ASSESSMENT INFORMATION

National Organic Program Assessment Review	
Reviewer	Penny Zuck, NOP Reviewer
Review Date	April 13, 2017
Action Required	Yes
National Organic Program Accreditation Assessment	
Assessment Date	January 19 – 20, 2017
Assessment Identifier	NP7015LCA
Assessment Activity (select one)	□ Documentation Adequacy Review □ Pre-decisional Assessment □ Initial Assessment √ Mid-Term Assessment □ Renewal Assessment □ Compliance Assessment □ Other
General Information	
Applicant Name	Boliviana de Certificacion (BOLI)
Physical Address	Colon Street 756, Floor 2, Office 2A Building Valdivia, La Paz, Bolivia
Mailing Address	Colon Street 756, Floor 2, Office 2A, P.O. Box 13030, La Paz, Bolivia
Contact & Title	Carmen Murillo Quiroga
E-mail Address	bolicert@mail.megalink.com
Phone Number	591-2-29-02103
Assessment Team	
Lead Auditor	Lars Crail
Second Auditor	NA
Other (Identify Role)	Adriana Murillo (Translator)
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 BOLI's certification
Audit & Review Scope	BOLI's certification services in carrying out the audit criteria during the period: December 20, 2014 through January 20, 2017

NOP conducted an onsite mid-term audit of the Boliviana de Certificacion (BOLI) January 19 - 20, 2017. The onsite audit focused on requested and submitted certification materials provided by BOLI. There were no accepted corrective actions of prior outstanding noncompliances to be verified. No witness or review audits were conducted.

BOLI was initially accredited as a USDA certifying agent on March 13, 2003 and maintains the accreditation scopes for crops, wild crops, and handling/processing. BOLI's current accreditation period expired on March 12, 2013. The accreditation renewal assessment occurred in late 2014 and early 2015. NOP issued a proposed suspension in 2015 due to BOLI's inability to adequately address systematic noncompliances and fulfil the terms a settlement agreement established with the NOP in January 2013. BOLI appealed NOP's decision. On February 8, 2016, NOP issued BOLI a proposed suspension for failing to address a noncompliance for updating the Organic Integrity Database on January 2, 2016. BOLI appealed NOP's decision. On May 24, 2016, BOLI entered a settlement agreement with AMS to resolve the two appeal cases. BOLI did not adhere to the settlement agreement terms. Bolicert failed to submit corrective actions and Bolicert failed to provide updates to its Accreditation Manager concerning the list of certified operations. AMS reinitiated its administrative process to suspend BOLI and the Administrator on October 12, 2016 denied BOLI's appeal cases. BOLI has requested an administrative judge hearing and the case is pending resolution.

BOLI's office is located in La Paz, Bolivia and its certification activities occur in Bolivia. BOLI certifies 37 operations: Crops (26), Wild Crops (4), and Handler/Processor/Exporters (15). BOLI certifies 16 grower groups producing and handling quinoa, coconut, and cacao.

BOLI's staff consists of 21 individuals: Administrative Director (1), Certification Officers (4), Reviewer/Inspector (1), Contract Inspectors (13), and Administrative/support staff (2).

NOP DETERMINATION

The NOP reviewed the findings identified during the onsite audit to determine whether noncompliances should be issued to BOLI. In addition, the NOP reviewed the Settlement Agreement currently in place between the NOP and BOLI to determine whether the terms are being met.

Noncompliances Identified during the Current Assessment

NP7015LCA.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, describes the elements of an organic certificate that should be included.

Comments: *The following issues were identified on BOLI issued certificates:*

1. *The certification scopes on BOLI certificates are not clearly listed as Crops, Wild Crops, Livestock, and Handling/Processing.*
2. *The effective date is stated on certificates as "Start Date."*
3. *The statement on BOLI certificates identifying the US organic standard does not state: "Certified to the USDA organic regulations, 7 CFR Part 205."*
4. *The statement on BOLI certificates does not state: "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked."*

NP7015LCA.NC2 - 7 C.F.R. §205.501(a)(15)(i) states, "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: *BOLI is not sending copies of notification of noncompliance corrections to the NOP.*

NP7015LCA.NC3 – 7 C.F.R. §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: *Email notifications issued by BOLI are not sent via a delivery service which provides dated return receipts.*

NP7015LCA.NC4 - 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…" §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 one certification file, a notice of noncompliance resolution could not be located.*

NP7015LCA.NC5 – 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: *Three of the three reviewed operation files where samples were collected by BOLI did not include a record demonstrating that the test results were provided to the operations.*

NP7015LCA.NC6 – 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: *The following issues were identified:*

- *Unannounced inspection issues of concern (findings) are not issued to the operations as noncompliances.*
- *An operation did not submit an annual update and BOLI did not issue a noncompliance.*
- *During the annual inspection of a grower group, the inspection report identified three major issues where members had used prohibited inputs or identified evidence of prohibited input use (plastic herbicide containers); however, BOLI issued a notification to the operator for five unrelated minor noncompliances.*
- *Several issues of concern were identified during an additional inspection, but no noncompliances were issued to the operation.*

NP7015LCA.NC7 - 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: *For one reviewed additional inspection in 2016, BOLI did not send the operation a copy of the inspection report.*

NP7015LCA.NC8 – 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: *Inspectors are not referencing the organic regulations on the exit interview forms for identified Issues of Concern.*

NP7015LCA.NC9 – 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… 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: *BOLI is not issuing operations proposed adverse actions if the operations fail to meet noncompliance notification deadlines for submitting corrective actions or rebuttals. In the one case reviewed, BOLI de-certified an operation for not providing an annual update and payment of fees.*

<u>Noncompliances Identified during the Review of Settlement Agreement</u>

AIA7103PZ.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." Settlement Agreement executed May 24, 2016 between Bolicert and the USDA states,

a. “Until all other terms of this settlement are successfully cleared, Bolicert further agrees to add any new clients or changes to existing clients it certifies to the INTEGRITY Database on a monthly basis, beginning the first day of the month following settlement execution.”

b. “Bolicert agrees that it will notify its Accreditation Manager via email on the first day of each month when it has completed its monthly submission of new clients or existing clients it certifies to the INTEGRITY database; OR Bolicert will notify its Accreditation Manager that it does not have any changes this month.”

Comments: *BOLI has not updated information in the INTEGRITY database since December 30, 2016 and has not notified its Accreditation Manager of no changes at all since the execution of the settlement agreement.*

AIA7103PZ.NC2 - 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.” Settlement Agreement executed May 24, 2016 between Bolicert and the USDA states, “Bolicert agrees that it will send at least one (1) staff member to the NOP’s annual training for Accredited Certifying Agents, which is typically held in January or February of each year in the United States. Bolicert agrees to hold training to review material from the NOP Annual Training for Accredited Certifying Agents with its staff within thirty (30) days of each session.”

Comments: *BOLI did not send any staff member(s) to the annual training.*

USDA Agricultural Marketing Service

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Room 2648-S, STOP 0268
Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

Boliviana de Certificacion
Carmen Murillo Quiroga
Colon Street 756, Floor 2, Office 2A
P.O. Box 13030
La Paz, BOLIVIA

Dear Sra. Murillo:

On January 19-20, 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 Boliviana de Certificacion (BOLI) organic certification program as part of its USDA Mid-Term Accreditation Assessment. On April 13, 2017, the NOP reviewed the results of the onsite audit to determine BOLI's compliance to the USDA organic regulations. A copy of the assessment report, NP7015LCA, is enclosed for your reference.

As the report indicates, nine new noncompliances, NP7015LCA.NC1 through NC9, 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 BOLI 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 BOLI'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,

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

Enclosure: Noncompliance Report

cc: AIA Inbox

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

APR 1 8 2017

Boliviana de Certificacion
Carmen Murillo Quiroga
Colon Street 756, Floor 2, Office 2A
P.O. Box 13030
La Paz, BOLIVIA

Dear Sra. Murillo:

On April 13, 2017, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) reviewed the current settlement agreement between Boliviana de Certificacion (BOLI) and the USDA. Two noncompliances, AIA7103PZ.NC1 & NC2, were identified. We have determined that BOLI is noncompliant with the USDA organic regulations, 7 CFR Part 205, as follows:

AIA7103PZ.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." Settlement Agreement executed May 24, 2016 between Bolicert and the USDA states,

a. "Until all other terms of this settlement are successfully cleared, Bolicert further agrees to add any new clients or changes to existing clients it certifies to the INTEGRITY Database on a monthly basis, beginning the first day of the month following settlement execution."

b. "Bolicert agrees that it will notify its Accreditation Manager via email on the first day of each month when it has completed its monthly submission of new clients or existing clients it certifies to the INTEGRITY database; OR Bolicert will notify its Accreditation Manager that it does not have any changes this month."

Comments: *BOLI has not updated information in the INTEGRITY database since December 30, 2016 and has not notified its Accreditation Manager of no changes at all since the execution of the settlement agreement.*

AIA7103PZ.NC2 - 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." Settlement Agreement executed May 24, 2016 between Bolicert and the USDA states, "Bolicert agrees that it will send at least one (1) staff member to the NOP's annual training for Accredited Certifying Agents, which is typically held in January or February of each year in the United States. Bolicert agrees to hold training to review material from the NOP Annual Training for Accredited Certifying Agents with its staff within thirty (30) days of each session."

Comments: *BOLI did not send any staff member(s) to the annual training.*

BOLI 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 BOLI management system will be modified to prevent a recurrence of the noncompliances. 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 noncompliances may result in proposed suspension or revocation of BOLI'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,

Cheri Courtney

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

cc: AIA Inbox

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Boliviana de Certificacion
Carmen Murillo Quiroga
Colon Street 756, Floor 2, Office 2A
P.O. Box 13030
La Paz, BOLIVIA

Dear Sra. Murillo:

On April 13, 2017, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) reviewed the current settlement agreement between Boliviana de Certificacion (BOLI) and the USDA. Two noncompliances, AIA7103PZ.NC1 & NC2, were identified. We have determined that BOLI is noncompliant with the USDA organic regulations, 7 CFR Part 205, as follows:

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If you have questions regarding this notice, please contact Penny Zuck, Accreditation Manager, at Penelope.zuck@ams.usda.gov or (202) 260-9444.

Sincerely,

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

cc: AIA Inbox

5-Year Renewal of Accreditation Audit Resolution Chronology Log

Audit Identifier: NP4125OOA

Accredited Certifying Agent Name: CAAE Certification Services

Accreditation Manager: Lars Crail (reviewed by Betsy Rakola)

Date	Activity
8/1/13	CAAE submitted an application for accreditation renewal to the NOP
2/13/14	CAAE's 5-year anniversary of accreditation occurred
5/5/14-5/8/14	Darrell Wilson conducted a renewal audit of CAAE's activities. CAAE has 23 NOP-certified clients. Darrell conducted one review audit of an olive grower/olive oil handler.
6/17-18	Betsy was assigned the review of the audit checklist. Betsy made minor edits for clarity of writing and also separated one noncompliance into two – a finding on continuing certification to 205.406(a)(1) was listed as a sub-bullet under 205.503(a)(1), but this citation should be listed independently.
6/19/14	Betsy submitted the report to management for review.
7/7/14	Betsy (acting director) received the approved file from Miles. Betsy signed the NoNC on Cheri's behalf and sent the NoNC and audit report to CAAE via RPost registered email.
8/12/14	Betsy sent a reminder to CAAE about the overdue corrective actions. Ricardo Porto's out of office message said that he would not return until August 25th and instructed correspondents to contact 'ct@ecovalia.org'. Betsy sent the reminder to this address.
8/15/14	NOP received response from CAAE
10/23/14	RY reviewed response; submitted CA report to Cheri for review.
11/13/14	File reviewed by Accreditation Committee. Committee decided to grant accreditation renewal when CAAE submits corrective actions for NP4125OOA.NC3 (ie. effective date on certificate) that are deemed adequate by AIA Director.
11/14/14	RY reviewed CA's submitted on 4/14/11 to verify whether CAAE is using the initial date of certification by CAAE or certification by the applicant's previous certifier (if applicable) as the effective date on the certificate. Information submitted only included a corrected certificate. RY sent email to CAAE seeking clarification of which date the certifier is currently using.
11/21/14	CAAE submitted via email their policy for determining the "effective date" on certificates, which confirmed that if the applicant has not been previously certified by another certifier, the date will be the initial certification date by CAAE; if the applicant was previously certified, the date will be the initial certification date by the previous certifier.
11/25/14	RY submitted file, including Notice of Accreditation Renewal, to Cheri for final review and signature.
12/1/14	RY issued via email Notice of Accreditation Renewal, Terms of Accreditation

12/15/14	RY received signed terms of accreditation, printed certificate; submitted to Cheri for signature

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a renewal assessment of CAAE Certification Service (CAAE). An onsite audit was conducted and the audit report reviewed to determine CAAE's capability to continue operating as a USDA accredited certifying agent. This report provides the results of the renewal assessment and review of CAAE's corrective actions.

GENERAL INFORMATION

Applicant Name	CAAE Certification Service (Servicio de Certificación CAAE S.L.U.)
Physical Address	Avenida Emilio Lemos n° 2. Edificio Torre Este, Modulo 603, 41020 Seville Andalucía, Spain
Mailing Address	Avenida Emilio Lemos n° 2. Edificio Torre Este, Modulo 603, 41020 Seville Andalucía, Spain
Contact & Title	Juan Manuel Sánchez Adame, Head of Quality
E-mail Address	jmsanchez@caae.es
Phone Number	34 902 521 555
Auditor(s) & Reviewer(s)	Robert Yang, NOP Reviewer; Darrell Wilson, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Review of Corrective Actions: October 22, 2014 Onsite Audit Dates: May 5-8, 2014
Audit Identifier	NP4125OOA
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 CAAE's certification system.
Audit and Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	Review of corrective actions submitted on August 15, 2014 for noncompliances resulting from the renewal assessment.

The CAAE Certification Service (CAAE) is part of the CAAE Association, which is a non-profit private organization. CAAE consists of the main office in Sevilla, Spain and four regional offices located in Castilla-La Mancha, Almeria, Granada, and Cordoba, Spain. All certification activities are carried out from the main office.

CAAE is currently accredited as a certifying agent to the USDA National Organic Program

(NOP) for the scopes of crops, wild crops, and handling. CAAE was initially accredited by the NOP on February 13, 2009. CAAE currently has 23 clients certified to the USDA organic regulations; 12 for crops and 11 for handling of which 10 are processors and 1 is a trader. CAAE certifies operations to the NOP in Spain. CAAE does not currently certify grower groups. CAAE also maintains accreditations for other organic certification programs, including Bio Suisse, JAS, and the EU (EC 834/2007 and 889/2008).

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether CAAE'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.

NP0270MMA.NC1 – Cleared
NP0270MMA.NC2 – Cleared
NP0270MMA.NC4 – Cleared
NP0270MMA.NC5 – Cleared
NP0270MMA.NC7 – Cleared
NP0270MMA.NC8 – Cleared
NP0270MMA.NC9 – Cleared
NP0270MMA.NC10 – Cleared
NP0270MMA.NC11 – 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.

NP0270MMA.NC3 – Accepted. 7 CFR §205.404(b)(2) and (3) states, "The certifying agent must issue a certificate of organic operation which specifies the: (2) Effective date of certification; and (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation." *CAAE is placing "First Certification Issuance Date" as the initial certification date of CAAE if first time applicants have never*

applied to another ACA. However, if the applicant was certified by another ACA then they are using the date the applicant was certified by the other ACA and not the date certified by CAAE. Additionally, the two certificates issued to wild crop operations did not identify the scope of certification as a wild crop.

Corrective Action (April 2011): CAAE adjusted the E-CERT system to include a new category, "wild harvest." The format of the certificates has been modified to include "wild crop" as a category of certification. Also, the Procedures Manual (1.1) has been modified to include "NOP Wild Harvest" as an applicable certification category. To correct the issue at the certified operation level, CAAE revised the applicable certificates to display "wild crops" as appropriate and forwarded the revised certificates along with a letter explaining the change to the operators. For all areas of response, CAAE provided objective evidence.

Verification of Corrective Action (May 2014): The 6 certificates reviewed did not contain the scope of certification (currently crops and handling). Therefore, certificates are still not in compliance with the USDA organic regulations.

Corrective Action: CAAE reissued the 6 organic certificates with the certification scopes properly identified and revised the certificate template in its E-CERT system to include the crops and handling certification scopes.

NP0270MMA.NC6 – Accepted. 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." *A review of personnel files verified that 9 of 33 CAAE personnel working with the NOP program did not have current conflict of interest statements.*

Corrective Action (April 2011): CAAE obtained current Conflict of Interest statements from all staff and submitted as objective evidence with the response. The Procedures Manual "has been modified to include the obligation to update the disclosure of conflict of interest statements by January 31st of each year."

Verification of Corrective Action (May 2014): There were no current conflict of interest statements for personnel involved with NOP certification. The Head of Quality indicated that they have restructured the conflict of interest document and did not get them sent out early enough to receive them back before the previously signed documents expired.

Corrective Action: CAAE obtained completed Conflict of Interest forms from all certification personnel. Procedures have been amended to state that even if the Conflict of Interest form is scheduled for revision the current version will be used in order to receive completed Conflict of Interest statements from staff by January 31st.

NP4125OOA.NC1 – Accepted. 7 CFR §205.404 (b)(4) states, "The certifying agent must issue a certificate of organic operation which specifies the name, address, and telephone number of the certifying agent." *Certificates in the files reviewed did not contain the address of the certifying*

agent.

Corrective Action: CAAE revised the certificate template in its E-CERT system to include the address of CAAE's head office and reissued organic certificates to all its certified operations using the revised template.

NP4125OOA.NC2 – Accepted. 7 CFR § 205.405 (d) states, "A notice of denial of certification must state the reason(s) for denial and the applicant's right to: (2) Request mediation pursuant to §205.663 or, if applicable, pursuant to a State organic program; or (3) File an appeal of the denial of certification pursuant to §205.681 or, if applicable, pursuant to a State organic program." *CAAE's Notices of Denial do not include the applicant's right to request mediation pursuant to §205.663 or file an appeal pursuant to §205.681.*

Corrective Action: CAAE revised its Notice of Denial to include the applicant's right to request mediation or appeal the denial of certification.

NP4125OOA.NC3 – Accepted. 7 CFR §205.406 (a)(1) states, "To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: (1) An updated organic production or handling system plan which includes: (i) 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 (ii) 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." *Letters that CAAE sends out notifying the operation that their annual update is coming up indicates that, if there are no changes, they do not need to make any reply to CAAE. If no reply is received, the inspector is directed to contact the operation and schedule an inspection.*

Corrective Action: CAAE amended its Procedures Manual (section 16.7 Annual renewals) to include a procedure for certified operators to be sent an Annex NOP Renovation/Modification form on which the operator will report changes to their Organic Management Plan. Staff training on the new procedure and form was conducted on July 23, 2014.

NP4125OOA.NC4 – Accepted. 7 CFR § 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." *The notifications of proposed suspension address the date by which the certified operation must respond to the proposed suspension. However, if the operation does not reply within the stated time frame, or the response is deemed insufficient or inappropriate in addressing the non-compliances, then the certified operation's certification may be suspended. The notices do not contain a defined date when the proposed suspension will become effective.*

Corrective Action: CAAE revised its Resolution of the N.O.P. Certifying Commission document to include a date when the proposed suspension or revocation becomes effective. Staff training on the revised document was conducted on July 23, 2014.

NP4125OOA.NC5 – 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." NOP 2609, Section 4.1.6 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 on 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 the appropriate representatives are present." *CAAE's current policy is to provide 24 hours prior notification to the operations (this mostly affects crop operations) for an unannounced inspection. The reasoning for this two-fold; first there are a number of operations where the responsible person does not live at the site of the operation and, in some cases, must travel longer than four hours to reach the site of the operation. Second, most of the crop operations that CAAE certifies are fenced and have locked access to the operation. Personnel and workers who are regularly on site at these operations in most cases do not have the knowledge or authority to assist inspectors with what they need for the unannounced inspections. However, this should not be standard policy for all operations.*

Corrective Action: CAAE revised its Procedures Manual (section 16.8 Control Visit) to state that unannounced visits should not be previously communicated to the operator and that operations may be notified up to four hours in advance only when extenuating circumstances make it impossible to conduct an unannounced inspection without notification. Staff training on the new procedure was conducted at the head office on July 23, 2014.

NP4125OOA.NC6 – Accepted. 7 CFR §205.670 (c) states, "A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense." *CAAE conducted two (2) samplings for NOP during the calendar year 2013. The tests for these samples were paid for by the certified operation.*

Corrective Action: CAAE issued refunds to its certified operators who were charged for sample testing. Additionally, CAAE revised its Resolution of the N.O.P. Certifying Commission document and Procedures Manual (section 17.6 Sampling) to state that the cost of the sampling will be paid by CAAE and not the operator. Staff training on the revised procedure and document was conducted on July 23, 2014.

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

The USDA National Organic Program (NOP) received Servicio de Certificación CAAE S.L.U. (CAAE)'s accreditation renewal application on August 1, 2013. The NOP reviewed this application and conducted an onsite audit of CAAE from May 5-8, 2014. The report below summarizes the NOP's assessment of CAAE's capability to operate as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name:	Servicio de Certificación CAAE S.L.U. (CAAE Certification Service)
Physical Address:	Avenida Emilio Lemos n° 2. Edificio Torre Este, Modulo 603, 41020 Sevilla-Andalucía, Spain
Mailing Address:	Avenida Emilio Lemos n° 2. Edificio Torre Este, Modulo 603, 41020 Sevilla-Andalucía, Spain
Contact & Title:	Juan Manuel Sánchez Adame, Head of Quality
E-mail Address:	jmsanchez@caae.es
Phone Number:	34 902 521 555
Auditor(s) and Reviewer (s):	Betsy Rakola, NOP Reviewer; Darrell Wilson, On-site Auditor.
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	Onsite audit completed May 5-8, 2014. NOP review completed June 17- 19, 2014.
Audit Identifier:	NP4125OOA
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 CAAE's certification system.
Audit and Determination Criteria:	7 CFR Part 205, National Organic Program as amended
Audit and Review Scope:	CAAE's certification services in carrying out the audit criteria during the period: October 1, 2010 (date of CAAE's initial assessment) – May 5, 2014

Certifier Overview Narrative:

ORGANIZATIONAL STRUCTURE: The CAAE Certification Service (CAAE) is part of the CAAE Association, which is a non-profit private organization. CAAE consists of the main office in Sevilla, Spain and four regional offices located in Castilla-La Mancha, Almeria, Granada, and Cordoba, Spain. All NOP certification activities are carried out from the main

office.

CAAE is currently accredited as a certifying agent to the USDA National Organic Program (NOP) for the scopes of crops, wild crops, and handling. CAAE was initially accredited by the NOP on February 13, 2009. CAAE currently has 23 clients certified to the USDA organic regulations; 12 for crops and 11 for handling of which 10 are processors and 1 is a trader. CAAE certifies clients to the NOP in Spain. CAAE does not currently certify any grower groups.

CAAE currently applies the USDA organic regulations and is certified for numerous Programs such as Bio Suisse, JAS, and the EU for the EC 834/2007 and 889/2008 Standards.

The CAAE organic certification program staff consists of the Director of Certification (one of four members on certification commission), two Director of Certification Assistants (both members of the certification commission), a Head of Certification (also a member of the certification commission), twelve Technical Certification, and eight staff inspectors. A review of the personnel files verified that personnel had sufficient combination of experience, education, and/or training in organic production and handling practices. A review of the files and personnel records did not identify any conflicts of interest with personnel. However, this assessment was based on previous year's conflicts of interest, since the current statements have not been completed.

CERTIFICATION PROCESS: When requests for certification are received, the applicants are provided a certification package. This package can be obtained from the CAAE website, emailed to the applicant, or sent via post at the applicant's request. The package consists of the CAAE Procedures Manual; the USDA organic regulations; an organic system plan and application appropriate to the scope of certification requested; a fee schedule; procedures outlining the certification process; a contract; procedures for the use of brands and certificates in compliance with the requirements; and procedures on complaints to the operators.

When the completed application and related documentation is received, a Technical Certification staff member first reviews the documents to ensure that the application is complete. Once it is complete, the same Technical Certification reviews the documents for compliance. The same person that does the initial review also reviews the labels for compliance. After all required information is gathered and the organic system is complete, it is assigned to a staff inspector. The applicants are notified of the results via a notification letter. After the inspection report is submitted to the CAAE office, a Technical Certification staff member will conduct a review of the inspection report and client file. This Technical Certification staff member can be the same one as the initial reviewer or a different Technical Certification staff member. In one of the six files reviewed, the same Technical Certification staff member conducted both the initial review and the final review. Once the review is complete, the Technical Certification staff member submits the results to the Certification Commission for the certification decision. The Certification Commission consists of four members, and at least two members must be present to make a certification decision. Non-compliances are drafted by the Technical Certification staff member and presented to the Certification Commission. The Certification Commission also makes the final determination for non-compliances. When corrective actions are received the Technical Certification staff member reviews them and, again, the Certification Commission

makes final determination.

For continuing certification, CAAE sends the certified operation a letter requesting any changes to the organic system plan. Once any changes are submitted, the review, inspection, and decision follow the same procedures as the initial application. The letter submitted to the certified client indicates that, if there are no changes to the certification, then they do not need to respond. If there is no response, the inspector is notified around the time the inspection is due and he/she contacts the certified operation to make necessary arrangements for the inspection (see findings).

Since the last assessment, there have been four denials of certification. All of these operations failed to respond to the requests for additional information needed to complete the initial review process. CAAE also issued eight proposed suspensions.

CAAE has conducted sampling of two product samples on two operations in 2013. Results were verified as having been provided to the clients via the certification decision document. Chain of custody was maintained from the inspector to the CAAE office and onto the laboratory. The client was charged for the testing (see findings).

The Technical Certification person conducting the initial review reviews the inputs for the applicant/certified operation. Various sources are used; the main source is the National List. Other sources include OMRI and any other agency recognized by NOP. There is a materials review program that is used in the event the Technical Certification staff member cannot make a determination as to the conformity of the product. CAAE maintains a list of these products, which are reviewed periodically for continuing conformance.

CAAE does not have established procedures for certifying grower groups and does not certify grower groups. If CAAE decides to certify grower groups to the USDA organic regulations in the future, they would have to establish grower group certification procedures and provide them to the NOP for review prior to implementing the procedures.

ADMINISTRATIVE RECORDS AND PROCESSES: The main basis of certification for the NOP is the NOP Program Manual. This manual is available on the CAAE website and can be obtained by regular post if requested. All forms for certification are also available on the CAAE website.

CAAE's annual review consists of an internal audit. A review of these audits verified that they are being conducted annually and that corrective actions are being taken as applicable.

Training is being conducted on a continuing basis. A review of personnel qualifications verified that all had numerous training sessions in NOP topics and other agricultural related areas. Some of the training was from outside sources, and some was within the company. Documentation of the training is being maintained and was available for review. Training is ongoing and is always conducted when changes to the program occur.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED: A

review audit was conducted on a crop/handling operation in Baena, Córdoba, Spain. The operation grows olives, which are processed into oil. They only produce organic products, which are certified both to the NOP and EU. The oil produced for NOP is labeled 100% organic. All areas were reviewed during the review audit. Buffer zones, records, and maps were verified.

NOP DETERMINATION

NOP conducted a review of the auditor's CAAE audit report. NOP has determined the following status of the prior noncompliance correction actions, the current identified noncompliances, and any observations:

Noncompliances from Prior Assessments – Cleared

NP0270MMA.NC1 – Cleared - NOP §205.201(a)(5) states, "An organic production or handling system plan must include: (5) A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances." *Observations made during the witness inspection of the wild crop verified that the maps that the inspector used did not indicate all of the areas where the wild crops were collected. Topographic maps were used of the areas controlled by the city where the collection of the wild crops occurs. The maps contained the area of the city along with wild areas, and plots that were owned by individuals. There was no identification of the buffer zones along the city area or plots that were owned by individuals; or the use of the plots by individuals to make any determination of possible contamination risks. It was observed during the witness inspection that some of the plots in the area had been cultivated but there had been no verification of the crops planted. It was noted during a review of operator files, that maps were included but there were few if any notations on the maps on the use of land surrounding the organic operations. Inspectors made notations in the inspection report that the buffers were viewed and that there was little risk of contamination. The buffer zones and collection areas were not well defined and identified in the organic system plan or maps.* **Corrective Action:** CAAE provided maps of plots for the specific producers in question from the witness / case file audits that demonstrate the buffer zone borders in use. CAAE also updated 18.3.2.f of the Procedures Manual to "include express instructions regarding the importance of checking for buffer zones." The CAAE Review Report has also been modified "to detail the information that needs to be shown on the maps;" a copy of this Review Report was attached for review. **NOP 2014 Verification of Corrective Action:** Plot maps of files reviewed indicated where buffer zones were.

NP0270MMA.NC2 – Cleared - NOP §205.303(b)(2) states, "Agricultural products in packages described in §205.301(a) and (b) must: (2) 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…" *Eighteen (18) of 25 approved organic labels reviewed had the statement "Certified NOP by S.C. CAAE."* **Corrective Action:**

CAAE provided an update to the Procedures Manual (18.3.2.f) to "include instructions to check that all labels contain the term „certified organic by CAAE," or in the case of those which might lead to confusion, „certified organic NOP by CAAE."" CAAE, in addition to the Procedures Manual update, forwarded 3 examples of the new label review process captured in the Manual; the label review process includes a review report that must be completed and approved for each label, and includes the requirement to verify the correct "COB…" statement. **NOP 2014 Verification of Corrective Action:** Labels reviewed verified that the statement is in the correct statement in the correct location.

NP0270MMA.NC4 – Cleared - 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." Also, 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." *CAAE is not properly documenting notifications of non-compliances which are submitted to clients. Notifications of non-compliances are provided by the inspectors during the exit interview. Inspectors can then accept corrective actions and also make a determination on when the non-compliances have to be addressed. In two of three files reviewed for the requirement, non-compliances identified by the inspectors were not identified as non-compliances by the certification technician or certification committee and were not included on the certification decision document which is where CAAE identifies non-compliances to clients. In one file the non-compliance was included on the decision document as a "reminder" to the client.* **Corrective Action:** CAAE created and implemented (completed: April 11, 2011) notices of non-compliance that clearly indicate the non-compliance issue cited. The Procedures Manual (16.6 and 16.9) has been updated to "provide detailed instructions regarding the different types of Resolution that the Certifying Commission may make, including the Resolution to send a Notice of Non-compliance." Further, the format of the Resolution of the Certifying Commission has been "modified to clearly differentiate between what is considered a "non-compliance" and what is simply a "comment or reminder." Inspectors have also been instructed to discontinue citing non-compliances at the time of audit and that they are not able to communicate issues of non-compliance at audit. Objective evidence was provided for all response points. **NOP 2014 Verification of Corrective Action:** Notices of non-compliance are now being issued as described in the corrective actions submitted by CAAE.

NP0270MMA.NC5 – 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." *A review of the files verified that on at least one occasion CAAE did not conduct a full review of the material inputs. Instead CAAE*

accepted an affidavit from the supplier of a fungicide that the inert ingredients were in compliance with the USDA organic regulations and listed on EPA List 4 or EPA List 3. On another occasion a crop operation sprayed their olive trees with a copper oxychloride product for fungus control in October 2009. The olives were harvested December through the beginning of February and the olive oil produced from the olives was subsequently processed as NOP eligible product. There was not enough information available at the time of the USDA audit to determine if product was actually marketed as NOP certified product. The copper oxychloride product contained mono-ethylene glycol as an inert. **Corrective Action:** at the operator level, inspections were conducted (Aug and Oct 2010) and found that the input in question (ZZ Cuprocol) was no longer in use. The CAAE "Policy Memorandum 11-4," which provides a list of materials approved for the NOP, has been revised to list this material (ZZ Cuprocol) as "prohibited." The evaluation report was modified to include the types of tests that should be conducted for materials in use, and the Procedures Manual (16.3.2.c, doc attached) was revised to include requirements for material review and approval. Objective evidence was submitted for all response points. **NOP 2014 Verification of Corrective Action:** File reviews and interviews conducted verified materials are being reviewed as required.

NP0270MMA.NC7 – Cleared - NOP §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." *Initial file reviews and final reviews prior to the file being sent to the two member certification committee was conducted by the same certification technician in five of seven files reviewed. In all cases the final review by the certification technician was the same day as the day the certification committee signed the certification decision documents prepared by the certification technician. The reviews conducted by the certification committee are cursory reviews based on the findings of the certification technician*. **Corrective Action:** CAAE's certification system is set up such that the application reviewer and inspection report reviewer may or could be the same personnel. The final decision is made by the Certifying Commission. The NOP accepts this structure, as the person(s) making the final decision is different from those that conducted a review of documents (application review) and / or the on-site inspection. **NOP 2014 Verification of Corrective Action:** CAAE is following their certification system correctly.

NP0270MMA.NC8 – 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: (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." *The list of non-compliances identified by CAAE included 61 notifications of non-compliance. None of which had been submitted to NOP*. **Corrective Action:** CAAE has revised the certification system to ensure all notices of non-compliance are submitted to AMS,

including minor non-compliance issues. The Procedures Manual has been modified to include a detailed section on Notices to AMS and which notices would apply; further, the format for the Resolution of the Certifying Commission was revised to include instructions regarding delivery of notices to the AMS Administrator. CAAE sent confirmation (objective evidence) showing that all applicable notices have been sent to AMS for the 2011 certification year thus far. **NOP 2014 Verification of Corrective Action:** CAAE is now maintaining a database of all notification of non-compliances, notification of proposed suspension or revocation, and notification of suspension or revocation. The database includes the date the items were sent to the NOP and a link to the document.

NP0270MMA.NC9 – 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 any requirements for the correction of minor non-compliances." *CAAE just recently started notifying inspectors of its decision regarding certification of operations. Inspectors are notified on a monthly basis. This change was due to a non-compliance identified during an internal audit. However, CAAE does not inform the inspectors of the requirement for correction of any minor non-compliances identified by CAAE.* **Corrective Action:** CAAE's Procedures Manual (18.3.8) has been revised to "detail which information should be sent to the inspectors and when it should be sent." Specifically, this update states, "inspectors will periodically receive copies of any resolutions (with the corrective measures proposed by the producer) which are issued for any inspections they carried out." CAAE also forwarded objective evidence showing a notification of this type to an inspector in 2011 in response. **NOP 2014 Verification of Corrective Action:** Interviews verified that corrective actions have been implemented.

NP0270MMA.NC10 – Cleared - NOP §205.510(a)(1) and (4) state, "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 report and fees: (1) A complete and accurate update of information submitted pursuant to §§205.503 and 205.504; (4) The results of the most recent performance evaluations …" *The 2010 annual report submitted to the Administrator did not include the results of the most recent performance reviews nor copies of 3 inspection reports and certification evaluation documents for production and handling operations certified by the applicant for each area of accreditation (NOP §205.504(d)(2).* **Corrective Action:** CAAE's system has been updated to require that the Annual Update include performance reviews and 3 copies of inspection reports / certification evaluation documents for each area of accreditation. The Procedures Manual (21.1) was revised to detail all information required for the Annual Update. CAAE also sent evidence of the 2010 Annual Update submission, completed in February 2011, which included required documents. **NOP 2014 Verification of Corrective Action:** CAAE is submitting the required documents for annual updates.

NP0270MMA.NC11 – Cleared: NOP §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 packages provided to applicants do not contain a copy of the CAAE fee schedule. A review of the NOP cost estimates sent by CAAE to operations indicates that the estimate/budget sent to the operator includes a charge for a risk factor that is applied to the operator based on the size of operation, number of employees, and number of sites. There is also a charge for "training" that CAAE applies to recoup expenses paid to another ACA for expenses incurred during the accreditation process. Travel expenses for inspections are also included in the estimate. None of these additional costs are described in the description of fees for NOP operators. The determination of the "risk" factor (margin) is not described in any procedure and is arbitrarily applied to operations. The fee schedule states that fees cannot be refunded once the subscription process has begun but does not identify the stages at which fees become non-refundable.* **Corrective Action:** CAAE now sends formal price lists to new applicants for certification. Further, CAAE revised the fee schedule to provide more transparent fees based on objective criteria. The Procedures Manual (16.1.4 and 16.1.5) was also updated to include instructions to provide a price list to new applicants, as well as a quote ("estimate") for the specific certification in question, calculated in accordance with the new pricelist. Objective evidence documents were submitted. **NOP 2014 Verification of Corrective Action:** All applicants are being sent price list. Review of invoicing of for clients verified that all costs charged were included on the price list.

Non-compliances identified during current audit

NP0270MMA.NC3 – Outstanding - NOP §205.404(b)(2) and (3) states, "The certifying agent must issue a certificate of organic operation which specifies the: (2) Effective date of certification; and (3) Categories of organic operation, including crops, wild crops, livestock, or processed products produced by the certified operation." *CAAE is placing "First Certification Issuance Date" as the initial certification date of CAAE if first time applicants have never applied to another ACA. However, if the applicant was certified by another ACA then they are using the date the applicant was certified by the other ACA and not the date certified by CAAE. Additionally, the two certificates issued to wild crop operations did not identify the scope of certification as a wild crop.* **Corrective Action:** CAAE adjusted the E-CERT system to include a new category, "wild harvest." The format of the certificates has been modified to include "wild crop"

as a category of certification. Also, the Procedures Manual (1.1) has been modified to include "NOP Wild Harvest" as an applicable certification category. To correct the issue at the certified operation level, CAAE revised the applicable certificates to display "wild crops" as appropriate and forwarded the revised certificates along with a letter explaining the change to the operators. For all areas of response, CAAE provided objective evidence. **NOP 2014 Verification of Corrective Action:** The 6 certificates reviewed did not contain the scope of certification (currently crops and handling). Therefore, certificates are still not in compliance with the USDA organic regulations.

NP0270MMA.NC6 – Outstanding: 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." *A review of personnel files verified that 9 of 33 CAAE personnel working with the NOP program did not have current conflict of interest statements*. **Corrective Action:** CAAE obtained current Conflict of Interest statements from all staff and submitted as objective evidence with the response. The Procedures Manual "has been modified to include the obligation to update the disclosure of conflict of interest statements by January 31st of each year." **NOP 2014 Verification of Corrective Action:** There were no current conflict of interest statements for personnel involved with NOP certification. The Head of Quality indicated that they have restructured the conflict of interest document and did not get them sent out early enough to receive them back before the previously signed documents expired.

NP4125OOA.NC1 – New. NOP §205.404 (b)(4) states, "The certifying agent must issue a certificate of organic operation which specifies the name, address, and telephone number of the certifying agent." *Certificates in the files reviewed did not contain the address of the certifying agent.*

NP4125OOA.NC2 – New. NOP § 205.405 (d) states, "A notice of denial of certification must state the reason(s) for denial and the applicant's right to: (2) Request mediation pursuant to §205.663 or, if applicable, pursuant to a State organic program; or (3) File an appeal of the denial of certification pursuant to §205.681 or, if applicable, pursuant to a State organic program." *CAAE's Notices of Denial do not include the applicant's right to request mediation pursuant to §205.663 or file an appeal pursuant to §205.681.*

NP4125OOA.NC3 – New. NOP §205.406 (a)(1) states, "To continue certification, a certified operation must annually pay the certification fees and submit the following information, as applicable, to the certifying agent: (1) An updated organic production or handling system plan which includes: (i) 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 (ii) 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." *Letters that CAAE sends out notifying the operation that their annual update is*

coming up indicates that, if there are no changes, they do not need to make any reply to CAAE. If no reply is received, the inspector is directed to contact the operation and schedule an inspection.

NP4125OOA.NC4 – New. 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." *The notifications of proposed suspension address the date by which the certified operation must respond to the proposed suspension. However, if the operation does not reply within the stated time frame, or the response is deemed insufficient or inappropriate in addressing the non-compliances, then the certified operation's certification may be suspended. The notices do not contain a defined date when the proposed suspension will become effective.*

NP4125OOA.NC5 – New. 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." NOP 2609, Section 4.1.6 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 on 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 the appropriate representatives are present." *CAAE's current policy is to provide 24 hours prior notification to the operations (this mostly affects crop operations) for an unannounced inspection. The reasoning for this two-fold; first there are a number of operations where the responsible person does not live at the site of the operation and, in some cases, must travel longer than four hours to reach the site of the operation. Second, most of the crop operations that CAAE certifies are fenced and have locked access to the operation. Personnel and workers who are regularly on site at these operations in most cases do not have the knowledge or authority to assist inspectors with what they need for the unannounced inspections. However, this should not be standard policy for all operations.*

NP4125OOA.NC6 – New. NOP §205.670 (c) states, "A certifying agent must conduct periodic residue testing of agricultural products to be sold, labeled, or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))." Samples may include the collection and testing of soil; water; waste; seeds; plant tissue; and plant, animal, and processed products samples. Such tests must be conducted by the certifying agent at the certifying agent's own expense." *CAAE conducted two (2) samplings for NOP during the calendar year 2013. The tests for these samples were paid for by the certified operation.*

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Juan Manuel Sánchez Adame
Head of Quality
Servicio de Certificación CAAE S.L.U. (CAAE Certification Service)
Avenida Emilio Lemos n° 2.
Edificio Torre Este, Modulo 603
41020 Sevilla-Andalucía
Spain

Dear Mr. Sánchez:

On May 5-8, 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 Servicio de Certificación CAAE S.L.U. (CAAE) organic certification program. The objective of the assessment was to determine CAAE's compliance to the USDA organic regulations as an accredited certifying agent. A copy of the assessment report, NP4125OOA, is enclosed for your reference.

As the report indicates, six noncompliances (NP4125OOA.NC1 through NC6) were identified during the assessment. Two noncompliances, NP0270MMA.NC3 and NP0270MMA.NC6, 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 CAAE'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, Lars Crail, at (202) 205-5536 or Lars.Crail@ams.usda.gov.

Sincerely,

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

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division

USDA Agricultural Marketing Service

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

JUL 7 2014

NOTICE OF NONCOMPLIANCE

Juan Manuel Sánchez Adame
Head of Quality
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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,

Betsy Rakola for cc

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

Enclosure

cc: NOP Appeals
USDA Quality Assessment Division

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Jake Lewin
CCOF Certification Services, LLC
2155 Delaware Ave, Suite 150
Santa Cruz, CA 95060

Dear Mr. Lewin:

On July 25, 2017, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) became aware that CCOF Certification Services' (CCOF) organic certificates do not contain all of the elements of the organic certificate outlined in NOP Instruction 2603 *Organic Certificates*. We have determined that CCOF is noncompliant with the USDA organic regulations, 7 CFR Part 205, as follows:

AIA7208RC.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 Instruction 2603 *Organic Certificates* section 3.1.

Comments: *A CCOF certificate submitted to the NOP for review did not include the following elements of the organic certificate.*

a) The term effective date is not used.
b) The term anniversary date is not used.
c) The statement, "Certified to the USDA organic regulations, 7 CFR Part 205" is not included on the certificate.
d) The statement "Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked" is not included on the certificate.

CCOF 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 CCOF 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 CCOF's USDA accreditation.

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

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Jake Lewin
CCOF Certification Services, LLC
2155 Delaware Ave, Suite 150
Santa Cruz, CA 95060

Dear Mr. Lewin:

On June 12, 2017, the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) received an anonymous complaint regarding an update to CCOF's livestock policy. We have determined that the requirements of CCOF's livestock policy is noncompliant with the USDA organic regulations, 7 C.F.R. Part 205, as follows:

AIA7236RC.NC1 – 7 C.F.R. §205.236(c) states, "The producer of an organic livestock operation must maintain records sufficient to preserve the identity of all organically managed animals and edible and nonedible animal products produced on the operation."

Comments: *CCOF's requirement that "animals eligible for slaughter must have visually distinct identification for those individual animals that meet slaughter stock requirements" is not supported by the regulations. Livestock operations must have records to identify which livestock are and are not slaughter eligible, however the regulations do not require that identification is visible.*

CCOF 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 CCOF 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 CCOF's USDA accreditation.

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

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of CCOF Certification Services, LLC (CCOF) organic program was conducted on April 25-27, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess CCOF's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	CCOF Certification Services, LLC (CCOF)
Physical Address	2155 Delaware Ave Suite 150, Santa Cruz, CA 95060
Mailing Address	2155 Delaware Ave Suite 150, Santa Cruz, CA 95060
Contact & Title	Kelly Lehman Goswamy, Quality Manager; Jody Biergiel Colclough, Director of Certification Operations
E-mail Address	Accreditation@ccof.org
Phone Number	(831) 423.2263, ext. 6255 & 6247
NOP Reviewer **On-Site Auditors**	Jason Lopez, NOP Reviewer Miguel Caceres, Lead Auditor; Rebecca Claypool, Second Auditor On-site Auditors.
Program	USDA National Organic Program (NOP)
NOP Review **Audit Dates**	NOP assessment review: October 26, 2017 Onsite audit: April 25-27, 2017 Review Audit: May 24, 2017
Audit Identifier	NP7115MMA
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 CCOF's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	CCOF's certification services in carrying out the audit criteria during the period: June 2014 through April 2017

The National Organic Program (NOP) conducted an on-site renewal assessment of the CCOF Certification Services, LLC (CCOF) organic certification program on April 25 – 27, 2017.

CCOF is a wholly-owned subsidiary of CCOF, Inc. and was initially accredited as a USDA certifying agent on April 29, 2002. CCOF's accreditation scopes are crops, wild crops, livestock, and handling/processing. CCOF's main office is located in Santa Cruz, California. CCOF also has a one-person office in Zapopan, Jalisco, Mexico. The Mexico office is solely accredited by SENASICA and does not make any final decisions of certifications. All certification services are performed at the CCOF main office in Santa Cruz, California.

CCOF's list of certified operations at the time of the assessment consisted of 3,380 operations: Crops (2,396), Wild Crops (7), Livestock (193), and Handler/Processor (1,724). CCOF does not certify any grower groups. Certification services are provided to operations in the following countries: United States, Canada, and Mexico.

As part of the onsite audit activities, two witness audits and one review audit was conducted. Witness audits of an annual, announced inspection of a livestock operation and an unannounced inspection of a crop operation were conducted. A review audit of a handling operation, which receives, processes, and repacks vegetable crops, was conducted.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether CCOF'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 CCOF.

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.

NP7115MMA.NC1 – **Accepted** - 7 C.F.R. §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 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 reasons for the proposed suspension or revocation…."

Comments: *The following two issues were identified during a review of notifications of noncompliance and proposed suspension issued to an operation: (1) The notice of noncompliance had five issues the operation was to address and the notice of proposed suspension indicated 11 issues. (2) The notice of proposed suspension did not include the reason for the proposed suspension as it was included in the notice of noncompliance which was issued prior to the proposed suspension notification.*

Corrective Action: CCOF has amended its work instructions to state that only existing issues can be escalated to a proposed suspension/revocation. CCOF also created an Adverse Action Checklist for staff use when preparing a proposed adverse action, and retrained staff on the adverse action process on September 12, 2017.

NP7115MMA.NC2 – **Accepted** - 7 CFR §205.662(c)(3) 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 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 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: *The following three issues were identified during a review of a proposed suspension issued to an operation: (1) The notice of proposed suspension issued to an operation did not include the impact of a suspension; (2) the option to request mediation; (3) and, the option to file an appeal.*

Corrective Action: CCOF changed its adverse action communication system to include all the required elements of a notification of proposed suspension in the CCOF Compliance Report issued to an operation. CCOF previously stated the impact of a suspension and the options to request mediation or file an appeal in the body of an email/cover letter that accompanied the compliance report.

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Jake Lewin
CCOF Certification Services, LLC
2155 Delaware Ave, Suite 150
Santa Cruz, CA 95060

Dear Mr. Lewin:

On April 25-27, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the CCOF Certification Services, LLC (CCOF) organic certification program as part of its USDA Renewal Accreditation Assessment. On July 17, 2017, the NOP reviewed the results of the onsite audit to determine CCOF's compliance to the USDA organic regulations. A copy of the assessment report, NP7115MMA, is enclosed for your reference.

As the report indicates, three (3) new noncompliances (NP7115MMA.NC1 through NC3), 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 CCOF 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 CCOF'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 NP7115MMA

cc: AIA Inbox

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) received CCPB SRL's (CCPB) application to become a U.S. Department of Agriculture (USDA) accredited certifier on October 17, 2013. The NOP reviewed CCPB's application, conducted an onsite audit (May 12 – 14, 2014), and reviewed the audit report to determine CCPB's capability to operate as a USDA accredited certifier. On June 30, 2014, NOP granted accreditation to CCPB, conditional upon CCPB submitting corrective actions in response to two remaining noncompliances. This corrective action report is a review of those two noncompliances.

GENERAL INFORMATION

Applicant Name	CCPB SRL
Physical Address	Via Jacopo Barozzi 8, 40126 Bologna, Italy
Mailing Address	Via Jacopo Barozzi 8, 40126 Bologna, Italy
Contact & Title	Roberto Setti, Technical Dept. & Quality Assurance Manager
E-mail Address	rsetti@ccpb.it
Phone Number	39 051 6089811
Reviewer(s) & Auditor(s)	Jason Lopez, NOP Reviewer
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	May 19-22, 2015
Audit Identifier	NP413200A
Action Required	None
Audit & Review Type	Pre-Decisional Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of CCPB's certification system.
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	CCPB SRL's system of preparation and carrying out audit certification criteria.

GENERAL NOTES FROM PRE-DECISIONAL AUDIT:
CCPB is a for profit body operating to check the compliance of food and non-food agriculture products in general, that are produced using organic farming methods. CCPB operates as an independent body according to the requirements of the Standard UNI CEI EN ISO/IEC 17065, in order to certify that products comply with the technical standards and other standards documents. CCPB maintains accreditations with ACCREDIA (17065 and 22005), EU 834/2007, International Federation of Organic Agriculture Movements (IFOAM), and COR and is certified for numerous Programs such as Bio Suisse, Japanese Agricultural Service (JAS), Italian Ministry for Agriculture, Food, and Forestry Policies (MiPAAF), and IOAS.

CCPB requested accreditation for the following scopes: Crops, Wild Crops, Livestock, and Handling/Processing. CCPB maintains their head office in Bologna, Italy. All NOP key certification activities will be conducted in the head office. CCPB currently maintains regional offices in Sicily, Veneto, and Tuscany, Italy. After the July 1, 2014, merger with Istituto Mediterraneo di Crtificazione (IMC), CCPB will have an additional regional office in Senigillia, Italy as well as offices in Tunisia, Egypt, Lebanon, Turkey, and Morocco.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether CCPB'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.

NP8022DDA.NC2 – Cleared
NP0111NNA.NC1 – Cleared
NP0111NNA.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.

NP4132OOA.NC1 – Accepted – NOP §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: *CCPB's policy and procedure is for the inspector to leave a copy of the unapproved inspection report with the applicant/certified operation after completing the inspection. The inspector would then submit the inspection report to CCPB for approval. The operator would only receive an approved inspection report if CCPB amended the inspector's original report. The operator would not receive an approved report if CCPB did not amend the report. CCPB is not in compliance because CCPB does not provide an approved copy of the complete inspection report to all applicants.*
Corrective Action: CCPB approves all inspection reports and results of audits prior to an initial review. CCPB has added a statement to form Mod.NO/VI - *Checklist of organic system plan,* stating, "This report and the result of the audit is confirmed in absence of different written communication from CCPB in the following 60 days from the inspection." CCPB amended the inspectors *Standard Control Procedure* - Operative procedure 2.3.7 to define "inspection report and

complete checklist" as the reports to be issued to the operator. CCPB made employees aware of these procedural changes in an email sent on August 11, 2014.

NP4132OOA.NC2 – Accepted – NOP §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: *Upon receiving a request for certification, the applicant is provided with CCPB's fee schedule. The applicant then determines their own cost estimate for certification. There is no review of this estimate by CCPB to ensure that the estimate is accurate. The applicant can however request an estimate from the CCPB if they so desire.*
Corrective Action: CCPB added section 2.4 "Fees for certification and for maintenance certification" to its Standard Control Procedure Organic Products USDA-NOP Scheme document. Section 2.4 states CCPB will provide a detailed total estimate of certification cost for the initial year of certification and an estimated annual certification maintenance cost. CCPB communicated this procedure to its employees via an email sent on August 11, 2014.

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NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

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GENERAL INFORMATION

Applicant Name	CCPB SRL
Physical Address	Via Jacopo Barozzi 8, 40126 Bologna, Italy
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Contact & Title	Roberto Setti, Technical Dept. & Quality Assurance Manager
E-mail Address	rsetti@ccpb.it
Phone Number	39 051 6089811
Reviewer(s) & Auditor(s)	Jason Lopez, NOP Reviewer
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	May 19-22, 2015
Audit Identifier	NP413200A
Action Required	None
Audit & Review Type	Pre-Decisional Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of CCPB's certification system.
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	CCPB SRL's system of preparation and carrying out audit certification criteria.

GENERAL NOTES FROM PRE-DECISIONAL AUDIT:
CCPB is a for profit body operating to check the compliance of food and non-food agriculture products in general, that are produced using organic farming methods. CCPB operates as an independent body according to the requirements of the Standard UNI CEI EN ISO/IEC 17065, in order to certify that products comply with the technical standards and other standards documents. CCPB maintains accreditations with ACCREDIA (17065 and 22005), EU 834/2007, International Federation of Organic Agriculture Movements (IFOAM), and COR and is certified for numerous Programs such as Bio Suisse, Japanese Agricultural Service (JAS), Italian Ministry for Agriculture, Food, and Forestry Policies (MiPAAF), and IOAS.

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NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether CCPB'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.

NP8022DDA.NC2 – Cleared
NP0111NNA.NC1 – Cleared
NP0111NNA.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.

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Corrective Action: CCPB approves all inspection reports and results of audits prior to an initial review. CCPB has added a statement to form Mod.NO/VI - *Checklist of organic system plan,* stating, "This report and the result of the audit is confirmed in absence of different written communication from CCPB in the following 60 days from the inspection." CCPB amended the inspectors *Standard Control Procedure* - Operative procedure 2.3.7 to define "inspection report and

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Corrective Action: CCPB added section 2.4 "Fees for certification and for maintenance certification" to its Standard Control Procedure Organic Products USDA-NOP Scheme document. Section 2.4 states CCPB will provide a detailed total estimate of certification cost for the initial year of certification and an estimated annual certification maintenance cost. CCPB communicated this procedure to its employees via an email sent on August 11, 2014.

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NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

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GENERAL INFORMATION

Applicant Name:	CCPB SRL
Physical Address:	Via Jacopo Barozzi 8, 40126 Bologna, Italy
Mailing Address:	Via Jacopo Barozzi 8, 40126 Bologna, Italy
Contact & Title:	Roberto Setti, Technical Dept. & Quality Assurance Manager
E-mail Address:	rsetti@ccpb.it
Phone Number:	+39 51 6089811
Auditor(s) and Reviewer (s):	Lars Crail, NOP Reviewer; Darrell Wilson, On-site Auditor.
Program:	USDA National Organic Program (NOP)
Audit and Review Date(s):	June 16 – 19, 2014.
Audit Identifier:	NP4132OOA
Action Required:	Yes
Audit and Review Type:	Pre-Decisional Assessment
Audit Objective:	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of CCPB SRL's certification system.
Audit and Determination Criteria:	*7 CFR Part 205, National Organic Program as amended*
Audit and Review Scope:	CCPB SRL's certification system in preparation in carrying out the audit criteria.

ORGANIZATIONAL STRUCTURE: CCPB is a for profit body operating to check the compliance of food and non-food agriculture products in general, that are produced using organic farming methods. This includes such operations as: animal rearing, product preparation, processing, distribution and importing, and also those operating in the eco-friendly agricultural production sector. CCPB operates as an independent body according to the requirements of the Standard UNI CEI EN ISO/IEC 17065, in order to certify that products comply with the technical standards and other standards documents.

CCPB was initially accredited as a USDA National Organic Program (NOP) certifying agent on

December 9, 2002. CCPB surrendered its accreditation on July 24, 2012 due to the implementation of the EU/US Equivalency Arrangement. However, in October 2013, CCPB requested accreditation for the following scopes: Crops, Wild Crops, Livestock, and Handling/Processing. In addition, CCPB indicated that on July 1, 2014, it was planning to merge with the USDA certifier Istituto Mediterraneo di Certificazione (IMC). CCPB has accreditations with ACCREDIA (17065 and 22005), EU 834/2007, International Federation of Organic Agriculture Movements (IFOAM), and COR and is certified for numerous Programs such as Bio Suisse, Japanese Agricultural Service (JAS), Italian Ministry for Agriculture, Food, and Forestry Policies (MiPAAF), and IOAS.

CCPB maintains their head office in Bologna, Italy. All NOP key certification activities will be conducted in the head office. CCPB currently maintains regional offices in Sicily, Veneto, and Tuscany, Italy. After the merger with IMC, CCPB will also have a regional office in Senigillia, Italy as well as offices in Tunisia, Egypt, Lebanon, Turkey, and Morocco.

CCPB's organic certification program staff consists of an Inspection and Certification Activity Manager (RAC), a RAC Assistant, an Operator's Dossier Management and Product Labels Verification, three inspectors partially involved in the application review (when necessary), and 37 independent inspectors. After the merger with IMC, there will be approximately 17 additional independent inspectors. All personnel appear to be qualified to fulfil the duties assigned.

There is a Board of Directors which consists of two to seven members. Currently there are three members residing on the Board. The Board's function is primarily financial and to appoint the general manager. The Board is designed so that there are no conflicts of interest within their structure.

CERTIFICATION PROCESS: When requests for certification are received, the applicants are provided a certification package. The package consists of a certification contract, OSP w/detail sheets, fee schedule, and a copy of the NOP. This package is sent via email or regular mail. Once CCPB is accredited, the required information will also be available on CCPB's website. After the application has been received, the RAC Assistant and/or the inspectors will review the application for completeness and compliance. When it is determined that the application conforms to the requirements, an inspector is assigned to conduct the inspection. The inspector submits the report to CCPB and the initial reviewer reviews the report and documentation. The results of the review are presented to and discussed with the RAC Manager. Non-compliances are drafted by the reviewer and also presented to the RAC Manager. The final decision on non-compliances and certification are made by the RAC Manager.

For continuing certification the certified operation submits an annual update form indicating any changes that have occured since the last inspection. Once the information is reviewed, the ceritfication process follows the same process as the initial certification process.

The individual that conducts the initial review, also reviews all inputs for compliance to the NOP. All materials, even if previously reviewed, are reviewed each time they appear on an application. Various sources are used; the main source is the National List. Other sources

include OMRI and any other agency recognized by NOP. All labels are reviewed by the Operator's Dossier Management and Product's Labels Verification person.

ADMINISTRATIVE RECORDS AND PROCESSES: The main basis of certification for the NOP is the PCS 002 - Standard Control Procedure Organic Production USDA-NOP Scheme. This manual will be available on the CCPB website and can be obtain by regular post if so requested. All forms for certification will be available on the CCPB website.

An annual review is conducted each year in accordance with their ISO 17065 requirements. Corrective actions will be implemented as necessary.

A review of the training program indicated that training is conducted on an ongoing basis including internal and external training. Training will be conducted with IMC personnel after the merger has been completed and IMC personnel involved officially become under the control of CCPB.

SUMMARY OF WITNESS INSPECTIONS AND REVIEW AUDITS CONDUCTED:
A witness inspection was conducted on one of IMC's current certified operations. The operation is located in Monte Colombo (RN) Italy. The operation is a crop operation consisting of 6.4 hectors of grape vineyard. The inspection was an announced annual inspection. The inspector reviewed all applicable areas during the review audit. Buffer zones, records, and maps were verified.

NOP DETERMINATION

NOP reviewed the onsite audit report and determined the status of CCPB's corrective actions to adequately address prior 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.

Unverified Noncompliances at the time of CCPB's Accreditation Surrender (2012)

NP8022DDA.NC2 – Cleared - NOP § 205.201(a)(1-6) states, "The producer or handler of a production or handling operation… intending to sell, label, or represent agricultural products… 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 (1-6)." *The NOP clients are all certified to EU2092/91 prior to any work being done for the NOP Certification. With the EU paperwork, the client is required to complete a "Technical Report" that identifies processes and procedures of organic management in general*

terms and in some places more specific. However, the organic system plans (OSP) developed by CCPB for NOP use and issued to the clients to complete and return to CCPB do not require the client to give adequate information about the practices, products, and procedures used by the client. The OSP asks the client if they are in compliance to the NOP in certain areas and the client only has to answer Yes or No. If the client answers yes, the client does not inform CCPB of how they are in compliance to the NOP. The same OSP is then used by the inspector to verify the operation. If the inspector determines that the client is complying then the inspector marks the box titled "confirmed". If the inspector does find a problem or concern then they are required to identify in detail the concern. Five of five files reviewed, showed that the clients are not completing the OSP in accordance with the NOP Rule and the same five files showed that the inspector noted all the clients areas were conforming and thus no concerns. In addition, the Technical Report does not give adequate information in all areas of the NOP Rule.

1. *One client file reviewed found that the client was using copper hydroxide to control disease in the vineyard. The OSP did not identify what monitoring practices the client would use to ensure that the accumulation of copper hydroxide in the soil is kept to a minimum, and the OSP did not identify what disease management practices are used prior to the use of the copper hydroxide. CCPB was informing the clients that as long as the application rate was less that 4KG/hectare/year (the EU2092/91 acceptability rate) the client was in compliance.*
2. *Three client files reviewed identified the use of composted animal manure on the fields, when in fact, the product was animal manure (uncomposted) and the clients did not identify how they were in compliance to the 90/120 day application rates.*
3. *The organic system plans as submitted by the clients, do not give adequate information for the certifying agent to review to determine if the client complies or is able to comply with the NOP Rule.*

Corrective Action: CCPB circulated a letter to all inspectors in which CCPB described the results of the onsite audit. CCPB provided training to staff and inspectors during the December 15-16, 2008 meeting of which scope and attendance were submitted. The scope of the training for the December meeting was identified on the second day as to the results of the NOP audit. CCPB also conducted training during the months of September, November, and December with the Certification Committee. These training scopes included the NOP Rule broken down into sections for each monthly meeting. CCPB is also revising procedures and forms like the organic system plan and checklist in which the companies were asked to completely and accurately describe the processes used to meet the NOP requirements. Due to the change in the EU Rule to become effective January 1, 2009, CCPB has had to concentrate their efforts on these changes and therefore the revisions, while still ongoing, will not be completed until February/March 2009. CCPB will provide specific training to the inspectors of CCPB in the month of March 2009. Although CCPB did not provide the revised procedures or forms, CCBP has a plan in place for finalizing these and they should be submitted once finalized along with the training conducted. **Corrective Action (Submitted May 11, 2009):** CCPB supplied additional training records of inspectors and certification

committee members that occurred in March 2009 as well as revised client application, OSP's for crops and processors/handlers, and inspection reports for crops and processor/handlers. These revisions and trainings should ensure that CCPB applies the NOP Rule (scheme) as published but cannot be cleared until onsite reviews confirm the changes are applied. **Verification of Corrective Action (2011): Sub-finding 1** of this outstanding non-compliance was again confirmed during the review of a file including the production of grapes and olives. Records indicated that copper hydroxide remains an input that is used regularly but within the limits prescribed by the authority which has this year been increased to 30kg/ha over a period of 5 years. There is no testing by CCPB to verify initial levels of this element in the soil prior to certification or at any time after. There is also no requirement by the ACA to require monitoring by the operator to ensure that there is no accumulation in the soil. This has not changed since the previous finding; therefore, the non-compliance remains outstanding. **Verification of Corrective Action (2014):** Inspectors were sent copies of these non-compliances as a warning. Training of certification staff was also conducted. The operation's Organic System Plan was revised to require the operation to provide their monitoring practices to ensure that copper is not increasing in the soil. Implementation of these corrective measures occurred in 2012. **Sub-finding 2 -** In the case of the company witnessed during the inspection for crops, the inspector identified a fertilizer being used that was not submitted as a part of the OSP and was not identified in an update. The product Organ Cap 11 is a leather meal based fertilizer that was applied to the basil field on June 18. The inspector put the incident in his report and identified a non-compliance based on the requirement for all inputs to be in the OSP. There has been no review on the acceptability of this product for use in NOP organic production. **Verification of Corrective Action (2014):** Material review templates and forms were updated and training was conducted with certification staff. Implementation of these corrective measures occurred in 2012. **Sub-finding 3** of this outstanding non-compliance was further substantiated during the review of 3 files related to apple production in Poland. Files reviewed from the operations in Poland indicated that the OSPs are completed in a joint effort between the producer and the purchaser of the apples raised in the cooperative. This company (Steinhauser Polska) has in the past, completed and submitted the OSPs developed by CCPB for NOP use for all of the Polish apple growers. The current observations indicated that the same OSPs are still in use and have not been amended or updated since the corrective actions were submitted to address the non-compliance. The OSPs for the three files reviewed were not complete and the elements and sub-elements were contradictory to the scope of the certification. The first file indicated that the scope of the certification requested was "wild harvest" and "not applicable" to many elements in 205.201-205.206. There were no maps included in the OSP and, therefore, no buffers or borders identified. Records showed that the buffers are still being established and their effectiveness determined by the inspector during the on-site inspection. CCPB initiated in February of 2010 the process of updating all operations in Poland to the new Organic System Plans and procedures amended to meet the corrective actions from the previous USDA audit. Steinhauser Polska is in charge of this process and has not submitted an updated operator program to date. Because these files have not been updated according to the corrective actions plan submitted, this element remains outstanding. **Verification of Corrective Action (2014):** Templates

and forms were updated and training was conducted with certification staff. Implementation of these corrective measures occurred in 2012.

NP0111NNA.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." *From file reviews and the witness inspections, it was apparent that the ACA is not conducting a thorough materials evaluation against the National List prior to inspections. Bortrac was listed in the OSP for an olive operation. Bortrac is a derivative of boric acid and was used for treating a mineral deficiency. Boric acid is only approved as a means of pest control. Also, processing facilities reviewed during the witness inspections and file reviews indicated that contracted pest management services were in use but the materials used in traps as baits or lures were not reviewed since these were not listed in the Organic System Plans. CCPB indicated that pest management is highly regulated by the Italian government and felt that a review of pest management was not necessary since the practices are regulated. Additionally, in some cases the inspector assigned to an operation is reviewing the compliance of materials and not the certifying body.* **Verification of Corrective Action (2014):** Certification staff were advised of the issues and were provided training; forms were updated to require more information from operators.

NP0111NNA.NC2 – Cleared - NOP § 205.406 (a) states, **"**To continue certification, a certified operation must… submit the following information, as applicable, to the certifying agent: (1) an updated organic production or handling system plan which includes: (i) 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 (ii) 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." NOP § 205.201(a) states, "The producer or handler of a production or handling operation, except as exempt or excluded under §205.101, intending to sell, label, or represent agricultural products as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent." *The ACA has not been reviewing the update materials submitted by certified operations. Operations can summit a letter declaring that there will be no changes to their organic system plan. Other operations have submitted information regarding anticipated changes to their organic system plan including new products, inputs and materials which are sent directly by CCPB to the assigned inspector for verification during the annual inspection. The CCPB quality manual does not describe any review of update information. Interviews with staff revealed that any update information received is forwarded to the assigned inspector for verification. This indicates that any approval decision on new materials or inputs would be made after an inspection is made. The only case where update information is reviewed prior to transfer to an assigned inspector is when a non-compliance had previously been identified and corrective*

actions by the operator are reviewed by a staff member in the update material submitted. **Verification of Corrective Action (2014):** Staff and inspectors were advised of the issues and were provided training.

Non-compliances Identified during the Current Assessment

NP4132OOA.NC1 – NOP §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." *CCPB's policy and procedure are for the inspector to leave a copy of the inspection report summary with the applicant/certified operation. This summary does not include the checklist portion of the inspector's report. Unless CCPB's review and assessment of the inspection report is different from the inspector's findings, there is no copy of CCPB's approved report sent to the operation.*

NP4132OOA.NC2 – NOP §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." *Upon receiving a request for certification, the applicant is provided with a CCPB's fee schedule. The applicant then determines their own cost estimate for certification. There is no review of this estimate by CCPB to ensure that the estimate is accurate. The applicant can however request an estimate from the CCPB if they so desire.*

Pre-Decisional Audit Resolution Chronology Log

Audit Identifier (if any): NP4132OOA

Audit Type: Pre-Decisional

Accredited Certifying Agent Name: CCPB

Accreditation Manager : Jason Lopez for CA review

Date	Activity
02/26/14	Signed GVD estimate returned to AIA by CCPB
06/05/14	MLC sends pre-decisional audit docs to CC. Docs in 01Folder. CC forwards to LC.
06/21/14	LC proposed conditional accreditation; NCs from audit are minor; the conditions will be for them to submit corrective actions within a month for the two minor NCs.
06/30/14	AIA emails CCPB conditional accreditation certificate, NP4132OOA NC Report, terms of accreditation. Due date for CAs: 07/30/14.
07/01/14	Signed terms returned to AIA.
07/30/14	CCPB sends CAs to AIAInbox
07/31/14	MLC forwards CAs to CC and LC.
04/06/15	JH reviewing Audit Life Cycle Report and WTL: CA report never assigned out. Emailed request to assign AM to RM.
4-6-2015	JL assigned CA for CCPB.
4-8-2015	JL Reviewed CCPB files. CA's found in the 2014 Pre-decisional Audit were to be corrected as a condition of accreditation. The original corrective actions CCPB submitted *proposed* what actions CCPB would take by Dec. 31, 2014.
4-13-2015	JL Sent Rpost email to CCPB requesting CA documentation of the corrective actions it had planned to complete 4 months prior (Dec. 31, 2014)
4-17-2015	CCPB submitted corrective actions.
5-18-2015	JL attended investigative interviewing training 4-22&23-2015. JL attended IOIA training in NC 4-26-2015 through 5-1-2015. JL began annual leave on 5-2-015 and returned on 5-18-201.
5-19-2015	JL reviewed and began preparing a CA report.
5-20-2015	JL emailed R. Setti for clarification of CCPB's policy added with the corrective action to charge all analysis fees to the operations. Verifying compliance with 205.670(b)(c).
5-22-2015	JL wrote CA Report and Notice of NC Resolution.
5-26-2015	Emailed Mr. Setti to specifically explain how CCPB policy of charging for testing and analysis complies with 205.670(b)(c).
5-28-2015	Mr. Setti replied confirming no operations have been charged for analysis in the 1st period of 2015. CCPB has changed the policy to comply with NOP regulations. The corrected policy to the general fee schedule is included in the file for reference.
6-1-2015	JL send documents to RM for review.

6-4-2015	JL made corrections and resubmitted to RM for review.
6-8-2015	JL emailed CCPB for additional clarification of the NC procedure to verify there is a proper separation of decision responsibilities. The information was due June 15, 2015. JL received an auto-reply stating Mr. Setti would return to the office on June 26, 2015.
6-29-2015	JL received the *Standard Control Procedure* from CCPB. Section 3.4 of this procedure describes the management of noncompliances. If a NC is observed during an inspection, the inspector is required to inform the operation of his observation of a noncompliance. The RAC (the inspection and certification manager) will make the decision, based on the inspection report, to issue the NC. The procedure separates decisional responsibilities. Submitted to RM for review via email.
6-30-2015	JL made edits and submitted to RM via email.
7-1-2015	JL submitted to CC for review.
7-6-2015	JL made CC suggested changes and submitted to Rm for review via email.
7-7-2015	Printed for approvals
7-8-2015	JL sent NoNC Res and report Rpost.

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

Applicant Name:	Colorado Department of Agriculture (CDA)
Physical Address:	700 Kipling Street, Suite 4000, Lakewood, CO 80215
Mailing Address:	Same
Contact & Title:	Amy Stafford, Organic Program Manager
E-mail Address:	Amy.stafford@state.co.us
Phone Number:	(303) 239-4143
Auditor(s):	Meg Kuhn, Agricultural Marketing Specialist
Program:	USDA National Organic Program (NOP)
Audit Date(s):	April 14 – 17, 2014
Audit Identifier:	AIA4066MMK (based on date NoNC was issued; audit ID was not noted on NoNC)
Action Required:	Yes
Audit Type:	Corrective Action
Audit Objective:	To verify review and approve corrective actions addressing the non-compliances identified during review of APL-010-14.
Audit Criteria:	7 CFR Part 205, National Organic Program; as amended.
Audit Scope:	CDA's April 7, 2014 response letter to the March 7, 2014 Notice of Noncompliance re: APL-101-14
Location(s) Audited:	Desk

GENERAL INFORMATION

On March 7, 2014, the National Organic Program (NOP) issued a Notice of Noncompliance to Colorado Department of Agriculture (CDA) for three violations to the USDA Organic regulations. See below for noncompliances, as well as CDA's corrective actions, preventive actions, and objective evidence responses dated April 7, 2014.

AUDIT INFORMATION

Three (3) noncompliances were cited in the March 7, 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 CDA's next on-site assessment, scheduled for April 2015 (Mid-Term assessment). One corrective action was not accepted.

FINDINGS

1. **AIA4066MMK.NC1 – Rebuttal Not Accepted** – §205.403(a)(1) states, *"A certifying agent must conduct an initial on-site inspection…. An on-site inpsection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether… the certification of the operation should continue."* Through review of the APL-010-14, it was noted that CDA did not conduct an annual

inspection of SVF for the 2013 certification year. The review of the APL-010-14 file showed that the operation did, in fact, submit an updated OSP for the 2013 certification year, though the submission resulted in confusion at the CDA office about the fields currently certified and new fields seeking certification. Regardless of the lack of a complete OSP update, the certifier remains responsible for conducting annual organic inspections.
Rebuttal Response: CDA rebutted this noncompliance, stating that §205.406(b) requires a complete updated application to be on file prior to inspection, according to §205.406(a)(1, 2, and 4). Because the operation did not provide a complete update application, CDA felt it was correct in not scheduling its annual inspection. In January 2013, the National Organic Program conducted its annual Accredited Certifying Agents (ACA) Training. One of the components of this training was a presentation on "Certification and Accreditation Updates," specifically, "Organic System Plan (OSP) Updates and Notification of Changes." In this presentation, on slide 25 under "certifying agent responsibilities:" it states, "Conduct annual inspections **even if the operation has not submitted an updated OSP**." Although CDA's read of the regulation is that an annual inspection cannot occur unless or until a complete updated OSP is on file, the NOP has provided a different interpretation and instructed ACAs accordingly. In addition to the ACA training, the NOP released a 2nd edition of NOP 2601 Instruction, The Organic Certification Process. In this Instruction, 3.7 fourth paragraph states, "The certifiers shall inspect the operation annually to determine whether its certification should continue. If an operation fails to submit an annual update prior to the onsite inspection, the certifier should issue a Notice of Noncompliance. **However, the failure of an operation to submit an annual update does not relieve the certifier of its obligation to conduct an annual inspection**. (See 7 CFR § 205.403(a)(1).)" In accordance with §205.501(a)(21), which states, "A private or governmental entity accredited as a certifying agent under this subpart must: (21) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary," CDA is obligated to comply with the Instruction requirements, the ACA annual training guidance, and the USDA organic regulations of §205.403(a)(1).

2. **AIA4066MMK.NC2 – Accepted** – §205.402(b)(1) states, *"Review of Application. (b) The certifying agent shall within a reasonable time: (1) Review the application materials received and communicate its findings to the applicant."* The October 8, 2013 Notice of Noncompliance, issued prior to the Notice of Proposed Suspension, provided a timeline of events for the 2013 OSP update. Specifically, it was noted that the OSP update was received at CDA on April 25, 2013; however, the email notification to the operation requesting additional information to complete the update was not sent until 4 months later, on August 12, 2013. The operation was given one week to submit requested information. When the operation met this timeframe, it then took CDA 7 weeks to submit the official Notice of Noncompliance, on October 8, 2013, because the response from the operator was incomplete. The NOP considers these timeframes between certification activities to be excessive and not "within a reasonable time" as required in the regulation.
Corrective Action: CDA's response explained that a portion of the timeframe issue was due to a lack of payment of fees by the operator. It is CDA policy that an operator's file does not move to the review stage of certification until all fees are paid in full. The operator did not pay their fees in full until July 16, 2013; after that time the file moved to the certification department for review. Copies of communication between the April 25, 2013 annual update

receipt date and July 16, 2013 payment date were included with CDA's response. Outside of payment issues, CDA agreed that timeliness could improve and updated its Organic System Plan Procedures to require the Program Manager to review the status of all files with outstanding noncompliances to ensure notices are addressed in a timely fashion. A copy of the revised procedures was provided with the response. CDA will also update its noncompliance report on a monthly basis.

3. **AIA4066MMK.NC3 – Accepted** – §205.681(c) *states, "Appeals. (c) Filing period. 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…."* The October 28, 2013 Notice of Proposed Suspension does not meet the requirements of this NOP regulation. Specifically, the effective date of the suspension was identified as November 24, 2013, 28 days after issuance of the Notice of Proposed Suspension, and identified November 28, 2013 as the last day to appeal or request mediation. As noted in the regulation, the certifier must provide 30 days from the time of the receipt of the notice for appeal or mediation proceedings, not 30 days from issuance of the notice. **Corrective Action:** CDA has revised its Review Procedures for organic operations to address this noncompliance. All adverse action notices now provide for a 35-day timeframe for effective dates and appeal and mediation proceedings, giving the operation 30 days from the receipt of the notice, rather than 30 days from issuance. CDA provided a copy of the revised procedures in its response. Additionally, CDA will forward to its Accreditation Manager copies of the next three (3) adverse action notices, demonstrating compliance with this corrective action.

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

Applicant Name:	Colorado Department of Agriculture (CDA)
Physical Address:	700 Kipling Street, Suite 4000, Lakewood, CO 80215
Mailing Address:	Same
Contact & Title:	Amy Stafford, Organic Program Manager
E-mail Address:	Amy.stafford@state.co.us
Phone Number:	(303) 239-4143
Auditor(s):	Meg Kuhn, Agricultural Marketing Specialist
Program:	USDA National Organic Program (NOP)
Audit Date(s):	April 14 – 17 and May 14, 2014
Audit Identifier:	AIA4066MMK (based on date NoNC was issued; audit ID was not noted on NoNC)
Action Required:	No
Audit Type:	Corrective Action
Audit Objective:	To verify review and approve corrective actions addressing the non-compliances identified during review of APL-010-14.
Audit Criteria:	7 CFR Part 205, National Organic Program; as amended.
Audit Scope:	CDA's April 7, 2014 and May 6, 2014 response letters to the March 7, 2014 Notice of Noncompliance re: APL-101-14 and April 22, 2014 Rebuttal Refusal letters, respectively
Location(s) Audited:	Desk

GENERAL INFORMATION

On March 7, 2014, the National Organic Program (NOP) issued a Notice of Noncompliance to Colorado Department of Agriculture (CDA) for three violations to the USDA Organic regulations. See below for noncompliances, as well as CDA's corrective actions, preventive actions, and objective evidence responses dated April 7, 2014 and May 6, 2014.

AUDIT INFORMATION

Three (3) noncompliances were cited in the March 7, 2014 Notice of Noncompliance. Corrective action responses for the noncompliances were reviewed during this desk assessment. All of the corrective actions were accepted. Accepted responses will be reviewed and verified at CDA's next on-site assessment, scheduled for April 2015 (Mid-Term assessment).

FINDINGS

1. **AIA4066MMK.NC1** – **Accepted** – §205.403(a)(1) states, *"A certifying agent must conduct an initial on-site inspection…. An on-site inpsection shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether… the certification of the operation should continue."* Through review of the APL-010-14, it was noted that CDA did not conduct an annual inspection of SVF for

the 2013 certification year. The review of the APL-010-14 file showed that the operation did, in fact, submit an updated OSP for the 2013 certification year, though the submission resulted in confusion at the CDA office about the fields currently certified and new fields seeking certification. Regardless of the lack of a complete OSP update, the certifier remains responsible for conducting annual organic inspections.

Rebuttal Response, April 7, 2014: CDA rebutted this noncompliance, stating that §205.406(b) requires a complete updated application to be on file prior to inspection, according to §205.406(a)(1, 2, and 4). Because the operation did not provide a complete update application, CDA felt it was correct in not scheduling its annual inspection. In January 2013, the National Organic Program conducted its annual Accredited Certifying Agents (ACA) Training. One of the components of this training was a presentation on "Certification and Accreditation Updates," specifically, "Organic System Plan (OSP) Updates and Notification of Changes." In this presentation, on slide 25 under "certifying agent responsibilities:" it states, "Conduct annual inspections **even if the operation has not submitted an updated OSP**." Although CDA's read of the regulation is that an annual inspection cannot occur unless or until a complete updated OSP is on file, the NOP has provided a different interpretation and instructed ACAs accordingly. In addition to the ACA training, the NOP released a 2nd edition of NOP 2601 Instruction, The Organic Certification Process. In this Instruction, 3.7 fourth paragraph states, "The certifiers shall inspect the operation annually to determine whether its certification should continue. If an operation fails to submit an annual update prior to the onsite inspection, the certifier should issue a Notice of Noncompliance. **However, the failure of an operation to submit an annual update does not relieve the certifier of its obligation to conduct an annual inspection**. (See 7 CFR § 205.403(a)(1).)" In accordance with §205.501(a)(21), which states, "A private or governmental entity accredited as a certifying agent under this subpart must: (21) Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary," CDA is obligated to comply with the Instruction requirements, the ACA annual training guidance, and the USDA organic regulations of §205.403(a)(1).

Corrective Action, May 6, 2014: The NOP notified CDA that the rebuttal submitted on April 7, 2014 was refused on April 22, 2014. On May 6, 2014, CDA responded to NOP's rebuttal refusal letter and provided a corrective action plan that addressed this noncompliance. Specifically, CDA updated its Organic Program Policy and Procedures Manual under "Continuation of Certification" to ensure annual inspections are conducted, even in absence of an annual organic system plan update or a complete update. CDA has also implemented a spreadsheet to track all clients' OSP submissions and inspection dates to ensure all clients receive an annual inspection. CDA will submit a copy of this spreadsheet to the NOP no later than October 31, 2014 showing that all operations up to that time have received the annual inspection.

2. **AIA4066MMK.NC2 – Accepted** – §205.402(b)(1) states, *"Review of Application. (b) The certifying agent shall within a reasonable time: (1) Review the application materials received and communicate its findings to the applicant."* The October 8, 2013 Notice of Noncompliance, issued prior to the Notice of Proposed Suspension, provided a timeline of events for the 2013 OSP update. Specifically, it was noted that the OSP update was received

at CDA on April 25, 2013; however, the email notification to the operation requesting additional information to complete the update was not sent until 4 months later, on August 12, 2013. The operation was given one week to submit requested information. When the operation met this timeframe, it then took CDA 7 weeks to submit the official Notice of Noncompliance, on October 8, 2013, because the response from the operator was incomplete. The NOP considers these timeframes between certification activities to be excessive and not "within a reasonable time" as required in the regulation.
Corrective Action: CDA's response explained that a portion of the timeframe issue was due to a lack of payment of fees by the operator. It is CDA policy that an operator's file does not move to the review stage of certification until all fees are paid in full. The operator did not pay their fees in full until July 16, 2013; after that time the file moved to the certification department for review. Copies of communication between the April 25, 2013 annual update receipt date and July 16, 2013 payment date were included with CDA's response. Outside of payment issues, CDA agreed that timeliness could improve and updated its Organic System Plan Procedures to require the Program Manager to review the status of all files with outstanding noncompliances to ensure notices are addressed in a timely fashion. A copy of the revised procedures was provided with the response. CDA will also update its noncompliance report on a monthly basis.

3. **AIA4066MMK.NC3 – Accepted** – §205.681(c) *states, "Appeals. (c) Filing period. 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…."* The October 28, 2013 Notice of Proposed Suspension does not meet the requirements of this NOP regulation. Specifically, the effective date of the suspension was identified as November 24, 2013, 28 days after issuance of the Notice of Proposed Suspension, and identified November 28, 2013 as the last day to appeal or request mediation. As noted in the regulation, the certifier must provide <u>30 days from the time of the receipt of the notice</u> for appeal or mediation proceedings, not 30 days from issuance of the notice.
Corrective Action: CDA has revised its Review Procedures for organic operations to address this noncompliance. All adverse action notices now provide for a 35-day timeframe for effective dates and appeal and mediation proceedings, giving the operation 30 days from the receipt of the notice, rather than 30 days from issuance. CDA provided a copy of the revised procedures in its response. Additionally, CDA will forward to its Accreditation Manager copies of the next three (3) adverse action notices, demonstrating compliance with this corrective action.

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Amy Stafford
Colorado Department of Agriculture
700 Kipling Street
Suite 4000
Lakewood, CO 80215-8000

Dear Ms. Stafford:

On February 24, 2014 the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) completed its appeals review of APL-010-14, an appeal by Sunny Valley Farms, Inc. (SVF) of an October 28, 2013 Notice of Proposed Suspension from Colorado Department of Agriculture (CDA). Our review identified three areas of noncompliance for CDA. The findings and regulatory citations for these noncompliances are provided below:

1. §205.403(a)(1) states, *"A certifying agent must conduct an initial on-site inspection…. An on-site in section shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether… the certification of the operation should continue."* Through review of the APL-010-14, it was noted that CDA did not conduct an annual inspection of SVF for the 2013 certification year. The review of the APL-010-14 file showed that the operation did, in fact, submit an updated OSP for the 2013 certification year, though the submission resulted in confusion at the CDA office about the fields currently certified and new fields seeking certification. Regardless of the lack of a complete OSP update, the certifier remains responsible for conducting annual organic inspections.

2. §205.402(b)(1) states, *"Review of Application. (b) The certifying agent shall within a reasonable time: (1) Review the application materials received and communicate its findings to the applicant."* The October 8, 2013 Notice of Noncompliance, issued prior to the Notice of Proposed Suspension, provided a timeline of events for the 2013 OSP update. Specifically, it was noted that the OSP update was received at CDA on April 25, 2013; however, the email notification to the operation requesting additional information to complete the update was not sent until 4 months later, on August 12, 2013. The operation was given one week to submit requested information. When the operation met this timeframe, it then took CDA 7 weeks to submit the official Notice of Noncompliance, on October 8, 2013, because the response from the operator was incomplete. The NOP considers these timeframes between certification activities to be excessive and not "within a reasonable time" as required in the regulation.

3. §205.681(c) states, *"Appeals. (c) Filing period. 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…." The October 28, 2013 Notice of Proposed Suspension does not meet the requirements of this NOP regulation. Specifically, the effective date of the suspension was identified as November 24, 2013, 28 days after issuance of the Notice of Proposed Suspension, and identified November 28, 2013 as the last day to appeal or request mediation. As noted in the regulation, the certifier must provide 30 days from the time of the receipt of the notice for appeal or mediation proceedings, not 30 days from issuance of the notice.

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. CDA must propose and implement measures that will correct this action. The proposed corrective actions must also indicate how the CDA 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 CDA as an accredited certifying agent for the USDA.

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

Sincerely,

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

cc: NOP Appeals
USDA Grading and Verification Division

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

MAR - 7 2014

Amy Stafford
Colorado Department of Agriculture
700 Kipling Street
Suite 4000
Lakewood, CO 80215-8000

Dear Ms. Stafford:

On February 24, 2014 the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) completed its appeals review of APL-010-14, an appeal by Sunny Valley Farms, Inc. (SVF) of an October 28, 2013 Notice of Proposed Suspension from Colorado Department of Agriculture (CDA). Our review identified three areas of noncompliance for CDA. The findings and regulatory citations for these noncompliances are provided below:

1. §205.403(a)(1) states, *"A certifying agent must conduct an initial on-site inspection.... An on-site in section shall be conducted annually thereafter for each certified operation that produces or handles organic products for the purpose of determining whether... the certification of the operation should continue."* Through review of the APL-010-14, it was noted that CDA did not conduct an annual inspection of SVF for the 2013 certification year. The review of the APL-010-14 file showed that the operation did, in fact, submit an updated OSP for the 2013 certification year, though the submission resulted in confusion at the CDA office about the fields currently certified and new fields seeking certification. Regardless of the lack of a complete OSP update, the certifier remains responsible for conducting annual organic inspections.

2. §205.402(b)(1) states, *"Review of Application. (b) The certifying agent shall within a reasonable time: (1) Review the application materials received and communicate its findings to the applicant."* The October 8, 2013 Notice of Noncompliance, issued prior to the Notice of Proposed Suspension, provided a timeline of events for the 2013 OSP update. Specifically, it was noted that the OSP update was received at CDA on April 25, 2013; however, the email notification to the operation requesting additional information to complete the update was not sent until 4 months later, on August 12, 2013. The operation was given one week to submit requested information. When the operation met this timeframe, it then took CDA 7 weeks to submit the official Notice of Noncompliance, on October 8, 2013, because the response from the operator was incomplete. The NOP considers these timeframes between certification activities to be excessive and not "within a reasonable time" as required in the regulation.

3. §205.681(c) states, *"Appeals. (c) Filing period. 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...." The October 28, 2013 Notice of Proposed Suspension does not meet the requirements of this NOP regulation. Specifically, the effective date of the suspension was identified as November 24, 2013, 28 days after issuance of the Notice of Proposed Suspension, and identified November 28, 2013 as the last day to appeal or request mediation. As noted in the regulation, the certifier must provide 30 days from the time of the receipt of the notice for appeal or mediation proceedings, not 30 days from issuance of the notice.

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. CDA must propose and implement measures that will correct this action. The proposed corrective actions must also indicate how the CDA 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 CDA as an accredited certifying agent for the USDA.

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

Sincerely,

Cheri Courtney

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

cc: NOP Appeals
USDA Grading and Verification Division

USDA Agricultural Marketing Service

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

NOTICE OF REBUTTAL REFUSAL

Amy Stafford
Colorado Department of Agriculture
700 Kipling Street, Suite 4000
Lakewood, CO 80215-8000

Dear Ms. Stafford:

On March 7, 2014, the National Organic Program (NOP) issued Colorado Department of Agriculture (CDA) a Notice of Noncompliance for not conducting an annual on-site inspection for an operation continuing in its organic certification cycle.

The March 7, 2014 notice required CDA to submit proposed corrective actions within 30 days of receiving the letter. On April 7, 2014, CDA submitted an initial response, stating that CDA's interpretation of §205.403(a)(1) differs from NOP's interpretation. This CDA letter offered no corrective actions to respond to the notice.

Attached is a Corrective Action report for CDA review, which addresses the rebuttal that CDA submitted to this noncompliance (AIA4066MMK.NC1). As noted, the NOP does not accept CDA's rebuttal at this time. Additional response with corrective action is required in order for CDA to adequately address the cited noncompliance.

Please submit proposed corrective actions to AIAInbox@ams.usda.gov within **14** days from the date of receipt of this letter, indicating how this noncompliance will be corrected. CDA must propose and implement measures that will correct this action. The proposed corrective actions must also indicate how the CDA 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 CDA 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 Assurance Division

USDA Agricultural Marketing Service

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

NOTICE OF REBUTTAL REFUSAL

22 APR 2014

Amy Stafford
Colorado Department of Agriculture
700 Kipling Street, Suite 4000
Lakewood, CO 80215-8000

Dear Ms. Stafford:

On March 7, 2014, the National Organic Program (NOP) issued Colorado Department of Agriculture (CDA) a Notice of Noncompliance for not conducting an annual on-site inspection for an operation continuing in its organic certification cycle.

The March 7, 2014 notice required CDA to submit proposed corrective actions within 30 days of receiving the letter. On April 7, 2014, CDA submitted an initial response, stating that CDA's interpretation of §205.403(a)(1) differs from NOP's interpretation. This CDA letter offered no corrective actions to respond to the notice.

Attached is a Corrective Action report for CDA review, which addresses the rebuttal that CDA submitted to this noncompliance (AIA4066MMK.NC1). As noted, the NOP does not accept CDA's rebuttal at this time. Additional response with corrective action is required in order for CDA to adequately address the cited noncompliance.

Please submit proposed corrective actions to AIAInbox@ams.usda.gov within **14** days from the date of receipt of this letter, indicating how this noncompliance will be corrected. CDA must propose and implement measures that will correct this action. The proposed corrective actions must also indicate how the CDA 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 CDA 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

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

cc: NOP Appeals
USDA Quality Assurance Division

NoNC Chronology Log

NOP Appeal Identifier (if any): NoNC re: APL-010-14

Accredited Certifying Agent Name: Colorado Dept of Ag (CDA)

Accreditation Manager: Bob Pooler/Renee Mann; assigned to Meg Kuhn

Date	Activity
02/21-24/14	Meg Kuhn was assigned the task of reviewing APL-010-14. Through review of the appeal file, 3 findings were identified for CDA regarding on-site inspections, timeliness of certification activities, and appeals "filing period" procedures. Through review with JT and AM Bob Pooler, it was determined a NoNC would be appropriate to address these findings.
02/24-25/14	NoNC drafted and submitted for final approval/management signature.
3/7/14	Mgt approved file and signed notice; AM (Bob Pooler) sent NoNC to CDA.
4/7/14	CDA responded to NOP with rebuttal to NC 1 and CAs to NCs 2 and 3.
4/14/14	MK was assigned to review response. CAs for NCs 2 and 3 are accepted; rebuttal is not accepted. MK sent email draft to be sent to CDA to CC for review/approval.
4/17/14	CC indicated email was not the best course of action, and would prefer a formal letter, in order to assist Division with tracking of NC. MK to draft letter to rebuttal for CDA's review/response. MK prepared folder for management review/approval/signature.
4/22/14	Renee Mann emailed Notice of Rebuttal Refusal and Corrective Action Report to CDA via RPost.
5/7/14	CDA submitted a response to the rebuttal refusal letter of 4/22/14.
5/13/14	CDA response assigned to MK for review and CA report completion.
5/14-15/14	MK completed review of CDA's response, CA report, and NoNC Resolution letter. MK working from home 5/14, so final folder printed 5/15 for management review/approval.

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite renewal assessment of Colorado Department of Agriculture (CDA) organic program was conducted on August 7, 2017. The National Organic Program (NOP) reviewed the auditor's report to assess CDA's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Colorado Department of Agriculture (CDA)
Physical Address	305 Interlocken Parkwy, Broomfield, CO 80021
Mailing Address	305 Interlocken Parkwy, Broomfield, CO 80021
Contact & Title	Mitch Yergert, Director, Division of Plant Industry
E-mail Address	Mitchell.yergert@state.co.us
Phone Number	303.869.9074
Reviewer & Auditors	Rebecca Claypool, NOP Reviewer; Penny Zuck and Graham Davis, On-site Auditor(s).
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: August 18, 2017 Onsite audit: August 7-11, 2017
Audit Identifier	NP7219PZA
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 CDA's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	CDA's certification services in carrying out the audit criteria during the period: June 2015 through August 2017

The Colorado Department of Agriculture (CDA) organic program is a state government certification program based in Broomfield, CO. It was initially accredited as a certifying agent by the USDA National Organic Program (NOP) on October 15, 2002. Current accreditation certification is good until October 16, 2017. At the time of this Accreditation Renewal Assessment, CDA provided organic certification for 206 operations in Colorado: crops (136), wild crops (1), livestock (11) and handling (93). The CDA is not currently accepting new clients for certification due to a moratorium imposed by the Colorado legislature. The moratorium was imposed because the legislature determined that the organic program resources (staffing) was at maximum capacity given its current client numbers and budget. There are no satellite offices, although staff inspectors (12) are distributed throughout the state and perform inspections for multiple CDA programs. The CDA organic program is administered by the Organic Program

Manager with the assistance of an Organic Certification Specialist. The program is overseen by the Division Director of the CDA.

The Accreditation Renewal Assessment included three witness audits. One Crops and Handling operation in Greeley, CO; one Crops, Livestock, and Handling operation in Fort Lupton, CO; and one Processing/Handling operation in Longmont, CO.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether CDA 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 CDA.

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.

NP5159RKA.NC1 – Cleared - 7 C.F.R. §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 2613, Responding to Results from Pesticide Residue Testing, Section 5.3.1.a.2 instructs certifiers that when the pesticide test analysis results indicate detection below 5 percent of the EPA tolerance, but above .01 ppm, they are required to assess why the residue is present.

2015 Comments: *The certifier correctly issued a letter to an operation to investigate the source of contamination (Chlorpropham .592 mg/g) including a date by which the operation was to respond. The operation did not respond by the specified date and the certifier did not conduct a follow up. Therefore, the certifier was unable to assess why the residue was present and to determine if a noncompliance should be issued to the operation.*

2015 Corrective Action: CDA updated their Organic Policy and Procedure Manual regarding procedures when residue tests show positive results below 5% of the EPA tolerance. CDA will issue a notice of noncompliance to operations that do not respond to their letter of investigation within the time period stated in the letter. A notice of noncompliance was sent to the operation regarding no response to the letter investigating the source of the contamination.

2017 Verification of Corrective Action: A review of CDA's Policy and Procedures Manual includes the revised procedure. A sample taken in 2016 tested positive for a prohibited substance below the 5% EPA tolerance level. The operation was contacted by CDA and issued a NoNC. The operation responded to the NoNC and was issued a NoNC Resolution letter by CDA. No other samples tested positive in 2016.

NP5159RKA.NC2 – **Cleared -** 7 C.F.R. §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 4009, "Who Needs to be Certified?" provides clarification to certifiers regarding the certification requirements for operations that produce or handle agricultural products to be sold, labeled or represented as organic.

2015 Comments: *During the witness audit of a fruit producer, the auditor identified that one of the apple orchards listed in the operation's OSP should be considered a separate certified entity. Under the current arrangement between the orchard owner and the certified operation, the orchard owner is under contract to sell his harvested fruit to the certified operation, but the certified operation does not manage the orchard (i.e. conduct cultural practices, pay labor, etc.), does not purchase and apply inputs, and does not maintain all the records that demonstrate compliance to the regulations.*

2015 Corrective Action: CDA issued a notice of noncompliance to the fruit producer, identifying that contracted farming operations are not allowed to be certified under another entity's certificate. CDA provided training for inspectors on June 26, 2015, regarding NOP Instruction 4009 and a Training Attendance sign-in sheet was submitted.

2017 Verification of Corrective Action: The contracted producer applied for certification and was denied by CDA. The denial was reviewed by the auditor and was issued in compliance with the USDA organic regulations. There are no other occurrences of contracted operations being certified under another entity's certification.

NP5159RKA.NC3 – **Cleared -** 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…"

2015 Comments: *During a witness audit, the inspector did not fully verify whether the contracted or rented fields in the operator's OSP were under the control (management) of the certified operation.*

2015 Corrective Action: A new inspection report cover sheet was created to be used in conjunction with new OSP module system being developed. Included in the cover sheet is a question specifically requesting information regarding control/management of rented portions of the certified operation. CDA trained inspectors on April 7, 2016, regarding use of new inspection forms and the cover letter.

2017 Verification of Corrective Action: Through file reviews and witness audits the auditor verified that the revised inspection cover sheet is being used.

NP5159RKA.NC4 – Cleared - 7 C.F.R. §205.403(d) states that during an exit interview, "the inspector must…address…any issues of concern."

2015 Comments: *During a witness audit of a split and parallel operation, the inspector did not identify as an issue of concern the lack of adequate controls to prevent contamination of products or fields. The storage of pesticides and fertilizers did not have a clear separation of approved and unapproved input materials. Input materials were located at spray rig filling stations in drums that were unlabeled. Brand names and sources are not listed on the OSP Input List; instead, some materials are listed with a generic identification: e.g. garlic oil, manganese, iron, sodium bicarbonate.*

2015 Corrective Action: CDA updated the Crop OSP Module 10 Soil.Ferility Inputs and Module 12 Weed.Pest.Disease Inputs to require the operation to include product names and manufacturers, to ensure full information (rather than just generic names) are included in the OSP. CDA also provided training on June 26, 2015, to inspectors regarding identifying issues of concern during inspections.

2017 Verification of Corrective Action: The witness audit of an inspection of a parallel operation verified the proper use of the revised OSP modules.

NP5159RKA.NC5 – **Cleared -** 7 C.F.R. §205.402(a)(2) states that "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..."

2015 Comments: *The certifier approved a "Made with Organic ***" granola cereal label that displayed the word "organic" on the front panel with no "Made with Organic" phrase.*

2015 Corrective Action: CDA issued a notice of noncompliance to the operation for the noncompliant cereal label. CDA updated the Organic System Plan Review Procedures Rev B 6.7 manual stating that the CDA logo, and USDA seal may not be used on the label of products certified to the "Made with Organic ***" labeling category. Training on label review is planned for June 17, 2016.

2017 Verification of Corrective Action: "Made with Organic***" labels reviewed by the auditor were in compliance with the regulations. Auditor verified the training records for label review training that took place in June 2016.

NP5159RKA.NC6 – **Cleared -** 7 CFR §205.403(e)(1) states that "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."

2015 Comments: *During a witness audit, a pesticide residue sample was obtained and proper sampling procedures were followed, with the exception that the operator was not provided a receipt.*

2015 Corrective Action: CDA updated the Sampling Form to clearly indicate that the pink sheet stays with the operation when samples are taken to serve as a receipt. Training was conducted on June 26, 2015, for all organic inspectors. The proper use of sampling forms, including leaving a copy with the operation as a receipt, was presented during the training.

2017 Verification of Corrective Action: During a witness audit, the auditor verified two samples were obtained and receipts were given to the operator. The chain of custody form is now being used as the receipt. The inspector prints a copy of the form and provides the copy to the operation as the receipt.

NP1595RKA.NC7 – **Cleared -** 7 CFR §205.662(c) states, "Proposed suspension or revocation. The notification of a proposed suspension…shall state: (3) The impact of a suspension…"

2015 Comments: *The auditor reviewed three letters of Notice of Proposed Suspension (NoPS) issued to clients. Two of the three letters issued do not explain the impact of the NoPS as stated in 205.100(a) "each production or handling operation…that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as "100 percent organic,' "organic," or "made with organic (specified*

ingredients or food group(s))" must be certified…" The auditor noted a discrepancy between the letters issued to clients and the CDA NoPS template, which actually does include language stating that "the operation will be unable to sell, or label its product as organic."

2015 Corrective Action: The notice of proposed suspension and combined notice of noncompliance and proposed suspension letter templates were updated to specifically state the impact of suspension. CDA created a document control system to ensure only the most current version of documents and letter templates are used in the future. Inspectors were trained on document control during the April 7, 2016 training.

2017 Verification of Corrective Action: The auditor verified the document control system being used is located on the shared server. Older versions of the documents are archived. The current Notice of Proposed Suspension template includes the impact of suspension.

NP1595RKA.NC8 – Cleared - 7 CFR §205.510(b)(2) states, "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."

2015 Comments: *In at least 3 files that were reviewed, the records of registered e-mails sent to the clients were not available during the audit. Currently, CDA sends registered e-mails from individual employee accounts and the delivery receipt required per 7 CFR §205.660(d) is not always retained (either electronically or as a hard copy).*

2015 Corrective Action: CDA adjusted the Policy and Procedures Manual to clearly outline the current process for issuance of notices, and created a new requirement to save the documentation that the noncompliance was received by the operation. A copy of the documentation is saved electronically in the operation's Company Specific Information folder in the shared organic folder on the CDA server. Training was provided to the Program Manager and Certification Specialist on May 19, 2016.

2017 Verification of Corrective Action: The auditor verified electronic copies of receipts are saved in the operation's files on the server.

AIA16120RK.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."

2016 Comments*: CDA did not conduct adequate surveillance of a crop operation including its website to ensure compliance with the USDA organic regulations. The following issues were identified:*

- *CDA did not issue a noncompliance to the operation for its use of the word "organic" in the company name and labels on uncertified products.*
- *CDA did not issue a noncompliance to the operation for use of the USDA seal on the website pages advertising uncertified products.*

2016 Corrective Actions: CDA has updated the Organic System Plan to specifically request website URL's from certified operations. All review personnel have been trained to review an operation's website for compliance with the USDA organic regulations, including organic marketing claims, use of the USDA organic seal, and the use of trade names with the word "organic" in them. CDA provided verification of staff training on these topics.

2017 Verification of Corrective Action: The auditor verified the revised organic system plan is currently being used. Certification staff review operator website addresses as part of the initial review of the organic system plan.

Noncompliances Identified during the Current Assessment

NP7219PZA.NC1 – 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: *CDA's Organic System Plans do not include questions about exporting, importing, or participation in trade arrangements. The Organic System Plan module 1 includes the following question, "Through what avenues does the operation sell or otherwise market their products? Mark all that apply…Exporting (where?)".*

NP7219PZA.NC2 - 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: *During witness inspections and interviews with staff, the following verification issues were identified:*

- *Inspector did not verify labels on-site were the same as the labels in the approved organic system plan.*
- *Operator indicated cleaning logs are kept for truck and equipment clean-outs, however inspector did not verify the record keeping by reviewing the logs.*
- *Pest management company service logs and/or invoices were not reviewed by the inspector to verify no prohibited materials were used in the facility.*
- *Inspectors do not verify compliance of imported and exported products or ingredients purchased and handled by certified operations. Inspection report documents do not require inspectors to record compliance verification of internationally traded products.*

NP7219PZA.NC3 - 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: *CDA does not have procedures for accepting a request for mediation and reaching settlement agreements with operations. CDA denied the request for mediation from an operator when the noncompliances were correctable and could be resolved.*

NP7219PZA.NC4 – 7 C.F.R. §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: (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: *Not all of CDA's templates for a Notice of Noncompliance include language that allows the operation to rebut the noncompliance.*

NP7219PZA.NC5 – 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: *The auditor could not determine the most recent labels approved as part of the organic system plans for operation files reviewed in the CDA filing system. There was no indication that product labels on file were either reviewed or approved by CDA. CDA indicated that Farmer's Market and Wholesale labels don't go through the formal label review process.*

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

Mitch Yergert
Colorado Department of Agriculture
305 Interlocken Parkway
Broomfield, CO 80021

Dear Mr. Yergert:

On August 7, 2017, representatives of the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP), completed an onsite audit of the Colorado Department of Agriculture (CDA) organic certification program as part of its USDA Renewal Accreditation Assessment. On August 21, 2017, the NOP reviewed the results of the onsite audit to determine CDA's compliance to the USDA organic regulations. A copy of the assessment report, NP7219PZA, is enclosed for your reference.

As the report indicates, that no noncompliances remain outstanding from a previous audit. Five new noncompliances (NP7219PZA.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 CDA 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 CDA's USDA accreditation.

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

Sincerely,

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

Enclosure: Noncompliance Report

cc: AIA Inbox

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

Applicant Name:	Certificadora Mexicana de Productos y Procesos Ecologicos SC
Physical Address:	Calle 16 de Septiembre Num. 204; Ejido Guadalupe Victoria; Oaxaca, Oaxaca, Mexico, C.P. 68026
Mailing Address:	Calle 16 de Septiembre Num. 204; Ejido Guadalupe Victoria; Oaxaca, Oaxaca, Mexico, C.P. 68026
Contact & Title:	Taurino Reyes Santiago, Executive Director
E-mail Address:	certimex@certimexsc.com
Phone Number:	951 520 2687
Auditor(s):	Betsy Rakola and Renée Gebault King, Accreditation Managers
Audit Date(s):	July 17 – October 1, 2014
Audit Identifier:	AIA14233RK
Action Required:	None
Audit Type:	Corrective Action Audit
Audit Objective:	To review and evaluate CMEX's capability to implement the USDA organic regulations for apiculture certification under the scope of livestock activities.
Audit Criteria:	*7 CFR Part 205, National Organic Program, as amended*
Audit Scope:	CMEX's July 18 and August 11, 2014 responses to the settlement agreement signed June 3, 2014.
Location(s) Audited:	Desk

GENERAL INFORMATION

Certificadora Mexicana de Productos y Procesos Ecologicos S.C. (CMEX) was initially accredited as a USDA National Organic Program (NOP) certifying agent on April 14, 2006 for crops, wild crops, and handling operations. CMEX consists of the main office in Oaxaca, Mexico. All NOP certification activities are carried out from the main office with certification provided throughout Mexico. The CMEX list of NOP certified operations included 85 operations with 70 certified for crops, 21 for handling, and no wild crop. Of the 85 certified operations there were 13 distributors/traders and 49 grower groups.

BACKGROUND INFORMATION

On August 1, 2013, CMEX received a Notice of Noncompliance regarding its 2013 Mid-Term Assessment Report. The Notice and corresponding assessment report detailed the nature and extent of the noncompliances. CMEX's response to the NOP on August 26, 2013 neither corrected nor successfully rebutted the noncompliances cited in the Notice of Noncompliance. On October 18, 2013, the NOP issued a Denial of Livestock Accreditation Expansion of CMEX's accreditation to the USDA organic regulations. CMEX filed an appeal of the denial of accreditation expansion on November 7, 2013. CMEX and the NOP executed a settlement agreement on June 3, 2014 to resolve this appeal. The settlement contained the following terms:

Settlement term 5.a. CMEX agrees not to accept any new clients seeking certification in the

livestock certification scope, including honeybees and all animals. CMEX agrees to tell new livestock certification applicants that it does not currently have the administrative capacity to accept that application.

Settlement term 5.b. Within 45 days of agreement execution, CMEX agrees to provide evidence that CMEX staff – specifically document reviewers, inspectors, and certification decision makers – have been taught NOP livestock requirements as they pertain to honey bee certification. This includes instruction that honey bees may only feed on certified organic feed and land to be certified organic.

Settlement term 5.c. Following NOP's review of this evidence, CMEX agrees to undergo a limited scope desk audit where the NOP will review selected honey bee files from the 2013 and/or 2014 certification year(s). CMEX will not be charged for this desk audit.

NOP Determination

This report summarizes the NOP's assessment of CMEX's response to the settlement agreement. The NOP has determined that CMEX is capable of implementing the USDA organic regulations for apiculture. During the next on-site assessment, the NOP will review the information below to verify that the certifying agent has effectively addressed all concerns.

Settlement term 5.a. – Accepted. CMEX corrective actions: CMEX submitted information to the NOP stating that it is no longer accepting any new clients seeking certification in the livestock certification scope. CMEX last inspected four apiculture client operations under the USDA organic regulations in 2013, and it is in the process of helping these operations transition to certification with BCS Oko-Garantie. CMEX has contracted with BCS to conduct the on-site inspections.

Settlement term 5.b. – Accepted. CMEX corrective actions: On June 18, 2014, CMEX held a training session on the USDA organic standards for apiculture certification. CMEX based the materials on the current USDA organic regulations and the October 28, 2010 National Organic Standards Board's Apiculture Recommendation. While the training slides mentioned the NOSB's recommendation to add thymol and carbon dioxide to the National List for use in apiculture, it was made clear to the attendees that only formic acid was currently allowed for pest control under the USDA NOP standards. The training session covered certification requirements, organic system plans, records, origin of bees, forage zones, wax control, product flow diagrams, reviews of internal control systems, and inspection techniques. CMEX submitted evidence showing that five inspectors, one reviewer, one records manager, and one quality manager attended the training.

Settlement term 5.c. – Accepted. CMEX corrective actions: The NOP reviewed CMEX livestock files for compliance with the USDA organic regulations. For example, CMEX submitted files for a honey cooperative that was inspected on March 6-15, 2013. The inspection report showed the following: 1) inspection staff visited 11.65 percent of the grower group's locations, 2) the apiaries near fields (within approximately 300 feet) where conventional crops,

herbicides and pesticides are used were removed from the organic apiculture cooperative and the operator plans to relocate the hives to zones that meet the organic requirements, and 3) only formic acid, an approved livestock input, is used as a pesticide to control varroa mites. The inspection report also confirmed that cooperative members who had previously provided sugar/powdered milk, in October 2012, or conventional sugar, in February 2013, were sanctioned by the Internal Control System (ICS) and are currently considered to be in-transition to organic but not organic.

CMEX's corrective action addressed a previous NOP concern regarding CMEX allowing the use of thymol. In 2013 CMEX recommended reinstatement for a honeybee operation that had used thymol, but the NOP denied reinstatement of certification to this honeybee operation. The NOP's recent desk audit shows that CMEX is no longer allowing thymol.

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

Applicant Name:	Certificadora Mexicana de Productos y Procesos Ecologicos SC (CERTIMEX)
Physical Address:	Calle 16 de Septiembre Num. 204; Ejido Guadalupe Victoria; Oaxaca, Oaxaca, Mexico, C.P. 68026
Mailing Address:	Calle 16 de Septiembre Num. 204; Ejido Guadalupe Victoria; Oaxaca, Oaxaca, Mexico, C.P. 68026
Contact & Title:	Taurino Reyes Santiago, Executive Director
E-mail Address:	certimex@certimexsc.com
Phone Number:	951 520 2687
Auditor(s):	Betsy Rakola, Accreditation Manager
Audit Date(s):	July 17 – XX, 2014
Audit Identifier:	
Action Required:	
Audit Type:	Corrective Action Audit
Audit Objective:	To review and evaluate CERTIMEX's capability to implement the USDA organic regulations for apiculture certification under the scope of livestock activities.
Audit Criteria:	*7 CFR Part 205, National Organic Program, as amended*
Audit Scope:	CERTIMEX's July XX and XXXX, 2014 response to the settlement agreement signed June 3, 2014.
Location(s) Audited:	Desk

GENERAL INFORMATION

Certificadora Mexicana de Productos y Procesos Ecologicos S.C. (CERTIMEX) was initially accredited as a USDA National Organic Program (NOP) certifying agent on April 14, 2006 for crops, wild crops, and handling operations. CERTIMEX consists of the main office in Oaxaca, Mexico. All NOP certification activities are carried out from the main office with certification provided throughout Mexico. The CERTIMEX list of NOP certified operations included 85 operations with 70 certified for crops, 21 for handling, and no wild crop. Of the 85 certified operations there were 13 distributors/traders and 49 grower groups.

BACKGROUND INFORMATION

On August 1, 2013, CERTIMEX received a Notice of Noncompliance regarding its 2013 Mid-Term Assessment Report. The Notice and corresponding assessment report detailed the nature and extent of the noncompliances. CERTIMEX's response to the NOP on August 26, 2013 neither corrected nor successfully rebutted the noncompliances cited in the Notice of Noncompliance. On October 18, 2013, the NOP issued a Denial of Livestock Accreditation Expansion of CMEX's accreditation to the USDA organic regulations. CERTIMEX filed an appeal of the denial of accreditation expansion on November 7, 2013. CERTIMEX and the NOP executed a settlement agreement on June 3, 2014 to resolve this appeal. The settlement contained the following terms:

Settlement term 5.a. CERTIMEX agrees not to accept any new clients seeking certification in the livestock certification scope, including honeybees and all animals. CERTIMEX agrees to tell new livestock certification applicants that it does not currently have the administrative capacity to accept that application.

Settlement term 5.b. Within 45 days of agreement execution, CERTIMEX agrees to provide evidence that CERTIMEX staff – specifically document reviewers, inspectors, and certification decision makers – have been taught NOP livestock requirements as they pertain to honey bee certification. This includes instruction that honey bees may only feed on certified organic feed and land to be certified organic.

Settlement term 5.c. Following NOP's review of this evidence, CERTIMEX agrees to undergo a limited scope desk audit where the NOP will review selected honey bee files from the 2013 and/or 2014 certification year(s). CERTIMEX will not be charged for this desk audit.

NOP Determination

This report summarizes the NOP's assessment of CERTIMEX's response to the settlement agreement. The NOP has determined that CERTIMEX is capable/is not capable of implementing the USDA organic regulations for apiculture. During the next on-site assessment, the NOP will review the information below to verify that the certifying agent has effectively addressed all concerns.

Settlement term 5.a. – Accepted. CERTIMEX corrective actions: CERTIMEX submitted information to the NOP stating that it is no longer accepting any new clients seeking certification in the livestock certification scope. CERTIMEX last inspected four apiculture client operations under the USDA organic regulations in 2013, and it is in the process of helping these operations transition to certification with BCS Oko-Garantie. CERTIMEX has contracted with BCS to conduct the on-site inspections.

Settlement term 5.b. – Accepted. CERTIMEX corrective actions: On June 18, 2014, CERTIMEX held a training session on the USDA organic standards for apiculture certification. CERTIMEX based the materials on the USDA organic regulations and the October 28, 2010 National Organic Standards Board's Apiculture Recommendation. The session covered certification requirements, organic system plans, records, origin of bees, forage zones, wax control, product flow diagrams, reviews of internal control systems, and inspection techniques. CERTIMEX submitted evidence showing that 5 inspectors, one reviewer, one records manager, and one quality manager attended the training.

The training slides also mentioned the NOSB's recommendation to add thymol and carbon dioxide to the National List for use in apiculture. Betsy emailed CERTIMEX on July 18, 2014 to ask what information was communicated to trainees about these substances. A previous CERTIMEX honeybee reinstatement request showed that the operation had used thymol, and CERTIMEX recommended the operation for reinstatement.

Page 3

Settlement term 5.c.

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Applicant Name:	Certificadora Mexicana de Productos y Procesos Ecologicos SC
Physical Address:	Calle 16 de Septiembre Num. 204; Ejido Guadalupe Victoria; Oaxaca, Oaxaca, Mexico, C.P. 68026
Mailing Address:	Calle 16 de Septiembre Num. 204; Ejido Guadalupe Victoria; Oaxaca, Oaxaca, Mexico, C.P. 68026
Contact & Title:	Taurino Reyes Santiago, Executive Director
E-mail Address:	certimex@certimexsc.com
Phone Number:	951 520 2687
Auditor(s):	Betsy Rakola and Renée Gebault King, Accreditation Managers
Audit Date(s):	July 17 – October 1, 2014
Audit Identifier:	AIA14233RK
Action Required:	None
Audit Type:	Corrective Action Audit
Audit Objective:	To review and evaluate CMEX's capability to implement the USDA organic regulations for apiculture certification under the scope of livestock activities.
Audit Criteria:	*7 CFR Part 205, National Organic Program, as amended*
Audit Scope:	CMEX's July 18 and August 11, 2014 responses to the settlement agreement signed June 3, 2014.
Location(s) Audited:	Desk

GENERAL INFORMATION

Certificadora Mexicana de Productos y Procesos Ecologicos S.C. (CMEX) was initially accredited as a USDA National Organic Program (NOP) certifying agent on April 14, 2006 for crops, wild crops, and handling operations. CMEX consists of the main office in Oaxaca, Mexico. All NOP certification activities are carried out from the main office with certification provided throughout Mexico. The CMEX list of NOP certified operations included 85 operations with 70 certified for crops, 21 for handling, and no wild crop. Of the 85 certified operations there were 13 distributors/traders and 49 grower groups.

BACKGROUND INFORMATION

On August 1, 2013, CMEX received a Notice of Noncompliance regarding its 2013 Mid-Term Assessment Report. The Notice and corresponding assessment report detailed the nature and extent of the noncompliances. CMEX's response to the NOP on August 26, 2013 neither corrected nor successfully rebutted the noncompliances cited in the Notice of Noncompliance. On October 18, 2013, the NOP issued a Denial of Livestock Accreditation Expansion of CMEX's accreditation to the USDA organic regulations. CMEX filed an appeal of the denial of accreditation expansion on November 7, 2013. CMEX and the NOP executed a settlement agreement on June 3, 2014 to resolve this appeal. The settlement contained the following terms:

Settlement term 5.a. CMEX agrees not to accept any new clients seeking certification in the

livestock certification scope, including honeybees and all animals. CMEX agrees to tell new livestock certification applicants that it does not currently have the administrative capacity to accept that application.

Settlement term 5.b. Within 45 days of agreement execution, CMEX agrees to provide evidence that CMEX staff – specifically document reviewers, inspectors, and certification decision makers – have been taught NOP livestock requirements as they pertain to honey bee certification. This includes instruction that honey bees may only feed on certified organic feed and land to be certified organic.

Settlement term 5.c. Following NOP's review of this evidence, CMEX agrees to undergo a limited scope desk audit where the NOP will review selected honey bee files from the 2013 and/or 2014 certification year(s). CMEX will not be charged for this desk audit.

NOP Determination

This report summarizes the NOP's assessment of CMEX's response to the settlement agreement. The NOP has determined that CMEX is capable of implementing the USDA organic regulations for apiculture. During the next on-site assessment, the NOP will review the information below to verify that the certifying agent has effectively addressed all concerns.

Settlement term 5.a. – Accepted. CMEX corrective actions: CMEX submitted information to the NOP stating that it is no longer accepting any new clients seeking certification in the livestock certification scope. CMEX last inspected four apiculture client operations under the USDA organic regulations in 2013, and it is in the process of helping these operations transition to certification with BCS Oko-Garantie. CMEX has contracted with BCS to conduct the on-site inspections.

Settlement term 5.b. – Accepted. CMEX corrective actions: On June 18, 2014, CMEX held a training session on the USDA organic standards for apiculture certification. CMEX based the materials on the current USDA organic regulations and the October 28, 2010 National Organic Standards Board's Apiculture Recommendation. While the training slides mentioned the NOSB's recommendation to add thymol and carbon dioxide to the National List for use in apiculture, it was made clear to the attendees that only formic acid was currently allowed for pest control under the USDA NOP standards. The training session covered certification requirements, organic system plans, records, origin of bees, forage zones, wax control, product flow diagrams, reviews of internal control systems, and inspection techniques. CMEX submitted evidence showing that five inspectors, one reviewer, one records manager, and one quality manager attended the training.

Settlement term 5.c. – Accepted. CMEX corrective actions: The NOP reviewed CMEX livestock files for compliance with the USDA organic regulations. For example, CMEX submitted files for a honey cooperative that was inspected on March 6-15, 2013. The inspection report showed the following: 1) inspection staff visited 11.65 percent of the grower group's locations, 2) the apiaries near fields (within approximately 300 feet) where conventional crops,

herbicides and pesticides are used were removed from the organic apiculture cooperative and the operator plans to relocate the hives to zones that meet the organic requirements, and 3) only formic acid, an approved livestock input, is used as a pesticide to control varroa mites. The inspection report also confirmed that cooperative members who had previously provided sugar/powdered milk, in October 2012, or conventional sugar, in February 2013, were sanctioned by the Internal Control System (ICS) and are currently considered to be in-transition to organic but not organic.

CMEX's corrective action addressed a previous NOP concern regarding CMEX allowing the use of thymol. In 2013 CMEX recommended reinstatement for a honeybee operation that had used thymol, but the NOP denied reinstatement of certification to this honeybee operation. The NOP's recent desk audit shows that CMEX is no longer allowing thymol.

Settlement Resolution Chronology Log

Accredited Certifying Agent Name: CERTIMEX

Accreditation Manager: Betsy Rakola

Date	Activity
6/3/14	CERTIMEX signed a settlement agreement with the NOP. The settlement stated that CERTIMEX must not accept any new honeybee clients, and that they must submit a limited number of files, along with evidence that staff have been trained on USDA organic requirements for apiculture, to the NOP within 45 days of the agreement.
6/10/14	CERTIMEX sent Betsy Rakola an email explaining their agreement with BCS to certify apiculture clients to the NOP while CERTIMEX is resolving their accreditation status. CERTIMEX inspectors conducted the inspections of the operations for BCS.
7/11/14	Betsy requested additional information from CERTIMEX, including 2 specific honeybee files and documented evidence of staff education in the form of training modules, policies, or other documents. The information is due to AIAInbox@ams.usda.gov by August 4, 2014.
7/18/14	Betsy reviewed the training information in Spanish and began writing the corrective action report. The training directly cited the USDA organic regulations and the NOSB recommendation on apiculture. However, the training slides cited the NOSB recommendation that thymol, formic acid, and carbon dioxide be added to the National List for use in apiculture. Only formic acid has been added for this purpose. Betsy emailed Juan Felipe Ortega Valdez to find out whether CERTIMEX explained this during the training session. The test taken by training participants included a multiple-choice question about allowed substances in NOP apiculture. The correct answer was "formic acid." This indicates that the correct information was most likely communicated to the trainees.
8/21/14	Assigned to Renée Gebault King (RGK).
9/10/14	RGK reviewed files and prepared Settlement Agreement Report. RGK sent questions to Standards re: phenol in apiculture/honey processing (more information requested from CMEX).
9/15/14	RGK sent e-mail to CMEX requesting more information on phenol in apiculture and honey processing for EDUCE and Kabi Habin inspection reports.
9/26/14	RGK received information from CMEX on phenolized drums used to store honey.
10/1/14	RGK reviewed information provided: • (item 5b)Trainings included NOSB recommendations on thymol and carbon dioxide but the final exam based on the training for CMEX staff showed that formic acid was currently the only acceptable input to control pests (i.e. varroa

	mites) in hives. • (item 5c) Inspection reports submitted for the honey cooperatives mention the use of phenol in the honey collection buckets, drums and storage tanks. • More information was provided by CMEX regarding these “phenolized” drums, which refers to a process whereby steel drums or other storage containers receive an interior coating of food-grade resin (plastic). • CMEX provided information (specification sheets) from the drum manufacturer (Valspar) to verify this drum coating material is food-grade, non-reactive (in reference to honey, which has an acidic pH) and approved by US Food and Drug Administration (FDA). • Upon review, RGK recommended acceptance of CAs for Settlement.
10/6/14	RGK edited (removed company names from report). R Mann reviewed and suggested edits.
10/9/14	RGK edited further and submitted file for review.

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SETTLEMENT AGREEMENT

THIS AGREEMENT is entered into by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), National Organic Program (NOP) and Certificadora Mexicana de Productos y Procesos Ecologicos SC – Certimex (CMEX), located in Oaxaca, Oaxaca, Mexico collectively referred to as the Parties.

WHEREFORE, USDA, AMS, NOP and CMEX have decided to settle the issues between them related to alleged violations of the Organic Foods Production Act of 1990 (7 U.S.C. §§ 6501 et seq.) (OFPA), and the USDA organic regulations (7 CFR §§ 205.1 et seq.), the Parties agree to the following:

1. The Secretary of Agriculture has jurisdiction in this matter.

2. On August 1, 2013, CMEX received a Notice of Noncompliance from the NOP regarding its 2013 Mid-Term Assessment Report. The Notice and corresponding assessment report detailed the nature and extent of the noncompliances.

3. CMEX's response to the NOP on August 26, 2013 neither corrected nor successfully rebutted the noncompliances cited in the Notice of Noncompliance. On October 18, 2013, the NOP issued a Denial of Livestock Accreditation Expansion of CMEX's accreditation to the USDA organic regulations.

4. CMEX filed an appeal of the denial of accreditation expansion on November 7, 2013.

5. CMEX agrees to the following:

    a. CMEX agrees not to accept any new clients seeking certification in the livestock certification scope, including honeybees and all animals. CMEX agrees to tell new livestock certification applicants that it does not currently have the administrative capacity to accept that application.

    b. Within 45 days of agreement execution, CMEX agrees to provide evidence that CMEX staff – specifically document reviewers, inspectors, and certification decision makers – have been taught NOP livestock requirements as they pertain to honey bee certification. This includes instruction that honey bees *may only feed on certified organic feed and land* to be certified organic.

    c. Following NOP's review of this evidence, CMEX agrees to undergo a limited scope desk audit where the NOP will review selected honey bee files from the 2013 and/or 2014 certification year(s). CMEX will not be charged for this desk audit.

6. If the terms in Item 5 are completed successfully, USDA AMS NOP will issue CMEX livestock accreditation to the USDA organic regulations, limited to the certification of honey bee clients.

7. If the terms of this agreement are not met, i.e., the elements of Item 5 are not completed

successfully, USDA, AMS, NOP may reissue a Proposed Notice of Denial of Livestock Scope Expansion.

This Agreement shall become effective upon execution by the Parties.

_____ Date: _____
Taurino Reyes
Certificadora Mexicana de Productos y Procesos Ecologicos SC / CMEX

_____ Date: _____
Miles V. McEvoy
Deputy Administrator, USDA, AMS, NOP

USDA Agricultural Marketing Service

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   a. CMEX agrees not to accept any new clients seeking certification in the livestock certification scope, including honeybees and all animals. CMEX agrees to tell new livestock certification applicants that it does not currently have the administrative capacity to accept that application.

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   c. Following NOP's review of this evidence, CMEX agrees to undergo a limited scope desk audit where the NOP will review selected honey bee files from the 2013 and/or 2014 certification year(s). CMEX will not be charged for this desk audit.

6. If the terms in Item 5 are completed successfully, USDA AMS NOP will issue CMEX livestock accreditation to the USDA organic regulations, limited to the certification of honey bee clients.

7. If the terms of this agreement are not met, i.e., the elements of Item 5 are not completed

successfully, USDA, AMS, NOP may reissue a Proposed Notice of Denial of Livestock Scope Expansion.

This Agreement shall become effective upon execution by the Parties.

CERTIFICADORA MEXICANA DE PRODUCTOS Y PROCESOS ECOLOGICOS S.C.
Certimex
ACCREDITED BY USDA NATIONAL ORGANIC PROGRAM (NOP)

Taurino Reyes
Certificadora Mexicana de Productos y Procesos Ecologicos SC / CMEX

Date: June 03rd 2014

Miles V. McEvoy
Deputy Administrator, USDA, AMS, NOP

Date: 3 June 2014

Mid Term Chronology Log

Audit Identifier (if any): NP5006LCA

Audit Type: Mid Term Assessment

Accredited Certifying Agent Name: Clemson University (CU)

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
4/24/15	Assigned to PZ
5/6/15	PZ reviewed audit documents. Please note: NP5006LCA.NC9 is highlighted in red on the report because I question whether this really is a noncompliance. Can correcting a noncompliance after proposed suspension stop the suspension or does it have to be through either mediation or rebuttal? Response from RM: Up until the ACA Training in February, 2015, we said that correction of a noncompliance cannot occur at the NoPS stage. It has to be mediation or rebuttal. This is kind of implied in the training, page 5 (http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5110700). Please flag this for Cheri to review.
5/7/15	PZ processed NoNC and Noncompliance Report. Emailed to RM for review.
5/12/15	PZ revised report and NoNC with RM edits and comments. To Cheri for review. Cheri reviewed and determined NP5006LCA.NC9 is a noncompliance. PZ revised and reprinted – to Cheri for signature.
6/11/15	Corrective Actions received via AIAinbox
6/16/15	CA assigned to PZ from RM
6/17/15	PZ reviewed Corrective Actions and rebuttals. All were accepted. The Notice of Noncompliance Resolution and Corrective Action Report were processed and emailed to RM for review.
6/23/54	RM provided comments and edits to the report.
7/14/15	PZ emailed CU for additional information regarding training and documented evidence for some corrective actions. Due by 7/28/2015
7/20/15	Rec'd email from CU with additional information as requested.
7/27/15	Reviewed email with information regarding a training scheduled for July 30, 2015 with staff to go over issues identified as NC1, NC2, and NC3. Emailed CA to RM for review and asked if we should wait to follow-up after the training on 7/30/15 for more documentation?
8/4/15	Emailed CU to notify them NOP does not accept their rebuttal for NC9 and asked them to submit corrective actions along with documented evidence that the staff training scheduled for 7/30/15 took place. This information is due to NOP by 8/18/15.
8/4/15	Received email from CU with training log attached from the training they conducted on July 30, 2015 on the topics of:

Mid Term Chronology Log

Audit Identifier (if any): NP5006LCA

Audit Type: Mid Term Assessment

Accredited Certifying Agent Name: Clemson University (CU)

Accreditation Manager (who is working on the project): Penny Zuck

Date	Activity
	• Auditing organic operations review • Materials verification • Residue sampling
8/18/15	Rec'd email from CU with corrective action for NP5006LCA.NC9 along with revised Notice of Proposed Suspension template and Adverse Action Work Instruction.
8/19/15	PZ reviewed documentation submitted by CU to correct NP5006LCA.NC9 and corrective action is accepted. Emailed CA Report and Resolution Letter to RM for review.
8/21/15	Emailed Ryan to submit any follow-up documentation on the correction of the COB statement on the label in the rebuttal for NP5006LCA.NC7.
8/26/15	Rec'd revised label – still not approved, but sufficient to accept the rebuttal for NP5006LCA.NC7. CU is requiring a revised copy of label in the next two weeks from the client and will submit it to NOP upon approval by CU. Processed NoNC Resolution and CA report – emailed to RM for review. Revised documents with RM edits and printed for review and signature.
8/27/15	PZ emailed NoNC resolution and CA report via Rpost to CU and AIAinbox.

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NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Clemson University (CU) organic program was conducted on January 6-8, 2015. The National Organic Program (NOP) reviewed the auditor's report to assess CU's compliance to the USDA organic regulations.

GENERAL INFORMATION

Applicant Name	Clemson University (CU)
Physical Address	511 Westinghouse Road, Pendleton, SC 29670
Mailing Address	511 Westinghouse Road, Pendleton, SC 29670
Contact & Title	Ryan Merck, Program Coordinator
E-mail Address	organic@clemson.edu
Phone Number	864-646-2129
Reviewer(s) & Auditor(s)	Penny Zuck, NOP Reviewer Lars Crail, Onsite Auditor Robert Yang, office audit only
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action review: August 19, 2015 NOP assessment review: May 6, 2015 Onsite audit: January 6-8, 2015 Review audit: July 11, 2014 Witness audit: July 10, 2014
Audit Identifier	NP5006LCA
Action Required	None
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 CU's certification system.
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	CU's certification services in carrying out the audit criteria.

GENERAL INFORMATION

Clemson University (CU) has been accredited by the USDA National Organic Program (NOP) since April 29, 2002 to certify crops, livestock, and handling operations. CU currently certifies 121 operations, which includes 77 crops, 6 livestock, and 49 handling operations. CU does not certify grower groups. The CU organic certification program is a program of the Department of Plant Industry, a department within the Division of Regulatory Services. CU's office is located in Pendleton, SC. All key certification activities are conducted from the Pendleton office.

As of June 2014, CU no longer accepts new applicants for certification outside the state of South Carolina. There are 81 Operations certified by CU in North Carolina, Georgia, and Virginia that are in the process of applying for organic certification with another accredited certifying agent. CU has informed the operations that they must either surrender or become certified by another accredited certifying agent by their 2015 anniversary date.

PERSONNEL
CU's organic certification program staff consists of the Program Manager; Program Coordinator; Administrative Assistant; and 3 staff inspectors. The Associate Director of Regulatory Service oversees the organic certification program, but is not involved in any certification activities.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether CU'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

None

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.

NP5006LCA.NC1 – Accepted - 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: *CU's crop inspection report form includes a section for the inspector to conduct a "trace-back audit (recall)". A review of three inspection reports revealed that the inspector did not conduct a trace-back audit, but instead either described the types of records the operation maintains or noted that the "recall exercise" was not applicable.*

Corrective Action: CU clarified that in 2 of these cases, the inspector outlined the records that were reviewed in conducting the trace-back audit but CU does not require inspectors to document the numbers from the records and accepts the recordkeeping information provided by the inspectors to sufficiently verify compliance of the operations. CU submitted a new work instruction that was developed for conducting audits of organic operations and it will be provided to all inspectors prior to conducting inspections with CU. The work instruction details how to perform the mass balance audit and trace-back audit. CU conducted training on July 30, 2015 to address this topic. The training log was submitted to NOP.

NP5006LCA.NC2 – Accepted - 7 CFR §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."

Comments: *A review of inspection reports revealed an instance where the inspector did not collect information regarding the source of materials used by the operation in order to verify whether prohibited substances were being used.*

Corrective Action: CU submitted their revised Materials Inventory form, which includes the brand/source information of input materials. The work instruction for Certification Decision was also submitted, which includes reviewing the application for use of prohibited substances. This work instruction was reviewed with all Staff. CU conducted staff training on July 30, 2015 to address this topic. The training log was submitted to NOP.

NP5006LCA.NC3 – 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."

Comments: *A review of three sample collection cases revealed that in all three instances a receipt for samples taken by inspector was not provided to the operator at the time of the inspection.*

Corrective Action: CU has added a receipt book to all inspector's sample bags and inspectors will be instructed to complete a receipt for the applicant in addition to completing the sample forms. The Sampling Procedures for Residue Testing has been revised to include this instruction and was submitted by CU. CU conducted training on July 30, 2015 to address this topic. The training log was submitted to NOP.

NP5006LCA.NC4 – Accepted - 7 CFR §205.404(a) states, "A certifying agent must review the on-site inspection report … and any additional information requested from or supplied by the applicant."

Comments: *The review of a new applicant certification file revealed that draft labels were collected by the inspector and submitted with the inspection report, but were not reviewed by the final reviewer.*

Corrective Action: CU submitted their newly developed label review instruction to be followed in conjunction with their label review documents to evaluate compliance of labels that are submitted at any stage of the certification process. All labels are reviewed by the Organic Certification Program Coordinator, who is the initial reviewer. CU indicated the Organic Certification Program Coordinator reviewed the regulations and developed the label review instruction that was submitted to the NOP.

NP5006LCA.NC5 – Accepted - 7 CFR §205.405(d) states, "A notice of denial of certification must state the reason(s) for denial and the applicant's right to: (1) Reapply for certification pursuant to §§205.401 and 205.405(e); (2) Request mediation pursuant to §205.663 or, if applicable, pursuant to a State organic program; or (3) File an appeal of the denial of certification pursuant to §205.681 or, if applicable, pursuant to a State organic program."

Comments: *CU's notice of denial template does not state the applicant's right to reapply for certification or request mediation.*

Corrective Action: CU submitted the revised template for Combined Notice of Noncompliance and Denial of Certification including the compliant language.

NP5006LCA.NC6 – **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." Furthermore, 7 CFR §205.304(a)(1)(i) states, "Agricultural products in packages described in §205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product: The statement: "Made with organic (specified ingredients) …."

Comments: *CU approved four "made with organic" product labels that display the statement "With organic (ingredient)"on the information panel.*

Corrective Action: CU issued a Notification of Noncompliance to the operation with noncompliant labeling. 7 CFR 205.304 was reviewed with all label reviewers to ensure the labels are reviewed for the verbiage "made with organic (specified ingredients)." A copy of the Notice of Noncompliance was also submitted.

NP5006LCA.NC7 – **Rebuttal 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." Furthermore, 7CFR §205.304(b)(2) states, "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 ***…."

Comments: *The "Certified organic by ***" statement on four Made with organic product labels was not below the information identifying the handler of the product. CU did not inform the operation that the labels are noncompliant and must be revised by January 1, 2016, pursuant to PM 12-2.*

Rebuttal: CU submitted a copy of the inspection report issued to this operation in June, 2013 where it was noted in the inspection report and in the exit interview that placement of the COB statement on labels must be revised by January 1, 2016 according to PM 12-2. CU also identified the noncompliant label in the certification decision document and in the inspection briefing for the inspector to follow up at the next inspection.

NP5006LCA.NC8 – **Accepted** - 7 CFR §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 and submit supporting documentation of each such correction when correction is possible."

Comments: *CU's Notice of Noncompliance template does not provide the operation with an opportunity to rebut the noncompliance.*

Corrective Action: CU submitted the revised template for Notice of Noncompliance including the compliant language.

NP5006LCA.NC9 – Accepted - 7 CFR §205.662 (e)(1) states, "If the operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension …, the certifying agent ... shall send the certified operation a written notification of suspension …."

Comments: *CU accepted corrective actions from an operation it had issued a Notice of Proposed Suspension to, and also sent a Notice of Proposed Suspension Resolution to the operation upon accepting the corrective actions.*

Corrective Action: CU submitted a revised Notice of Proposed Suspension template and adverse action work instruction indicating CU will notify any operation receiving a Notice of Proposed Suspension that their options are to appeal pursuant to 205.681 or request mediation pursuant to 205.663.

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

An onsite mid-term assessment of the Clemson University (CU) organic program was conducted on January 6-8, 2015. The National Organic Program (NOP) reviewed the auditor's report to assess CU's compliance to the USDA organic regulations. This report provides the results of NOP's assessment.

GENERAL INFORMATION

Applicant Name	Clemson University (CU)
Physical Address	511 Westinghouse Road, Pendleton, SC 29670
Mailing Address	511 Westinghouse Road, Pendleton, SC 29670
Contact & Title	Ryan Merck, Program Coordinator
E-mail Address	organic@clemson.edu
Phone Number	864-646-2129
Reviewer & Auditor	Penny Zuck, NOP Reviewer Lars Crail, On-site Auditor Robert Yang, office audit only
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: May 6, 2015 Onsite audit: January 6-8, 2015 Review audit: July 11, 2014 Witness audit: July 10, 2014
Audit Identifier	NP5006LCA
Action Required	Yes
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 CU's certification program.
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	CU's certification services in carrying out the audit criteria.

GENERAL INFORMATION

Clemson University (CU) has been accredited by the USDA National Organic Program (NOP) since April 29, 2002 to certify crops, livestock, and handling operations. CU currently certifies 121 operations, which includes 77 crops, 0 wild crops, 6 livestock, and 49 handling operations. CU does not certify grower groups. The CU organic certification program is a program of the Department of Plant Industry, a department within the Division of Regulatory Services. CU's office is located in Pendleton, SC. All key certification activities are conducted from the Pendleton office.

As of June 2014, CU no longer accepts new applicants for certification outside the state of South Carolina. There are 81 Operations certified by CU in North Carolina, Georgia, and Virginia that are in the process of applying for organic certification with another accredited certifying agent. CU has informed the operations that they must either surrender or become certified by another accredited certifying agent by their 2015 anniversary date.

PERSONNEL

CU's organic certification program staff consists of the Program Manager; Program Coordinator; Administrative Assistant; and 3 staff inspectors. The Associate Director of Regulatory Service oversees the organic certification program, but is not involved in any certification activities.

CU requires all program staff, including the Associate Director of Regulatory Service, to complete a conflict of interest disclosure report and confidentiality statement annually. A review of personnel files and interviews conducted confirmed that all personnel involved in the certification process had sufficient experience, training, and education. A review of training records indicated that all certification staff, including inspectors, received annual training on the USDA organic regulations and NOP requirements.

CERTIFICATION PROCESS

Applicants requesting certification information via email are provided with a link to CU's website where the applicant can download the applicable organic system plan(s) and other supplementary application forms; the USDA organic regulations; CU's fee schedule; and information about the certification process. CU provides applicants with certification information in paper only when requested.

Upon receiving a new application or annual update, the program coordinator conducts an initial review for completeness and compliance. The program coordinator then assigns the inspection to a staff inspector based on qualification and availability. Upon receiving the inspection report from the inspector, the program coordinator reviews the report for completeness. The certification file is then forwarded to the program manager who conducts a final review for compliance and makes the final certification decision. All notices resulting from the initial and final reviews, including organic certificates, are issued by the administrative assistant.

CU's policy for unannounced inspections is to conduct unannounced inspections of at least 5% of their total certified operations per year. The program coordinator develops a plan for the unannounced inspections at the beginning of each year, and operations are selected based on risk or as a result of a complaint or investigation. CU only conducts limited-scope unannounced inspections.

Material evaluations are conducted by the program coordinator. For the review of branded (formulated) inputs, CU recognizes product reviews conducted by OMRI, WSDA, and PCO. CU does not have a material evaluation program for liquid nitrogen fertilizers with a nitrogen content greater than 3 percent, and therefore only allows those approved by a material evaluation program such as OMRI.

Product labels are reviewed and approved by the program coordinator, and the use of the approved labels is verified by the inspector during the on-site inspection. CU has a label review checklist that the program coordinator refers to when reviewing and approving labels.

CU currently has 4 certified operations that export to Canada and have been verified to the requirements of the US-Canada Equivalency Arrangement. CU has not issued any import/export certificates for Taiwan, Japan, Korea, or the EU.

ADMINISTRATIVE RECORDS AND PROCESS

Annual reviews of CU's organic certification program are conducted in the fall by auditors of the Georgia Crop Improvement Association. The implementation and effectiveness of corrective actions resulting from the annual review are reviewed by the auditors during the next annual review. The last annual review was conducted on November 26, 2014.

CU conducts organic certification refresher training for all certification staff, including inspectors, annually. The training typically is conducted at the beginning of the year, after the annual Accredited Certifier Association training. Inspectors are additionally required to receive 8 hours of continuing education; undergo a witness audit prior to receiving approval to conduct inspections (per scope); and undergo two field evaluations each year. One evaluation is conducted by a peer and the other by the program coordinator.

SUMMARY OF WITNESS AND REVIEW AUDITS CONDUCTED

The witness and review audits were conducted prior to the office audit. A witness audit of the annual inspection of a crops operation that produces vegetables and strawberries was conducted on July 10, 2014, and a review audit of a crops and livestock (beef cattle) operation was conducted on July 11, 2014.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether CU'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 CU.

Noncompliances from Prior Assessments

None

Noncompliances Identified during the Current Assessment

NP5006LCA.NC1 – 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: *CU's crop inspection report form includes a section for the inspector to conduct a "trace-back audit (recall)". A review of three inspection reports revealed that the inspector did not conduct a trace-back audit, but instead either described the types of records the operation maintains or noted that the "recall exercise" was not applicable.*

NP5006LCA.NC2 – 7 CFR §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."

Comments: *A review of inspection reports revealed an instance where the inspector did not collect information regarding the source of materials used by the operation in order to verify whether prohibited substances were being used.*

NP5006LCA.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: *A review of three sample collection cases revealed that in all three instances a receipt for samples taken by inspector was not provided to the operator at the time of the inspection.*

NP5006LCA.NC4 – 7 CFR §205.404(a) states, "A certifying agent must review the on-site inspection report … and any additional information requested from or supplied by the applicant."

Comments: *The review of a new applicant certification file revealed that draft labels were collected by the inspector and submitted with the inspection report, but were not reviewed by the final reviewer.*

NP5006LCA.NC5 – 7 CFR §205.405(d) states, "A notice of denial of certification must state the reason(s) for denial and the applicant's right to: (1) Reapply for certification pursuant to §§205.401 and 205.405(e); (2) Request mediation pursuant to §205.663 or, if applicable, pursuant to a State organic program; or (3) File an appeal of the denial of certification pursuant to §205.681 or, if applicable, pursuant to a State organic program."

Comments: *CU's notice of denial template does not state the applicant's right to reapply for certification or request mediation.*

NP5006LCA.NC6 – 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, 7 CFR §205.304(a)(1)(i) states, "Agricultural products in packages described in §205.301(c) may display on the principal display panel, information panel, and any other panel and on any labeling or market information concerning the product: The statement: "Made with organic (specified ingredients) …."

Comments: *CU approved four "made with organic" product labels that display the statement "With organic (ingredient)"on the information panel.*

NP5006LCA.NC7 – 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, 7CFR §205.304(b)(2) states, "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 ***…."

Comments: *The "Certified organic by ***" statement on four Made with organic product labels was not below the information identifying the handler of the product. CU did not inform the operation that the labels are noncompliant and must be revised by January 1, 2016, pursuant to PM 12-2.*

NP5006LCA.NC8 – 7 CFR §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 and submit supporting documentation of each such correction when correction is possible."

Comments: *CU's Notice of Noncompliance template does not provide the operation with an opportunity to rebut the noncompliance.*

NP5006LCA.NC9 – 7 CFR §205.662 (e)(1) states, "If the operation fails to correct the noncompliance, to resolve the issue through rebuttal or mediation, or to file an appeal of the proposed suspension …, the certifying agent ... shall send the certified operation a written notification of suspension …."

Comments: *CU accepted corrective actions from an operation it had issued a Notice of Proposed Suspension to, and also sent a Notice of Proposed Suspension Resolution to the operation upon accepting the corrective actions.*

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
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Washington, DC 20250-0268

NOTICE OF NONCOMPLIANCE

MAY 13 2015

Ryan Merck
Clemson University
511 Westinghouse Road
Pendleton, SC 29670

Dear Mr. Merck:

On January 6-8, 2015, a representative of the United States Department of Agriculture (USDA), National Organic Program (NOP), completed an onsite audit of Clemson University's (CU) organic certification program as part of its USDA Mid Term Accreditation Assessment. On May 6, 2015, the NOP reviewed the results of the onsite audit to determine CU's compliance to the USDA organic regulations. A copy of the assessment report, NP5006LCA, is enclosed for your reference.

As the report indicates, nine new noncompliances, NP5006LCA.NC1 – 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 CU 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

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

Enclosure: Noncompliance Report

cc: AIA Inbox

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a compliance assessment of Control Union Certifications (CUC) in accordance with the requirement set forth on October 21, 2016 as a result of CUC's 2015 Midterm Assessment. An onsite audit was conducted, and the audit report reviewed to determine CUC's capability to continue operating as a USDA accredited certifier.

GENERAL INFORMATION

Applicant Name	Control Union Certifications (CUC)
Physical Address	Meeuwenlaan 4-6, 8011 BZ ZWOLLE, P.O. Box 161, Dr. Klinkertweg 28A, Ad Zwolle, 8000, Netherlands
Mailing Address	Meeuwenlaan 4-6, 8011 BZ ZWOLLE, P.O. Box 161, Dr. Klinkertweg 28A, Ad Zwolle, 8000, Netherlands
Contact & Title	Daniel Szalai, Program Manager
E-mail Address	dszalai@controlunion.com
Phone Number	31 038 426 01 00
Reviewer & Auditor	Rebecca Claypool, NOP Reviewer; Lars Crail, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Dates	NOP assessment review: July 25, 2017 Onsite audit: February 13 - 14, 2017
Audit Identifier	NP7044LCA
Action Required	None
Audit & Review Type	Compliance Assessment
Audit Objective	To evaluate the conformance to the audit criteria; and to verify the implementation and effectiveness of CUC's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	CUC's certification services in carrying out the audit criteria during the period: September 21, 2016 through February 13, 2017

The National Organic Program (NOP) conducted an onsite compliance audit of Control Union Certification (CUC) on February 13-14, 2017 at CUC's main office in Zwolle, Netherlands. On October 21, 2016, the NOP issued a Midterm Audit Assessment stating that corrective actions submitted were accepted, and that CUC must consent to a compliance audit within one year allowing NOP to determine if the accepted corrective actions were effectively implemented.

During the onsite compliance audit, the auditor also reviewed the status of CUC's submitted corrective action for the one noncompliance that was identified during an October 15, 2016 witness audit at a honey processing facility in Ukraine.

CUC was accredited as a certifying agent on October 18, 2002. CUC is a limited liability company with its main certification office located in Zwolle, Netherlands. CUC satellite offices are located in Peru, Korea, Turkey, Indonesia, South Korea, Ethiopia, Israel, Sri Lanka, and India. At the time of the onsite compliance audit, CUC certifies 1552 operations: Crops (976), Wild Crops (12), Livestock (36) and Handler/Processor/Exporters (1406). CUC certifies 417 grower groups. CUC's current accreditation ends October 18, 2017. There were no witness or review audits conducted during the compliance audit.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether CUC 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 CUC.

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.

NP6278LCA.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 Control Union Certification organic certificate elements are incorrect or missing on the certificates issued to operations:*

1. *The certificate does not list an anniversary date.*
2. *"Effective Date" is not used, instead the date is listed as "Date of certification."*
3. *Specific product and/or brand name(s) are not listed.*

Corrective Action: CUC amended its NOP organic certificate template to include dates properly identified as an "Effective Date" and "Anniversary Date." CUC also amended its organic certification instruction document to clearly state that all products must be individually listed on the certificate and grouping was not allowed. CUC notified and trained its staff on these changes on February 27, 2017. On December 16, 2016, CUC archived the noncompliant organic certificate template in its centralized system.

2017 Verification of Corrective Action: CUC implemented a new certificate template (version 25) on January 10, 2017. CUC notified certification personnel of the new certificate template through CUC's database network on February 10, 2017. The auditor reviewed the certificate template and an example of an issued certificate and both were compliant.

NP2253AKA.NC2 – Cleared - NOP §205.403(c)(1, 2, 3) states, "Verification of Information. The on-site inspection 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…."

Comments:

- *At 2 witness inspections, inspectors did not have a copy, in the OSP, of the labels used in order to verify the CUC-approved label against the label used on-site.*
- *At 1 witness inspection, the inspector did not review labels on-site (bulk pepper boxes), which displayed a non-compliant USDA seal. The inspector included this as a "finding" on the non-compliance summary report given to the client at the end of the inspection; however, was aware of the issue only after the NOP auditor brought it to his attention.*
- *At 2 witness inspections, the inspector did not properly verify materials used; specifically, active ingredients of fertilization and insecticide materials were not reviewed. In two cases, the NOP auditor questioned active ingredients in materials the inspector thought to be approved; the inspector did not have an issue with the ingredients and also did not refer to the NOP materials list before making such decision (though he had a copy of the materials list with him on-site). So that the client was aware, as well as the inspector and the CUC-staff member in attendance, the NOP auditor discussed the materials on-site with prohibited active ingredients. The inspector then listed these materials in the non-compliance summary after the inspection.*
- *At 1 witness inspection, the certified operation did not have an implemented measure to prevent commingling of organic oil with conventional oil during the receiving stage of the process; the tanks were allowed to drain completely, but this could leave approximately 2% of conventional oil in the tank (residue along the inside). The inspector did not identify this issue as a concern during the on-site inspection.*
- *At 2 witness inspections, covering 3 different production areas, there were no audit trail exercises conducted to verify traceability or that organic outgoing product did not exceed incoming product.*

2013 Corrective Action: In November 2013, CUC amended its OSP template to request more detailed information on labels and materials used by the operation to improve its label review and material review procedures. CUC also provided additional instruction for its reviewers to ensure label reviews are included in the OSP review. CUC also amended its OSP review checklist for verifying labels, and audit trail documentation. In November 2013, CUC conducted training for inspectors on label review, material review, audit trail analysis, and commingling assessments.

2015 Corrective Action Verification: This noncompliance is partially addressed. CUC's OSP templates have been revised, and include sections for applicants to provide a list of materials being used and product labels. A label review checklist has been developed and is being used to review product labels. Material verification is part of the Inspection Instruction and was verified by the auditors during the witness inspections. The CUC inspection report checklist reviews measures taken to prevent commingling and contamination and the auditors confirmed the inspectors verify these measures at the witness inspections. The final bulleted item in the noncompliance above has not been addressed because CUC is not conducting audit trail

exercises. Audit trail exercises (in/out balance and traceback audit) were not performed by inspectors during the witness inspection. Audit trail exercises are not included as part of the inspection checklists.

2016 Corrective Actions: CUC has defined what is expected of audit trail exercises during inspections and witness audits and is requiring auditors to provide more information when reporting the mass (in/out) balance exercise. Specifically, auditors are to completely verify and trace incoming product ingredients back to organic certification. CUC's amended Inspection Instruction (INSP.ORG.w01) requires CUC auditors to complete and attach the "Audit trail and mass balance report" for all USDA NOP inspections. CUC will notify staff of the change in procedures via the CUC IT certification system and the topic we be included in the CUC annual training expected to be held no later than January 2017.

2017 Verification of Corrective Action: Auditor reviewed the Audit Trail and Mass Balance Report template and training materials provided to CUC staff during two webinar trainings in December 2016 and January 2017. The auditor determined that the new template and requirements for inspectors to conduct trace-back and mass balance activities were communicated adequately.

NP2253AKA.NC4 – Cleared - NOP §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 organic certificate includes the following statement, "This certificate is in force until further notice, provided that the above-mentioned client continues meeting the conditions as laid down in the client contract with Control Union Certifications."* ***A client receives up to 3 different documents that make up the Terms of Contract;*** *specifically: Procedure Manual Annex A3 Terms of Contract, Annex 16 CU Inspection Regulation, and Chapter 3 – Additional rules for the certification program: Organic Production Methods (USDA NOP****). Review of the multiple conditions provided in the Terms of Contract demonstrate there are a number of contract requirements that go above and beyond the NOP regulations;*** *for example, Annex A3 section 12.3 states, "The Agreement can be terminated by the Company (CUC) with immediate effect by written notice to the Principal (operation) without having to take a notification period into account in any case if: (i) the Principal has acted contrary to terms of the Agreement and/or the terms of the Documents; …(iii) the Principal is entered into bankruptcy or if a filing for its bankruptcy has been requested or if it has been granted a suspension of payments; (iv) the Principal fails to pay any amount it owes to the Company within one month after the expiration of the payment deadline..."* ***So, based on this contract, if a certified operation declares bankruptcy or if the operation does not pay their fee, they have broken their contract; per the statement on the certificate, if the client breaks the contract then they are no longer certified. This is not a compliant practice for NOP certification.*** *Below are additional examples of contract requirements that would invalidate the organic certificate if the client does not "continue meeting the conditions…":*

- *Annex 16 CU Inspection Regulation:*
    - *Article 7 – Register complaints and remedial actions: The client shall safeguard that all complaints received…are centrally registered.*

- *Annex 2 Conditions for publication and use of the Certification Logo, article 12 – "When the Certificate-holder does not respect these conditions for use of certification logos… CU can take the following measurements (actions): suspension or withdrawal of the Certificate."*

- *Procedure Manual Annex A3*
  - *Section 3.1 – Obligations and restrictions of the Principal: The Principal must report any change or discontinuation in a production method or unit which is included in the certification program immediately to the Company.*
  - *Section 13 – Appeals: this section (13.1-4) details requirements that the Principal must follow if an appeal is desired. There is no information in the contract for NOP clients regarding appeal process, or indication that the appeals requirements in the contract do not apply to NOP clients.*

2013 Corrective Action: On November 8, 2013, CUC provided copies of its database assessment system model showing how only NOP regulation requirements will be applied to NOP certification. The system is designed to ensure staff will not implement requirements beyond the NOP regulations. CUC will review its quality management system to identify program requirements applicable to other standards will not be applied to NOP certification. CUC also amended its certificate template to add the statement "once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended or revoked." CUC's Notice of Proposed Suspension/Revocation template states information on the right to appeal.

2015 Corrective Action Verification: Auditors verified CUC's system continues to apply requirements beyond the NOP regulations in the "Terms of Contract" issued to NOP certified operations. Auditors certificate reviews found CUC added the following compliant language: "*Once certified, a production or handling operation's organic certification continues in effect until surrendered, suspended, or revoked*."

2016 Corrective Actions: CUC specifically states in the organic offer letter following parts of the terms of contract are not applicable for those clients who are contracted only for USDA NOP: Annex A3 section 3.1, 12.3, 13; Annex16 CU Inspection regulation: Article 7, Annex2. CUC will inform all staff of the change to template contract document via the CUC centralized certification system. The revised contract documents will be the only documents available in the CUC quality system.

2017 Verification of Corrective Action: CUC implemented modified operation contracts which state that USDA organic certified operations must undergo the noncompliance and adverse action process to be suspended or revoked. The auditor verified this corrective action by reviewing the modified contracts with operations. Since the implementation of the updated contract, there have been no operations de-certified.

NP5264PZA.NC1 – **Cleared -** 7 CFR §205.403 (c)(3) states that "The on-site inspection of an operation must verify: That prohibited substances have not been and are not being applied to the operation…" Additionally, 7CFR §205.301(b) Products sold, labeled, or represented as "organic" States, "A raw or processed agricultural product sold, labeled, or represented as "organic" must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product

ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part."

Comments: *Documentation of non-organic ingredients to verify compliance with the National List is not verified at the inspection or reviewed by the CUC office staff. CUC office staff informed the auditor that the inspector is instructed to verify this information during the on-site inspection. The auditor interviewed the inspector who was under the assumption that no verification of input annotation onsite was necessary since the product specification is reviewed and approved by the staff in the CUC office.*

2016 Corrective Actions: CUC updated the "planning chapter" of the inspection instruction to specify an operation's OSP and all substances/materials (inputs) must be reviewed by a qualified CUC staff member prior to the inspection. The CUC material/input review will require documentation of a product's ingredients and determine its compliance with all NOP regulations and material annotations or conditions. CUC will inform all staff through the CUC certification system of the change to the procedure. CUC has added material review verification to the certification decision checklist.

2017 Verification of Corrective Action: The modified CUC reviewer and inspector checklists were reviewed by the auditor. CUC staff were trained on the new procedure to conduct an initial review including the review of material inputs. Completed checklists were not available during the audit since these documents were recently published and implemented. The auditor interviewed one reviewer who had been trained on the new checklists.

NP5264PZA.NC2 – Cleared - 7 CFR §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 the regulations in this part... Additional inspections may be announced or unannounced…as required by the Administrator…" Furthermore, NOP 2609 - *Unannounced Inspections*, Sections 4.1.1 and 4.1.9, state, "We [NOP] 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… 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: *CUC is conducting additional inspections, but these cannot be considered unannounced because the operations are notified more than four hours prior to the inspection.*

2016 Corrective Action: CUC has amended its Program Manual and contract template for organic production to specify clients of unannounced inspections may be notified a maximum of four hours prior to the audit and refers readers to NOP 2609 for additional information. CUC will notify staff of instructional changes via the CUSI news document and the scheme coordinator will randomly check the implementation of this change during the annual internal audit.

2017 Verification of Corrective Action: The auditor reviewed modified operation contracts allowing for unannounced inspections. Inspectors were notified of the new procedure and one compliant unannounced inspection occurred on February 1, 2017. This corrective action appears to be effectively implemented by CUC.

NP5264PZA.NC3 – Cleared - 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: *CUC does not issue Notices of Noncompliance to clients when annual updates are not received by the due date.*

2016 Corrective Actions: CUC has changed its Program Manual procedure for inspection and inspection planning to state if an annual update is not received timely the certification office must issue a noncompliance before the audit. CUC will notify staff of instructional changes via the CUSI news document and the scheme coordinator will randomly check the implementation of this change during the annual internal audit.

2017 Verification of Corrective Action: The auditor reviewed 14 noncompliance notifications issued since October 2015 for operations failing to submit annual updates. CUC is following their updated procedure.

NP5264PZA.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;" Furthermore, NOP 4009 - *Who Needs to Be Certified* clarifies that any producer or handler of a production or handling operation, except as exempt or excluded, intending to sell, label, or represent agricultural products as organic must be certified.

Comments: *CUC allows for the certification of "projects" which are certified operations that include uncertified subcontracted entities that produce and/or handle organic products. These subcontracted operations are listed in the certified operations organic system plans; however, these operations are not exempt or excluded and must be separately and individually certified.*

2016 Corrective Action: CUC has amended its instruction on contracting units to state all units must be registered/application review/certified as individual "projects." CUC staff is to register/application review/certify each subunit (related to the USDA NOP certified project) to separate scope certificate resulting in the subunits own certification to the USDA NOP. CUC has notified all staff of this change through the CUC newsletter and the Scheme coordinator will randomly monitor the implementation of this change during the annual internal audit.

2017 Verification of Corrective Action: CUC developed an action plan for 267 projects where uncertified independent processing units are producing and handling organic products. The auditor reviewed a letter that was issued in January 2017 to certified operations and associated uncertified operations producing and handling organic products for those certified operations. CUC certification personnel were informed that all subunits must be individually certified through a webinar that occurred in December 2016 and January 2017.

NP5264PZA.NC5 – **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"; and §205.501(a)(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 deficiencies in CUC's OSP and inspection report templates were identified:*

a) *CUC's OSP template does not require applicants to provide clearly defined monitoring practices and procedures. CUC's inspection report templates do not require inspectors to review and record verification of monitoring practices and procedures.*
b) *CUC's OSP template does not require applicants to provide clearly defined practices to maintain or improve natural resources and conserve biodiversity. CUC's inspection report templates do not require inspectors to review and record verification of the applicant's natural resources maintenance/improvement and biodiversity conservation practices.*
c) *CUC's OSP template does not require applicants to provide a description of their international activities. CUC's inspection report templates do not require inspectors to review and record compliance of the applicant's international activities to the applicable International Agreement.*

2016 Corrective Action: CUC amended its crop/wild crop, livestock and handling OSP templates requiring operations provide information and descriptions of monitoring practices, monitoring frequency, international agreements, and practices to maintain or improve natural resources and conserve biodiversity. CUC's inspection report templates for crop/wild crop and processing were updated to require inspectors to annotate verification of the operation's international agreement activities and practices to maintain or improve natural resources and conserve biodiversity. CUC will inform its staff through it automated certification system of the changes to templates and will only make the revised templates available for use. The scheme coordinator will check the implementation of this corrective action during the annual internal audit.

2017 Verification of Corrective Action: The auditor reviewed the modified OSP and inspection checklist templates and they were determined to be adequately modified to address the noncompliance. Both the OSP and inspection checklist sufficiently addressed internationally traded organic products.

NP5264PZA.NC6 – **Cleared -** 7 CFR §205.501 (a)(21) states that a certifier must "Comply with, implement, and carry out any other terms and conditions determined by the Administrator to be necessary." Certifier and operator requirements concerning international arrangements are located on NOP's website. Certifiers are required to monitor and ensure compliance of products shipped via trade agreements.

Comments: *Auditors identified two incidents where shipped products were not compliant to the US/COR equivalency arrangement terms:*

- *CUC issued a verification statement to an operation exporting product to Canada under the terms of the US/COR equivalency arrangement that inaccurately stated the terms. The document issued to the operation confirming the status of the products stated: "Contain no products derived from animals." A correct attestation must state: "Agricultural products derived from animals (with the exception of ruminants) must be produced according to livestock stocking rates as set out in CAN /CGSB32.310-2006."*
- *CUC issued a transaction certificate for an organic product shipped from China to Canada without an attestation statement. No attestation statement was contained on any of the shipping documents.*

2016 Corrective Action: CUC updated the export affidavit using the correct livestock language. Additionally, CUC has amended its Import and Transaction certification instruction to include the correct and appropriate information for the US/Canadian agreement and other agreements and equivalencies. The CUC staff will be notified via the CUCI Newsletter and the Scheme manager will check implementation during the annual internal audit.

2017 Verification of Corrective Action: The auditor reviewed examples of completed affidavits and no issues were identified.

NP5264PZA.NC7 – Cleared - 7 CFR §205.504 (b)(5)(i – iv) states "A private or governmental entity…(b) *Administrative policies and procedures.* (5) 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; and."

Comments: *CUC does not have complete procedures or instructions in place to provide the required information, defined above, to the public upon request.*

2016 Corrective Actions: CUC updated its organic production instruction to state points i-iv above will be made available to any member of the public upon request. The CUC staff will be notified via the CUCI Newsletter and the Scheme manager will check implementation during the annual internal audit.

2017 Verification of Corrective Actions: The Organic Production Instruction was reviewed by the auditor and contains the required administrative procedure for making information available to the public. There have been no requests for information from the public.

NP5264PZA.NC8 – 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: *The following facts demonstrate that CUC staff are not be adequately trained or sufficiently knowledgeable of the USDA organic regulations:*

a) *CUC issued a Notice of Revocation after issuing a Notice of Suspension to an operation for a willful violation.*
b) *During a review of labels, there are several organic chocolate bar labels that were approved by CUC with the USDA seal in white with a transparent background.*
c) *During the review of organic product labels, the auditor found the "Certified organic by***" statement was missing on an organic ghee label.*
d) *During the review of organic product labels, the auditor found that sea salt is listed along with organic ingredients in the ingredient panel with the title "all organic ingredients:…" This appears to be identifying the sea salt as organic on various chocolate bars containing sea salt.*
e) *During the witness inspection, the auditor asked the inspector about the requirements for retail and wholesale labels and his response demonstrated a lack of knowledge about labeling requirements.*
f) *During the witness inspection of a perennial crop operation the inspector indicated in the inspection report that the crop rotation practice standard was not applicable.*

2016 Corrective Action: CUC amended its instruction to state a notice of suspension or a revocation can be sent in the adverse action process and additionally clarified uncertified clients will be sent a denial of certification. CUC has amended its inspection instruction procedure explaining the correct use of the "USDA Organic" seal, certifier identification and ingredient labeling. CUC has provided additional information for inspectors to actively verify the crop rotational requirement of perennial crops. CUC will conduct an annual training (tentative date Dec. 2016/Jan 2017) of auditors and CUC staff on the USDA NOP audit findings and the related topics to improve the understanding of the USDA regulations. The CUC staff will be notified via the CUCI Newsletter and the Scheme manager will check implementation during the annual internal audit.

2017 Verification of Corrective Action: The auditor reviewed the training presentation given to CUC certification staff in December 2016 and January 2017 and the modified procedures and templates. No issues were noted. Approved labels were sampled and reviewed, and all were compliant.

NP5264PZA.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." 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. "NOSB Recommendation November 19, 2008 *Certifying Operations with Multiple Production Units, Sites, and Facilities under the National Organic Program* states," III.D. Inspecting the Producer Group Operation. "Verification of the OSP is largely accomplished by a thorough audit of the functioning of the Internal Control System, accompanied by a physical examination of every Production Unit (generally the headquarters or common regional handling or collection facility) and a meaningful sample of subunits within any given Production Unit (with one exception – all new entrants to a Production Unit must be inspected in their first year with the group. In subsequent years, all successfully certified operations will be inspected per the sampling method described below) In a producer group operation, the Production Unit is the smallest portion of the operation that must be inspected every year."

Comments: *The auditors found a Grower Group certification file was unclear whether all new entrants to a Production Unit were inspected by CUC during their first year with the group. It appears that new entrants are inspected as part of the Internal Control System (ICS) during the new entrants conversion years. Also, CUC procedures state that each member operation must be inspected by CUC prior to selling organic products through the group, however, when the auditor asked for documentation to verify this procedure, CUC was not able to produce the records. The auditors later obtained the following CUC inspection work procedure:*

(INSP.ORG.W01(22)) 2. Farm visits (re-inspections) and witness audits.
b. Selection of farms for re-inspection states, "When selecting farmers for re-inspection the following information is relevant to the selection:
Total number of farmers at each project site? Any new farmers or even new project sites?
□ The basic approach would be to plan the number of re-inspections per project site proportionally to number of farmers at each site; i.e., site with more farmers □ more re-inspections.
□ Any new projects sites will be particularly interesting to inspect.

This CUC policy does not require the inspection of all new entrants to a production unit in their first year with the group.

2016 Corrective Actions: CUC amended its inspection instruction to state all entrants with new organic status to a grower group must be inspected in the first year by the certifier. CUC notified staff about the procedure change via the CUC certification system and the Scheme manager will randomly check the implementation of the change during the annual internal audit.

2017 Verification of Corrective Action: The auditor reviewed the updated procedures in the CU Programme Manual Organic Production, which were compliant. The new procedure was recently implemented and there were no grower group inspections reports available for review.

NP5285ZZA.NC1 – **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." 7 CFR §205.205 (a-d) states, "The producer must implement a crop rotation including but not limited to sod, cover crops, green manure crops, and catch crops that provide the following functions that are applicable to the operation: Maintain or improve soil organic matter content; Provide for pest management in annual and perennial crops; Manage deficient or excess plant nutrients; and Provide erosion control." Furthermore, 7 CFR §205.2 defines crop rotation as: The practice of alternating the annual crops grown on a specific field in a planned pattern or sequence in successive crop years so that crops of the same species or family are not grown repeatedly without interruption on the same field. Perennial cropping systems employ means such as alley cropping, intercropping, and hedgerows to introduce biological diversity in lieu of crop rotation."

Comments: *The crop witness audit inspector indicated the crop rotation practice standard was not applicable to a perennial crop operation and did not identify any issue of concern for the operation not addressing it.*

2016 Corrective Action: CUC updated the inspector instruction to clarify the meaning of crop rotation in perennial crops as defined in the USDA organic regulations. Staff and inspectors were informed of the change in inspection instruction through CUC's newsletter. The scheme coordinator will randomly check the implementation of this change during the review of inspection reports.

2017 Verification of Corrective Actions: The auditor reviewed the training presented to certification staff in December 2016 and January 2017. The auditor reviewed the procedure changes in the inspection instructions, inspection report template, and the organic system templates. No issues were noted by the auditor.

NP5285ZZA.NC2 – **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."

Comments: *The certified handling operation was not provided, nor informed about the NOP Handbook by CUC.*

2016 Corrective Action: CUC has added the NOP handbook to its public website and included the website link information in the welcome letter sent to all newly contracted clients. Additionally, CUC has added the link to the client portal in CUC's electronic certification system. Staff and inspectors were informed of the change through CUC's newsletter. The scheme coordinator will randomly check the implementation of this change during the annual internal audit.

2017 Verification of Corrective Action: The auditor reviewed the training presentation provided to CUC certification staff that covered the NOP Handbook as a resource. The auditor reviewed the CUC website with a link to NOP Handbook. CUC will conduct an annual review in September 2017 and will assess the effectiveness of the measures implemented.

NP5285ZZA.NC3 – **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: *Auditor interviews with the CUC Thailand inspectors and CUC Indonesia certification manager revealed they were not aware of the NOP Handbook.*

2016 Corrective Action: CUC has added the NOP handbook to its internal and external website and included the website link information in the inspection procedure under the definitions section. Staff and inspectors were informed of the change through CUC's newsletter. The scheme coordinator will randomly check the implementation of this change during the annual internal audit.

2017 Verification of Corrective Action: The auditor reviewed the training presentation provided to CUC certification staff that covered the NOP Handbook as a resource. The auditor reviewed the CUC website with a link to NOP Handbook. The CUC will conduct an annual review in September 2017 and will assess the effectiveness of the measures implemented.

NP5285ZZA.NC4 – **Cleared -** 7 CFR §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;" 7 CFR §205.201(a)(5) states, "…An organic production or handling system plan must include: A description of the management practices and physical barriers established to prevent commingling of organic and nonorganic products on a split operation and to prevent contact of organic production and handling operations and products with prohibited substances;" 7 CFR §205.272(a) states, "The handler of an organic handling operation must implement measures necessary to prevent the commingling of organic and nonorganic products and protect organic products from contact with prohibited substances."

Comments: *The handling witness audit inspector did not identify an issue of concern regarding the certified operation's OSP not addressing commingling of organic and nonorganic products. The operation infrequently processes non-organic products. The inspector verified the steps taken by the operation to prevent commingling and reviewed records verifying the prevention of commingling but did not identify that these procedures must be included in the approved OSP.*

2016 Corrective Action: CUC confirms that its current procedure is to review OSP's prior to inspections and the inspector is to verify the OSP to the operations actual practice. CUC is reiterating this practice to the inspectors via the CUC newsletter. Also, CUC will provide training (December 2016/January 2017) to auditors and CUC staff about the importance of comparing the OSP with the activities performed by operators. The scheme coordinator will randomly check the implementation of this change during the annual internal audit.

2017 Verification of Corrective Action: The auditor reviewed the training provided to CUC certification staff and the new procedure. No issues were identified.

CERTISYS Mid-term Assessment Chronology Log

Audit Identifier (if any): NP4195OOA

Audit Type: Mid-term Assessment

Accredited Certifying Agent Name: CERTISYS (CSYS)

Accreditation Manager: Robert Yang

Date	Activity
7/31/14	NOP received audit checklist and report.
8/13/14	Audit report review assigned to RY
8/25/14	RY reviewed audit report. Drafted Noncompliance Report and Notice of Noncompliance. Submitted to RM/LC for review.
8/27/14	Reviewed by LC. Revised, contacted Darrell Wilson for additional information.
9/2/14	Confirmed with Darrell Wilson via phone that the inspector identifies potential noncompliances at inspection, final determination made by Certification Officer thereafter; updated Noncompliance Report accordingly.
9/3/14	RY submitted to Cheri for final review and signature.
9/23/14	RY issued NC report, NoNC via email.
11/13/14	RY received CA submission from CSYS.
11/28/14	RY reviewed, requested the following additional information. 1) NP4195OOA.NC1 a. The noncompliance states that document MA1629en01 was found to be incorrectly stating that EU-certified organic ingredients could be used in NOP-certified organic finished products if the EU-certified organic ingredients met the terms of the EU-US Organic Equivalency. • *Has this document been revised? If so, please submit the revised version.* b. The noncompliance states that during the witness audit, the operation (Belcolade) was found to be using EU certified ingredients in an NOP-certified product. • *Aside from the general notification you have submitted, has any follow-up with that specific operation taken place in order to bring the operation into compliance at this time? If so, please submit documented evidence of the actions taken both by CSYS to ensure that the operation is currently compliant.* • *Also, has CSYS conducted a review of its other NOP-certified operations to ensure that all other operations are compliant? If so, what were the results of the review?* 2) NP4195OOA.NC2

	a. According to your Corrective Actions Report, CSYS has updated the templates of notification of noncompliance, notification of noncompliance resolution, proposed suspension, proposed revocation, and suspension. However, the noncompliance states that the following notifications were also not being sent via a delivery service which provides dated return receipts: i. rejection of mediation ii. revocation iii. CSYS's responses to all notifications stated in the noncompliance • *Please clarify what actions CSYS has taken to correct the noncompliance regarding the above notices, and submit documented evidence of the corrections.*
12/8/14	RY received response, including additional supporting documentation.
12/19/14	RY reviewed response, drafted CA report
12/2314	RY submitted CA report, NoContAccred to Renee M for review.
1/12/14	RY received file from RM with instructions for further editing and verification.
1/13/15	RY requested from CERTISYS (Nathalie) via email the following: • Information regarding the actual service used for sending the NoNC that states "sent via: Certified mail." • Explanation of how staff have been made aware of the change in procedures, including dates of training provided, revised procedures
1/15/15	Nathalie responded with the following: On every NOP lettre sent out we now mention 'Sent via: Certified mail'. This is the instruction to the person responsable for putting the letters in the mail. These letters are thus sent via the normal Belgian post service which provides a service which we call AR (Accusé de Réception). We receive the signed stubb back after a few days, this attests to the reception of the letter by our client. As I said, the instruction is thus on the letter itself. Additionnally, I sent out an instruction by email to explain this change. See document attached (email of 29th Augsut 2014). As an example I include a recent letter sent to our operator Barry Callebaut with the signed studd AR included. RY updated the CA report; submitted the revised CA report, NoContAccred to Renee M for review

USDA Agricultural Marketing Service

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Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Certisys (CSYS). An onsite audit was conducted and the audit report reviewed to determine CSYS's capability to continue operating as a USDA accredited certifying agent.

GENERAL INFORMATION

Applicant Name	Certisys (CSYS)
Physical Address	Rue Joseph Bouché 57/3, B-5310 Bolinne, Belgium
Mailing Address	Same as above
Contact & Title	Nathalie Boes, Manager of Quality Department
E-mail Address	nathalie.boes@certisys.eu
Phone Number	+39 081 600 377
Reviewer(s) & Auditor(s)	Robert Yang, NOP Reviewer; Darrell Wilson, On-site Auditor.
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: August 18, 2014 Onsite Audit Date(s): July 14-17, 2014
Audit Identifier	NP4195OOA
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 CSYS's certification system.
Audit & Determination Criteria	7 CFR Part 205, National Organic Program as amended
Audit & Review Scope	CSYS's certification services in carrying out the audit criteria during the period October 7, 2011 through July 17, 2014

ORGANIZATIONAL STRUCTURE:

Certisys is a for-profit business, which was initially accredited as a USDA NOP certifying agent on February 12, 2007 for the scopes of crops, wild crops, and handling. Certisys is also accredited by the Belgian Accreditation Body (BELAC) to EN 45011 for the certification of products in accordance to (EC) No 834/2007 and the Belgian Organic Standard.

Certisys maintains three offices in Belgium -- in Bolinne, Ghent, and Brussels. Certification activities are only conducted out of the main office in Bolinne. The office in Ghent, Belgium is utilized by inspectors to access the certification network system or to conduct office work. The office in Brussels, Belgium is used for administrative purposes only.

Certisys's staff includes a quality manager; a certification officer (the final decision maker), an administrative staff member, and 2 staff and 2 contract inspectors. Records confirmed that personnel had sufficient education, training, and experience. Current conflict of interest disclosure reports were on file for all staff. Confidentiality statements are signed upon hire.

CERTIFICATION PROCESS:

Operations applying for certification are provided with an application package that includes an application, applicable organic system plan, general information on certification, a fee schedule, service provision contract, and a link to the Final Rule (e-CFR) on the NOP and Certisys websites. The initial review for completeness and compliance is conducted by the inspector. The inspectors also review the labels for operations that process products that require labeling. After completion of the review, the inspector conducts the inspection. During inspections, inspectors identify potential non-compliances along with corrective actions to be taken and due dates for implementation. Any potential non-compliance identified by the inspector is reviewed by the Certification Officer or designee for validity and final determination. If there is a change in what the inspector discussed with the operation it is identified in the determination letter sent to the operation. The Certification Officer is also responsible for reviewing corrective actions once they are received. Continuing certification follows the same process as initial certification with the exception that only changes to the organic system plan need to be submitted.

Certisys has a system in place for reviewing materials. Inspectors conducting initial/update reviews review the materials indicated on the organic system plans and then verify the materials during the onsite inspection against those listed on the organic system plan. Certisys does not conduct reviews for liquid nitrogen products where the nitrogen content is greater than 3%. If a review is needed they will verify the product against an approved list from an accredited certifier that conducts such reviews.

Since the previous USDA NOP assessment in 2011, there were 60 operations which surrendered their NOP certification. The majority of these surrendered as a result of the EU-US equivalency Arrangement implementation. During the same period, no applicants were denied certification and no notices of suspension/revocation were issued. There were no requests for mediation, no appeals, and no cases of willful violations.

Certisys has a procedure for conducting grower group certification. At least 25% of the sub-units must be randomly selected. A risk factor is considered when selecting some of the sub-units. A review of one of the grower groups verified that selection of sub-units was in accordance with the established procedures.

Certisys's certified operations are exporting product to the United States under the US/EU Equivalency arrangement.

ADMINISTRATIVE RECORDS AND PROCESSES:

The primary document for NOP certification is the General management of NOP applicants. This document is supported by various documents and procedures. All forms/templates are

mailed or emailed, and are available on Certisys's website. Annual reviews are being conducted in accordance with procedures. Review of training indicated that ongoing training is being conducted.

SUMMARY OF WITNESS AND REVIEW AUDITS CONDUCTED:
One announced annual inspection was witnessed during the assessment. The operation was a handler/processor that produces various chocolate products, which are then sold in bulk to processors that produce chocolate retail products. The inspection activities conducted, including the conclusions of the inspector, were appropriate.
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NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether Certisys'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 Certisys.

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.

From 2008 Initial Assessment:

NP8252ZZA.NC1 – Cleared - NOP §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." *CERTISYS currently has two documents identified in their quality system used to document performance of Administrative Staff and Certification Staff for annual evaluation; however, the records of evaluations for 2007 were not available for review during the audit.* **Corrective Action:** CERTISYS revised their performance evaluation form (OR3411) to specifically address the performance of staff related to their NOP responsibilities. CERTISYS established a performance evaluation schedule to ensure annual performance evaluations are conducted and documented using the new form. **2011 Renewal Assessment Finding:** *Annual performance reviews were not conducted for certification personnel (inspectors or Director) or the Quality Manager and there is no performance evaluation procedure in place for the Certification Director or Quality Manager. There is an "Annual*

Performance Evaluation" document on file for all inspectors; however, this is a form for the inspector to provide feedback to CERTISYS addressing process issues, questions, and concerns. In some inspector files, there were evaluations for individual files, but this did not take into account overall performance on an annual basis. **Corrective Action 2012:** CSYS provided a revised performance evaluation procedure that clearly shows all personnel to be evaluated; this includes all certification personnel. The procedure requires all performance evaluations be completed within the first two months of the calendar year. CSYS also provided templates for performance evaluations, based on title and job description (which clearly defines job duties and responsibilities). **Corrective Action Verification:** Review of the performance evaluations confirmed that annual performance reviews were conducted for all personnel involved with NOP certification. Reviews were compiled in February and reviewed and signed by the individual being evaluated.

From 2011 Renewal Assessment:

NP1273MMA.NC1 – **Cleared -** NOP §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." *In general, organic system plans (OSP) do not have sufficient information to meet the requirements of §205.201 on what must be included in the OSP. A review of one OSP verified that it did not include information for 5 of the 6 required areas; an inspection was conducted and then the lack of an inadequate OSP was identified by CERTISYS. A review of the a second OSP verified it did not provide a description of practices and procedures to be performed other than general information on the processing steps but not the specifics of the production processes, cleaning practices, and equipment utilized*. **Corrective Action**: CSYS implemented a new review reporting form that requires all §205.201 be provided prior to inspection. A copy of the review form was provided for the NOP's review. Inspectors were trained (December 15, 2011, post-audit) on the new report form and on NOP requirements prior to inspection. [NOTE – CSYS's system is to have the inspectors be both the application reviewer and the inspector. The in-house NOP training that occurred on December 15, 2011, clarified the certification role of inspectors specifying that they cannot obtain information to complete an OSP at the inspection.] **Corrective Action Verification:** A review of several certified operation files confirmed that the new reporting form is used. Reviewed OSPs were confirmed to be complete and had adequate information to determine compliance.

NP1273MMA.NC2 – **Cleared -** NOP §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; 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." *During the witness audit of the wild crop and handling operation the following was found:*

1) Not all harvesting areas were visited; 1 of 3 harvesting areas were visited and of

that one area which had 5 subplots, only 2 subplots were visited;
2) There were no audit trail exercises conducted for traceability or balance;
3) There was no verification of compliance with §205.271 for the facility pest management practice standard; and
4) There was not a full review or verification of the recordkeeping system in place for the wild crop or handling portions of the operation. The inspector requested that quantities be recorded on decanting documents and that cleaning records be implemented.

Corrective Action: CSYS correctly asserts in its response that this NC is specific to one witness audit, not all that were conducted. The client in question has since discontinued NOP certification in light of the US-EU Organic Equivalency Arrangement (US-EUOEA). Also, the inspector observed during this witness audit is no longer contracted for inspection work. About the issues noted above, CSYS indicated that these were topics for training of inspectors in November 2011; CSYS also cited the client with a Notice of Non-compliance for lack of recordkeeping issues identified. About the lack of audit trail exercise, the inspector continued his inspection after the witness audit (in subsequent days at different harvesting locations) and submitted calculations with his report. **Corrective Action Verification:** Observations made during the witness audit indicated that the inspector verified the operation's compliance to the regulations during the inspection.

NP1273MMA.NC3 – **Cleared -** NOP §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, the results of any analyses… If the certifying agent determines that the organic system plan and all procedures and activities of the applicant's operation are in compliance… the agent shall grant certification." *A review of the records provided verified that certification decisions were not being conducted within a reasonable time for the 2009 and 2010 certification years. For 2009, the time from inspection to a certification decision being made (where the operation was issued certification, a notice of non-compliance, or an updated certificate) was between 2 to 23 months with an average of 14 months. For 2010, the time was from 2 to 12 months with an average of 8 months. For 2010, there were 10 new applicants for certification with the time from inspection to the certification decision being made from 2 months to 21 months with an average of 9 months. CERTISYS stated that this was due to a delay in receiving the inspection reports from the Italy office (Ecogruppo Italia) or having to go back and forth with the Italy office to obtain sufficient information in the inspection report in order to make a certification decision and had taken steps to correct this by creating new inspection report review forms and redoing their agreement with the office*. **Corrective Action:** As noted in the NC above, CSYS also notes that the issue with long timeframes for certification decisions was a result of delay in receiving information from the Italy office (operated by Ecogruppo Italia), including further delays of having to go back/forth with the Italy office for incomplete information. No discrepancies were noted with certification timeframes for files handled exclusively at CSYS; these timeframes were considered "reasonable" at audit and remain so in CSYS' response. At this time, CSYS has dissolved its relationship with Ecogruppo Italia as of June 1, 2012, when the US-EUOEA was implemented; CSYS is the sole operation

responsible for certification activities. CSYS provided a spreadsheet for all processing times of CSYS Belgium files in 2011, demonstrating a reasonable timeframe for certification decision. CSYS is confident in its ability to maintain these timeframes, especially as it is also expecting loss of more files due to US-EUOEA. As a result of the dissolution of the Ecogruppo Italia relationship with CSYS, identified as the source of this NC, no corrective action plan was specifically provided. As noted, evidence of "reasonable" certification timeframes was provided. **Corrective Action Verification:** A review of certified operation files confirmed that decisions are made within a reasonable time.

NP1273MMA.NC4 – **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." *For the wild crop and handling operation visited during the witness audit, there were two certificates issued (CNOP-1101790-en and CNOP-1100385-en). Neither certificate identified the operation as a wild crop*. **Corrective Action:** CSYS notes that its database has been updated to include "wild crop" as a scope of NOP certification, a component missing in the past. As the operation in question surrendered NOP certification, the specific certificate was not updated; however, CSYS provided a template certificate showing the display of "wild crop" as a certification scope. CSYS has no wild crop clients at this time. If effectively implemented for future wild crop clients, CSYS' response demonstrates capability to comply with NOP accreditation requirements. **Corrective Action Verification:** Certisys currently does not have any wild crop operations; however all certificates reviewed display the correct category on the certificate.

NP1273MMA.NC5 – **Cleared -** NOP §205.405 (d)(1) states, "A notice of denial of certification must state the reason(s) for denial and the applicant's right to: Reapply for certification pursuant to §§205.401 and 205.405(e)." *A combined notice of non-compliance and denial of certification was issued to a crop, wild crop, and handling operation. The notification did not include the applicant's right to reapply for certification. In addition, the notification was contradictory in that it stated it was an official denial of certification pursuant to §205.405(a) but gave 30 days to provide corrective actions and avoid denial and stated the operation could "file an appeal to this proposed suspension.*" **Corrective Action:** CSYS implemented a new Notice of Denial template that meets the requirements into its system; a copy of the template was provided for objective evidence. CSYS notes in its response that this new template has not yet been needed for use, and it is the only template available for this type of Notice in its database. **Corrective Action Verification:** No Notice of Denials were issued since the last assessment: however, Notice of Denial template presented for the auditor's review complies with requirements.

NP1273MMA.NC6 – **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." **Corrective Action:** Please see responses to

individual points below.

Updates to the organic system plans (OSP) are received prior to inspection; however, the "update" is a newly submitted OSP without 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, pursuant to §205.200. **Corrective Action:** CSYS updated its annual update form for all clients, which has been implemented. The changes made include the requirement of submitting a summary statement, as well as any documentation detailing deviations from, changes to, and/or modifications to the previous year's OSP. CSYS has made this updated form available on its website to all operators. **Corrective Action Verification:** Files reviewed confirmed that the updated reporting form and process is implemented. Requests for additional information are sent to the certified operation as required.

In one handler file reviewed, the product was certified as 100% organic but only qualified for the "organic" classification because the processor was utilizing organic sugar as opposed to 100% organic sugar. **Corrective Action**: CSYS revised the certificate for this operation to properly note the correct NOP labeling category of "organic," based on product compliance with §205.301(b). **Corrective Action Verification:** All files reviewed and observations at the witness audit demonstrated that labeling categories are correctly approved.

NP1273MMA.NC7 – **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 noncompliances with the Act and the regulations in this part that are identified in the evaluation." *The annual program review in place is an internal audit and management review which is only an audit of the quality management system. There is no inclusion of certification activities as they pertain to the review of files from application review through the certification decision in comparison to NOP standards*. **Corrective Action:** CSYS revised its policy and procedure for annual reviews to ensure all certification activities are properly addressed; a copy of the revised procedure has been attached for review. CSYS also implemented a new document in the annual review process to specifically address certification decision making; separate documents are used for OSP reviews and inspector evaluations. **Corrective Action Verification:** Certisys conducts internal reviews specific to each program (e.g. NOP Certification) they provide services and the reviews are then incorporated into a master internal audit for management review.

NP1273MMA.NC8 – **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." *Notices of non-compliance include a table attachment which includes a required/prescribed corrective action plan that the operation is directed to implement to address the identified non-compliance. This extends into "consultancy services, to… certified operations, for overcoming identified barriers to certification.*" **Corrective Action:** CSYS revised its notices of non-compliance and inspection forms so that prescribed noncompliance (NC) corrective actions are no longer included; specifically, the inspection form, from where prescribed NCs were generated, has been revised to exclude the prescribed NC table. This topic was covered in inspector trainings in November and December 2011. Former versions of the forms are not available for inspector use. **Corrective Action Verification:** Notices of Non-compliance reviewed no longer include a column for required/prescribed corrective action plan.

NP1273MMA.NC9 – **Cleared -** NOP §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." *Inspectors are responsible for the organic system plan (OSP) review prior to inspections for initial applications and annual updates, as well as identifying non-compliances at the time of inspection. Inspectors are also responsible for verifying information within the OSP, collecting new OSP information, citing non-compliances, identifying corrective actions and due dates for implementation, and obtaining a commitment of correction from the operator. The Certification Director and/or other assigned staff member do not conduct a technical review of the clients file prior to issuing the official notice of non-compliance. In most cases, the notice of non-compliance mirrors that of the exit interview in the inspection report which is the citation of non-compliance issues. Lastly, inspectors are responsible for reviewing corrective actions when they are received. This leaves the inspector responsible for the certification determination*. **Corrective Action:** CSYS notes that the job descriptions of the inspectors and certification manager have been revised to show a clear separation in the responsibilities of each. The revised job description of the inspector indicates application review and inspection responsibilities and no longer indicates responsibility of review of corrective action responses. The certification manager job description now clearly requires technical review of the file before any certification decision. The inspectors also received training on this topic at the November 2011 training session. CSYS provided copies of all revised job descriptions as part of its response. **Corrective Action Verification:** Corrective actions continue to be reviewed by the inspector; however, once the inspector is through with their review, the information is then forwarded to the Certification Manager who reviews the documents and makes the final decision.

NP1273MMA.NC10 – **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."

At the time of the audit CERTISYS was using four fee schedules for NOP certification; one for the Belgium office, one for countries outside of Europe, one for the Italy office, and one for Portugal. The Portugal fee schedule was not submitted to the Administrator. **Corrective Action:** As a result of the US-EUOEA and dissolution of the relationship with Ecogruppo Italia (and also Certiplanet, the Portugal certifier CSYS was working with at the time of audit), CSYS now has only two fee schedules. CSYS intends to submit current versions of these fee schedules with their next annual update in 2013 (February); previous versions were already submitted. The Portugal fee schedule, cited in the NC above, is one that is no longer applicable as a result of Certiplanet no longer working with CSYS. Given these structural changes, there is no applicable corrective action for this issue. **Corrective Action Verification:** The two fee schedules in use have been submitted to the Administrator.

NP1273MMA.NC11 – **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, including administrative staff, certification inspectors, members of any certification review and evaluation committees, contractors, and all parties responsibly connected to the certifying agent." *The job description for inspectors does not include the responsibility of conducting the initial review for compliance which has been placed on them by CERTISYS. The certification director's job description is too general in the responsibilities of conducting the final review and making the certification decision*. **Corrective Action:** As noted in NC9 above, job descriptions for all inspectors to reflect initial application review as a responsibility. The job description for the certification officer has been updated to reflect certification decision as a responsibility. All staff has seen the new job descriptions and inspectors were trained on such in November 2011. **Corrective Action Verification:** Job descriptions remain as submitted for corrective actions. Interviews and observations confirm that the changes have been implemented and are effective.

NP1273MMA.NC12 – **Cleared -** NOP §205.642 states, "Fees charged by a certifying agent must be reasonable… 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 set the nonrefundable portion of certification fees; however, the nonrefundable portion of certification fees must be explained in the fee schedule… The fee schedule must explain what fee amounts are nonrefundable and at what stage during the certification process fees become nonrefundable." *CERTISYS provides fee estimates to foreign applicants but not to those operations in European countries. In the files reviewed, five of the seven operations did not receive a fee estimate for the cost of certification and the annual cost of updating the certification. Not all of the fee schedules describe the non-refundable fees and the stages at which they become non-refundable. Additionally, the Italy fee schedule gives a range of what the certification fees can be but does not include the criteria for how the fees are determined*. **Corrective Action:** As noted in NC10, the Italy fee schedule is now null and void as a result of the US-EUOEA and the dissolution of the certification

arrangement with CSYS. The two fee schedules in place describe non-refundable fees; a copy of the 2012 fee schedules has been provided in the response and includes non-refundable fees and when they apply. CSYS notes that all clients will receive an estimate in the 2013 certification year. The template for fee determination requires an estimate be included, and will be used with each tariff beginning in the 2013 year. **Corrective Action Verification:** Review of files selected confirmed that cost estimates are being sent out to clients. Cost estimates are sent out at the end of each year for operations renewing certification. There have been no new applicants since the last assessment.

NP1273MMA.NC13 – Cleared - NOP §205.662 (a)(1) – (2) states, "When an inspection, review, or investigation of a certified operation… reveals any noncompliance with the Act… 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." *Notices of non-compliance issued by CERTISYS do not provide a description of the non-compliance or the facts upon which the non-compliance is based. Notices identify the non-compliance to the extent of including a citation number from the NOP standard for the "observation of non-compliance" heading in the attachment to the notice. The notice attachment does not include what information was observed, reviewed, or verified at the time of inspection as the basis for the facts upon which the non-compliance is based*. **Corrective Action:** As noted in NC8, CSYS revised its inspection form and notice of non-compliance templates so that specific, prescribed non-compliances are not cited. Rather, CSYS notes that the revision to the forms, as well as certification template letters, have been adapted to clearly state on what information the NC is based. **Corrective Action Verification:** Non-compliances reviewed contained descriptions and facts upon which each noncompliance is based.

NP1273MMA.NC14 – Cleared - NOP §205.670 (d)(1) states, "Results of all analyses and tests performed under this section: Must be promptly provided to the Administrator." *CERTISYS submits test results which are positive but does not submit those results which are negative. Of 66 samples tested, only four (those that were positive) were submitted to the Administrator*. **Corrective Action**: CSYS notes that all samples taken for NOP operator files now have an "NOP" designation in the database for identification – both for forwarding to the NOP and for identifying clearly those that are "negative." Inspectors were trained on this new system in the November 2011 training. **Corrective Action Verification:** Sample results are no longer required to be submitted; sample results were available for review during the onsite audit.

NP1273MMA.NC15 – Cleared - NOP §205.670 (d)(2) states, "Results of all analyses and tests performed under this section: Will be available for public access, unless the testing is part of an ongoing compliance investigation." *Contracts with clients indicate that CERTISYS will not share information collected at inspection with outside parties, unless required through official governmental or accreditation bodies' request. Although no requests from the public have been received, the system is not set up to allow for the release of the results if requested*. **Corrective Action:** CSYS has revised

its contract for NOP clients to reflect that results of analyses and tests may be made public. Contracts are signed annually, upon initial request for certification service as well as in continuing certification years. **Corrective Action Verification:** Revised contracts were sent to clients to be signed. CSYS has received most of them but are still waiting on a few clients to respond.

Noncompliances Identified during the Current Assessment

NP4195OOA.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". Additionally, 7 CFR §205.102 (b) states, "Any agricultural product that is sold, labeled or represented as "100 percent organic," "organic," or "made with organic (specified ingredients or food group(s))" must be: … handled in accordance with the requirements specified in §205.101 or §§205.270 through 205.272 and all other applicable requirements of this part 205." Organic ingredients used in products certified to the USDA organic regulations must be certified to the USDA organic regulations. *Certisys' MA1629en01states "NOP operators, operating on EU or US Territory, are able to use EU-certified organic ingredients in NOP-certified organic finished products IF and only IF, the EU-certified ingredients meet the terms of the EU-US Organic Equivalency Arrangement." It was also observed during the witness audit that the operation was using EU certified ingredients in product that was being certified as NOP certified organic.*

NP4195OOA.NC2 – 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 of noncompliance, rejection of mediation, noncompliance resolution, proposed suspension, proposed revocation, suspension, revocation and responses to these notifications are sent via postal mail and do not provide for a dated return receipt.*

USDA Agricultural Marketing Service

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

NOTICE OF NONCOMPLIANCE

SEP 2 3 2014

Ms. Nathalie Boes
CERTISYS sprl/bvba/GmbH
Rue Joseph Bouche 57/3
B-5310 Bolinne
Belgium

Dear Ms. Boes:

On July 14-17, 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 CERTISYS sprl/bvba/GmbH (CSYS) organic certification program as part of the its USDA Mid-term Accreditation Assessment. On August 18, the NOP reviewed the results of the onsite audit to determine CSYS's compliance to the USDA organic regulations. A copy of the assessment report, NP4195OOA, is enclosed for your reference.

As the report indicates, 16 corrective actions for prior noncompliances, NP8252ZZA.NC1 and NP1273MMA.NC1 through NP1273MMA.NC15 were cleared and determined to be implemented and effective. Two new noncompliances, NP4195OOA.NC1 through 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 CSYS 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

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

Enclosure

cc: AIA Inbox
USDA Quality Assessment Division

Ecocert ICO Audit Chronology Log

Audit Identifier (if any): NP5166NNA

Audit Type: MidTerm

Accredited Certifying Agent Name: Ecocert ICO

Accreditation Manager (who is working on the project): Robert Yang

Date	Activity
7/14/15	Audit report review assigned to RY (RY out of office due to certifier audits 7/11 ~ 7/18; 7/28)
8/14/15	RY reviewed audit report (RY out of office conducting certifier audit 8/17 – 19)
8/21/15	RY discussed audit observations with auditor (Patty) via phone; drafted NoNC, NC Rpt
8/24/15	RY submitted drafts to RM for review
8/27/15	RY issued NoNC, NC Rpt
9/29/15	ECO ICO submitted corrective actions to NOP
10/5/15	CA Review assigned to RY (RY out of office due to certifier audits 10/17 ~ 10/29; annual leave: 11/16 ~ 11/30)
12/8/15	RY reviewed submission, sent ECO ICO email requesting additional information/CAs, due by 12/18/15: **NC1** - Procedure for Residue Testing [P11(v4(f)] incorrectly states, "Send a copy of the test result to the USDA only if test exceeds the NOP thresholds" 12/16 ECO ICO response: Resolved - Submitted corrected procedures (v5.f). **NC2** - Response did not address issues with Section 1, Conclusions of the inspection 12/16 ECO ICO response: Not Resolved – Did not address issues with Section 1. 3/2 ECO ICO response: Resolved – Provided revised inspector summary template – Inspection Findings; Instructions and examples of how Section 1 is used; evidence of training provided (emails, Power Point) **NC3** - Example 1: Attached objective evidence of training are records from certification training conducted for staff prior to the onsite assessment (on 3/20/13 and inspector report writing on 3/18/15) 12/16 ECO ICO response: Not resolved – referred again to past training provided

	12/28 ECO ICO response: Resolved – submitted email sent to inspectors with instructions on verifying an operation's compliance with §205.271 and §205.201 Organic Production and Handling System Plan via email. - Example 3: Submitted revised notice of noncompliance for failure to pay fees is still incorrect – refers to noncompliance with 205.642. Same mistake found on the 2015 Fee Schedule. 12/16 ECO ICO response: Not fully resolved – On NoNC template only changed reference to 205.405; 205.662(a); continues to use language from 205.642; submitted corrected 2016 fee schedule. 12/22 Call: Jessica explained that the incorrect template was submitted. 12/28 ECO ICO response: Resolved – submitted corrected NoNC template, correctly refers to 205.406(a) **NC4** - Compliance statements on TM-11 for products to Japan and NAQS certificate incorrect 12/16 ECO ICO response: Resolved – submitted revised TM-11 and NAQS certificate with correct compliance statements **NC5** - Submitted PO1 document is draft form in track changes 12/16 ECO ICE response: Resolved – submitted final, approved version. - TO1 document states that Ecocert ICO will provide a fee estimate verbally. 12/16 ECO ICE response: Resolved – submitted revised 2016 fee schedule with statement regarding verbal estimates removed.
12/18/15	ECO ICO submitted additional responses
12/21/15	RY reviewed additional responses (see above for review notes); discussed unresolved issues with Jeff Evard and Jessica Ervin via phone; sent follow up email – written response due by 12/28/15
12/28/15	Additional response received; (RY out of office from 12/31 to 01/04 due to annual leave, 1/12 – 1/15 certifier training)
1/21/16	RY reviewed additional response; drafted CA Report and Notice of Con Accred
1/26/16	Submitted to RM for review
2/11/16	Further discussed NC2 with CC – review of inspection report submitted with recent reinstatement request revealed that the information reported in Section 1 could be understood as the inspector reporting issues of concern.
2/12/16	RY called Jeff, explained the outstanding issue with Section 1. Jeff stated that ECO-ICO will be switching over to Ecocert SA's inspection report templates at the end of

	February or early March. Jeff will submit copy of the new inspector report template and plan for implementation. Jeff informed RY via email that he would not be able to obtain the draft template and timeline for implementation until early next week.
2/18/16	Jeff informed RY via email that Ecocert ICO will be working with Ecocert SA to address the additional issue.
2/19/16	RY held conference call with Aude Bonnet (Ecocert SA) to discuss NC2
3/2/16	Jeff submitted additional response and objective evidence for NC2
3/4/16	RY reviewed additional response and submitted documentation; revised CA Rpt
3/7/16	Submitted to CC for review

USDA Agricultural Marketing Service

1400 Independence Avenue, SW.
Room 2646-S, STOP 0268
Washington, DC 20250-0201

NATIONAL ORGANIC PROGRAM: CORRECTIVE ACTION REPORT

AUDIT AND REVIEW PROCESS

The National Organic Program (NOP) conducted a mid-term assessment of Ecocert ICO, LLC. An onsite audit was conducted, and the audit report reviewed to determine Ecocert ICO, LLC's capability to continue operating as a USDA accredited certifying agent. This report provides the results of the mid-term assessment and review of Ecocert ICO, LLC's corrective actions.

GENERAL INFORMATION

Applicant Name	Ecocert ICO, LLC (ECO ICO)
Physical Address	201 W Main Street, 2nd Floor
Mailing Address	Plainfield, IN 46168
Contact & Title	Jeffry Evard, Certification Manager
E-mail Address	Jeffry.evard@ecocert.com
Phone Number	(888) 337-8246
Reviewer(s) & Auditor(s)	Robert Yang, NOP Reviewer; Patricia Heckart, Onsite Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	Corrective Action Review: December 8, 2015 through March 4, 2016 NOP assessment review: August 21, 2015 Onsite audit: June 15-19, 2015
Audit Identifier	NP5166NNA
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 ECO ICO's certification system.
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	ECO ICO's certification services in carrying out the audit criteria during the period: May 31, 2012 through June 19, 2015

Ecocert ICO, LLC (ECO ICO), formerly Indiana Certified Organic, LLC, is a for-profit organization that has been accredited by the USDA National Organic Program (NOP) since April 29, 2002 to certify crops, livestock, wild crops, and handling operations. Ecocert ICO, LLC is a subsidiary of Ecocert, INC, a wholly-owned subsidiary of Ecocert SA. All certification activities are conducted from ECO ICO's sole office in Plainfield, IN.

NOP DETERMINATION:

NOP reviewed the onsite audit results to determine whether ECO ICO'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.

NP2121OOA.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.

NP5166NNA.NC1 – Accepted. 7 CFR §205.403(e)(2) states, "A copy of … any test results will be sent to the inspected operation by the certifying agent."

2015 Comments: *For two of the three files reviewed for pesticide residue sampling ECO ICO did not send a copy of the test results to the operation.*

2015 Corrective Action: ECO ICO revised its *Procedure for Residue Testing (P11.v5.f)* to include procedures for administrative staff to mail a hard copy of the test results to operations that do not have an email address. Operations that communicate with ECO ICO via email will continue to receive an electronic copy of their test results. ECO ICO conducted certification and administrative staff training on the revised procedures on September 10, 2015.

NP5166NNA.NC2 – Accepted. 7 CFR §205.403(c)(1) – (3) 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 §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; 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."

2015 Comments: *ECO ICO's inspection report template "Section 1. Conclusions of the Inspection" instructs the inspector to describe improvements, strengths, special attention items, and on-site conditions of the inspection. Additionally, the inspection report template has no section for the inspector to describe verification of corrective actions resulting from prior noncompliances.*

2015 Corrective Action: ECO ICO developed instructions on the use of Section 1. The instructions include examples of information that the inspector may record in the section, and clarify that the information noted in the section should not include issues of concern or advice to the operator. ECO ICO provided its certification staff and inspectors with training on the instructions via email on March 1, 2016, and has scheduled additional group training to take place on March 15, 2016. ECO ICO additionally submitted its revised inspection report summary template, *Inspection Findings*, which it plans to begin using on April 15, 2016. The template includes a statement that the implementation of corrective actions resulting from prior noncompliances was verified by the inspector. The details of the verification are to be documented by the inspector in Ecert. As a result, ECO ICO revised its *P05 Procedure for Conducting Inspections* and *P07 Procedure of Certification* documents to include instructions for the inspector to document the verification in Ecert and certification staff to verify whether the verification has been documented. ECO ICO provided its certification staff and inspectors with training on the revised template and instructions via email on February 27, 2016.

NP5166NNA.NC3 – Accepted. 7 CFR § 205.501(a)(1) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part; …."

2015 Comments: *Below are four examples identified during the onsite audit in which certification staff referenced the incorrect USDA organic regulation or made an incorrect certification determination:*

- *The review of an exit interview form indicated that the inspector noted that there was "no list of pest control and cleaner and sanitizer inputs included with the OSP and hence the inputs were not reviewed by office staff." The inspector referenced §205.271 (Facility pest management practice) even though the issue was an incomplete organic system plan/ annual update. The certification determination letter ECO ICO subsequently issued to the operation also referenced §205.271.*
- *The review of a certification determination letter ECO ICO issued indicated that ECO ICO had determined that "erosion was evident" at the operation, and that the operator had stated that oats could have been planted to prevent the erosion. ECO ICO did not issue the operation a notification of noncompliance for not complying with §205.203(a), which requires the implementation of cultivation practices that minimize soil erosion.*
- *The review of a Notice of Noncompliance ECO ICO issued to a new applicant for nonpayment of fees incorrectly referenced §205.405(Denial of Certification) and §205.642(Fees).*

- *The review of a label determination letter ECO ICO issued to an operation indicated that ECO ICO informed the operation that the processed product could be labeled as "100% organic" even though the product only qualified for the "organic" labeling category.*

2015 Corrective Actions:

- ECO ICO updated its Ecert database with the appropriate references for incomplete OSP's and provided its inspectors with instructions on verifying an operation's compliance with §205.271 and §205.201 Organic Production and Handling System Plan via email.
- ECO ICO clarified that the operation's issue with erosion was addressed in the certification determination letter as a minor issue instead of a noncompliance because the certification reviewer had determined that appropriate cultivation practices to minimize soil conversion were in place, and that the wind erosion would be resolved through planting of the next crop.
- ECO ICO revised its Notice of Noncompliance template for nonpayment of fees with the correct, applicable regulation. ECO ICO conducted staff training on the revised template on September 29, 2015.
- ECO ICO clarified that auditor was mistakenly provided with an incorrect, draft label determination letter. ECO ICO submitted the correct approval letter, which indicated that the operation's products were approved to be labeled as "organic."

NP5166NNA.NC4 – 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."

2015 Comments: *A review of TM-11 export certificates ECO ICO issued in February and April 2015 indicated that the certificates did not include the following compliance statement in the Remarks section: "Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances*."

2015 Corrective Action: ECO ICO updated its *P16 Issuance of Export or Import Certificate for Organic Certified Products under Equivalency Agreements* procedure with the compliance statement that must be included in documentation accompanying products exported to Taiwan. ECO ICO conducted certification and administrative staff training on the updated procedure on September 29, 2015.

NP5166NNA. NC5 – Accepted. 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."

2015 Comments: *ECO ICO does not provide a fee estimate for the total cost of certification. A fee estimate is provided only if the operation requests one.*

2015 Corrective Action: ECO ICO revised its *PO1 Procedure for Initial Application and Renewal* with instructions to provide new applicants with an estimate for the total cost of certification and certified operations with an estimate of the annual cost of updating certification

based on the previous year's certified products/site list. ECO ICO conducted certification and administrative staff training on the revised procedure on September 29, 2015.

USDA Agricultural Marketing Service

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NATIONAL ORGANIC PROGRAM: NONCOMPLIANCE REPORT

AUDIT AND REVIEW PROCESS

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

GENERAL INFORMATION

Applicant Name	Ecocert ICO, LLC
Physical Address	201 W Main Street, 2nd Floor
Mailing Address	Plainfield, IN 46168
Contact & Title	Jeffry Evard, Certification Manager
E-mail Address	Jeffry.evard@ecocert.com
Phone Number	(888) 337-8246
Reviewer(s) & Auditor(s)	Robert Yang, NOP Reviewer; Patricia Heckart, On-site Auditor
Program	USDA National Organic Program (NOP)
Review & Audit Date(s)	NOP assessment review: August 21, 2015 Onsite audit: June 15-19, 2015
Audit Identifier	NP5166NNA
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 ECO ICO's certification
Audit & Determination Criteria	*7 CFR Part 205, National Organic Program as amended*
Audit & Review Scope	ECO ICO's certification services in carrying out the audit criteria during the period: May 31, 2012 through June 19, 2015

ORGANIZATIONAL STRUCTURE:

Ecocert ICO, LLC (ECO ICO) is a for profit organization that was accredited as a certifying agent on April 29, 2002 to the National Organic Program (NOP) for crops, livestock, wild crops and handling operations. Since the 2012 assessment, ECO ICO (formerly Indiana Certified Organic, LLC) was acquired by ECOCERT Group and renamed Ecocert ICO, LLC. ECO ICO is a company established and registered in Indiana and is a 100% subsidiary of Ecocert INC., which is incorporated in Delaware and registered in California. Ecocert INC. is a 100% owned subsidiary of Ecocert SA. All certification activities are conducted out of ECO ICO's office in Plainfield, IN.

CERTIFICATION PROCESS:

Certification requests may be received via mail, email, fax, or by phone. Applications and certification forms are sent to the requestor via mail or email along with a link to the USDA organic regulations on the USDA website. All certification documents are available on the company's website – www.ecocertico.com. Upon receipt of an application and fees, a certification officer reviews the information for completeness and the applicant's ability to comply. Upon approval of the application, an inspector is assigned. After an inspection is conducted, a certification officer reviews the inspection report for completeness and the certification manager makes the certification decision.

All certified operations are required to submit their annual update by March 1st. The updated information is reviewed for completeness and compliance. Upon satisfactory completion of the annual update review a qualified inspector is assigned to conduct the inspection. The inspection report and any documents collected by the inspector are reviewed by a certification officer. The certification manager determines whether the operation continues to comply. If the operation is found to be compliant the operation is issued an updated certificate.

All materials must be reviewed and approved by ECO ICO prior to use. ECO ICO provides its certified operations with a material review guidance document. There are also documented procedures for staff to follow when reviewing materials. The certification officers are responsible for reviewing materials and may refer to the approved lists of OMRI or WSDA when making a determination of whether a material is allowed under the USDA organic regulations. For blended or multi-ingredient materials, the reviewer contacts the manufacturer to receive ingredient and manufacturing information as part of the material review process.

Certification officers use a labeling guide when reviewing labels for compliance. Label approvals are communicated to the client via letter or email. A copy of the approved label signed by the reviewer is maintained in the client's file. Inspectors verify label use during the onsite inspection.

ECO ICO has issued a limited number of TM-11 export certificates for products exported to Taiwan. ECO ICO has documented procedures for issuing export certificates and maintains a log for all certificates issued. Staff were found to be knowledgeable of the various export requirements.

ADMINISTRATIVE RECORDS AND PROCESSES:

ECO ICO maintains a quality manual and has documented procedures for all aspects of the certification process, including material and label review. ECO ICO uses ECERT for document and record control. Most records are maintained electronically. All documents and records are backed up to Ecocert SA's company server in France.

ECO ICO conducts internal audits and management reviews annually. Records of findings from the internal audit and subsequent corrective actions were available for review.

Staff and subcontracted inspectors are required to receive ongoing training each year. A record of all training conducted by ECO ICO and external training attended by certification staff is maintained in ECO ICO's T08 log.

SUMMARY OF WITNESS AND REIVEW AUDITS CONDUCTED:
A review audit of a crops and livestock operation in Waupan, Wisconsin was conducted. The operation grows organic corn, hay, peas, sweet corn, and pasture. The operation's organic livestock included dairy cows, which were providing milk for the purchased organic calves that were being raised for meat. Livestock were provided with access to outdoors year round. The operation was inspected annually, and was provided with an updated organic certificate each year. The operation's organic system plan, inspection report, and exit interview were verified to accurately depict the operation and activities conducted there.

An annual inspection of a handling operation in Fort Wayne, Indiana was witnessed.
The operation was a cosmetic, candle, and home perfume manufacturer. The operation was first certified in 2014. The inspector verified information provided by the operation through its 2015 annual update, which included new labels and inputs. The inspector conducted a mass balance of one product. One issue of concern was noted by the inspector for an organic certificate for raw materials received. An exit interview was conducted with the certified operation's management.

NOP DETERMINATION

The NOP reviewed the onsite audit results to determine whether ECO ICO'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 ECO ICO.

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.

NP2121OOA.NC1 – 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: *The following issues were found in 2 of the 10 case files reviewed (these were the only files with a retail label):*

- *There were 8 labels reviewed for which the "Certified organic by ***" statement was not in compliance with §205.303(b)(2). The labels did not include the word "organic" in the statement; and*
- *There were 9 labels reviewed where the "certified organic by…" statement was not located below the information identifying the handler or distributor of the product as required in §205.303(b)(2).*

Corrective Action: Indiana Certified Organic, LLC (ICO) responded to this non-compliance indicating policies would be updated, staff would be trained, and the training would be documented. ICO submitted objective evidence supporting the response to the non-compliance; specifically, the Guidance for Handling and Labeling procedure (TS08) was revised to indicate that "certified by…" is not an acceptable phrase to "certified organic by…" and also that the "certified organic by…" statement must appear below the information identifying the final handler or distributor of the product. ICO also notified all staff of this issue and required staff to acknowledge and read the changes to the labeling procedure. All staff responded affirmatively to the changes and confirmed reading the new policy via email submissions to the Certification Director, copies of which were provided in ICO's response. Review of the response and corresponding objective evidence demonstrates ICO is capable of remaining in compliance with the National Organic Program regulations as an accredited certifier.

Verification (June 2015): ECO ICO developed new procedures and guidelines for label review. All approved labels are dated and signed by the approver and included in the operation's file. Training records were reviewed and demonstrate that ECO ICO conducted training sessions for all personnel who review labels.

Noncompliances Identified during the Current Assessment

NP5166NNA.NC1 – 7 CFR §205.403(e)(2) states, "A copy of … any test results will be sent to the inspected operation by the certifying agent."

Comments: *For two of the three files reviewed for pesticide residue sampling ECO ICO did not send a copy of the test results to the operation.*

NP5166NNA.NC2 – 7 CFR §205.403(c)(1) – (3) 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 §§205.401, 205.406, and 205.200, accurately reflects the practices used or to be used by the applicant for certification or by the certified operation; 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: *ECO ICO's inspection report template "Section 1. Conclusions of the Inspection" instructs the inspector to describe improvements, strengths, special attention items, and on-site conditions of the inspection. Additionally, the inspection report template has no section for the inspector to describe verification of corrective actions resulting from prior noncompliances.*

NP5166NNA.NC3 – 7 CFR § 205.501(a)(1) states, "A private or governmental entity accredited as a certifying agent under this subpart must: Have sufficient expertise in organic production or handling techniques to fully comply with and implement the terms and conditions of the organic certification program established under the Act and the regulations in this part; …."

Comments: *Below are four examples identified during the onsite audit in which certification staff referenced the incorrect USDA organic regulation or made an incorrect certification determination:*

- *The review of an exit interview form indicated that the inspector noted that there was "no list of pest control and cleaner and sanitizer inputs included with the OSP and hence the inputs were not reviewed by office staff." The inspector referenced §205.271 (Facility pest management practice) even though the issue was an incomplete organic system plan/ annual update. The certification determination letter ECO ICO subsequently issued to the operation also referenced §205.271.*
- *The review of a certification determination letter ECO ICO issued indicated that ECO ICO had determined that "erosion was evident" at the operation, and that the operator had stated that oats could have been planted to prevent the erosion. ECO ICO did not issue the operation a notification of noncompliance for not complying with §205.203(a), which requires the implementation of cultivation practices that minimize soil erosion.*
- *The review of a Notice of Noncompliance ECO ICO issued to a new applicant for nonpayment of fees incorrectly referenced §205.405(Denial of Certification) and §205.642(Fees).*
- *The review of a label determination letter ECO ICO issued to an operation indicated that ECO ICO informed the operation that the processed product could be labeled as "100% organic" even though the product only qualified for the "organic" labeling category.*

NP5166NNA.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."

Comments: *A review of TM-11 export certificates ECO ICO issued in February and April 2015 indicated that the certificates did not include the following compliance statement in the Remarks section: "Organic agricultural products and organic processed products, accompanied by this certificate, were produced or processed using zero prohibited substances*."

NP5166NNA. NC5 – **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."

Comments: *ECO ICO does not provide a fee estimate for the total cost of certification. A fee estimate is provided only if the operation requests one.*

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NOTICE OF NONCOMPLIANCE

AUG 2 7 2015

Jeffry Evard
Certification Manager
Ecocert ICO, LLC
PO Box 158
Plainsfield, IN 46168

Dear Mr. Evard:

On June 15 – 19, 2015, a representative of the United States Department of Agriculture (USDA), National Organic Program (NOP), completed an onsite audit of the Ecocert ICO, LLC (ECO ICO) organic certification program as part of its USDA Mid-term Accreditation Assessment. On August 21, 2015, the NOP reviewed the results of the onsite audit to determine ECO ICO's compliance to the USDA organic regulations. A copy of the assessment report, NP5166NNA, is enclosed for your reference.

As the report indicates, one prior noncompliance, NP2121OOA.NC1, was cleared and the corrective action determined to be implemented and effective. No noncompliances remain outstanding from your previous audit. Five new noncompliances, NP5166NNA.NC1 through NC5, were identified during the onsite 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, indicating how the noncompliances will be corrected. The proposed corrective actions must also indicate how the ECO ICO 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,

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

Enclosure: Noncompliance Report

cc: AIA Inbox