Recap of All Written Public Comments

Comments submitted in advance of the

National Organic Standards Board

Spring 2016 Meeting

April 25 – 27 Washington, D.C.

Submissions delineated by:

Farmers and Citizens Public Interest Groups Food Processors and Handlers Manufacturers and Ingredient/Input Suppliers Distributors and Retailers Trade Associations and Industry Consultants Organic Certifiers and Material Review Organizations





How to Use This Document

For the benefit of National Organic Standards Board members, and other organic stakeholders, The Cornucopia Institute has compiled a recap of all formal written comments from all organic stakeholders that were submitted prior to the **Spring 2016 NOSB meeting**. We have endeavored to catalogue the totality of these public comments as accurately and objectively as possible.

Cornucopia greatly appreciates the work, dedication and enormous time commitment required to serve on the NOSB. Our hope is to provide a valuable resource for the Board better enabling members to more fully understand the scope and sentiment of organic community participants, including:

- Farmers/Citizens
- Public Interest Groups
- Food Processors/Handlers
- Manufacturers/Ingredient Suppliers
- Distributors/Retailers
- Trade Associations/Industry Consultants
- Organic Certifiers/Materials Review Organizations

This document is organized by NOSB Subcommittee, in alphabetical order (please note there is a table of contents at the beginning of the document, as well as an index at the end). Under each agenda item, a table shows the number of comments submitted and the positions of various stakeholders on that particular item. The "Notes" section under each table provides additional explanation.

We have attempted to represent individual comments as accurately as possible. Because of the late notice in the federal register, our staff, the NOSB, and the organic community at large were handicapped by having a shorter amount of time to review all of the comments submitted. Our staff worked overtime to analyze all of the comments within the constrained time period between comment posting and the NOSB meeting.

Thank you for your work on behalf of all organic stakeholders. Please feel free to contact us regarding this summary or our methodology.

Will Fantle Research Director The Cornucopia Institute

Note:

Although some of the certifiers represent their formal comments as being "neutral," if the sentiments of their customers/clients either favor or oppose a given material or proposal, we often categorized their comments accordingly in this recap.

Because of the inherent conflict of interest, and in the spirit of acting as independent arbitrators/referees, The Cornucopia Institute is on record as discouraging certifiers from acting as surrogates, or lobbyists, on behalf of their paying clients. Alternatively, they would serve their clients and the organic community better by encouraging farmers and processors to submit their own comments when a material is up for Sunset review, allowing the certified entities to submit their own comments.

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Abbreviation & Acronym Key

ASPCA	American Society for the Prevention of Cruelty to Animals
Aurora	Aurora Organic Dairy
BP	Beyond Pesticides
CCOF	California Certified Organic Farmers
CFS	Center for Food Safety
CR	Consumer Reports/Consumers Union
Corbion	Corbion Purac
Cornucopia	Cornucopia Institute
CROPP	CROPP Cooperative
Ferrara	Ferrara Pan Candy Company Inc.
Fetzer	Fetzer Vineyards (Bonterra Vineyards)
FWW	Food and Water Watch
Hain	Hain Celestial Group
IDFA	International Dairy Foods Association
IFAC	International Food Additive Council
Infant Nutrition Council	Infant Nutrition Council of America
IOS	Independent Organic Services, Inc.
MOSA	Midwest Organic Services Assoc.
MOFGA	Maine Organic Farmers and Gardeners Association
Nature's Path	Nature's Path Foods
NOC	National Organic Coalition
NODPA	Northeast Organic Dairy Producers Alliance
NOFA-VT	Northeast Organic Farming Association Vermont
OEFFA	Ohio Ecological Food and Farm Association
OMRI	Organic Materials Review Institute
OPWC	Organic Produce Wholesalers Coalition
OTA	Organic Trade Association
OTCO	Oregon Tilth Certified Organic
OSGATA	Organic Seed Growers Trade Association
PCC	PCC Natural Markets
PCO	Pennsylvania Certified Organic
Perrigo	Perrigo Nutritionals
RIDEM	Rhode Island Department of Environmental Management
Silica Association	Synthetic Amorphous Silica and Silicate Industry Association
SDI	Seed Dynamics, Inc.
Stonyfield	Stonyfield
USG	United States Gypsum Company
Wolf/DiMatteo	Wolf, DiMatteo + Associates
WODPA	Western Organic Dairy Producers Alliance
WWF	White Wave Foods

MATERIALS SUBCOMMITTEE

DISCUSSION DOCUMENTS

Excluded Methods Terminology

Purpose: Proposal and Discussion Document.

The proposal has three sections, to be used in NOP Guidance on Excluded Methods:

- 1. Approve the definitions of Genetic Engineering (GE), Genetically Modified Organism (GMO), Modern Biotechnology, Non-GMO, and Synthetic Biology as written above.
- 2. Approve the Principles and Criteria above that will be used in the evaluation of new technologies and terminologies.
- 3. Adopt the Terminology chart proposed above and the listings in it as presented, recognizing that this will be added to as further deliberations occur in the future.

Excluded method terminology: third discussion document:

This Discussion Document contains the technologies, terms, and issues that we have not been able to agree on or do not yet have enough information on or that pose challenges that we have not yet taken up. These items are put out for discussion to collect further public comment. They will be reviewed at future NOSB meetings.

Subcommittee Vote: Proposal

The NOSB Materials/GMO subcommittee approves the three sections of this proposal as stated above.

Motion by: Zea Sonnabend; Second: Tracy Favre

Yes: 6, No: 0, Abstain: 0, Absent: 0, Recuse: 0

Subcommittee Vote: Discussion Document

Motion to adopt the third discussion document on Excluded Methods.

Motion by: Zea Sonnabend; Second: Emily Oakley

Yes: 6, No: 0, Abstain: 0, Absent: 0, Recuse:0

	Support Proposal	Oppose Proposal	Neutral/ Seeks Clarification
Farmers / Citizens			1 _a
Public Interest Groups	Cornucopia _x , BP _d	OSA _p , FOE _b , CR _e , CFS _u , FWW _t	NOC _i ,
Food Processors / Handlers		Nature's Pathw	
Ingredient Suppliers / Material Manufacturers		Aurora _g , CROPP ₁	FGJ _h ,
Wholesalers /Distributors / Retailers			
Trade Associations / Industry Consultants		ASTA _k , OTA _s	OPWCn, OSGATAq,
Certifiers	MOSA _c , CCOF _f IOS _r	PCOv	NOFA-VT _j , OEFFA _m , OTCO _o ,

- a. Richard Theuer objects "to your wholesale classification of all CRISPR applications as 'Excluded methods'."
- b. Friends of the Earth (FOE) states: "We recommend several modifications to the definitions, and also recommend that several 'TBD' techniques be included in the list of excluded methods before moving the proposal forward as a recommendation to the NOP. We also suggest that the 'principles and criteria' and 'process and products' section should be directed back to the subcommittee for additional work, and that a new proposal be brought to the NOSB in the Fall 2016 meeting."
- c. Midwest Organic Services Association (MOSA) states: "In summary, we support the direction of this proposal. We think it will help to define and strengthen messaging regarding organic's prohibition on use of excluded methods. We have some feedback on potential enforcement challenges, and we have some comments on some moral principles related to use of genetic engineering."
- d. Beyond Pesticides (BP) states: "Subject to (hopefully minor) technical corrections that might be provided by others, such as the Center for Food Safety, we support this proposal and urge its rapid adoption."
- e. Consumer Reports (CR) states: "In terms of the proposal put forward by the Materials Subcommittee, for the reasons mentioned below we will make a few recommendations on modifications on the definitions proposed, and also feel that the Principles and Criteria section should be returned to the subcommittee for further work to make it clear all engineered organisms (...) should be excluded from organic agriculture. In addition, for the Terminology chart, we believe the subcommittee should consider convening a small groups of scientists and all affected stakeholders (e.g., industry, consumers, farmers and organic seed breeders) to more fully discuss the methods on the chart and come back with a further proposal at the fall NOSB meeting."
- f. California Certified Organic Farmers (CCOF) states: "CCOF supports the three motions that will move the guidance forward: to approve the definitions; approve the principles and criteria; and adopt the Terminology Chart."
- g. Aurora Organic Dairy suggests "the term' Embryo Transfer' in Animals be allowed provided no reproductive hormones are used in the organic animal and no genetic bioengineering occurs within the embryo." And states: "In closing we seek for further clarification regarding the term "embryo rescue in animals" to ensure it is more clearly defined. We respectively request that the vote to adopt the *Proposal* as guidance be tabled until the fall 2016 NOSB meeting. It is understandable that the MS is ready to move forward with the *Proposal* at this time; however, given the circumstances, it is our opinion that further clarification is needed and more input from stakeholders is warranted."
- h. Forest Glen Jerseys (FGJ) states: "As a committed organic farmer, I have to be proactive in my approach to the health of my animals. When faced with a herd health issue we do not have as many tools as conventional producers. Using <<in vitro fertilization and/or embryo transfer>> allows me to improve the genetics of my herd faster than more traditional methods. Before considering these practices excluded methods, please consult with industry professionals and keep in mind the benefits and improvements that can be made on our organic farms."
- i. The National Organic Coalition (NOC) offers "suggested revisions (to the proposed definitions) for clarity and consistency," and states: "It is acknowledged that several of these definitions could be combined under the suggested definition of modern biotechnology; however, we concur with the Board's inclusion of multiple terms to avoid any confusion or potential discrepancies. We also support the principles and criteria put forth in the Excluded Methods Terminology proposal and intended to guide the review of biotechnology processes.
- j. Northeast Organic Farming Association of Vermont (NOFA-VT) states: "We support the development of a comprehensive set of definitions of excluded methods terminology to be sure that the specific nature of new and evolving biotechnologies is fully captured, especially as it relates to organic production. In addition, we support NOC's suggested revisions and clarifications of the terms Genetic Engineering (GE), Genetically Modified Organism (GMO), and Non-GMO."
- k. The American Seed Trade Association states: "The American Seed Trade Association recognizes that the NOP has chosen to exclude genetically modified organisms from organic certification. However, as plant breeders continue to learn more and more about plant genomes, plant physiology, and the remarkable ways in which organisms adapt and evolve, the natural boundaries of genome exchange are becoming less clear. In addition, new techniques are being developed at a rapid pace and could have a profound effect on the development of useful varieties for all agriculture production methods, including organic agriculture. The American Seed Trade Association recommends that the NOSB take into account all of the principles of organic production and weigh them when determining whether a specific technique should be excluded. For example, many of the techniques listed in the table have enabled breeders to develop disease and pest resistant varieties, limiting the need to use synthetic chemical inputs. While the NOP has an obligation to uphold organic principles in order to support organic farmers and retain consumer confidence in the USDA organic label, it is also critical to make decisions only after thorough investigation to ensure that excluded methods do not have negative consequences in the future."
- 1. CROPP Cooperative (CROPP) states: "As a member of Organic Trade Association (OTA), and a contributor to their submitted comments on the topic of seed purity, we fully support the positions outlined in the detailed document submitted under this set of discussion documents by the OTA. In addition to those comments,

several areas of substantial concern to cooperative members have also been included in this document which weren't relevant to the more broadly representative OTA comment assembly process." And adds: "Please reconsider your position on embryo transfer. While restrictions to use are a reasonable consideration, ET is in essence the same process as artificial insemination and should be carefully considered in all of its relevant use-cases both on organic farms, and upstream of organic operators in the livestock breeding industry."

- m. Ohio Ecological Farm and Food Association (OEFFA) states: "In summary, please note:
 - Ensuring crop varieties are usable for further crop improvement and propagation is crucial;
 - Consider a national pilot study for GE presence in seeds;
 - Of the options presented, the affidavit system for ACAs to use for varieties derived from excluded methods should be explored further; and
 - Consider a national reporting system for genetically manipulated crop and animal material."
- n. Organic Produce Wholesalers Coalition (OPWC) states: "We agree with the Materials SC's idea of using the IFOAM Principles to evaluate whether a method should be allowed or excluded. (...) OPWC encourages further development of the "Chart of Terminologies" to present information about different types of GE methods. As more types of fruits and vegetables are being affected by genetic engineering, we appreciate information that helps us make a clear determination about whether a technology is considered to be an "excluded method".
- o. Oregon Tilth (OTCO) states: "This proposal is a good step forward in closing the gap between new methods and regulatory frameworks. We support the goal of establishing a structure that is flexible enough to evaluate newly developed methods and techniques in the future for adherence with specified principles and criteria. The Subcommittee's approach to creating this structure is sound establishing clear definitions, principles & criteria, and developing a terminology chart. Being aware of approaches already taken by other countries is valuable to maintain harmonization of organic standards and practices at a global level. Oregon Tilth also agrees with creating this structure within the context of guidance instead of changes to regulations or the Act. Evolving and updating guidance as new technologies emerge is a more responsive and timely process, which is of the essence both now and in the future." OTCO goes on to provide input "for addressing these issues included in the discussion document..."
- p. Organic Seed Alliance (OSA) states: "In general, we believe the proposal for excluded methods terminology needs more work. We believe the definitions need further clarification, the principles and criteria need further refining, and the broad nature of the principles need to be re-considered in the context of unintended consequences to organic seed innovation and organic seed availability. The NOSB should continue working with the organic community especially the public and private breeding sectors on a new proposal that addresses these needs."
- q. Organic Seed Growers and Trade Association (OSGATA) states: "OSGATA stands behind the use of IFOAM-Organics Principles of Organic Agriculture as a framework for developing positions on GMO technology when coupled with additional criteria. The criteria outlined within the proposal1 is a solid foundation. ... OSGATA's principles largely mirror the criteria proposed for adoption. However, there are a few key differences. Notably, these principles define organic plant breeding as remaining farm-centered, with any plant breeding being able to occur on-farm. ... We would encourage the NOSB in adopting such principles to utilize as a litmus test for all allowable methods in organic plant breeding."
- r. Independent Organic Services (IOS), states: "I generally support the proposal and think it should be adopted as soon as possible. (...) My only reservation with respect to the current proposal has to do with the prohibition on embryo transfer that appears to have been imported from FiBL. I seriously question why we would want to prohibit the certification of progeny produced by this method. ... I would therefore urge the Board to amend the proposal, so as to strike this section, before adoption."
- s. The Organic Trade Association (OTA) states: "In summary, OTA continues to support a process-based approach to evaluating the use of excluded methods. We believe that the proposed definitions will be useful, and with some revisions, they will be "proposal ready." The "terminology chart" and the "criteria and principles," however, need a considerable more amount of time and attention. OTA recommends taking the entire proposal back to subcommittee for further work with the goal of releasing a final proposal prior to the Fall 2016 NOSB meeting. We also recommend separating out the 'definitions' from the rest of the proposal, and moving the definitions section forward as an independent recommendation."
- t. Food and Water Watch (FWW) states: "Descriptions or definitions of techniques should refer not only to plants, but also to animals and organisms; [g]ene drive and gene editing techniques should be specifically mentioned, not just for plants but for all organisms."
- u. The Center for Food Safety (CFS) states: "Both the proposal and discussion document for excluded methods terminology are still works in progress, with many aspects requiring additional research and clarification. CFS requests that both documents be referred back to the Material/GMO Subcommittee, and that the Subcommittee consult with an array of independent scientists, including molecular biologists and crops breeders, to further refine the documents."
- v. Pennsylvania Certified Organic (PCO) states: "PCO recommends postponing a vote on this proposal to also include the terms on the discussion document that were identified as "TBD", the terms in the current NOP definition of Excluded Methods (S205.2 Definitions), and other terms received through the comment period, as requested by the subcommittee. PCO noticed the exclusion of cloning of plants through tissue cultivation or micropropogation, while the cloning of animals is included."

- w. Nature's Path Foods states: "In light of the ever evolving complexity in the field of seed engineering, and the unknown factors around how to define yet-to-be-developed new technologies and the testability for all these, we feel that perhaps one solution could be for NOSB to focus on developing a framework of what aspects of seeds and plant breeding need to be included for use in an organic system, rather than what should not be allowed. In essence this would be replacing the concept of "excluded methods" with "approved methods". Of course the current excluded methods would not be part of the approved methods."
- x. The Cornucopia Institute states: "Some technical corrections and additions, provided by others such as the Center for Food Safety, may be required but Cornucopia supports the overall proposal and its expedited enactment."

In terms of the discussion document, The Cornucopia Institute "recommends that:

- The additional criteria by the FiBL be included in the proposal.
- The NOSB call upon the Secretary of Agriculture to reverse its policy allowing an increasing number of genetically engineered crops in conventional agriculture.
- The NOSB to request and support legislation that would place liability for damages on the patent holder, providing a recourse for organic producers facing the genetic contamination of their crops."

Seed Purity

Purpose: Discussion Document on Next Steps for Improving Seed Purity February 23, 2016.

Vote in Subcommittee

Motion to adopt the discussion document on Next Steps for Improving Seed Purity Yes: 4, No: 0, Abstain: 0, Absent: 2, Recuse:0

	Support	Oppose	Nuanced
	Document	Document	
Farmers / Citizens	1		
Public Interest Groups	OSAr, CFSh,		BP _a , Cornucopia _l ,
	NOCc		OSGATAp
Food Processors /		Nature's	
Handlers		$Path_o$	
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors	CROPP _j		
/ Retailers			
Trade Associations /	OPWC _i , OTA _k ,		IOS _m
Industry Consultants	Wolf/DiMatteo _b ,		
	The American		
	Seed Trade		
	Association _q		
Certifiers	NOFA-VT _d ,		PCOn
	OTCO _e , MOSA _f ,		
	CCOFg		

- a. Beyond Pesticides (BP) states: "Seeds treated with insecticides are a major contributor to pollinator decline. For organic production to contribute to this decline through allowing the use of treated seed is incompatible with organic practices and contrary to OFPA."
- b. Wolf, DiMatteo + Associates state: "...we believe that priority should be given to strengthening the organic seed requirement and establishing a Seed Purity Advisory Task Force."
- c. National Organic Coalition (NOC) "supports our member organizations, Organic Seed Alliance and the Center for Food Safety, in their more thorough comments on this topic."
- d. Northeast Organic Farming Association of Vermont (NOFA-VT) "support(s) the NOSB's proposal to require a seed purity declaration for nonorganic seed, and hope that the Board's recommendations will encourage producers to source more organic seed.
- e. Oregon Tilth (OTCO) states: "We believe asking ACAs to serve the data collection role is inappropriate because it would adversely compromise our unique role within the organic certification and regulatory framework." And "Oregon Tilth recommends enhancing the NOP Seed Guidance to begin with specifying a minimum of three reasonable seed sources and then establishing organic seed usage as a specific Organic System Plan goal."
- f. Midwest Organic Services Association (MOSA) states: "we find that current standards and NOP direction leave some uncertainties related to determining compliance; we support GMO testing as way of determining thresholds to inform enforcement; we want to enable seed purity improvements without being overly burdensome to organic producers; we have great concerns with contamination of organic seed; and, we are thankful for the solutions suggested by the discussion document."
- g. California Certified Organic Farmers (CCOF) states: "Each of the suggestions A-D made by the Subcommittee present an important task that will move the effort forward. CCOF recommends that suggestion B, establish a USDA Seed Purity Advisory Task Force, be implemented first. CCOF also recommends that the USDA Seed Purity Advisory Task Force be assigned to develop processes to implement all of the suggestions, including: 1. Consider phasing in a requirement that certifiers require verification that at-risk seed (seed of crops with GMO counterparts) is non-GMO. 2. Gather data on the incidence of GMO presence in nonorganic seed used in organic production. Additionally, it would be helpful to gather data on all possible sources of contamination (seed, pollen transfer in field, or commingling during harvest, transport, and packaging) to better inform prevention strategies. 3. Design a feasibility study on establishing a threshold for GMO presence in nonorganic seed used

for organic production. 4. Strengthen implementation of the organic seed requirement in the federal standards. CCOF is identifying baseline levels of organic seed use for all of its growers and plans to use the information to increase organic seed use. 5. Initiate a pilot soybean testing program.

- h. The Center for Food Safety (CFS) states: "CFS supports Option A, 'Enabling Data Collection,' as an appropriate, potential next step in the effort to protect organic seed integrity. As we have stated in past comments, data are urgently needed to assess the current state of seed contamination and the availability of high quality, non-GE and untreated seed for organic producers. These data are also needed to inform a comprehensive assessment of the scope and breadth of the contamination problem, including the potential impacts on seed producers, seed savers, and organic and non-GE growers. Requiring an evaluation of the non-GE status of any conventional seed intended for use in organic is a step in the right direction. However, it is critical that the burden for such an evaluation and certification should be placed on the conventional seed seller, not the organic buyer. "
- i. Organic Produce Wholesalers Coalitions (OPWC) states: "We are very clear that finding ways to keep the seed and planting stock for fruits and vegetables free from contamination by genetic engineering is critically important to the OPWC member businesses. We support establishment of a Seed Purity Advisory Task Force within USDA to increase the focus on this topic."
- j. CROPP states: "It is our strong opinion that the main focus should be on reducing and ultimately eliminating the use of conventional untreated seed in at-risk crops."
- k. The Organic Trade Association (OTA) states: "With respect to establishing a seed purity standard, OTA strongly supports NOSB taking a multi-faceted approach in moving this topic forward by developing two separate recommendations:
 - Strengthening organic seed sourcing practices through a revision to the NOP's Guidance on Seeds, Annual Seedlings and Planting Stock (NOP 5029)
 - Convening a Seed Purity Advisory Task Force that would design threshold feasibility studies and act as an expert panel to interpret the data being collected."
- l. The Cornucopia Institute states: "This issue threatens all of organics and needs to be dealt with by applying the precautionary principle first and foremost. Organic farmers should be relived of some of the financial burden caused by seed contamination."
- Independent Organic Services, Inc. (IOS) states: "While I generally applaud the Subcommittee for trying to m. tackle this recognized threat to organic integrity, I take issue with a number of the proposals as presented. Discussion question A- I don't think the burden should fall on ACAs and inspectors to collect this information. With all the tasks currently being asked of inspectors, including materials verification, fee verification, feed audits, DMI/pasture verification, and trace back and mass balance exercises, my average crop inspection now lasts over 5 hours and dairy inspections are now stretching to 10+ hours. This represents a significant burden for small operations, even with cost share. Performing proper testing, so as to reduce the risk of potential false positives, takes time. If inspectors were expected to take a sample every time we come across a NOG variety of corn or other high-risk crop on a farm, we are talking about hundreds of additional hours annually for many inspectors. In addition, the cost of performing these tests should not have to be borne by the certifiers, who also face significant time, financial and labor constraints. I support the idea of a task force for monitoring the extent of GMO contamination in foundation seed used for organic seed production. Another possibility would be to provide a grant to AOSCA to test the GMO contamination of seed lines and varieties in high risk crops and publish that information. In that way, ACAs could inform growers to avoid certain conventional varieties of seed, while organic seed growers and breeders would similarly know which lines/varieties to avoid."
- n. Pennsylvania Certified Organic (PCO) states: "PCO supports the efforts of the materials Subcommittee to tackle this difficult topic and propose new ideas to improve purity of seed used in organic systems. While PCO is in general support of data collection activities, we have significant concerns regarding ACAs being the data collectors. ... PCO supports the creation of a Seed Purity Task Force. ... PCO is in general support of the concept of strengthening the organic seed requirement. However it is difficult to offer feedback in the abstract as the devil is often in the details, and as a certifier, that is where we spend most of our time."
- o. Nature's Path Foods states: "We feel that the NOSB discussion documents are making the issues more complex than they need to be. Other private standard programs have shown that testing and functioning below a threshold is feasible for all GMO risk ingredients in finished product."
- p. Organic Seed Growers and Trade Association (OSGATA) states: "Ideally, data collection would not rely upon funding from ACAs, seed companies, seed growers, and contracted buyers. Under the Polluter Pays Principle it is essential that the manufacturers of GE seed pay for all costs of testing in order to protect the organic industry. We reject any assertion that placing the financial responsibility of testing on the biotech industry is not a workable option. USDA must acknowledge that inextricably linked to the deregulation of GE crops are the issues of GE contamination."
- q. The American Seed Trade Association states: "...The American Seed Trade Association is troubled by the duality of the testing recommendation. Having two requirements, one for certified organic seed and another

for conventional untreated seed, will create confusion in the organic program and put organic producers at a disadvantage."

r. Organic Seed Alliance (OSA) states: "We also request that the organic seed requirement be an agenda topic at the NOSB's 2016 fall meeting. Organic Seed Alliance would appreciate the opportunity to present a five-year update on our State of Organic Seed project at this meeting, including recommendations pertaining to the NOP, NOSB, and ACAs and their role in encouraging increased sourcing of organic seed, ensuring ongoing growth in organic seed availability."

LIVESTOCK SUBCOMMITTEE

PROPOSALS

Annotation Changes for Lidocaine and Procaine

Purpose: used as local anesthetics.

Proposal:

Motion to amend the Lidocaine listing as follows: (4) Lidocaine– as a local anesthetic. Use requires a withdrawal period of 90 days <u>8 days</u> after administering to livestock intended for slaughter and 7 days 6 days after administering to dairy animals.

Motion to amend the Procaine listing as follows: (7) Procaine– as a local anesthetic. Use requires a withdrawal period of 90 days <u>8 days</u> after administering to livestock intended for slaughter and 7 days <u>6 days</u> after administering to dairy animals.

Vote in Subcommittee

Recommendation to amend §205.603(b) As topical treatment, external parasiticide, or local anesthetic,

as applicable:

1. That the deleted language be removed and underlined language added at: §205.603(b) Yes: 6, No: 0, Abstain: 0, Absent: 0, Recuse: 0

2. That the deleted language be removed and underlined language added at: §205.603(b) Yes: 6, No: 0, Abstain: 0, Absent: 0, Recuse: 0

	Support Annotation Change	Oppose Annotation Change	Neutral/ Seeks Clarification
Farmers / Citizens			
Public Interest Groups	Cornucopia _h , ASPCA _i	BP _a ,	NOC _b
Food Processors / Handlers			
Ingredient Suppliers / Material Manufacturers			
Wholesalers/Distributors / Retailers	CROPP		
Trade Associations / Industry Consultants	IOS _e OTA _f , NODPA	MOFGAg	
Certifiers	OTCO _d , MOSA, NOFA-VT _c		

- a. Beyond Pesticides (BP) states: "We recommend that the LS reconsider its recommendations in light of this new evidence. We support the animal welfare motivations to reduce the withdrawal period for a local anesthetic, but we believe that the assessment of the CVMP needs to be taken into account."
- b. National Organic Coalition (NOC) states: "New evidence that supports the current withholding period of 90 days has been brought forth in a recent assessment by the European Committee for Medicinal Products for Veterinary Use (CVMP)"
- c. Northeast Organic Farming Association of Vermont (NOFA-VT) states: "The NOSB recommendation to change the required withholding times....is reasonable, consistent with withholding recommendations for other livestock materials and will improve animal welfare on organic farms."

- d. Oregon Tilth (OTCO) states: "Not only are these withdrawal times based on scientific data regarding the half--life of the materials once administered, we agree that reducing the withdrawal period as proposed will increase the likelihood of these materials being used during painful yet necessary physical alteration procedures."
- e. Independent Organic Services, Inc. (IOS) states: "I support the annotation change. As producer or dairy goats, I use these materials to attempt to minimize animal suffering associated with dehorning. Dehorning involves the application of a hot iron to the heads of baby goats. It is quite painful for the animals and is certainly one of my least favorite procedures to perform. Because of the current restrictions on the products, I know that many producers forego the use of these materials during dehorning. On our own operation, while we briefly tried to avoid dehorning by allowing animals to grow horns, in a more "natural" way, we have found that the pain and injuries they inflict on each other when they have horns are far greater than the brief moments of pain associated with dehorning. Therefore we are compelled to use Lidocaine so as to minimize suffering."
- f. The Organic Trade Association (OTA) states: "These are reasonable recommendations (2x the FDA recommended withholding times) supported by public comment and will ensure that producers are not performing physical alterations or other necessary surgeries without the aid of these important local anesthetics."
- g. Maine Organic Farmers and Gardeners Association (MOFGA) states: "Ideally the availability of procaine HCl would become a reality and eliminate the need for lidocaine."
- h. The Cornucopia Institute states: "Lidocaine is a widely used, readily available, and relatively safe local anesthetic with no better alternatives. The Cornucopia Institute supports the recommendations of the Livestock Subcommittee to shorten the withholding periods for meat and dairy animals after treatment with lidocaine or procaine."
- i. American Society for the Prevention of Cruelty to Animals (ASPCA) states: "As with livestock raised under all production systems, pain control for organic animals is central to their welfare. Farmers must be able to provide animals with anesthetics as needed, no matter the point in their production cycle."

Annotation Change for Parasiticides

Purpose: for control of parasites in livestock.

This proposal recommends:

- That parasiticides continue to be prohibited in slaughter stock.
- That the milk withholding period after treatment with Fenbenzadole or Moxidectin be changed from 90 days to 2 days for dairy cows, and 36 days for goats and sheep.
- That the listing for Ivermectin remains as presently listed, with a 90-day withdrawal period.
- That Moxidectin be allowed for both internal and external use.
- That fleece and wool from fiber bearing animals be allowed to be certified organic, even if use of parasiticides was necessary at some time in the animal's life.
- That Fenbenzadole be allowed without written order of a veterinarian.

Vote in Subcommittee

1. That the strikethrough language be removed, and the underlined language be added at: §205.238(b)(2).

Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

2. That the underlined language be added at: §205.238(b)(3) and §205.603(a)(18).

Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

3. That the underlined language be added at: §205.238(b)(3) and §205.603(a)(18).

Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

4. That the underlined language added at: §205.603(a)(18)(ii).

Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

5. That the strike through language be removed and the underlined language added at: \$205.603(a)(18)(iii).

Yes: 6, No: 0, Abstain: 0, Recuse: 0, Absent: 0

	Support	Oppose	Neutral/
	Proposal	Proposal	Nuanced
Farmers / Citizens		9,	
	1	Consumers supporting BP -	
		164	
Public Interest Groups		BPa, NOC _{b,} CFSg,	
		Cornucopia _n	
Food Processors /			
Handlers			
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors	CROPP		
/ Retailers			
Trade Associations /	Cloverleaf Farm _f ,		
Industry Consultants	NODPA _l , IOS _h ,		
	OTA _i , WODPA _e ,		
	MOFGAm		
	OTCO _c , CCOF _d ,		
Certifiers	PCO _j , OEFFA _k ,		
	NOFA-VT		

- a. Beyond pesticides (BP) states: "While we are pleased that the LS considered all three parasiticides together, we believe that the subcommittee should have also brought forward motions to remove ivermectin and moxidectin."
- b. National Organic Coalition (NOC), "asks the NOSB livestock subcommittee to develop an "emergency use" definition as it relates to a livestock operation in the final regulation." NOC continues to support the removal of Ivermectin and the retention of the 90-day withdrawal period. NOC would like further discussion on the use of parasiticides for organic fiber bearing animals.
- c. Oregon Tilth (OTCO) states: "The proposed language takes into consideration the science behind the withdrawal times, the farmers' nee for emergency treatment options, and the welfare of the animals."
- d. California Certified Organic Farmers (CCOF) states: "CCOF agrees with the proposed changes in the annotation for parasiticides. These changes clarify the rules guiding parasiticide use in certified organic livestock production, making them more workable for producers and easier to verify by certifiers."
- e. Western Organic Dairy Producers Alliance (WODPA) states: "WODPA's position is that all parasiticide use must be 'by or on the lawful written order of a licensed veterinarian.' This is a key piece in assuring that the parasiticides are used only in an emergency situation. It also helps in creating an auditable paper trail of compliance."
- f. California Cloverleaf Farms states: "...we support continuing the 90 days withdrawal time for all Parasiticides."
- g. The Center for Food Safety (CFS) states: "As delisting is not a possibility, with the current proposal, we urge NOSB to send the proposal back to Subcommittee to further research the compatibility of moxidectin with OFPA criteria and bring forth proposals at the fall 2016 meeting that adequately address the full range of options supported by public comment. We also urge the NOSB to clarify the term "emergency use" on a livestock operation. Clarification of emergency use" is imperative to prevent greater use of synthetic parasiticides as an unintended consequence of the shortened withdrawal times.
- h. Independent Organic Services, Inc. (IOS) states: "I strongly support the adoption of the proposal, particularly the allowance for the certification of wool from animals treated with parasiticides and the change in the annotation, allowing the use of Febenzadole without a prescription."
- i. The Organic Trade Association (OTA) states: "We encourage NOSB to consider additional guidelines they can provide to operators and ACAs to properly identify and document emergency situations, so that the changes to annotations and use of parasiticides proposed by the Livestock Subcommittee do not result in routine use of these substances."
- j. Pennsylvania Certified Organic (PCO) states: "PCO supports the subcommittee's proposal. The proposed revisions are sound and sensible. However, PCO is concerned that with reduced withhold periods, it may be more challenging for a certifier to determine if the operator's use was in accordance with the "Allowed in emergency treatment..." part of the annotation."
- k. The Ohio Ecological Food and Farm Association (OEFFA) "requests NOSB create a definition of 'emergency use.' Please consider doing so by further clarifying the hierarchy defined at §205.238(a-b), perhaps drawing from the structure of the Facility pest management standard at §205.271."
- Northeast Organic Dairy Producers Alliance (NODPA) states: "NODPA would like further discussion on the use of parasiticides for organic fiber bearing animals... NODPA asks the NOSB livestock subcommittee to develop an "emergency use" definition as it relates to a livestock operation in the final regulation."
- m. Maine Organic Farmers and Gardeners Association (MOFGA) states: "It is necessary for organic sheep and goat farmers especially to have two parasiticides for controlling internal parasites. Without being able to alternate the use the incidence of parasite drug resistance increases significantly."
- n. The Cornucopia Institute states: "The Cornucopia Institute opposes the recommended changes made by the Livestock Subcommittee as they apply to Ivermectin."

POLICY DEVELOPMENT SUBCOMMITTEE

PROPOSAL

Policy and Procedures Manual Revisions

Revisions on the operating manual of the NOSB.

Background of this proposal: The objective of this proposal is to revise the April 11, 2012 version of the PPM to reflect the current procedures for the collaborative and productive functioning of the NOSB. It is designed to assist the NOSB in its responsibilities to serve as a link to the organic community, advise USDA on the implementation of OFPA, propose amendments to the National List of Allowed and Prohibited Substances, and protect/defend the integrity of organic standards. It compliments and aligns with other governing documents, including the Organic Foods Production Act (OFPA), the USDA organic regulations at 7 CFR Part 205, the NOSB Charter, FACA procedures, and other government laws and regulations (e.g. FOIA) as applicable.

Proposal: The NOSB moves to adopt the February 23, 2016 drafted version of the Policy and Procedures Manual.

Vote in Subcommittee

The NOSB PDS subcommittee approves the three sections of this proposal as stated above. Motion by: Tom Chapman; Second: Lisa de Lima Yes: 5, No: 0, Abstain: 0, Absent: 1, Recuse: 0

	Support Revisions	Oppose Revisions	Nuanced/ Seeks Clarification
Farmers / Citizens		822	
Public Interest Groups		BPa, FWW _c ,	
		Cornucopia _e ,	
		NOC _b , CFS _f	
Food Processors /			
Handlers			
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors			
/ Retailers			
Trade Associations /	OPWC _d		
Industry Consultants			
Certifiers			

a. Beyond Pesticides (BP) states: "OFPA created the NOSB as a means of ensuring that the organic community retained key lines of authority over the organic program, despite being located within USDA, which often takes positions viewed as hostile to organic integrity. The Policy and Procedures Manual (PPM) is the instrument through which the NOSB maintains its ability to set the course for organic production in the United States and advise the Secretary of Agriculture on implementation of organic law. The NOSB must not relinquish that

independent authority and the high degree of public involvement that has been the cornerstone of a burgeoning organic sector by weakening the decision making process contained in the PPM."

- b. National Organic Coaltion (NOC) states, "The NOSB must not relinquish that control by weakening the PPM."
- c. Food and Water Watch (FWW) states: "The September 16, 2013 Federal Register notice on the sunset process was a legislative rule issued without notice and comment as required by law. This legislative rule is currently the subject of litigation in federal court. Food & Water Watch believes that during the pendency of the litigation, NOSB should not be recommending any further changes to the sunset process."
- d. Organic Produce Wholesalers Coalition (OPWC) "supports the Policy Subcommittee's work to update the Policy and Procedures Manual (PPM) so that it reflects the current operating procedures of the Board."
- e. The Cornucopia Institute states: "Taken as a whole, the changes made to the PPM represent a dramatic shift in policy for the NOSB. Chief among the changes is that the draft proposal adopts is the increased role of the NOP in NOSB administration. As discussed, this is problematic because the NOSB fills a very specific niche in the administration of organics. Another part of this shift in control is evidenced by changes in the PDS: the draft lessens the ability of the NOSB to manage its own policy and procedures. As dictated by federal law, the duties of the NOSB should remain theirs alone."
- f. The Center of Food Safety (CFS) states: "CFS has serious concerns regarding the following proposed changes to the current PPM:
 - The revision significantly reduces NOSB authority and control over the PPM.
 - The section on NOP-NOSB Collaboration has been revised to be less collaborative.
 - The revisions reduce the independence of NOSB.
 - The section on NOSB work agendas (formerly work plans) removes NOSB authority to initiate agenda items.
 - The revised role of the Policy Development Subcommittee diminishes the ability of the NOSB to establish its own procedures.
 - Changes to the requirements for minority reports decrease the full understanding of the NOSB and the public.
 - The allowance for voting by 'show of hands' hinders transparency in voting.
 - The revision adopts the new sunset policy and procedures. The change in the sunset policy imposed by the NOP has never been proposed for public comment. These revisions are currently the subject of a lawsuit in federal court. CFS believes the NOSB should wait before adopting revisions that are currently the subject of judicial review.
 - The revision conflates the distinctly separate roles and responsibilities of the CMO/DFO/Staff Director.
 - The revisions fail to align with recordkeeping requirements of FACA."

DISCUSSION DOCUMENT

Sunset Timeline Reorganization

Purpose: Sunset review efficient work load reorganization.

Discussion: We are seeking comment from the public on the following:

- 1. Which of the four options would be most advantageous for a reorganization of Sunset review?
- 2. If Option C is preferred are there other items that should be grouped together? (Later materials on the 2/7 reviews cycle will be reordered as a result of any changes earlier in the list).

Vote in Subcommittee

Motion to accept the Sunset timeline reorganization discussion document Motion by: Tom Chapman, Seconded by: Ashley Swaffar

Yes: 5, No: 0, Abstain: 0, Absent: 1, Recuse: 0

	Support	Oppose	Nuanced
	Proposal	Proposal	
Farmers / Citizens			
Public Interest Groups	BP _a , CR _i ,		
	CFS _h ,		
	Cornucopia _l ,		
	$NOC_b FWW_c$		
Food Processors /			
Handlers			
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors	CROPP _g		
/ Retailers			
Trade Associations /	$OTA_j OMRI_k$		OPWC _f ,
Industry Consultants			
Certifiers	MOSA _d ,		
	CCOF _e ,		
	PCOm		

- a. Beyond Pesticides (BP) states: "We do have an opinion... regarding the best option, but the most important thing is for the NOSB to adopt some option –even if it requires locking stakeholders in a room until they can all agree."
- b. National Organic Coalition (NOC) states: "Option B--Like groupings referred together, groupings combined to make even numbers" most closely matches NOC's ideas on how to proceed."
- c. Food and Water Watch (FWW) states: "We agree that the way to resolve the uneven distribution of materials throughout the years of a Sunset cycle is to review some of the materials *before* their existing sunset date because extending a material's review cycle would result in its delisting, as stated in OFPA."
- d. Midwest Organic Services Association (MOSA) states: "Option C seems to be the best balance of efficiency and transparent impartiality."
- e. California Certified Organic Farmers (CCOF) states: "CCOF commends the Subcommittee for analyzing three separate approaches to reorganizing the sunset review process and joins the Subcommittee in supporting Option C. This system will divide the workload most evenly over the 5-year review period."
- f. Organic Produce Wholesalers Coalition (OPWC) states: "It is very important to the stability of the organic trade that any decisions made to delist or reduce the use of materials that have been reviewed earlier than their originally scheduled sunset be implemented on the timeline associated with their original Sunset cycle."
- g. CROPP states: "The Organic Trade Association comments are in alignment with our thoughts on option C. We also agree with the materials grouping presented in their comments. We would like to emphasize the importance of a phase in period for the first round of the new sunset review dates. Items set to sunset in 2022 may be reviewed according to option C but must not sunset until 2022."

- h. The Center for Food Safety (CFS) states: "CFS understands the need to reorganize the sunset review timeline to more evenly distribute the material reviews and Board-member work load. The many benefits of reviewing materials approved for the same function or purpose in the same cycle make option B the best strategy proposed."
- i. Consumer Reports (CR) states: "We support grouping similar materials for review, and support Option B. We also see benefits to Option's C proposal of grouping materials regardless of which National List section they are listed on. We would support a reorganization that combines Option B and Option C, if this would be feasible. This means grouping similar materials together, and reviewing them across lists. We support the proposal that materials that are reviewed on a shorter timeline than 5 years and are voted for removal would still be removed at their original sunset date."
- j. The Organic Trade Association (OTA) "supports NOSB's efforts to towards reorganizing the Sunset Review timeline provided the following outcomes occur:
 - Every input on the National List is reviewed every five years;
 - Every item on the National List is reviewed completely against OFPA and National List Criteria;
 - The review process is transparent and lends itself to a fair, objective and open public process with adequate time to comment;
 - If grouping occurs as suggested in Option C, additional "like" groupings are adopted as suggested in our comments;
 - National List items that are reviewed early under a reorganization plan should be allowed to sunset (for the first abridged Sunset Review) on their original timeline, and a resolution must be adopted to make decisions according to information available at the time of the review rather than the scheduled sunset date."
- k. Organic Materials Research Institute (OMRI) states: "OMRI supports Option C, which groups similar materials together regardless of their location on the National List."
- I. The Cornucopia Institute states: "The current 30-day comment period after the NOSB meeting agenda and materials are released is not enough time to thoroughly review each agenda item. In addition, there is not enough time between when comments are submitted to regulations.gov and the time the NOSB meeting begins. Board members cannot properly read and interpret all comments submitted without exorbitant time commitments."
- m. Pennsylvania Certified Organic (PCO) states: "PCO considers option C to be the most advantageous option for reorganization of sunset review. ... However, PCO is requesting clarification from the Policy Development subcommittee regarding the sunset timeline. The subcommittee states that materials reviewed early should be allowed to sunset on their original timeline in 2022. Would materials reviewed early always sunset based on their original 2/7 cycle, or would sunset dates after 2022 reflect the adopted regrouping?"

SPECIAL COMMENT

CACS: Eliminating the Incentive to Convert Natural Ecosystems into Organic Production

The Wild Farm Alliance proposed that the CACS add work agenda an item on "Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production."

Discussion: CACS notes of August 11, 2015 say, "After a lengthy discussion about the scope of the problem, and the possible paths and outcomes, the members acknowledged that conversion of native ecosystems into organic crop production is a serious problem, but that it is too large in scope for the CACS or NOSB to take up."

	Support Adding Work Agenda	Oppose Adding Work Agenda	Neutral/ Seeks Clarification
Farmers / Citizens			
Public Interest Groups	BP _a ,		
	Cornucopia _e ,		
	NOC _b , FWW _c ,		
	CFS _d , WFA _g		
Food Processors /			
Handlers			
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors			
/ Retailers			
Trade Associations /			
Industry Consultants			
Certifiers	OEFFA _f		

- a. Beyond Pesticides (BP) states: "The CACS notes reveal that there is only one item on the CACS work agenda, and it is on hold. The rush of the 2017 sunset has passed. WFA has offered its expertise to the subcommittee. We suggest that this is an opportune time for the subcommittee to undertake this important issue."
- b. National Organic Coalition (NOC) states: "NOC submits these comments in support of the Wild Farm Alliance (WFA) request to add to the CACS work agenda an item on 'Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production.' Instead of incentivizing the conversion of native ecosystems to organic crop production, the NOSB should guide the NOP to place emphasis on converting conventional land and improving current or former farmland that has been degraded under nonorganic management. Until such a time that a rule can be put into place, NOC would request that the NOSB recommend that the NOP issues guidance on this issue."
- c. Food and Water Watch (FWW) states: "Instead of incentivizing the conversion of native ecosystems to organic crop production, the NOSB should guide the NOP to emphasize converting conventional land and improving current or former farmland that has been degraded under nonorganic management."
- d. The Center for Food Safety (CFS) states: "CFS submits these comments in strong support of the Wild Farm Alliance (WFA) request to add to the Compliance, Accreditation & Certification (CACS) Subcommittee work agenda an item on 'Eliminating the Incentive to Convert Native Ecosystems into Organic Crop Production."
- e. The Cornucopia Institute states: "The Cornucopia Institute agrees with WFA that supporting conservation practices, addressing natural resource issues, and supporting biodiversity conservation within agriculture is essential. The conversion of native ecosystems in particular is a serious problem that *must* be dealt with in a timely manner. When untouched native ecosystems are destroyed, there is no way to get them back to a pristine character. Habitat loss is the single most pervasive threat to wildlife and native plant life. Finally, incentivizing

the conversion of native ecosystems is contrary to standing organic policy and hurts the integrity of the organic label."

- f. Ohio Ecological Food and Farm Association (OEFFA) states: "While we support the continued growth of the organic industry and expansion of organic acreage, we feel that it should not be at the cost of natural ecosystems, which organic standards are intended to protect."
- g. Wild Farm Alliance (WFA) states: "While Wild Farm Alliance is very willing to work with the NOSB in any capacity, we feel it is unfair for interested NOSB members to have to unofficially help with this issue on the side when they already volunteer a large amount of time officially. The NOP should work with the NOSB to put this on their workplan, and should provide staff time to help with this effort. The NOSB should be full participants in conducting an analysis and drafting a recommendation. While the integrity of the organic label is improving with the above-mentioned guidance, it falls short of excellence with this glaring problem. Let's work together to make organic the premier eco-label (as in ecological label) it was meant to be."

HANDLING SUBCOMMITTEE

2018 SUNSET MATERIALS: §205.605(A)

Agar-Agar

Purpose: stabilizer, thickener, gelling agent, texturizer, moisturizer, emulsifier, flavor enhancer, and absorbent.

Petitioned/Added: 1995 TAP; 2011 TR

Sunset 2018: to be voted on Fall, 2016.

Discussion: *Additional information requested by NOSB:* The 2011 TR provides possible agricultural alternatives to agar-agar in food applications, including: 1. gelling agents, such as pectin (high methoxy), gelatin, unmodified starches, and konjac flour; and 2.thickeners, emulsifiers, and stabilizers, such as vegetable gums (Arabic, locust/carob bean, guar), unmodified starches, tragacanth gum, konjac flour.

1. Have there been any new developments with alternatives to agar-agar?

2. Why is agar-agar used instead of alternatives? What are the unique characteristics that make it essential to organic handling?

	Support Relisting	Oppose Relisting	Nuanced/ Seeks Clarification
Farmers /	1	0	1 _e
Citizens			
Public Interest			BP _a , Cornucopia _d
Groups			
Food Processors	Ferrara _f , Amy's		
/ Handlers	Kitchen _b		
Ingredient			
Suppliers /			
Material			
Manufacturers			
Wholesalers/Dist	WhiteWave		
ributors /			
Retailers			
Trade	IFAC _c , IDFA		OTA – 4 handlers
Associations /			
Industry			
Consultants			
Certifiers			OTCO – 1 operation

Notes:

a. Beyond Pesticides (BP) states: "We support the continued listing of agar-agar on §205.605(a) Non-synthetics allowed, with the annotation, 'from *Gellidium* species, processed without alkaline pretreatment.' We oppose the proposed listing of agar-agar on §205.605(b) Synthetics allowed."

b. Amy's Kitchen states: "There are no other non-animal derived polysaccharides that have the same properties as agar-agar."

c. International Food Additives Council (IFAC) said, "Agar-agar is also less temperature sensitive than certain alternatives, making it particularly useful in gels that need to remain firm at room temperature or temperatures below 50 degrees C.

- d. The Cornucopia Institute states:" The Cornucopia Institute would **support** relisting agar-agar if an annotation is added stating "from Gelidium species only, processed without alkaline treatment and sourced from areas managed for sustainability."
- e. A citizen states: "We support the continued listing of agar-agar on 205.605(a) Non-synthetics allowed, with the annotation, 'from Gellidium species, processed without alkaline pretreatment. We oppose the proposed listing of agar-agar on 205.605(b) Synthetics allowed.'"
- f. The Ferrara Pan Candy Company states: "Agar-Agar is essential to the manufacture of the organic gummy candy we produce. Currently there is not a source of organic gelatin. It will likely be several years until the pork supply chain grows enough to support organic gelatin manufacture. Until then, we are dependent upon a combination of Agar-Agar and Organic starches to provide the gummy texture that consumer's expect in a gummy product."

Animal Enzymes

Purpose: a coagulant to curdle milk, to be made into cheese or sour cream.

Petitioned/added: 2000 TAP; 2011 TR; 2015 TR.

Sunset 2018: to be voted on Fall, 2016.

Additional information requested by NOSB: Are any animal derived enzymes currently being produced from organic livestock? If yes, on what scale? In the 2011 TR on Animal Enzymes, manufacture of the substance is focused on rennet. Please submit information if the manufacture of other types of animal enzymes differ from rennet.

	Support Relisting	Oppose Relisting	Neutral/ Nuanced
Farmers / Citizens	1		
Public Interest Groups			BPa, NOCh, CFSe
			Cornucopia _f
Food Processors /	Aurora _b		
Handlers			
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors	CROPP _d		
/ Retailers			
Trade Associations /	IOS		OTA – 2 handlers
Industry Consultants			
Certifiers	CCOF		MOSA _g – 2 clients, OTCO _c ,
			PCO – 8 operations

- a. Beyond Pesticides (BP) states: "The 2011 and 2015 TRs –the latter addressing ancillary substances– leave unanswered some important questions."
- b. Aurora Organic Dairy states: "Animal enzymes are essential for the production of certain organic cheeses (Romano, Blue Cheese, etc.), when plant based enzymes or microbial enzymes are not sufficient."
- c. Oregon Tilth (OTCO) states: "Most certified cheese manufacturers are using animal-derived rennet. OTCO certifies dozens of operations that use animal-derived rennet, microbial-derived rennet, or both."
- d. CROPP states: "To the best of our knowledge, there is no lipase formulation available derived from organic livestock."
- e. The Center for Food Safety (CFS) states: "The NOSB should continue to push for more animal enzymes from organic animals and prohibit the use of non-organic animal enzymes as more organic sources become available. Likewise, it should continue to view GE microbe-produced enzymes as excluded methods."
- f. The Cornucopia Institute states: "Animal enzymes are a necessary processing medium for some organic foods and there is limited availability of organic animal enzymes. Other than enzymes derived from a genetically engineered source, no other products have the exact qualities needed for making certain types of cheese and cultured products."
- g. Midwest Organic Services Association (MOSA) states: "Some animal rennet is used by MOSA cheese processors, but vegetable rennets are more common."
- h. National Organic Coalition (NOC) states: "We encourage the NOSB to continue the search for organic animal enzymes beyond our borders, and if not available, to discover the barriers and how to overcome them."

Calcium Sulfate - Mined

Purpose: coagulant (for tofu), nutrient, yeast food, dough conditioner, firming agent, sequestrant, jelling agent, baking powder ingredient, carrier, pH buffer, and abrasive agent.

Petitioned/added: Petitioned in 2000; 1996 TAP; 2001 TAP.

Sunset 2018: to be voted on Fall, 2016.

Discussion: Information from the petition and 2001 TAP review maintain that this material is consistent with OFPA criteria. Unless new information is provided from the public about impacts to the environment or human health this material should be renewed.

	Support Relisting	Oppose Relisting	Nuanced/ Seeks Clarification
Farmers / Citizens			
Public Interest Groups			BP _a , Cornucopia _f
Food Processors /	Amy's		
Handlers	Kitchen _c ,		
	Hain _e		
Ingredient Suppliers /	USGg		
Material Manufacturers			
Wholesalers/Distributors			
/ Retailers			
Trade Associations /	IOS		OTA - 3 handlers
Industry Consultants			
Certifiers	CCOFb		OTCO _d - 14
			operations

- a. Beyond Pesticide (BP) states: "We have not seen sufficient evidence to support the use of calcium sulfate for all food uses. Therefore we support renewing the listing of calcium sulfate with the annotation, 'For use only as a coagulant in bean curd (tofu and similar products)."
- b. California Certified Organic Farmers (CCOF) "supports relisting materials upon consideration of the following:
 - Clear alternatives with demonstrated viability for organic operations have not emerged since the original listing
 - The material remains in use by organic producers
 - Substantively new information has not been brought forward to demonstrate that the material is incompatible with organic principles."
- c. Amy's Kitchen states: "Calcium sulfate is used by an Amy's Kitchen soy cheeze supplier (used in the manufacture of the tofu they use as an ingredient for the cheeze)."
- d. Oregon Tilth (OTCO) states: "OTCO certifies at least 14 operations that are using calcium sulfate as part of their manufacturing process."
- e. Hain Celestial Group states: "We utilize Calcium Sulfate as the sole coagulant or in combination with other coagulants in many of our organic tofu products."
- f. The Cornucopia Institute states: "Given the potential environmental and human health effects associated with mining, The Cornucopia Institute recommends that a new Technical Report be prepared to fully evaluate and discuss these concerns before the relisting proceeds."
- g. The United States Gypsum Company (USG) states: "USG respectfully submits that the available data continue to support including "calcium sulfate mined" as an "allowed" substance in the National List."

Carrageenan

Purpose: food additive.

Petitioned/added: 1995 TAP, 2011 TR; 2016 Limited Scope TR.

Sunset 2018: to be voted on Fall, 2016.

Discussion: Additional information requested by NOSB:

1. After the last review in 2012 we know some companies pledged to remove carrageenan from their products. Has this been successful and what alternatives have been used? Are there any products for which it has not been successful, and why?

2. Are there any stakeholders who rely on this material? If so for what uses and why have alternatives not been successful?

3. Is "sensitivity" to a food ingredient enough of a reason to prohibit a substance in organic products if it is clearly listed as an ingredient on a food label?

	Support Relisting	Oppose Relisting	Neutral/ Seeks Clarification
Farmers / Citizens	Shanghai, China – 33 Indonesia Farmers _b – 6 Philippines Farmers - 7	Consumers - 15	
Public Interest Groups		Cornucopia _o , NOC _k , BP, CR _j , FWW _p , CFS _r	
Food Processors / Handlers	Aurora Kuen Lee _h	, ,	
Ingredient Suppliers / Material Manufacturers	FMC _c - 71; Ingredients Solutions – 2; Shanghai Brilliant Gum Co., Ltd; Perdue Foods; Perrigo _t		Ferrarau
Wholesalers/Distri butors / Retailers	CROPP _m Robin Coon _e	PCC _i	
Trade Associations / Industry Consultants	 FMC Facebook Campaigna 1,102; Celtic Colloidsd; Nutrition Edge Comm.; Marinalg Int.; Natural Products Assoc.; United 4Food Sciencel; UI/WSU School of Food Science; Harvard Medical Schoolg; UMD Prof. Emeritus Mark Varner; Allied Food Prod., Inc.; Griffiths Foods; IFACn; Richard Theuerf; Int'l Dairy Foods Assoc.; Infant Nutrition Councils 		OTA-6 handlers
Certifiers	CCOFq		OTCO – 16 operations, PCO – 2 operations

- a. An FMC website (Food Science Matters) launched a Facebook Campaign: 1,102 respondents submitted the form letter "Dear Mr. McEvoy, The AMS plays a critical role in ensuring the quality and availability of food for all Americans..."
- b. Ludy Tarsius, a seaweed farmer in Indonesia states: "We are selling seaweed, which maintains excellent relationships with our farming families that cultivate the seaweed we use to make carrageenan. We know, firsthand, how those jobs allow our farmers to care for their families and provide a life that might otherwise not be possible."
- c. Pierre Leclerc of FMC states: "I am an employee of FMC, a leading manufacturer of carrageenan for more than 75 years. FMC is the largest tax payer in Rockland, Maine and we are the only carrageenan producer in North America. Employment in our plant is crucial, not only to us as employees, but to the local economy. As demand decreases for a crucial product like carrageenan, manufacturing jobs are obviously impacted."
- d. William Blakemore, President of Celtic Colloids states: "The majority of work on carrageenan funded by industry was conducted by independent consultant contractors, such as me. The fact that I was employed by the carrageenan industry for over 30 years, and have been a carrageenan chemist for more than 50 years was why the industry contracted with me... I have been retired from FMC for ten years, starting my company, Celtic Colloids."
- e. Robin Koon, of a softgel encapsulation company states: "There are very few plant based materials that mimic the polysaccharide chains that carrageenan's have and are extremely strong, enabling it as a replacement for gelatin (and gelatin is from an animal source).
- f. Richard Theuer, a former member of the NOSB (1992-1994), an original TAP reviewer of carrageenan in 1995, and a nutritional scientist involved in infant formula states: "Perhaps foods labeled as "organic" should not be exempted from labeling "incidental additives" including "processing aids," etc., but be held to the higher labeling standard of hypoallergenic foods (21 CFR 105.62).
- g. Andrew Onderdonk of Harvard Medical School states: "Low molecular weight, degraded carrageenan given to germfree or gnotobiotic guinea pigs in the absence of specific strains of *B. vulgatus* did not lead to colitis."
- h. Kuen Lee states: "Carrageenan is an important ingredient as stabilizer and thickener in many of our organic certified non-dairy beverages."
- i. Trudy Bialic of PCC Natural Markets states: "We disagree with the discussion document statement that the decision on carrageenan revolves around the premise that humans have varying degrees of sensitivity to carrageenan in the diet, similar to allergenic foods. Carrageenan is not a food, it's an additive, a synthetic additive. No one would buy carrageenan to eat. It is not necessary in food. Providing improved emulsion and mouth feel is not necessary to enjoy fresh whipping cream, or to render whipping cream into its ultimate end purpose, in a whipped form."
- j. Consumer Reports (CR) states: "[Allergic] Foods that contain gluten or fall in the category of dairy or legumes do not undergo evaluation to OFPA criteria because they are actual foods that can be produced organically. Carrageenan is an additive that is otherwise prohibited in organic foods."
- k. National Organic Coalition (NOC) states: "After four years, the reasons for removing carrageenan have become even more compelling, as more scientific studies questioning its safety have been published and companies have removed it from more products."
- I. United 4Food Science states: "As an emulsifier and stabilizer, carrageenan gives infant formulas a palatable taste and texture and ensures that infants receive a balanced packet of nutrients from the first sip to the last drop. The same can be said for adult nutrition drinks consumed by seniors, as well as medical nutrition products often given by feeding tube to patients with cancer and other serious illnesses"
- m. CROPP states: "We expect complete removal by May 1, 2016. Although we have successfully removed carrageenan from our products we believe this is a material that is useful for certain applications. There is no scientific reason to remove it from the National List."
- n. International Food Additives Council (IFAC) states: "One of carrageenan's most important functional properties is its unique protein interaction, which makes it particularly functional in protein rich matrices like dairy products and meats to prevent separation of key components even at very low usage levels."
- o. The Cornucopia Institute states: "The study that the Joint FAO/WHO Expert Committee on Food Additives (JECFA) partially based its decision contained several critical flaws which we outline."
- p. Food and Water Watch (FWW) states: "In addition to questions of safety, carrageenan fails to meet the criteria of essentiality."
- q. California Certified Organic Farmers (CCOF) states: "Nine CCOF members include carrageenan on their Organic System Plan, one as a frozen soy product stabilizer, the others in beer production, personal care products, and in edible gel capsules used to package dietary supplements. It is unclear to CCOF whether alternatives exist to these uses for carrageenan."
- r. The Center for Food Safety (CFS) states: "Fewer companies rely on carrageenan as an additive, and its lack of essentiality has been sufficiently demonstrated by the growing number of companies and products made without it. Given this, and the potential for harm form degraded carrageenan in the human digestive system, the time has come for carrageenan to sunset."
- s. The Infant Nutritional Food Council states: "the Joint FAO/WHO Expert Committee on Food Additives (JECFA) has determined the use of carrageenan in infant formula and formulas for special medical purposes does not present safety concerns. As an international expert scientific committee that reviews the safety of food additives and is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World

Health Organization (WHO), Infant Nutrition Council encourages the NOSB to consider this JECFA evaluation when making determinations on carrageenan safety in infant formula. Removing carrageenan from the National List could negatively impact the availability of liquid organic infant formula products and reduce organic options available to consumers."

- t. Perrigo Nutritionals states: "At the present time we have no alternative for carrageenan and therefore we request that carrageenan continue to be allowed and listed as a non-synthetic ingredient allowed in or on processed products labeled as "organic" or "made with organic" under CFR 7 205.605(a). The delisting of carrageenan may have a significant impact to organic consumers who currently purchase products containing carrageenan."
- u. The Ferrara Pan Candy Company states: "There are confections on the market made with carrageenan as a gelling agent. We did evaluate carrageenan in the formulation of some of our organic products. It does produce a nice gel. However, it leaves a slimy coating in your mouth for about 15 minutes after eating. We chose not to formulate with carrageenan because other ingredients provide better functionality."

Glucono Delta-Lactone

Purpose: primarily in silken tofu; but also used as a curing agent, leavening agent, pH control agent and sequestrant.

Petitioned/added: Petitioned in 2002; 2002 TAP & 2016 TR.

Sunset 2018: to be voted on Fall, 2016.

Additional information requested by NOSB:

- 1. Is GDL being used in applications other than tofu production for organic processed foods?
- 2. If GDL was removed from the national list, are alternative tofu coagulants such as calcium and sulfate salts sufficient to produce all forms of tofu?

3. Should GDL produced from enzymes be prohibited or further restricted due to concerns around GMOs?

	Support Relisting	Oppose Relisting	Neutral/ Seeks Clarification
Farmers / Citizens			
Public Interest Groups		Cornucopia _c ,	
		BPa	
Food Processors /	HCG _b		
Handlers			
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors	WhiteWave		
/ Retailers			
Trade Associations /	IDFA		OTA – 2 handlers
Industry Consultants			
Certifiers			OTCO - 3 operations

- a. Beyond Pesticides (BP) states: "The 2016 technical review (TR) suggests that the current annotation is not sufficient to ensure that the glucono delta-lactone (GDL) in use is nonsynthetic.113 It also states that some enzymes used in the production of GDL may be genetically engineered. If it decides to relist GDL, the NOSB should consider an annotation change to correct these issues."
- b. Hain Celestial Group states: "GDL is well known for its ability to produce silken tofu with its smooth, jelly-like texture."
- c. The Cornucopia Institute states: "This listing would be more compatible with organic principles of handling with an annotation change including the phrase '*from a non-genetically modified source and method of production.*"

Tartaric Acid

Purpose: acidulant, pH control agent, preservative, emulsifier, chelating agent, flavor enhancer and modifier, stabilizer, anti-caking agent, and firming agent.

Petitioned/added: 2011 TR; 2011 Petition to remove from §205.605(b) - made from malic acid.

Sunset 2018: to be voted on Fall, 2016.

Additional information requested by NOSB: The Handling Subcommittee requests public comment on the use of Tartaric acid and its essentiality in organic processing.

	Support Relisting	Oppose Relisting	Neutral/ Seeks Clarification
Farmers / Citizens			
Public Interest Groups			Cornucopia _d , BP _a
Food Processors /	Fetzer _c , Nature's		_
Handlers	Path _e , Bronco Wine,		
	6 winemakers		
Ingredient Suppliers /	Ferrara _f		
Material Manufacturers			
Wholesalers/Distributors			
/ Retailers			
Trade Associations /	Juice Products		OTA – 2 handlers
Industry Consultants	Association, IOS		
Certifiers	CCOF _b		
			OTCO – 12 operations

- a. Beyond Pesticides (BP) states: "The HS should investigate whether tartaric acid from organic grape wine is available or would be available if this listing did not discourage its use. Since tartaric acid is a waste product from winemaking, its sale could provide additional revenue to organic vintners."
- b. California Certified Organic Farmers (CCOF) "supports relisting materials upon consideration of the following:
 - Clear alternatives with demonstrated viability for organic operations have not emerged since the original listing
 - The material remains in use by organic producers
 - Substantively new information has not been brought forward to demonstrate that the material is incompatible with organic principles."
- c. Fetzer Vineyards (dba Bonterra Vineyards) states: "Tartaric Acid is a very important part of the organic winemaking process and we strongly support its continued use."
- d. The Cornucopia Institute states: "because this listing may discourage the use of organic Tartaric acid from organic grape wine, The Cornucopia Institute strongly recommends the addition of an annotation specifying that the nonorganic form of Tartaric acid can only be used when the product is not commercially available in organic form."
- e. Nature's Path Foods states: "We have not been able to find any alternatives to tartaric acid to achieve the desired effects of "rising" dough."
- f. The Ferrara Pan Candy Company states: "We are planning to use Tartaric Acid on several confectionery products in development. When compared to Citric acid, Tartaric is much more stable when used as a coating on the surface of gummy and jelly candies. When exposed to warm temperatures, sour coated candy can "sweat" making the product look wet. This is much less likely to happen when tartaric acid is used. Tartaric acid provides unique functionality and high impact sourness that other acids cannot."

2018 SUNSET MATERIALS: §205.605(B)

Cellulose

Purpose: for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

Petitioned/added: 2001 petition; with 2001 TAP & 2016 TR.

Sunset 2018: to be voted on Fall, 2016.

Additional information requested by NOSB:

- 1. Have there been any new sources for either a non-synthetic or an organic form of cellulose identified during this current Sunset Cycle? If so please provide the NOSB with information on this source.
- 2. Are there any new or potential uses not covered by the current annotation that should be brought to the NOSB's attention? If so please explain.
- 3. Have there been any possible alternatives to any of the allowed uses for cellulose identified during this current Sunset Cycle, and if so please provide the NOSB with their names and how they compare to the use of cellulose for the specific use.
- 4. What impact would the inclusion of the word "powdered" as part of the annotation have on your handling process? Should the NOSB consider bringing forth a separate proposal to make this change to the cellulose annotation?
- 5. Could you help us to identify any ancillary substances that might be used with cellulose in organic handling or processing? The new Technical Evaluation Report mentions several potential ones for both powdered and the inedible form used in regenerative casings. Are any of these currently being used in organic handling and processing?

	Support	Oppose	Neutral/
	Relisting	Relisting	Seeks Clarification
Farmers / Citizens			
Public Interest Groups		BP _a ,	Cornucopia _{i,} NOC _b
Food Processors /	Amy's		
Handlers	Kitchen _c ,		
	Aurora _d ,		
	Fetzer _g , Bronco		
	Wine _k		
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors	WhiteWave _j ,		
/ Retailers	CROPP _h		
Trade Associations /	IFAC _e , Juice		OTA – 7 handlers
Industry Consultants	Products		
	Association,		
	IOS, IDFA		
Certifiers	CCOF _f		OTCO – 14 operations,
			PCO – 3 products

- a. Beyond Pesticides (BP) states: "It appears that cellulose can be removed from the National List as unnecessary. As an alternative, the recommendation for an annotation change passed by the board in 2012 should be revisited."
- b. National Organic Coalition (NOC) supports an annotation "to the listing to prohibit cellulose derived from pulp."
- c. Amy's Kitchen states: "Amy's Kitchen requests that cellulose remain on the National List because we understand some of our suppliers use cellulose based filtering aids."
- d. Aurora Organic Dairy states: "Cellulose repels moisture thereby allowing shelf stability and consumer satisfaction. Cellulose powder (non-chlorine bleached) is essential for organic cheese production/handling."
- e. International Food Additives Council (IFAC) said, "Most commercially available cellulose is produced from wood pulp or other plant sources through a delignification process that results in sufficient chemical change to render the substance synthetic. While the production of nonsynthetic cellulose is technically possible, no commercial sources of non-synthetic cellulose are currently known. Food Additive Council is also not aware of any organic cellulose currently available."
- f. California Certified Organic Farmers (CCOF) states: "In response to question 4, CCOF does not think that adding the word "powdered" to the annotation makes sense for sausage casings, in which the cellulose is used to retain the shape. Most technical data sheets that we have reviewed describe the material as powdered, fiber, or pulp."
- g. Fetzer Vineyards (dba Bonterra Vineyards) states: "Diatomaceous Earth (DE) filtration, commonly used on smaller lots of wine, uses Cellulose as a base coat for the filter frames used in DE filtration. The fabric in filter frames is pre-coated with Cellulose prior to using the DE solution to increase filtration efficiency. Therefore, this product is an important use in the filtration of small lots of organic wines and the industry needs it to continue to be an allowed tool."
- h. CROPP states: "We use cellulose in two applications cellulose casings and as an anti-caking ingredient in shredded cheese."
- i. The Cornucopia Institute states: "Cornucopia would support relisting if the annotation were changed to limit the types of cellulose used in organic handling to 'amorphous powdered cellulose and inedible cellulose casing."
- j. WhiteWave Foods (via Earthbound Farm) states: "The cellulose has a technical anti-caking effect on the shredded cheese, which keeps the cheese from clumping together."
- k. Bronco Wine Company states: "Cellulose is used as our key filtration aid to remove any spoilage organisms. The removal of Cellulose, from the National List will have a direct impact on our quality of wine. To my knowledge there has been no organic replacement or any other material that has the same effect or provides the same quality as the material in question."

Potassium Hydroxide

Purpose: used in soap making and the lye peeling of fruits and vegetables.

Petitioned/added: 2001 petition, 2011 Amend annotation.

Sunset 2018: to be voted on Fall, 2016.

Additional information requested by NOSB: The Handling Subcommittee requests public comment on the use of Potassium hydroxide and its essentiality in organic processing.

	Support Relisting	Oppose Relisting	Neutral/ Seeks Clarification
Farmers / Citizens	2		2 _{f,h}
Public Interest Groups	Cornucopia _g		BP _a , NOC _b
Food Processors /	Amy's		
Handlers	Kitchen _c ,		
	Bronco		
	Wine		
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors	CROPP _e		
/ Retailers			
Trade Associations /	IOS		OTA – 4 handlers
Industry Consultants			
Certifiers	CCOF _d		MOSA – 2, OTCO – 16
			operations; PCO – 30 operations

- a. Beyond Pesticides (BP) states: "Potassium hydroxide is a hazardous material, possibly (with sodium hydroxide) one of the most hazardous and toxic on the National List.131 The 2016 TR does not seem to have resolved the issue of the essentiality for potassium hydroxide in processing peaches, but the essentiality of other allowed uses also needs to be examined. We suggest that the HS address the following questions: 1. For what purposes is potassium hydroxide used in organic processing? 2. What are the alternatives for those uses? 3. Is further annotation necessary?"
- b. National Organic Coalition (NOC) states, "The HS should propose an annotation that addresses all allowed uses of potassium hydroxide."
- c. Amy's Kitchen states: "Potassium hydroxide is likely used to adjust the acidity in several ingredients supplied to Amy's Kitchen."
- d. California Certified Organic Farmers (CCOF) "supports relisting materials upon consideration of the following:
 - Clear alternatives with demonstrated viability for organic operations have not emerged since the original listing
 - The material remains in use by organic producers
 - Substantively new information has not been brought forward to demonstrate that the material is incompatible with organic principles."
- e. CROPP states: "The reason Potash is a better fit as a processing aid is that it is much gentler to the proteins in the Buttermilk. It is also used to adjust the Alkali in Organic Cocoa Nibs which are used in the making of Chocolate."
- f. A citizen states: "Potassium hydroxide is a hazardous material, possibly (with sodium hydroxide) one of the most hazardous and toxic on the National List. The 2016 TR does not seem to have resolved the issue of the essentiality for potassium hydroxide in processing peaches, but the essentiality of other allowed uses also needs to be examined."
- g. The Cornucopia Institute states: "For certain applications, such as lye peeling of peaches, Potassium hydroxide is currently essential. There are several alternative approaches to peel peaches that are being developed; only one of them is now available commercially."
- h. Former NOSB member states: "Annotation: prohibited for lye peeling of anything but peaches."

Silicon Dioxide

Purpose: used as a defoamer and allowed for other uses when organic rice hulls are not commercially available.

Petitioned/added: 1996 TAP, 2010 TR; 2010 petition to remove.

Sunset 2018: to be voted on Fall, 2016.

Discussion: Sunset Review. Comments regarding relisting Perlite on the National List under §205.605(a)

	Support Deliating	Oppose Delisting	Neutral/
	Relisting	Relisting	Seeks Clarification
Farmers / Citizens	2		1
Public Interest Groups			Cornucopia _{n,} BP _a ,
			NOC _m ,
Food Processors /	Aurora _b , ABI _e ,		
Handlers	Hain _h , California		
	Nat. Prod. _j , Seed		
	Dynamics Inc., PP1		
Ingredient Suppliers /			Ferrara
Material Manufacturers			
Wholesalers/Distributors	Whitewave	PCCd	
/ Retailers			
Trade Associations /	IOS, IFAC _c , The		OTA – 6 handlers
Industry Consultants	American Seed		
	Trade		
	Association _i ,		
	Silica Assoc. _k ,		
	IDFA		
Certifiers	CCOF _f		OTCOg-21operations,
			PCO – 8 operations

- a. Beyond Pesticide (BP) states: "...the NOSB should revisit the annotation to determine whether it should be changed to the language as originally passed by the NOSB or to a slightly less restrictive version (but still more restrictive than the version adopted into the regulations)..."
- b. Aurora Organic Dairy states: "Is used as an anticaking agent in organic powders, including organic cheese powders as rice hulls aren't able to meet the various applications where silicon dioxide is used."
- c. International Food Additives Council (IFAC) states: "Food Additive Council is unaware of any suitable organic alternatives to silicon dioxide that can replace this important component of defoamers in all food and beverage applications. While Food Additive Council acknowledges that there may be specific, limited applications where organic substitutes might provide acceptable performance, these organic alternatives do not achieve suitable functionality in all of the organic applications where silicon dioxide is currently being used."
- d. PCC Natural Markets states: "PCC Natural Markets recently has designated silicon dioxide as not acceptable as an additive in organic foods after learning it can be a product of nanotechnology. We have seen it on ingredient panels, and apparently is used as a flow agent with powdered flavorings.
- e. Abelei, Inc. states: "Organic rice hulls do not perform as well as silicon dioxide."
- f. California Certified Organic Farmers (CCOF) "supports relisting materials upon consideration of the following:
 Clear alternatives with demonstrated viability for organic operations have not emerged since the original listing
 - The material remains in use by organic producers
 - Substantively new information has not been brought forward to demonstrate that the material is incompatible with organic principles."
- g. Oregon Tilth (OTCO) states: "Some operations require the use of silicon dioxide. The most common reason for a request to use silicon dioxide in place of organic rice hulls is related to form or quality."

- h. Hain Celestial Group states: "The current annotation allows for the use of silicon dioxide when organic rice hulls are not commercially available. Rice hulls are not the same substance as silicon dioxide, and rice hulls do not have the same anticaking functionality as silicon dioxide."
- i. The American Seed Trade Association states: "The American Seed Trade Association supports keeping silicon dioxide (sand) on the National List of organically compliant materials, currently under review and discussion during the NOSB's April 2016 meeting. Seed treatment companies prepare seed and apply plant protectants onto many seed varieties, including vegetable seeds. These companies depend on silicon dioxide as a major part of their organic compliant portfolio."
- j. California Natural Products states: "I am writing in support of re-listing silicon dioxide along with all the annotations; especially crucial is the annotation part allowed for other uses when organic rice hulls are not commercially available. Without this listing and without this part of the annotation, organic products we have made for years will no longer be made."
- k. The Synthetic Amorphous Silica and Silicate Industry Association states: "SASSI respectfully requests that Silicon dioxide remain on the USDA National List of allowable ingredients for food production at 205.605(b). Based on a review by a number of our member companies (reported to NOSB in our comment letters dated Nov. 11, 2011, Dec. 20, 2013 and April 7, 2015) and recent experience reported by food processors, Silicon dioxide remains an essential and irreplaceable ingredient in a number of applications including but not limited to anti-caking and free flow applications."
- I. PowderPure (PP) states: "Silicon dioxide is an important anti-caking agent for PowderPure as 95% of our organic and conventional fruit and vegetable powders require its anti-caking properties to maintain their condition as flowable powdered food products. Currently, 50% of our products produced at our facility in Oregon are Organic Certified."
- m. The National Organic Coalition (NOC) states: "...research on rice hulls and other natural alternatives suggests that they could effectively replace both cellulose and silicon dioxide for anti-caking and filtration uses. The NOSB should encourage further development of these alternatives to facilitate the sunset of cellulose and silicon dioxide during the next review cycle."
- n. The Cornucopia Institute states: "The Cornucopia Institute supports the relisting of Silicon dioxide in 205.605(b) with the recommendation that the availability of organic biogenic sources of silica products be further investigated. In addition, the Cornucopia Institute strongly recommends that the annotation be changed in order to encourage the development and commercialization of alternative organic biogenic substitute is not commercially available"

2018 SUNSET MATERIALS: §205.606

Colors: Beta-Carotene Extract

Purpose: used as a colorant.

Petitioned/added: Petitioned 2007, 2009, TR 2011.

Sunset 2018: To be voted on Fall, 2016.

Discussion: §205.606(d) Colors derived from agricultural products - Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

NOSB asked: 1. Has there been any change in the ability of manufacturers to produce beta-carotene color from carrots using NOP compliant extraction methods? 2. Is this color necessary for organic processors? 3. Which species of algae are used and from where are they harvested? 4. If the typical species used are from the genus Dunaliella (as cited in the TR) is harvesting of these species of micro algae from the wild, certified wildcrafted, or cultivated? 5. When used as a color, is this material also a source of Vitamin A?

The NOSB is in the process of reviewing use of all marine plants which are presently on the National List, and will be requesting a limited Technical Report. The marine plants topic will be reported on as a separate item at the Fall 2016 meeting.

	Support Relisting	Oppose Relisting	Neutral/ Seeks Clarification
Farmers / Citizens			1
Public Interest Groups		BP _a , CR _g , Cornucopia _h	
Food Processors / Handlers	Aurora _b , Hain _f		
Ingredient Suppliers /	Ferrara		
Material Manufacturers			
Wholesalers/Distributors /			
Retailers			
Trade Associations / Industry	Color		OTA – 3
Consultants	Manufacturers _e		handlers
Certifiers	CCOF _c		PCO _i ,
			OTCO _d – 8
			operations

Notes:

a. Beyond Pesticides (BP) states: "The NOSB must take into consideration pesticide use on nonorganic carrots."

- b. Aurora Organic Dairy states: "Beta-carotene may be used alone or in conjunction with organic annatto to color organic cheese. This agricultural product is essential to organic food production as it is an alternative to annatto and has less color bleed."
- c. California Certified Organic Farmers (CCOF) states: "Nine CCOF members include colors on their Organic System Plan. Colors are used in organic juices, beverages, condiments, and candy. Colors are an important tool for organic processed food producers to create products that meet consumer expectations. In turn, the success of organic processed foods in the marketplace leads to greater organic crop acreage to meet demand for more organic raw materials to fulfill manufacturing needs. For organic products to compete successfully with conventional, organic processors need access to the full range of OFPA-compliant food colors. There does not seem to be an organic alternative for beta-carotene extract color at this time."
- d. Oregon Tilth (OTCO) states: "Many non-organic agricultural colors are a mixture of agricultural substances and some contain beta-carotene extract as part of their formulation."
- e. International Association of Color Manufacturers states: "Beta Carotene Extract Color should remain on

§205.606(d) of the National List because there is insufficient supply to warrant its Sunset."

- f. Hain Celestial Group states: "The commercially available organic colors do not provide the stability and desired color of the beta-carotene derived from algae."
- g. Consumer Reports (CR) states: "Beta carotene extract is used as a color additive and fails to meet the essentiality criterion. We urge the NOSB to remove it from the National List. Coloring is not an essential processing step for making organic foods, and it is therefore questionable whether any non-organic food ingredient whose primary or only function is to color foods should be deemed "essential." The sunset review of 17 colors in Fall 2015 revealed that certified organic colors, derived from organic crops, are now widely available to handlers. So for the food manufacturers that wish to color their foods, it appears organic options are available."
- h. The Cornucopia Institute states: "The Cornucopia Institute opposes the relisting of β -carotene extract color ... The Cornucopia Institute questions the essentiality of using a color from a non-organic agricultural source, considering that colors from non-organic fruit or vegetable sources may contain significant amount of pesticide residues, a human health threat. In addition, there appears to be a sufficient commercial supply of organic sources of beta-carotene color and of an organic alternative to beta-carotene color to justify the removal of betacarotene from §205.606(d)(2)."
- i. Pennsylvania Certified Organic (PCO) states: "PCO does not currently approve any products under the listing of beta-carotene extract color at §205.606. Beta-carotene can be used as a source of Vitamin A which is on 21 CFR 104.2 and therefore meets the listing of vitamins at §205.605(b). PCO has approved some products as nutrient vitamins and minerals that contain beta-carotene."

HANDLING SUBCOMMITTEE

PETITIONS

Lactates - Sodium and Potassium

Purpose: Petition for substances used in meat processing as pathogen inhibitors.

Petitioned/added: Petitioned for in January 5, 2004. On January 22, 2004, the NOP notified the petitioner that their petition would not be necessary since the materials sodium and potassium lactate were composed of substances that were already included on the National List (sodium hydroxide, lactic acid, and/or potassium hydroxide). Eventually, this interpretation was deemed inconsistent with previous NOSB recommendations on the classification of materials and was causing some confusion within the organic industry regarding the status of the two materials (sodium lactate and potassium lactate) as well as other lactate salts (example: calcium lactate) (McEvoy 2014). Thus, the NOSB (Handling Subcommittee) took up the request for the consideration of sodium lactate and otassium lactate for inclusion to the National List, §205.605 (b) Synthetics Allowed. **This proposal was referred back to the Handling Subcommittee at the fall 2015 NOSB meeting in Stowe, VT.**

	Support Petiton	Oppose Petition	Neutral/ Seeks Clarification
Farmers / Citizens	6	1	
Public Interest Groups		BPa, NOC _b ,	
		Cornucopia _i	
Food Processors / Handlers	Bontaical		
	Food Co.c		
Ingredient Suppliers /	Corbionh		
Material Manufacturers			
Wholesalers/Distributors /		PCCe	
Retailers			
Trade Associations / Industry			OTAg
Consultants			
Certifiers	CCOF _f		OTCO _d

- a. Beyond Pesticides (BP) states "Potassium lactate and sodium lactate are unnecessary. They are synthetic chemicals used for purposes not allowed in organic processing. Therefore, they should not be added to the National List."
- b. National Organic Coalition (NOC) states, "These synthetic materials have multiple technical functions, including function as synthetic preservatives, and should not be allowed in certified organic foods."
- c. Botanical Food Company states: "8 certified organic herb/spice growers supply our business and the listing of Sodium Lactate is critical to the continuing production of our Gourmet Garden 'Made with Organic' herb and spice pastes and our business, which has been using Sodium Lactate for over 6 years."
- d. Oregon Tilth (OTCO) states: As a certifier that has approved the use of these materials, including calcium lactate, we believe it is important to understand if and how the other lactate salts were included in further discussions and/or deliberations regarding the proposal at the NOSB and/or NOP level to address the expectations for the other salts not covered by this proposal.

- e. PCC Natural Market states: "Consumers expect organic standards to be more rigorous than standards for "natural." It is not congruent that organic always would allow a preservative that is not always allowed for "natural" meats."
- f. California Certified Organic Farmers (CCOF) states: "CCOF supports the classification of sodium lactate and potassium lactate as synthetic, as well as the listing of these materials on §205.605 (b) with the annotation "for use as an antimicrobial agent and pH regulator only."
- g. The Organic Trade Association (OTA) states: "Member outreach was inconclusive as to whether these two materials are needed."
- h. Corbion Purac states: "Both salts are approved by amongst others by FDA, by EU legislators and by JECFA/WHO to be used at high or even quantum satis levels in a large variety of foods."
- i. The Cornucopia Institute states: "There are many alternatives to these substances, some natural and some organic agricultural as listed in the TR; therefore these alternatives should be carefully considered by the NOSB when evaluating the listing of sodium and potassium lactates on the National List..."

Oat Beta-Glucan

Purpose: To supplement processed food to increase fiber content.

Petitioned/added: Oat beta glucan is being petitioned by manufacturer Tate & Lyle for addition at §205.606, as a natural component of oats, an agricultural commodity. According to the petition, the substance is isolated through a simple process of grinding, enzyme treatment, water extraction, and drying. No synthetic chemical additions or solvents are used in the manufacturing process being petitioned.

Discussion: The subcommittee felt that there were alternatives currently available and alternative sources for which these petitioned needs could be met.

Listing Motion: Move to list Oat Beta Glucan at §205.606 of the National List

Motion by: Lisa de Lima; Seconded by: Jean Richardson Yes: 0, No: 4, Abstain: 0, Absent: 2, Recuse: 0

	Support Petition	Oppose Petition	Neutral/ Seeks Clarification
Farmers/Citizens			
Public Interest Groups		BP _a , NOC _b , CR _c ,	
		Cornucopia _d	
Food Processors/ Handlers			
Ingredient Suppliers/			
Material Manufacturers			
Wholesalers/Distributors/			
Retailers			
Trade Associations/Industry			
Consultants			
Certifiers			

Notes:

- b. National Organic Coalition (NOC) states: "there are plenty of organically produced sources of fiber."
- c. Consumer Reports states: "We oppose listing oat beta glucan because it fails the OFPA criteria of essentiality and compatibility with organic handling."

d. The Cornucopia Institute states:" The Cornucopia Institute believes that the petition fails in its discussion of oat beta glucan in regard to its essentiality to organic production and handling and because it could be manufactured from organic oats."

a. Beyond Pesticides (BP) states: "Beyond Pesticides opposes the listing of oat beta-glucan because it is grown using chemical intensive methods, is not essential for organic production and handling, and is incompatible with organic production and handling."

Sodium Dodecylbenzene Sulfonate

Purpose: antimicrobial/sanitizer for use in treating fruits and vegetables in the premises of organic food retail establishments.

Petitioned/added: On October 9, 2015 the NOP received a petition to add Sodium dodecylbenzene sulfonate (SDBS) (CAS # 25155-30-0) to the National List at §205.605 – Non-agricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s)) (b) Synthetics Allowed. Ecolab, Inc. is the petitioner. SDBS is being petitioned for use as an active ingredient (1 of 2 active ingredients, the other is Lactic acid) in an antimicrobial formulation, for use in treating fruits and vegetables in the premises of organic food retail establishments.

Listing Motion: Motion to list Sodium dodecylbenzene sulfonate at §205.605 Yes: 1, No: 5, Abstain: 1, Absent: 1, Recuse: 0

	Support Petition	Oppose Petition	Neutral/ Seeks Clarification
Farmers / Citizens	3	148	
Public Interest Groups		BP _a , CR _c , Cornucopia _d	
Food Processors / Handlers			
Ingredient Suppliers / Material Manufacturers			
Wholesalers/Distributors / Retailers			
Trade Associations / Industry Consultants		OPWC _b	
Certifiers			

- a. Beyond Pesticides (BP) states: "Beyond Pesticides opposes the listing of SDBS at this time. SDBS has advantages over other antimicrobials, particularly chlorine-based materials, including acidified sodium chlorite. However, we believe that the NOSB needs to base any decisions on petitions for antimicrobial products on a thorough review of the need for all antimicrobials and the available products. Please see our comments on hypochlorous acid for more discussion of that issue."
- b. Organic Produce Wholesalers Coalition (OPWC) states: "we do not see a compelling argument that SDBS is essential for sanitizing organic raw and ready-to-eat organic fruits and vegetables at the retail level."
- c. Consumer Reports states: "SDBS is petitioned as an active ingredient in an antimicrobial formulation for use in treating fruits and vegetables in the premises of organic food retail establishments. It is petitioned as a processing aid, not an ingredient. We noted, however, that there is no Technical Report (TR) available for this material. For any material petitioned to be added to the National List, and especially for an antimicrobial material like SDBS, the NOSB should not vote to list it on the National List without a TR."
- d. The Cornucopia Institute states: "This substance is not necessary for organic production and there are unanswered questions about its safety for humans and the environment."

PROPOSALS

Ancillary Substances Procedure

Additives intentionally added to a nonorganic substance on the National List that are not removed and have a technical or functional effect on the nonorganic substance, not on the final organic product in which the nonorganic substance is used.

Background: Ancillary substances have been discussed by the NOSB for several years now, with an overall policy being passed in 2014 and ancillaries being looked at in Technical Reports and NOSB reviews since then.

Listing Motion: Motion to adopt the proposal as stated above for the definition, criteria for compliance, and procedure for the review of ancillary substances. Motion by: Zea Sonnabend; Seconded by: Jean Richardson Yes: 6, No: 0, Abstain: 0, Absent: 2, Recuse: 0

	Support Proposal	Oppose Proposal	Nuanced/ Seeks Clarification
Farmers / Citizens		181	
Public Interest Groups		BP _{a,} CR _g , Cornucopia _h	
Food Processors / Handlers	Stonyfield _e		
Ingredient Suppliers / Material Manufacturers			
Wholesalers/Distributors / Retailers			
Trade Associations /	OTA _f , IOS,		OTA _h
Industry Consultants	OMRIf		
Certifiers	CCOF _c , MOSA _d ,		OTCO _b , PCO _j

- a. Beyond Pesticides (BP) states: "Definitions are needed [and] [e]ach ancillary substance must be reviewed and approved for each particular use."
- b. Oregon Tilth (OTCO) states: "Modification to clarify the IARC and NTP list of known and probably carcinogens to include the specifics about why a particular material is considered carcinogenic or potentially carcinogenic would help certifiers make clear and sound decisions related to the compliance of these materials."
- c. California Certified Organic Farmers (CCOF) states: "The proposed definition of "ancillary substance" is useful. In section 2, the first two criteria for assessing compliance are clear and easily enforceable. However, criteria 3-5 may be problematic if there is no clearly referenced, central listing of all FDA-approved GRAS materials, direct food additives, incidental additives, and food contact substances. This could lead to the rule not being applied evenly by all ACAs. Providing additional examples of common known or probably carcinogenic ancillary ingredients would be helpful because it would allow ACAs to list those materials on the review forms as outlined in section 4. CCOF supports the proposed procedure for NOSB review of ancillaries."
- d. Midwest Organic Services Association (MOSA) states: "We find that most of the concerns we noted in our previous comments on this subject have been addressed in the new proposal. We still have concerns regarding the practicality of requiring more compliance verification. However, we recognize that this new part of the

sunset review process, which now will also need consideration as we review materials on a daily basis, represents due diligence and will provide needed clarification regarding any substances that might be of concern."

- e. Stonyfield states: "We suggest the NOSB consider the criteria for compliance proposed by the Organic Trade Association in their comments."
- f. Organic Materials Research Institute (OMRI) states: "To maintain continuity and build on the previous work of the subcommittee, OMRI suggests that the list of baseline criteria from the April 2013 NOSB recommendation on Ancillary Substances is integrated into future iterations of recommendations on this subject."
- g. Consumer Reports (CR) states: "We do not support the current proposal by the Handling Subcommittee, which is not consistent with the requirements in OFPA and could lead to approval of unreviewed ancillary substances, including materials that would not meet OFPA criteria for use in organic foods. Specifically, the Handling Subcommittee proposes: "The vote to approve a new substance will be considered to also approve the ancillaries that are associated with that substance unless the NOSB specifically states that one is not approved." This could lead to the use of ancillary substances that have not been reviewed.
- h. The Cornucopia Institute states: "Ancillary substances should only be allowed if they meet OFPA criteria. In addition, Cornucopia agrees that defining terms for any policy document is needed. Cornucopia wholeheartedly supports Beyond Pesticide's comments and rationale on this issue."
- i. The Organic Trade Association (OTA) states: "When we compare the baseline criteria to the criteria included in this proposal, there appear to be inconsistencies."
- j. Pennsylvania Certified Organic (PCO) states: "PCO is seeking clarification on the proposed criteria for compliance of ancillary substances. PCO would like the subcommittee to address whether it is its intent to use the proposed criteria as a replacement for or as a supplement to the criteria included in the April 2013 recommendation. If it is the latter, PCO recommends that the handling subcommittee combine both criteria into one comprehensive list."

DISCUSSIONS

Nutrient Vitamins and Minerals §205.605(b) Annotation Change

The Handling Subcommittee would like to change the annotation for the listing for Nutrient Vitamins and Minerals.

Background: The Discussion Document covers the background on the issue and presents several options for changes to the annotation. Members of the Handling Subcommittee are not unanimous on any of these options but wish to explain them and solicit public input on the pros and cons of them.

Subcommittee Vote: Motion to adopt the discussion document on Nutrient Vitamins and Minerals Motion by: Zea Sonnabend Second: Harold Austin Yes: 7, No: 0, Abstain: 0, Absent: 1, Recuse: 0

	Support an	Oppose	Nuanced
	option	Proposal	
Farmers / Citizens			48
Public Interest Groups		NOC _c , FWW _d ,	BP _a , Cornucopia _t
		CFS _k , CR _m ,	
Food Processors / Handlers	Stonyfield _i	HCG _j	
Ingredient Suppliers /		Nature's One _p ,	
Material Manufacturers		Perrigos	
Wholesalers/Distributors /	WhiteWave _h		
Retailers	, CROPP _g		
Trade Associations / Industry	OTA _n ,	1 _q , INC _r	OMRI
Consultants	Wolf/DiMatt		
	eob		
Certifiers	CCOF _f , PCO _o	MOSA _e	

- a. Beyond Pesticides (BP) states: "We agree –for the most part– with option 1. However, we believe that although nonsynthetic vitamins and minerals required by law should be allowed in food, those described in annotation #3 (for food, those identified as essential in 21 CFR 101.9; for infant formula, as required by 21 CFR 107.100 or §107.10) should be allowed only in products labeled "made with organic."
- b. Wolf, DiMatteo + Associates states: "Of the options offered in the discussion document, Wolf, DiMatteo + Associates generally supports Option 2 as it reflects most accurately the intent of the 1995 NOSB recommendation."
- c. National Organic Coalition (NOC) states: "NOC supports elements of Option #1, but we do not believe that a categorical listing is appropriate nor that an annotation referencing FDA regulations is the best approach. Therefore, we propose listing "vitamins and minerals" as a category on both 205.605(a) and (b) with individual vitamins and minerals listed underneath after they have undergone full review to OFPA criteria."
- d. Food and Water Watch (FWW) states: "... we do not think that referencing FDA in an annotation is the best solution and instead propose that "vitamins and minerals" be listed on both 205.605(a) and (b) as a header, with the individual vitamins and minerals listed underneath after each has gone through the full NOSB review process."
- e. Midwest Organic Services Association (MOSA) states: "After careful review of the documents related to this topic, and taking into account the needs of our staff and clients, MOSA is in support of a hybridized version of Option #1..."
- f. California Certified Organic Farmers (CCOF) states: "As an accredited certification agency (ACA), CCOF supports Option 2 because it will allow for succinct and clear standards." ..." One concern with each of the proposed options is the notation "for food." CCOF and other ACAs have allowed supplement and personal care product manufacturers to add vitamins and minerals to their products when the products are consumed by mouth. The annotation "for food" could preclude certification of these products, as they are not considered food. CCOF

certifies 39 supplement and/or personal care manufacturers who use vitamins and minerals in their products. The supplement industry is a purchaser of organic products and helps increase demand for organic products and organic acreage. CCOF recommends that the annotation identify organic products generally, not only food."

- g. CROPP states: "As a member of the Vitamin and Mineral Task Force, we support the detailed comments submitted by the Organic Trade Association and share the concern for the length of time to complete rule-making on the 2012 proposed rule. We are in favor of option #4."
- h. WhiteWave Foods states: "We have been long supporters of a finite list of Nutrient Vitamins and Minerals for use in organic production. As the NOSB and NOP work toward an annotation for NVM we hope they take into consideration the products that could be forced out of the market place if certified entities do not have ample opportunity to petition or re-petition their substances."
- i. Stonyfield states: "Stonyfield agrees with the Organic Trade Association's comments that the annotation for vitamins and minerals should be associated with clearly defined listing of what is allowed."
- j. Hain Celestial Group (HCG) states: "Our proposed annotation decreases complexity. It allows for the rational fortification of food in accordance with FDA's fortification policy to correct dietary insufficiencies in the population. It also gives consumers the maximum freedom of choice."
- k. The Center for Food Safety (CFS) states: "We do not believe that a categorical listing is appropriate, nor is an annotation referencing FDA regulations for vitamins and minerals. While we support elements of Options #1, for food we propose listing "vitamins and minerals" as a category on both 205.605(a) and (b) with individual vitamins and minerals listed underneath after they have undergone full review to OFPA criteria.
- I. Organic Materials Research Institute (OMRI) states: "A proposed rule was published in January 2012 to implement the April 2011 NOSB recommendation to revise the listing for nutrient vitamins and minerals to read, "Vitamins and minerals. For food—vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or 107.10." OMRI supports the previous work of the NOSB that led to this proposed rule, and encourages the NOP to complete rulemaking."
- m. Consumer Reports (CR) states: "We propose listing "vitamins and minerals" as a category in both 7 C.F.R. § 205.605(a) and (b) with individual vitamins and minerals listed underneath after they have undergone full review to OFPA criteria. For infant formula, a categorical listing and reference to FDA regulations is appropriate, since FDA requires the addition of certain nutrients to infant formula. For infant formula, we support Option #1 with one modification: referencing 21 C.F.R. § 107.100 rather than referencing both 21 C.F.R. § 107.10 and 21 C.F.R. § 107.100."
- n. The Organic Trade Association (OTA) "believes the (annotation) option that most accurately captures the intent of the 1995 Recommendation is Option #2: *Allow vitamins and minerals for food as essential in 21 CFR 101.9 and for infant formula as required by 21 CFR 107.100 or 107.10 in "ORGANIC" and "MADE WITH ORGANIC" products."*
- o. Pennsylvania Certified Organic (PCO) states: "PCO recommends that the National Organic Program (NOP) complete rulemaking on the 2012 proposed rule that has yet to be finalized. This proposed rule was based on NOSB discussion and feedback, and revisiting this at the NOSB level is redundant. ... Of the two options presented by the NOSB for the listing of Nutrient Vitamins and Minerals, PCO supports option 2....
- p. Nature's One, Inc. states: "Because vitamins and minerals are essential to the nutritional health of not just infants but also young children with medical conditions affecting their ability to consume foods and because the FDA does not have a standard of identity nor regulations pertaining to toddler formulas, we request that the final annotation address nutritionally complete pediatric enteral formulas. Unless synthetic vitamins and minerals are allowed in these formulas, there will no longer be an organic option for feeding this nutritionally vulnerable group of children, children who most need an organic option."
- q. Richard Theuer states: "I suggest that you reconsider this proposal."
- r. Infant Nutrition council of America states: "If the NOSB wishes to recommend an annotation based on the existing discussion document, Infant Nutrition Council supports a new annotation for infant formula that would also reference 21 CFR 101.9. Below is suggested language: §205.605 (b) Vitamins and minerals. For Food Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula— vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula— vitamins and minerals identified as essential in 21 CFR 101.9 or as required or permitted by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled "organic" and "made with organic (specified ingredients or food group(s))." Infant Nutrition Council also supports the addition of essential nutrients to organic infant foods, regardless of whether there is a Standard of Identity requiring such addition."
- s. Perrigo Nutritionals states: "We suggest a revision which clearly delineates the essential vitamins and minerals that are permitted in food and infant formula: §205.605 (b) Vitamins and minerals. For Food Minerals (including trace elements) and vitamins identified as essential in 21 CFR 101.9. For infant formula— vitamins and minerals identified as essential in 21 CFR 101.9 or as required <u>or permitted</u> by 21 CFR 107.100 or § 107.10 are allowed for use in agricultural products labeled "organic" and "made with organic (specified ingredients or food group(s))."" We have added the words "or permitted" and removed "synthetic" because paragraph (5) of 21 CFR §107.10 permits but does not require all of the nutrients that have been deemed essential by the National Academy of Sciences (NAS) and some vitamins and minerals may be non-synthetic. The revised annotation will permit the use of any future vitamin or mineral that is deemed essential by the NAS.
- t. The Cornucopia Institute states: "The Cornucopia Institute supports the annotation change for Nutrient Vitamins and Minerals ... under option #1 with respect to synthetic vitamins and minerals. However, The Cornucopia Institute believes that non-synthetic vitamins and minerals should be subject to the same restrictions as synthetic ones. Consequently, the Cornucopia Institute opposes option #2, the alternate annotation change also proposed in the HS discussion document that would allow non-synthetic and synthetic vitamins and minerals in products labeled "made with organic" or "organic"."

CROPS SUBCOMMITTEE

SUNSET 2018

Copper Sulfate

Purpose: use as an algaecide and as tadpole shrimp control in aquatic rice systems.

Sunset 2018: To be voted on in Fall, 2016.

Additional information requested by NOSB:

- 1. Has there been any new information regarding the viability of alternatives to these uses of copper?
- 2. Have ACAs noticed any increase in baseline soil test values for copper and done anything about it?

	Support Relisting	Oppose Relisting	Neutral/ Seeks Clarification
Farmers / Citizens	7		
Public Interest Groups		BPa, NOC _b ,	CFS _h , FWW _e ,
		Cornucopia _g	WFAi
Food Processors /	Amy's		
Handlers	Kitchen _d ,		
	Fetzer _f		
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors			
/ Retailers			
Trade Associations /	IOS		OTAj – 4
Industry Consultants			producers
Certifiers	CCOF _c		ОТСО

- a. Beyond Pesticides (BP) states: "the use of copper sulfate in an aquatic environment like a rice field is inconsistent with a system of organic and sustainable agriculture."
- b. National Organic Coalition (NOC) states: "Before voting on the relisting of copper sulfate, the NOSB must have a report on recent research on alternatives. If there is no satisfactory research on alternatives to copper sulfate, a robust research strategy must be recommended by the NOSB to the NOP with a recommendation that funding is urgently needed to ensure that the research is carried out."
- c. California Certified Organic Farmers (CCOF) "supports relisting materials upon consideration of the following:
 Clear alternatives with demonstrated viability for organic operations have not emerged since the original
 - IstingThe material remains in use by organic producers
 - Substantively new information has not been brought forward to demonstrate that the material is incompatible with organic principles"
- d. Amy's Kitchen states: "Used for plant disease control and as a micronutrient by several suppliers to Amy's Kitchen."
- e. Food and Water Watch (FWW) states: "We urge the USDA to allocate funds to assist in the development of alternative management practices, and ask the subcommittee to report on any research concerning alternatives that has been done since the last sunset decision, as well as commission a technical review to address the current uses and possible alternatives for copper sulfate in organic production."

- f. Fetzer Vineyards (dba Bonterra Vineyards) states: "...this input is necessary for continued success in growing quality organic grapes."
- g. Cornucopia Institute states: "Copper sulfate contains arsenic which rice accumulates and is toxic to aquatic animals, many of which provide biological control for algae."
- h. The Center for Food Safety (CFS) states: "Before voting on the relisting of copper sulfate, the NOSB must have a report on recent research regarding alternatives. If there is no satisfactory research on alternatives to copper sulfate a robust research strategy must be endorsed by the NOSB to the NOP with a recommendation that funding is urgently needed to ensure that the research is carried out."
- i. Wild Farm Alliance (WFA) states: "We recommend that the NOSB conditionally allow this pesticide to be used, requiring that the organic rice industry work with researchers to find alternatives to this product, and report back to the NOSB about possibilities and achievements before it comes up for sunset again."
- j. The Organic Trade Association (OTA) states: "It's critical that NOSB hear from certified producers on whether these inputs are consistent with and necessary for organic crop production, or whether there are other effective natural or organic alternatives available."

Ozone Gas

Purpose: use as an irrigation system cleaner.

Sunset 2018: To be voted on in Fall, 2016.

Additional information requested by NOSB:

The Crops Subcommittee would like to know if ozone is currently in use for irrigation system cleaning. The subcommittee asks certifiers, inspectors, and producers to provide feedback on whether or not ozone is listed on organic system plans and used in organic crop production, to help evaluate if it is still necessary for ozone to remain on the National List.

	Support Relisting	Oppose Relisting	Neutral/ Seeks Clarification
Farmers / Citizens	1		
Public Interest Groups			BP _a , Cornucopia _f
Food Processors /	Amy's		
Handlers	Kitchen _c		
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors			
/ Retailers			
Trade Associations /	IOS,		OTA _e – 5
Industry Consultants	OPWC _d		producers
Certifiers	CCOF _b		OEFFA

- a. Beyond Pesticides (BP) states: "In view of the dangers associated with the use of ozone, the Crops Subcommittee should ask:
 - Does the use of ozone in organic crop production pose a hazard for workers?
 - Would restrictions on the use of ozone help protect workers?"
- b. California Certified Organic Farmers (CCOF) "supports relisting materials upon consideration of the following:
 - Clear alternatives with demonstrated viability for organic operations have not emerged since the original listing
 - The material remains in use by organic producers
 - Substantively new information has not been brought forward to demonstrate that the material is incompatible with organic principles."
- c. Amy's Kitchen states: "Ozone is used by some suppliers to Amy's Kitchen and so we would like to have it remain on the list so that our ingredients still meet our requirements from a food safety perspective."
- d. Organic Produce Wholesalers Coalition (OPWC) states: "As a result of our initial findings that ozone is necessary for some produce farmers, OPWC supports relisting of Ozone Gas for use in cleaning irrigation line
- e. The Organic Trade Association (OTA) states: "It's critical that NOSB hear from certified producers on whether these inputs are consistent with and necessary for organic crop production, or whether there are other effective natural or organic alternatives available."
- f. The Cornucopia Institute states: "Cornucopia would support relisting if a new Technical Report were prepared that would convincingly establish that the use of ozone gas in irrigation systems is safe for environmental and human health, and that existing alternatives are less compatible with the tenets of organic production."

Peracetic Acid

Purpose: disinfecting equipment, seed, and asexually propagated planting material; controlling fire blight.

Sunset 2018: To be voted on in Fall, 2016.

Additional information requested by NOSB:

1. Can organic crop producers or certifiers provide the full committee with any information that can explain why this material (or one of the alternative materials) is a better option for use, in organic crop production, for the listed allowed uses?

2. Has anything changed during the current Sunset cycle that would make this material no longer necessary for its intended uses for organic crop production? If so, please help to explain.

3. It would help the NOSB in the review of this material if we could get feedback as to whether the current annotation (at a concentration of no more than 6%) presents any unforeseen problems for organic stakeholders, certifiers, or for product formulation. Also, could you provide input as to whether or not this annotation is even necessary?

	Support Relisting	Oppose Relisting	Neutral/ Seeks Clarification
Farmers / Citizens	4		
Public Interest Groups	NOC _a , Cornucopia _h		BPb
Food Processors /	Amy's Kitchen,		
Handlers	Aurora _c , Fetzer _g		
Ingredient Suppliers /			BioSafe Systems _n
Material Manufacturers			
Wholesalers/Distributors	WhiteWave		
/ Retailers			
Trade Associations /	Juice Products		Wolf/DiMatteo _d ,
Industry Consultants	Association _j ,		OTA _l – 3 producers
	OPWC _k , IOS		
Certifiers	CCOF _f , OEFFA _m ,		OTCO _i , PCO – 2
	NOFA-VT _e		operations

Notes:

- a. National Organic Coalition (NOC) states: "...supports keeping peracetic acid on the National List for use as a sanitizer and disinfectant. Sanitizers and disinfectants as a class should be reviewed to help organic operators and the greater community understand which ones are most "compatible with organic production."
- b. Beyond Pesticides (BP) states: "A new technical review was published after the CS completed its sunset review document. It reveals that there are several distinct substances called "peracetic acid," and that not all are permitted under NOP regulations."
- c. Aurora Organic Dairy states: "Peracetic acid is a very effective oxidizing sanitizer and is primarily non-corrosive to aluminum and equipment used in irrigation systems."
- d. Wolf, DiMatteo + Associates states: "It is important that Peracetic acid remain on the list and that the annotation is revised to read "Also permitted in hydrogen peroxide formulations as allowed in §205.601(a)."
- e. Northeast Organic Farming Association of Vermont (NOFA-VT) states: "These materials can be practical alternatives to chlorine for killing post-harvest disease organisms as well as potential human pathogens, the latter being increasingly important in light of new food safety requirements under FSMA. Peracetic acid products are an alternative to use of copper for managing late blight in some cases, which is helpful in avoiding over-use of copper."

f. California Certified Organic Farmers (CCOF) "supports relisting materials upon consideration of the following:

- Clear alternatives with demonstrated viability for organic operations have not emerged since the original listing
- The material remains in use by organic producers
- Substantively new information has not been brought forward to demonstrate that the material is incompatible with organic principles."

- g. Fetzer Vineyards (dba Bonterra Vineyards) states: "Peracetic acid (PAA) has very effective broad antimicrobial properties and is a relatively new tool being used to treat irrigation drip lines, especially where water has high biological activity."
- h. The Cornucopia Institute "recommends that the NOSB subcommittees commission a TR that (1) determines what disinfectant/sanitizer uses are required by law, and (2) comprehensively reviews the most organically compatible methods and materials to determine which disinfectants/sanitizers are best for specific purposes."
- i. Oregon Tilth (OTCO) states: "About 10% of OTCO crop clients use either PAA or PAA/hydrogen peroxide products as sanitizing agents in their operation. Many of them rely on these products as a "tried and true" sanitizer that may be used in direct product contact."
- j. Juice Products Association states: "The continued use of this substance is important for organic fruit Production."
- k. Organic Produce Wholesalers Coalition (OPWC) "would welcome clarification of which types of peracetic acid are most appropriate for use in organic systems in order to provide clear information for Materials Review Organizations (MROs), certifiers, and the trade about which brand name products may be used for different application."
- 1. The Organic Trade Association (OTA) states: "It's critical that NOSB hear from certified producers on whether these inputs are consistent with and necessary for organic crop production, or whether there are other effective natural or organic alternatives available."
- m. The Ohio Ecological Food and Farm Association (OEFFA) states: "We question whether the annotation should be changed to reflect information in the TR that not all substances identified as "peracetic acid" are permitted under NOP regulations. We encourage the NOSB to undertake a comprehensive review of disinfectant/sanitizer materials in order to effectively determine necessity, and assess other criteria, such as worker and environmental health impacts, as is required under OFPA."
- n. BioSafe Systems states: "We do not support the annotation "Also permitted in hydrogen peroxide formulations as allowed s (in §205.601(a) at concentration of no more than 6% as indicated on the pesticide product label" as written.
- Pennsylvania Certified Organic (PCO) "has not prohibited any substances containing Peracetic acid due to the inability to obtain concentration information from the manufacturer or due to concentrations exceeding that listed in the current annotation."

EPA List 3 – Inerts of Unknown Toxicity

Purpose: for use only in passive pheromone dispensers.

Sunset 2018: To be voted on in Fall, 2016.

Discussion: This listing will be superseded by the annotation change approved by the NOSB for EPA List 4 and List inerts (§205.601(m)(1)). The NOSB is continuing the Sunset review process for these EPA List 3 inerts in case that change cannot be implemented through rulemaking before the 11/03/2018 Sunset of EPA List 3 inerts.

	Support	Oppose	Neutral/
	Relisting	Relisting	Seeks
			Clarification
Farmers / Citizens		172 - BP	
		supporters	
		C. Bondera _k	
Public Interest Groups		BP _a , FWW _f ,	
		Cornucopia _l ,	
		NOC _b CFS _h	
Food Processors /	Amy's Kitchen _c ,		
Handlers	Aurorad		
Ingredient Suppliers /			Biosafe
Material Manufacturers			Systems _m
Wholesalers/Distributors			
/ Retailers			
Trade Associations /	IOS _j		OPWC _g , OTA _i
Industry Consultants			
Certifiers	CCOF _e		PCO – 2
			operators

- a. Beyond Pesticides (BP) states: "List 3 'inerts' should be delisted. The NOSB has already recommended an expiration date for these chemicals."
- b. National Organic Coalition (NOC) states, "NOC urges the NOSB take the sunset review of List 3 "inerts" seriously and act in a timely manner, as it must with the review of all sunset materials."
- c. Amy's Kitchen states: "Pheromone traps are used by a number of suppliers to Amy's Kitchen so we would like to see this continue to be included on the National List."
- d. Aurora Organic Dairy states: "We agree with the relisting of EPA List 3 Inerts of Unknown Toxicity to allow inert manufactures sufficient time to register their products with the EPA Safer Choice Program."
- e. California Certified Organic Farmers (CCOF) states: "CCOF previously commented on EPA List 4 inerts in support of the annotation change. CCOF encourages NOP to finalize rulemaking on NOSB's suggested annotation changes before the List 3 inerts are removed from the National List to avoid disrupting producers' ability to use passive pheromone dispensers, which are critical, nontoxic, and highly effective pest management tools in organic tree fruit production."
- f. Food and Water Watch (FWW) states: "The NOSB-recommended expiration date has already passed, and the new listing is unlikely to go into effect before the 2018 sunset date. Therefore, the NOSB must do a full review of these chemicals and List 3 inerts should be delisted."
- g. Organic Produce Wholesale Coalition (OPWC) states: "Until the new regulatory system is operational, we support relisting of List 3 inerts for use only in passive pheromone dispensers."
- h. The Center for Food Safety (CFS) states: "NOSB must not allow a potential future rule change to impact current sunset deliberations and must conduct a full review of these chemicals.
- i. Organic Trade Association (OTA) "supports the subcommittee in that Nonylphenol Ethoxylates (NPEs) should be prohibited for use as an inert ingredient in organic pest control materials. However, we disagree with the subcommittee that developing a recommendation to prohibit this specific class of inerts prior to shifting of inerts review from List 3 and 4 to the Safer Choice Program (SCP) is the best way to phase out their use in organic pest control materials."

- j. Independent Organic Services, Inc. (IOS) states: "I strongly support the continue allowance of these materials for use in pheromone traps, where they do not come into contact with crops or soil. As a grower, inspector and consultant I respectively utilize, widely observe and recommend pheromone traps in a variety of cropping systems. They are an integral part of many, many organic systems, where they serve to reduce the application of expensive and environmentally more disruptive materials, including those allowed on the National List."
- k. Colehour Bondera states: "Since the NOSB has already recommended an expiration date for the List 3 inerts it is time for NOP to move forward with what we voted on!"
- I. The Cornucopia Institute states: "Delist the List 3 "inerts". The NOSB previously voted in 2012 to place an expiration date of December 31, 2015 on these substances and this recommendation should be followed. Should the NOP continue to refuse to follow this motion, then the NOSB should be involved with a timely and initial review of these chemicals and any subsequent Sunset review of these chemicals."
- m. Biosafe Systems, LLC states: "We remain hopeful, although frustrated, that there will soon be definitive information on how input companies, such as ours, can proceed using the EPA Safer Choice Program in formulating products for use in organic production. We ask that the time frame be set at 3 years from the publication of the Final Rule, not from the publication of this discussion paper."

Calcium Chloride

Purpose: prohibited for use except as a foliar spray to treat a physiological disorder associated with calcium uptake.

Petitioned: 1996 TAP, 2001 TAP; Petitioned in 2000 by FarmSoy Company requesting that it be approved for use in processing.

Additional information requested by NOSB: None.

	Support Relisting	Oppose Relisting	Neutral/ Seeks Clarification
Farmers / Citizens	3	1	
Public Interest Groups	NOC _b ,		BPa
	Cornucopia _d		
Food Processors /	Amy's		
Handlers	Kitchen _c		
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors			
/ Retailers			
Trade Associations /	OPWC _f IOS		
Industry Consultants			
Certifiers	CCOF _e ,		PCO – 3 operators
	OEFFAg		

- a. Beyond Pesticides (BP) states: "Questions: 1. Is there any evidence that the prohibition is inappropriate? 2. What are the alternatives to the use "as a foliar spray to treat a physiological disorder associated with calcium uptake?"
- b. National Organic Coalition (NOC) "supports relisting of Calcium Chloride, with an annotation that allows the material to be used as a foliar spray to treat a physiological disorder associated with calcium uptake."
- c. Amy's Kitchen states: "It is only used when a physiological disorder associated with calcium uptake is identified."
- d. The Cornucopia Institute states: "Potential overuse could result in subsoil, surface water and ground water contamination with chloride, therefore the limitation on its use should be continued."
- california Certified Organic Farmers (CCOF) "supports relisting materials upon consideration of the following:
 Clear alternatives with demonstrated viability for organic operations have not emerged since the original
 - Clear alternatives with demonstrated viability for organic operations have not emerged since the original listing
 - The material remains in use by organic producers
 - Substantively new information has not been brought forward to demonstrate that the material is incompatible with organic principles."
- f. Organic Produce Wholesalers Coalition (OPWC) "supports relisting calcium chloride as a prohibited nonsynthetic material, along with its current annotation, which allows its 'use as a foliar spray to treat a physiological disorder associated with calcium uptake'."
- g. The Ohio Ecological Food and Farm Association (OEFFA) states: "We request the continued listing of calcium chloride, clarification about the interpretation of the calcium chloride annotation, and that NOSB consider rewording the annotation for better clarity and broader understanding by producers."

CROPS SUBCOMMITTEE

DISCUSSION DOCUMENT

EPA List 4 on §205.601(m) Annotation Change

Purpose: Proposed annotation change to prohibit NPEs.

Discussion: The Crops Subcommittee has presented a discussion document to consider an annotation change for EPA List 4 Inerts at §205.601(m) to prohibit substances from the group known as nonylphenol ethoxylates (NPEs). This annotation change would be presented as an additional recommendation prior to the implementation of the October, 2015 NOSB recommendation. The October, 2015 recommendation is for a new annotation for inerts to replace references to obsolete EPA Lists 3 and 4 with references to FIFRA 25(b) inerts list and EPA's Safer Chemical Ingredients Lists.

Proposal to Prohibit NPEs. The Proposed Annotation change for discussion is as follows: §205.601(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with non-synthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. Except for inerts from the group known as Nonylphenol Ethoxylates.

Vote in Subcommittee

Yes: 7, No: 0, Abstain: 0, Absent: 0, Recuse: 0

	Support Document	Oppose Document	Neutral/ Seeks Clarification
Farmers / Citizens			
Public Interest Groups	CR _g BP _a , NOC _k		
	Cornucopia		
Food Processors /			
Handlers			
Ingredient Suppliers /	PBC _j		
Material Manufacturers			
Wholesalers/Distributors / Retailers			
Trade Associations /	Wolf/DiMatteo _b ,	OTA _l ,	
Industry Consultants	IOSh	OPWC _e	
		OMRI _f	
Certifiers	OEFFAi	PCO _m ,	OTCOc
		MOSAd	

- a. Beyond Pesticides (BP) states: "In the recent annotation change to the inerts listing, the reference to FIFRA Section 25(b) and the Safer Chemical Ingredient List, while helpful in guiding the NOSB's decision making, does not allow the board to forego a review process to ensure compliance with OFPA criteria. Therefore, the annotation may cite other governmental review programs, but it must ensure ongoing review of individual materials or classes of materials, in compliance with OFPA."
- b. Wolf, DiMatteo + Associates states: "We appreciate that the NOSB Crops Subcommittee has made it clear that inert ingredients in the category of nonylphenol ethoxylates (NPEs) will not be allowed, and that input companies should work to phase out their use. We ask that the NOSB and the NOP allow input companies sufficient time to reformulate effective products without NPEs."
- c. Oregon Tilth (OTCO) states: "It appears this will be a redundant effort once the NOSB recommendation to work with the Safer Choice Program is implemented" and "We would also appreciate further guidance and clarification on the allowance for NPEs in iodine livestock products, and other surfactants such as linear alcohol ethoxylates..."
- d. Midwest Organic Services Association (MOSA) states: "In summary, we do not support the direction of this discussion. We feel it's not necessary, provided that a proposal made last Fall is acted upon. That proposal was for the annotation change of EPA list 4 inerts on National List sections 205.601(m) and 205.603(e). Materials called out in that previous discussion are not found on the lists that now proposed to replace EPA list 4."
- e. Organic Produce Wholesalers Coalition (OPWC) "supports the recent activities of the Inerts Working Group to collaborate with the EPA's Safer Choice program in order to identify inerts that are suitable for formulating pest control products allowed in organic production. While this collaborative work is underway, OPWC supports continued use of the existing system for regulating inert ingredients used in organic production."
- f. Organic Materials Research Institute (OMRI) states: "NPEs are a complex group of substances, and the industry will need sufficient guidance to ensure accurate and thorough identification of specific substances that should be included under the group of NPEs. Manufactures could end up having to reformulate once to comply with the NPE prohibition, and a second time to comply with the October 2015 recommendation. This seems to be an undue burden on the manufacturers of these materials. An additional recommendation to prohibit NPEs as inerts in crop pest control materials would not result in a complete removal of NPEs from use in organic input materials. NPEs are also used as inerts in livestock pest control materials per §205.603(e) and as excipients in livestock health care materials per §205.603(f)."
- g. Consumer Reports (CR) states: "We support the Crops Subcommittee's proposal to remove nonylphenol ethoxylates (NPEs) from use in organic agriculture, and urge the NOSB to recommend an end to their use."
- h. Independent Organic Services, Inc. (IOS) states: "I support the proposed change to the annotation. While this change will admittedly cause some disruption in the availability of some crop production materials, I believe that 3 years would be an adequate time for manufacturers to re-formulate a majority of materials. PPEs are known to be a highly potent estrogen mimic and should have been prohibited from organically-approved inputs long ago."
- i. The Ohio Ecological Food and Farm Association (OEFFA) states: "We appreciate the timeline discussed in the document and urge the NOSB to continue its efforts to removeNPEs from use in organic agriculture."
- j. Pacific Biocontrol Corporation (PBC) states: "Since the EPA is no longer maintaining the inert lists, we agree that this annotation should be updated to "Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122" to allow for continued use of pheromones mating disruption in organic farming."
- k. National Organic Coalition (NOC) states: "NOC believes there is a necessary next step remaining after the approval of last fall's recommendation for Safer Choice "inerts" to be placed on the National List. The NOP (with NOSB involvement) and the EPA should draft and sign a Memorandum of Understanding detailing the interaction of the EPA Safer Choice program with the NOP's National List."
- 1. The Organic Trade Association (OTA) "supports the subcommittee in that Nonylphenol Ethoxylates (NPEs) should be prohibited for use as an inert ingredient in organic pest control materials. However, we disagree with the subcommittee that developing a recommendation to prohibit this specific class of inerts prior to shifting of inerts review from List 3 and 4 to the Safer Choice Program (SCP) is the best way to phase out their use in organic pest control materials. NOSB could consider advocating for all inerts on List 4 that do not currently appear on SCIL or are not specifically permitted for use in 25(b) minimum risk pesticides to be reviewed by SCP for inclusion on SCIL (Safer Chemical Ingredient List)."
- m. Pennsylvania Certified Organic states: "PCO does not support this annotation change because it is unnecessary and redundant given the upcoming implementation of the October 2015 recommendation for a new annotation for inerts. PCO has approved no products for use on crops that contain Nonylphenol Ethoxylates (NPEs) but has approved several products for use on livestock that do contain NPEs. The proposed annotation change would not address the majority of substances containing NPEs that PCO has reviewed and are being used by our clients."

CROPS SUBCOMMITTEE

PETITIONED MATERIALS

Ash from Manure Burning

Petition: EnergyWorks BioPower, LLC submitted a petition to revise 7 CFR §205.602(a), Ash from Manure Burning, to include the following annotation: "except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients."

Vote in Subcommittee

Motion to annotate ash from manure burning at §205.602 – non-synthetic substances prohibited for use in organic crop production - with the following annotation: "except where the combustion reaction does not involve the use of synthetic additives and is controlled to separate and preserve nutrients."

Yes: 0, No: 5, Abstain: 0, Absent: 0, Recuse: 0

	Support Petition	Oppose Petition	Neutral/ Seeks Clarification
Farmers / Citizens		2	
Public Interest Groups		BPa, NOCb, FWWc,	
		Cornucopia _g ,	
		CFS _e , CR _f	
Food Processors / Handlers			
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors /			
Retailers			
Trade Associations /		OPWC _d	
Industry Consultants			

- b. National Organic Coalition (NOC) states: "Utilizing burning as a method to recycle millions of pounds of excess poultry manure inadvertently supports the business of CAFOs by creating an organic industry demand for ash."
- c. Food and Water Watch (FWW) states: "We support the subcommittee's position to maintain the full prohibition on ash from manure burning."
- d. Organic Produce Wholesalers Coalition (OPWC) states: "Burning manure removes the carbon and nitrogen, which has two negative results; lessening the soil-building value of the manure, and converting organic matter to carbon dioxide and other gases that enter the atmosphere to contribute to global warming."
- e. The Center for Food Safety (CFS) states: "CFS strongly supports the Subcommittee's current proposal to reject the petitioned annotation change for the listing of ash from manure burning and retain the existing blanket prohibition."
- f. Consumer Reports (CR) states: "We urge the NOSB to reject the petition for an annotation change to "ash from manure burning" listing. We believe all ash from manure burning should remain prohibited in organic production. We agree with the Crops Subcommittee that "utilizing burning as a method to recycle millions of pounds of excess poultry manure inadvertently supports the business of CAFOs by creating an organic industry demand for ash" and that the annotation change fails to meet OFPA criteria."
- g. Cornucopia Institute states: "Burning manure is not an appropriate method for recycling organic wastes, because the majority of the carbon goes into the atmosphere. This contributes to climate change and prevents the carbon from restoring soil with organic matter."

a. Beyond Pesticides (BP) states: "While carbon may not be a plant "nutrient," its presence as food for microbes and as humus is essential to organic soils, and therefore, the organic production system."

Squid & Squid Byproducts

Petition: Shoreside Organics, LLC submitted a petition in April, 2015 to add "Squid and Squid Byproducts" to the NL §205.601(j)(7) for use as a fertilizer.

Vote in Subcommittee: Move to list Squid & Squid Byproducts at §205.601(j) of the National List – with the annotation – can be pH adjusted with Sulfuric, Citric, or Phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5. Yes: 6, No: 0, Absent: 1, Abstain: 0, Recuse: 0

	Support Petition	Oppose Petition	Neutral/ Seeks Clarification
Farmers / Citizens	1	2	
Public Interest Groups		BPa,	Cornucopia _c , CFS _e
Food Processors /			
Handlers			
Ingredient Suppliers /	Dramm		
Material Manufacturers	Corporation,		
	Shoreside Organics		
Wholesalers/Distributors			PCC _b
/ Retailers			
Trade Associations /	IOS _f , OTA _g ,		OPWC _d
Industry	RIDEMi		
Consultants/Government			
Certifiers			OEFFA _h

- a. Beyond Pesticides (BP) states: "Beyond Pesticides urges the NOSB to deny the petition for synthetic extracts of squid and squid byproducts because they cause environmental harm, are not essential, and are not compatible with organic production."
- b. PCC Natural Markets states: "Squid byproducts must be sourced from squid harvested for human consumption and must not lead to an increase in wild squid harvesting solely for the purpose of producing fertilizer. Squid byproducts must not be processed in a way that negatively impacts workers' health. Heavy metals have been reduced in the squid byproducts, particularly in the liver and muscle tissue."
- c. The Cornucopia Institute "opposes the petition to add "Squid and Squid Byproducts" as petitioned to 205.601(j) As plant or soil amendments, but would support adding "Squid Byproducts" to the National List."
- d. Organic Produce Wholesalers Coalition (OPWC) "supports the use of squid by-products as fertilizer feedstock, but does not support the practice of harvesting squid solely for use in fertilizer."
- e. The Center for Food Safety (CFS) states: "CFS opposes the addition of squid to the NL as an organic fertilizer, and cautiously supports the addition of squid byproducts with the aforementioned issues addressed accordingly. CFS urges the NOSB to send the petition back to the Crops Subcommittee to amend the language to prohibit the use of whole squid and limit the listing to squid byproducts from the human food industry that are processed in a manner that reduces risks to workers and reduces heavy metal contamination."
- f. Independent Organic Services, Inc. (IOS) states: "I support the addition of this material to the National List, but further propose that NOP be directed to change the annotation to allow for the inclusions of products from *all* marine animals. There is no logical reason why the rule should not allow the inclusion of products derived from squid, but also from shrimp, crab, plankton and a myriad of other marine animals. In practice, these materials are already found in many inputs currently approved by OMRI and many ACAs. For that reason, I suggest the NOSB direct the NOP to make the following change to 205.601(j)(7): 'Liquid products derived from marine animals—can be pH adjusted with sulfuric, citric or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5."
- g. The Organic Trade Association (OTA) states: "Squid-based fertilizers appear to be an alternative to fish products that can support the growth of the industry and maintain the commitment to environmental stewardship that is a hallmark of organic production. We urge the full NOSB to approve the proposal and add squid and squid

byproducts to the National List for use in organic crop production."

- h. The Ohio Ecological Food and Farm Association (OEFFA) states: "In consideration of the complex circumstances surrounding squid harvest, OEFFA supports the listing of "squid byproducts" to the National List, but *not* a listing for 'squid' as a primary fertilizer resource."
- i. Rhode Island Department of Environmental Management (RIDEM) states: "The addition of squid and squid byproducts to the National List would allow squid byproducts to be pH adjusted using synthetic sulfuric, citric or phosphoric acid, and would make possible the production of a stable and high quality liquid fertilizer for use in organic crop production. Such fertilizer would be produced using existing byproducts from the commercial squid fishery in Rhode Island."

Hypochlorous Acid

Purpose: antimicrobial/sanitizer for use in equipment and raw agricultural products.

Petitioned: In May, 2015 the NOP received a petition to add Hypochlorous acid (CAS #7790-92-3) to the National List at §205.601, §205.603, and §205.605 - Synthetic substances allowed for use in organic crop and livestock production, and handling.

Vote in Subcommittee: In 2016, the handling, crops and livestock subcommittees all voted in favor of the petition to add Hypochlorous acid to the National List.

	Support Petition	Oppose Petition	Neutral/ Seeks Clarification
Farmers / Citizens	8 _{k,l}	154 (BP)	
Public Interest Groups		BPa	Cornucopia _{b,} CFS _f
Food Processors /			
Handlers			
Ingredient Suppliers /	Aquafew		1 _m
Material Manufacturers	Ernest F.		
	Mariani		
	Company _n		
Wholesalers/Distributors	CROPP		
/ Retailers			
Trade Associations /	OPWC _d ,		OMRI _g WODPA _e ,
Industry Consultants	Wolf/DiMatteo,		
	IOS _h , OTA _i		
Certifiers	CCOFc		OEFFA _j

- a. Beyond Pesticides (BP) states: "Rather than simply proposing another chlorine-based material, the NOSB subcommittees should commission a TR that (1) determines what disinfectant/sanitizer uses are required by law, and (2) comprehensively examines more organically-compatible methods and materials to determine whether chlorine-based materials are actually needed for any uses. In doing so, the TR authors should consult with EPA's Safer Choice Program and investigate materials on the Safer Chemical Ingredients List. If there are uses for which chlorine is necessary, then the NOSB should include them in the National List and limit the use to those particular uses with an annotation. In addition, in considering the inclusion of hypochlorous acid, the NOSB should evaluate the need for proper disposal of the sodium hydroxide and hydrogen gas that is co-generated with hypochlorous acid."
- b. The Cornucopia Institute states: "We believe the NOSB and NOP should investigate the potential elimination of the use of chlorine-based materials and develop guidance for the adoption and appropriate usage of alternative materials and practices."
- c. California Certified Organic Farmers (CCOF) states: "CCOF supports the three listing motions which would add hypochlorous acid to §205.601 (a) (2), §205.603 (a) (7), and §205.605 (b). These materials appear to represent a less toxic, more environmentally friendly, and superior option in addition to existing chlorine allowances. CCOF sees these materials as a positive step forward. Supporting this petition will reduce confusion in certification. CCOF is not aware of any meaningful rationale for not listing the material."
- d. Organic Produce Wholesalers Coalition (OPWC) "concurs with the findings of the NOSB Subcommittees and supports use of Hypochlorous Acid in all scopes of organic production through its specific listing as an approved chlorine material."
- e. Western Organic Dairy Producers Alliance (WODPA) states: "WODPA supports the listing of Hypochlorous acid produced by the electrolysis of sodium chloride and water. However, the listing, as proposed, requires an annotation to limit how the Hypochlorous acid is produced. For example, Hypochlorous acid is formed when chlorine is added to water... Further, WODPA also recommends addition to §205.603 as an approved material for use as a teat dip used pre and post milking. Listing of this product for use as a teat dip would reduce the use of iodine."

- f. The Center for Food Safety (CFS) states: "CFS strongly urges NOSB to review Electrolyzed Water (EW) In the context of all available and allowed sanitation and disinfection materials and practices in organic production. In particular, CFS requests that the Board considers how the addition of EW to the NL can facilitate the removal of other chlorine-based materials currently listed at their respective sunsets, and how to best promote the use of non-chemical sanitation practices by organic crop and livestock producers and organic handlers."
- g. Organic Materials Research Institute (OMRI) "suggests that all three recommendations be brought back to their respective subcommittees for further deliberation and consideration within the context of other sources of hypochlorous acid and other listings of chlorine materials on the National List."
- h. Independent Organic Services, Inc. (IOS) states: "I strongly support the addition of the product to the National List for both Crop, Livestock and Handling scopes. Given the perceived and real risks of food safety facing the industry, and the justified environmental concerns involving the use of chlorine materials, the adoption of any material that provides sanitizing action, while at the same time reducing the actual amount of free chlorine released into the environment, seems like a "win-win" situation."
- i. The Organic Trade Association (OTA) "supports the listing of electrolyzed water on the National List. However, OTA recommends that NOSB return all three proposals to their respective subcommittees for further discussion and refinement of the recommendations."
- j. The Ohio Ecological Food and Farm Association (OEFFA) states: "Consider engaging in a comprehensive review of approved sanitizers/disinfectants in order to assess them according to OFPA criteria."
- An herb farmer states: "As a herb grower of Certified Organic produce we find that this is user friendly and easily kills bacteria on equipment and product. Also we wish organic produce to retain its safe food reputation. No protective clothing is required by staff and it can be generated on farm from salt and water. From experience due to its rapid breakdown it has no adverse environmental effects."
- I. A farmer states: "We use hypochlorous in our business as a sanitizer for equipment, crops and raw horticultural produce. It is easy for us to use as we don't have to use any protective clothing and it is made on the farm by the electrolysis of salt and water, so what could be more friendly to us and the environment and also so easy to use. For us it is a cost effective method of maintaining our on farm food safety requirements without comprising our organic beliefs."
- m. Earl Boyce states: "Our customers typically set the target pH at 4.0, and a few tenths of a pH point on either side of this point, have not caused noticeable off gassing of chlorine odors in use."
- n. Ernest F. Mariani Companyⁿ states: "This process was under very strict test criteria by both Coke and Pepsi Cola Companies and was proven more effective and environmentally safer than conventional chemicals."

Soy Wax

Soy wax has been petitioned as a synthetic substance for use in organic mushroom production.

Petitioned/added: Beyond Pesticides submitted the petition to list soy wax.

Vote in Subcommittee

Move to list soy wax at §205.601 of the National List (o) - As production aids. Soy wax (CAS # 8016-70-4) - for use in log grown mushroom production. Must be made from non-GMO soybeans. Yes: 4, No: 0, Abstain: 0, Absent: 1, Recuse: 0

Proposed Annotation: Must be made from non-GMO soybean oil.

	Support Petition	Oppose Petition	Neutral/ Seeks Clarification
Farmers / Citizens	1 _e	1	
Public Interest Groups	BPa,		
	Cornucopia _b ,		
	NOC _f		
Food Processors /			
Handlers			
Ingredient Suppliers /			
Material Manufacturers			
Wholesalers/Distributors			
/ Retailers			
Trade Associations /	IOS _d , OPWC _c		
Industry Consultants			
Certifiers			

- a. Beyond Pesticides (BP) states: "We petitioned for it to give those who grow mushrooms on logs a nonpetroleum alternative for sealing inoculation sites on logs. We agree with the CS annotation proposal to include the annotation, "must be made from non-GMO soybeans." We found soy wax that is certified to be non-GMO, but that does not guarantee that all soy wax is non-GMO."
- b. The Cornucopia Institute "supports the petition to add soy wax to §205.601 (o) as production aids, with the annotation, "must be made from non-GMO soybeans," and with a 5-year expiration date to encourage the production of organic soy wax."
- c. Organic Produce Wholesalers Coalition (OPWC) "support the listing of Soy Wax as an alternative to the use of Microcrystalline Cheese Wax....with an annotation that specifies that the wax must be made from non-GMO soybeans."
- d. Independent Organic Services, Inc. (IOS) states: "I support the use of this material in the limited application for the production of mushroom and as a possible alternative to microcrystalline cheesewax. While I am not particularly a fan of the use of hydrogenation in this product, the limited scope of use would not mean that the hydrogenated oil was being consumed. On the other hand, the option to use non-GMO, domestically produced soybeans seems a good alternative to microcrystalline cheesewax, which is a petroleum product."
- e. A shiitake mushroom farmer states: "I want the NOSP to approve non-GMO soy bean wax for use in covering the inoculation sites in logs inoculated with sawdust spawn or wooden dowels. I am looking for an approved material that is not petroleum based."
- f. The National Organic Coalition (NOC) states: "We believe that soy-based waxes are more compatible with organic and sustainable production and should be allowed for use in organic mushroom culture. We are not currently calling for the removal of microcrystalline cheesewax, but we foresee that possibility if there should prove to be sufficient quantities of soy wax available."

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