



April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Avenue, SW  
Room 2648-So., Ag Stop 0268  
Washington, DC 20250-0268

**Docket: AMS-NOP-18-0071**

## **Comments to the National Organic Standards Board**

April 2019  
Seattle, WA

National Organic Standards Board:

Thank you for this opportunity to provide comment on multiple topics. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others.

One of OTA's strongest assets as an organization is the diversity and breadth of its membership. Unlike many trade associations, OTA is uniquely structured to include the full value chain for the organic industry, ensuring that all segments, from farm to marketplace, have a strong voice within the organization. It also creates a platform for a diverse group of stakeholders to work together to catalyze solutions, form coalitions and collaborate on matters critical to the organic sector.

Addressing critical issues and growing the organic industry are all part of our work together. It all fits in with OTA's Mission, to promote and PROTECT ORGANIC with a unifying voice that serves and engages its diverse members from farm to marketplace.

### **WHAT IS OTA'S COMMENT PROCESS?**

OTA submits comments on behalf of its membership. Our positions and policies are primarily shaped through our member task forces. In all cases, OTA's regulatory and legislative staff carry out an extensive process of membership engagement to capture how current issues and activities such as proposed rules or NOSB recommendations will impact certified farmers and handlers. Prior to submission of final comments, draft comments are distributed to membership at least a week in advance. Members are provided an opportunity to weigh in and shape any changes that may be needed prior to final submission. To carry out a meaningful comment process under OTA's governance structure, a comment period needs to be at least 30 days.

## **CONTENTS (please note the PDF bookmark feature to navigate comments):**

### **General**

- Limited Comment Period

### **Materials Subcommittee**

- Excluded Methods Terminology
- Marine Materials in Organic Crop Production
- Genetic Integrity Transparency of Seed Grown on Organic Land
- Assessing Cleaning and Sanitation Materials Used in Organic Crop, Livestock and Handling

### **Compliance, Accreditation and Certification Subcommittee**

- Oversight Improvements to Deter Fraud
- Update on OTA's Organic Fraud Prevention Solutions Program

### **Livestock Subcommittee**

- Use of Excluded Method Vaccines In Organic Livestock Production
- 2021 Sunset Reviews

### **Handling Subcommittee**

- Pullulan
- Celery Powder
- Nutrient Vitamins and Minerals
- 2021 Sunset Reviews

### **Crops Subcommittee**

- Strengthening the Organic Seed Guidance
- Paper (Plant Pots and Other Crop Production Aids)
- 2021 Sunset Reviews



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**RE: Inadequate Public Comment Period for National Organic Standards Board meetings**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the spring 2019 National Organic Standards Board (NOSB) meeting.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Organic Trade Association again expresses its strong disappointment in the number of days given to the public to comment on NOSB's extensive packet of proposals and agenda topics. The proposals were made available to the public on the evening of, April 13, 2019, resulting in a **22-day comment period** (16 business days). The U.S. Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) continues to release NOSB meeting materials a week to over a week late from the date that would provide a 30-day comment period. The shortened amount of time continues to be a disservice to NOSB members and the time and resources that go into NOSB's work. Typically, USDA releases an announcement when the proposals become available. However, to the best of our knowledge, a public announcement was not made around the proposals for this meeting. News of the proposals quickly spread via announcements made by organic stakeholder groups such as ours.

The Organic Trade Association now represents more than 9,500 businesses through direct membership and formal agreements with farmer-governed organizations that make up OTA's Farmers Advisory Council. As a member-based organization, our comments and positions take shape through our task forces and extensive outreach to our members. Prior to submission of final comments, draft comments are distributed to membership at least a week in advance of the comment deadline. The entire process takes a significant amount of time, especially when we are dealing with 17 complex topics, 51 Sunset materials and a 239-page packet.

To carry out a meaningful comment process under the Organic Trade Association's governance structure, a comment period needs to be **at least** 30 days. Given the number and complexity of topics that are



typically on any NOSB meeting agenda, we argue that with the number of topics that are included on every meeting agenda, even 30 days is inadequate, and the comment period should be extended to **60 days**.

The Organic Trade Association requests a longer comment time and a USDA public announcement when the proposals become available. A 22-day public comment period is not acceptable for the number and complexity of topics we are working with. It equates to an extremely unreasonable public comment opportunity and one that does not pay respect to the NOSB public comment process. The Organic Trade Association understands that this is not the fault of NOSB members. We write this comment as a call to action in the interest of correcting the deficiency. We urge NOSB and members of the organic community to voice this concern to USDA.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard  
Vice President, Regulatory and Technical Affairs  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association



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Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP

**Docket:** AMS-NOP-18-0071

**RE: Materials Subcommittee – Excluded Methods Terminology (Proposal)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee's Proposal on Excluded Methods Terminology. The Subcommittee is requesting comments from organic stakeholders on its proposal to clarify transposons as part of the excluded methods terminology chart as well as the definitions of cisgenesis and intragenesis.

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The Organic Trade Association recognizes that the definition of "excluded methods" was based on the efforts of NOSB in 1995, and is now outdated. Organic producers and handlers as well as Accredited Certifying Agencies (ACAs) and USDA's National Organic Program (NOP) must have clear and up-to-date definitions to make consistent and concrete determinations regarding compliance with the prohibition of GMOs. For this reason, we continue to be supportive of the work being done in this area.

We support updating the proposal's terminology chart with the following definitions:

**Cisgenesis:** The gene modification of a recipient plant with a natural gene from a crossable sexually compatible plant. The introduced gene includes its introns and is flanked by its native promoter and terminator in the normal-sense orientation.

**Intragenesis:** The full or partial coding of DNA sequences of genes originating from the sexually compatible gene pool of the recipient plant, and arranged in sense or antisense orientation. In addition, the promoter, spacer and terminator may originate from a sexually compatible gene pool of the recipient plant.

In regard to **transposons**, we did not have enough time to thoroughly research the topic and conduct member outreach. Generally speaking, we understand transposons that are activated or directed through in vitro techniques to fit the definition of "excluded methods," whereas activation of transposons under natural stress conditions (e.g., drought or heat) would not. The latter are activities that are naturally



occurring, and activate naturally occurring transposons. We do not believe they should be listed in the table of methods.

Transposons activated under chemical and radiation stress warrant further evaluation as part of the “induced mutagenesis” discussion document on this meeting’s agenda, since allowing or disallowing chemical/radiation-induced mutations affect both the determination for induced mutagenesis and the activation of transposons under these types of stress. Unfortunately, we did not have adequate time to address this topic or the associated Discussion Document titled “Excluded Methods: Induced mutagenesis and embryo transfer in livestock.”

The Organic Trade Association continues to be supportive of moving recommendations forward to NOP that will not only improve the practices used to keep GMOs out of organic seed, feed and crops, but will also clarify the standards and terminology used for making clear and consistent compliance determinations.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard  
Senior Director of Regulatory and Technical Affairs  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association



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**RE: Materials Subcommittee – Marine Materials in Organic Crop Production (Discussion)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee's Discussion Document on Marine Materials in Organic Crop Production. The subcommittee is inviting discussion on a potential future proposal that would require aquatic plants used in crop input materials to be organically produced.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

### **Summary**

- ✓ OTA continues to support the efforts of NOSB and the organic sector to move towards the allowance of only aquatic plants produced and harvested in a sustainable manner.
- ✓ We are not able to take a position of support on any of the suggested approaches due to the inability to fully engage our membership within the abbreviated comment period.
- ✓ OTA is committed to developing a member task force on this issue, and requests that NOSB keep this discussion document open for comment through to the fall meeting, when we can be better prepared with feedback on the subcommittee's discussion questions and be in a better position to engage with the Expert Panel.

**We offer the following more detailed comments:**

## **Background**

Aquatic plants (e.g., seaweeds, kelp) are commonly used in the manufacture of crop production inputs such as fertilizers and soil conditioners. These materials are largely harvested from wild native ecosystems. During the 2015 Sunset Review of the §205.601(j) listing of aquatic plant extracts, concerns were raised about the increase in global harvesting of seaweeds and the accelerated potential for destruction of marine ecosystems.

A discussion document was posted for the fall 2018 meeting that explored a potential requirement for marine plants to be certified organic when used in crop inputs. This initiated a robust response from public commenters. In OTA's comments at that time, we expressed agreement with the subcommittee's logic of using existing organic certification tools as a means of verifying sustainable production practices, and identified questions and areas where further study is needed. In particular, we had questions about whether organic certification is feasible as a solution for achieving the subcommittee's intended sustainability goals, and if so, whether it is feasible for the organic industry to build up sufficient organic supply to accommodate the needs of organic producers.

For this spring 2019 meeting, the subcommittee has presented a second discussion document<sup>1</sup> that continues to explore a means of addressing the environmental impact of harvesting seaweed for use in organic crop production through existing organic certification tools, by requiring that aquatic plants be certified organic. Such an approach would involve the following regulatory amendments (proposed language changes are underlined):

- §205.601 (j) As plant or soil amendments. (1) Aquatic plant extracts (other than hydrolyzed) –Extraction process is limited to the use of potassium hydroxide or sodium hydroxide; solvent amount use is limited to that amount necessary for extraction. Marine algae ingredients must be certified organic.
- §205.602 Non-synthetic substances prohibited for use in organic crop production. (j) Marine algae -- unless certified organic.

The discussion document summarizes and attempts to address the concerns raised at the last meeting about this approach, specifically regarding the authority of NOSB to require organic inputs, and the effectiveness of organic certification to meet sustainability goals. The document also summarizes a number of alternative approaches that were suggested in the last meeting. Those approaches include: limiting or prohibiting harvest of certain marine algae; exploring other existing third-party standards for sustainable harvesting; or adding annotations to material listings on National List to require sustainable harvesting. Each of these approaches is met with its own set of questions and concerns that are outlined in the document.

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<sup>1</sup> <https://www.ams.usda.gov/sites/default/files/media/MSMarineMaterialsSpring2019DDWeb.pdf>



## **Using organic certification to address environmental impact of marine materials used as crop inputs**

The Materials Subcommittee has posed several questions for discussion, the first one asking, *“If you are not in support of requiring organic certification, what approach do you support?”*

**At this point, OTA is not able to take a position of support on any of the suggested approaches.** In the limited time available for this comment period, OTA was not able to conduct sufficient outreach to our membership, and we cannot responsibly take a position on this important issue without the full engagement of our members.

OTA maintains agreement with the logic of using existing organic certification tools as a means of verifying sustainable production practices, but our questions of whether organic certification is feasible as a solution for achieving the Subcommittee’s intended sustainability goals, and whether it is feasible for the organic industry to build up sufficient organic supply to accommodate the needs of organic producers remain outstanding. Additional analysis and member engagement are needed to fully understand how this approach, albeit logically and theoretically agreeable, would work out in reality.

Furthermore, there does not appear to be agreement among public commenters that organic certification is the appropriate tool to address the environmental impact of marine materials used as crop inputs. Thus, there is a need to better understand these concerns in order to build consensus around the appropriate solution. Some of the concerns expressed in the public comments that need to be better understood and addressed include:

- *Lack of confidence that organic certification can achieve the intended sustainability goals for marine algae.* Although organic certification has the potential to address the subcommittee’s concerns for environmental impact of marine algae harvesting through the provision at §205.200 (the requirement to maintain or improve the natural resources of the operation), the actual sustainability outcomes will vary due to the lack of regulations and guidance specific to marine algae production. There are questions about the extent to which the NOP regulations and guidance, as they currently exist, can achieve the subcommittee’s goals. And without a clearer picture of what/how the NOP regulations and/or NOP guidance could be improved to specifically address marine environments, it is not possible to assess whether future organic standards could effectively address these environmental concerns.
- *Uncertainty if industry can build up sufficient supply of certified organic marine algae to meet needs of organic producers.* An assessment of the supply chain is needed to better understand the currently available quantities and sources of organic marine algae and what the needs would be of organic crop producers. The assessment must take into account the demands for organic marine algae from other sectors of the organic industry. For instance, a new requirement for organic marine algae in crop inputs may impact the availability for livestock producers who are required to use organic kelp in livestock feed rations. This information is needed to prevent unintended consequences for the various supply chain participants including producers of organic marine algae, manufacturers of algae-based fertilizers, and crop producers using the manufactured inputs. This information is also essential for determining an appropriate phase-in period for any potential new requirements.

- *Lack of consensus about the extent of the problem that needs to be solved.* Although public comments were generally supportive of addressing environmental impact and several commenters specifically identified a concern about over-harvesting of rockweed in Maine, there is a segment of public commenters that said current government regulations and permitting requirements are adequate to protect the environment. Additionally, the Subcommittee stated that it is not able to identify specific species, regions, or harvest methods for which a limited or prohibited harvest should be recommended, indicating that there may be a need for greater understanding of the environmental impacts of marine algae harvesting across species, regions, and harvest methods. This information is essential for identifying the appropriate tool for addressing the problem.

### **Request for subcommittee to keep the discussion document open through the fall 2019 meeting**

The Subcommittee's discussion document is very comprehensive. It includes an overview of the various options for addressing the environmental impact of marine materials used in crop inputs, a thorough summary of feedback from past comment periods, appendices with full references to other relevant third party standards, and a list of seven discussion questions that effectively challenge stakeholders to explore workable solutions for addressing the Subcommittee's sustainability concerns. This discussion document is very well scoped-out and now deserves the full attention of organic stakeholders to weigh in. **In order to fully analyze this information and engage our membership in exploring the discussion questions, we respectfully request that NOSB keep this discussion document open for comment through to the fall 2019 meeting.**

OTA is committed to establishing a member task force to accomplish the additional analysis and member engagement needed on this issue. OTA member task forces<sup>2</sup> make recommendations to OTA on policy issues, association programs and special projects. The OTA Marine Materials Task Force can be convened following the spring 2019 NOSB meeting, work over the summer on these issues, and return to the fall 2019 NOSB meeting with well-informed responses to the discussion questions that truly represent the interest of our members and of the organic industry. Furthermore, this opportunity to more deeply engage on these issues will allow us to be better informed about outstanding questions that should be posed to the Expert Panel planned for the fall 2019 NOSB meeting. We believe this process will allow for maximum engagement and preparation for an informed discussion and panel in the fall. We also believe this process will better equip NOSB to develop a proposal that has the highest possible chance of gaining consensus support from stakeholders, which does not appear to exist at this time.

To be clear, we don't want the conversation on this issue to stop. Sourcing of inputs, including those from natural resources, can have a significant impact on the sustainability of agricultural systems, and NOSB is responsible for making recommendations for inputs on the National List that would not harm the environment. There is a lot of information to consider. We want to give this issue the space, time and attention needed to fully understand the implications of various solutions and build consensus around the most appropriate option.

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<sup>2</sup> <https://ota.com/about-ota/member-councils-forums-task-forces/task-forces>

### **Conclusion**

At this time, OTA is not able to take a position of support on any of the suggested approaches due to the inability to fully engage our membership within the abbreviated comment period. However, we are committed to establishing a member task force to accomplish the additional analysis and member engagement needed on this issue. To allow the time needed to conduct this effort, we respectfully request that NOSB keep this discussion document open for comment through to the fall 2019 NOSB meeting. We believe this process will allow for maximum engagement and preparation for an informed discussion and panel in the fall, and better equip NOSB to develop a proposal that can receive maximum stakeholder support.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink that reads "Johanna Mirenda".

Johanna Mirenda  
Farm Policy Director  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association



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**RE: Materials Subcommittee Discussion Document – Genetic Integrity Transparency of Seed Grown on Organic Land**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee's Discussion Document on Genetic Integrity Transparency of Seed Grown on Organic Land. The subcommittee is asking several questions to help inform a future proposal that will include gathering of information for a database, providing farmers with transparency on the seed purity of corn they may plant on organic land.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Organic Trade Association continues to support the goal of planting clean seed. We acknowledge that GMO contamination prevention practices must be in place throughout the organic supply chain, but that having control at the beginning of the process sets a critical stage for successful GMO avoidance. We have long supported the use of testing as an important tool to determine compliance with a process-based standard, and we have strongly advocated for setting limits for controlling GMO contamination in feed, crops, food and fiber. We believe that planting clean seed is a fundamental practice that encourages prevention of GMO contamination throughout the supply chain.

**In summary**

- The Organic Trade Association did not have enough time to adequately survey members and collect feedback on the questions being asked. We have drafted comments that best reflect the current thinking of our membership, but additional time is needed. The short comment period continues to be a disservice to the entire NOSB process and the organic sector. We urge NOSB and members of the organic community to unite and voice this concern to USDA.
- The current discussion document is confusing, and the end-goal (proposal) is not clear. The current approach is running a parallel track of trying to understand the problem while at the same time prescribing the solution. Posting seed purity information in a public database that is

uncoupled from a seed purity standard could hurt the organic sector rather than help it. The Organic Trade Association recommends a much more measured approach that will allow NOSB to evaluate testing data, evaluate the problem, and then decide what kind of testing and reporting protocols are needed, if any. We continue to recommend that data collection be administered and carried out by USDA or a similar entity through a task force effort.

- The use of genetic engineering in organic production and handling is prohibited under the USDA organic regulations. Contact between organic products and prohibited substances is also prohibited and certified operations must have approved contamination prevention measures in described in the Organic System Plan. Testing is one of the most definite and effective tools the organic sector can use to evaluate whether an organic operation has adequate measures in place to prevent contact with GMOs. The Organic Trade Association encourages NOSB to focus on a recommendation to NOP requesting guidance on GMO testing for certifying agencies and industry.

***We offer the following more detailed comments:***

The Organic Trade Association has submitted extensive comments on this topic since 2012. Despite great efforts to develop a seed purity standard, the organic sector has struggled to agree on a proposal because of the various obstacles identified through the public comment process, one of which is the need to collect more data to shape the feasibility of a fair and effective seed purity standard. NOSB's efforts to keep this important topic alive at the NOSB level and its perseverance to shape a workable solution are commendable, but after reading this spring 2019 Discussion Document, we have concerns about the direction we are heading, and the unintended consequences this current approach may have.

There is a notable divergence in the current proposal from the original intent of the GMO Ad hoc Sub-Committee that formed in 2012. The Sub-Committee was exploring means of strengthening seed purity as one step to avoid the potential of contamination of crops with GMOs. Seed was identified as perhaps the most impactful and efficient point in the supply chain at which contamination could be limited and controlled. The focus, when this conversation started, was to recommend a standard for the genetic content of seed used in organic production. Without repeating the entire history that has occurred over the past six years, we can say that we have moved from collecting statistically significant and meaningful data to inform the feasibility of an effective and fair seed purity standard to the gathering of information for a public database, for the intended purpose of providing organic farmers with transparency on the seed purity of corn they may plant on organic land. The intended proposal will not include tolerance levels that could prohibit the planting of seed that exceeds any specific tolerance.

**The Organic Trade Association's primary concerns and comments are as follows:**

**Limited comment time:** The proposals were again released to the public a week and a half late, resulting in a 22-day comment period (16 business days). The shortened comment period continues to be a real disservice to NOSB members and the time and resources that go into the NOSB proposals and the public comment process. It is also a disservice to the entire NOSB process and the organic sector. As a member-based organization, our comments and positions are shaped through our task forces and extensive outreach to our members. To carry out a meaningful comment process under OTA's governance structure, a comment period needs to be ***at least*** 30 days. Given the number and complexity of topics that are

typically on any NOSB meeting agenda, such as this one, we argue that the comment process needs to be *at least* 60 days. Unfortunately, for this meeting, the 22-day time allotment is extremely unreasonable and does not pay respect to NOSB or the process. Organic stakeholders are becoming increasingly disgruntled by the process, and action needs to be taken. The Organic Trade Association understands this is not the fault of NOSB members, and we offer our support in all ways possible. We urge NOSB and members of the organic community to unite and voice this concern to USDA.

**The proposal is confusing:** The Organic Trade Association is unclear at this point whether the fall proposal will be for a regulatory change or instruction or both. We are also unclear about who will be required to do the testing, who will be collecting the data, and ultimately, what will happen with the data. Given the lack of clarity and the short comment period, if the subcommittee decides to move forward, we request that a proposal be released for DISCUSSION prior to the fall 2019 meeting (or preferably sooner). We are still in the process of collecting feedback from members on the subcommittee's questions due to the short comment period, and we still do not have a clear picture of the proposal that is being shaped. We understand that the current proposal is aimed at collecting GE contamination data on corn seed for the sake of transparency rather than to inform the feasibility of seed purity standard. We believe more information needs to be gathered to determine if this approach is in fact the best solution to meet the end goal of clean seed and GMO contamination prevention.

**Meaningful data collection to inform a solution is needed:** The Organic Trade Association has consistently emphasized that any data collection effort that will yield statistically significant and meaningful results needs to be designed systematically according to established sampling protocols and testing specifications. If the goal is to collect information to understand the extent of GE contamination in corn seed used by organic growers, then the collection of data should be done via a well-designed research product conducted by USDA or a similar third-party entity. In other words, the data collection should happen outside of the certification and compliance system. Throughout the public comment process, stakeholders have conveyed the need to first identify the problem before moving to the solution. However, this proposal is aimed at data collection and transparency, which in effect will turn the problem over to the private sector (and the public at large) to figure out the solution. The Organic Trade Association recommends a much more measured approach that will allow NOSB to evaluate testing data, evaluate the problem, and **then** decide what kind of testing and reporting protocols are needed, if any. The current approach is running a parallel track of trying to understand the problem while at the same time prescribing the solution.

The Organic Trade Association emphasizes that all reputable seed companies are testing, and that seed growers and suppliers are already making great strides to be transparent about detectable levels of GE traits, and taking measures to protect the genetic integrity of their seed through contamination prevention measures. The organic sector continues to shoulder the burden of GMO contamination prevention, both in terms of action and cost. The Organic Trade Association continues to request that any proposal NOSB passes on the topic of seed purity must ensure the following guiding principles are met:

- Incentivize the development and use of organic seed
- Be established per crop (corn, soy, alfalfa, cotton, etc.)
- Be based on data conducted through feasibility studies for this intended purpose
- Establish levels, if any, of unavoidable presence of GMOs per crop



- Apply to adventitious or unavoidable presence only. The intentional use or presence of GMOs will continue to be strictly prohibited with a zero-tolerance level.
- Be acceptable to consumers, seed growers and users of organic and non-organic seed.
- Avoid inadvertent and negative impact on organic farmers and organic seed growers and genetic diversity of organic seed.

**The approach of the proposal could lead to less available corn seed varieties.**

The demand for tested product is growing, and the marketplace will continue to respond to demand. In the long run, it may be that required transparency will spark innovation and will increase organic seed breadth and depth. The concern is a proposal that gets out ahead of where the market can realistically move in the short term, and the long-term harm that might occur as a result. Members have expressed concern that at least in the short term, the proposal may result in fewer seed varieties that will be available to organic farmers. Choices may be limited because there is a large economic risk in producing organic seed corn. Seed companies growing organic hybrid seed corn will choose to limit this risk by only producing hybrids with a high probability of achieving a low level of GMO. Many of the inbreds used to grow organic seed corn test positive for GMO at a low level. The acceptable threshold for inbred seed will necessarily go down if transparency is required in hybrid seed. This tighter threshold will limit the number of hybrids the seed industry can produce. In addition, seed companies growing conventional untreated seed corn for organic farmers have the luxury of “cherry-picking” lots. In other words, they can produce a large quantity of a given hybrid that is sold as treated and untreated, and then choose the lots (or seed sizes) that have low levels of GMO to sell to organic farmers. This gives them an unfair advantage over organic seed corn producers.

The major seed suppliers understand the importance of adventitious presence to their customers, and already take a lot of steps to prevent the contamination from occurring. The major immediate impact to organic seed companies would be the forced tightening of inbred seed standards, which would in turn reduce the number of organic hybrids available to organic farmers.

**The proposal does not provide certifying agents or industry with formal NOP guidance on GE testing.**

Testing is a critical tool that certifiers use to determine compliance with a process-based standard. Certifiers use testing to determine if organic operations have adequate contamination prevention measures in place and this of course includes GMO contamination prevention measures. Certifiers are currently testing for GMO contamination under the requirements of § 205.670 (Inspection and testing of agricultural products to be sold as “organic”), and industry is voluntarily testing as well.

Ironically, after years of discussing genetic integrity and the need to keep GMOs out of the organic supply chain, NOP’s Guidance on Periodic Residue Testing (NOP 2610, 2611 and 2613) is out of date, in general, and does include procedures and criteria specific to GE testing. An update to NOP’s existing residue testing guidance and inclusion of guidance on GE testing should be viewed as a top priority. For the sake of consistency and accuracy, a maintained list of tests and testing laboratories along with approved methods of sampling and testing methods would be very helpful whether it is used to support the collection of seed purity data or for general testing of excluded methods under the organic regulations. Guidance on how to respond to positive results would also be very helpful. Certifiers are now able to require increased GE contamination prevention efforts if they have the data to support the action.

The stage for guidance on GMO testing has already been set. On November 9, 2012, NOP published a Final Rule on Periodic Residue Testing. The rule clarifies a provision of the Organic Foods Production Act (OFPA) of 1990 and the regulations issued **require** periodic residue testing of organically produced agricultural products by ACAs. NOP received several comments regarding types of residues that would be considered acceptable targets for testing under the rule. Four commenters, including OTA, requested clarification on testing for GMOs.

NOP responded by saying that it does not intend for the testing conducted under section 205.670 to be limited to pesticides residues. NOP further clarified that under the existing residue testing regulations, certifying agents have the flexibility to test for a range of prohibited materials and excluded methods, including, but not limited to, pesticides, hormones, antibiotics, and GMOs.

The Organic Trade Association recommends that NOSB focus on a recommendation to NOP requesting guidance on GMO testing for certifying agencies and industry. **This is a request we continue to repeat in our comments.** Testing is one of the most definite and effective tools the organic sector can use to evaluate whether an organic operation has adequate measures in place to prevent commingling with non-organic GMO crops as well as intentional or unintentional contact with GMOs. With all the time spent on trying to establish seed purity, it is unfortunate that NOP has not issued any instruction or guidance on GMO testing. This is incongruent with NOSB discussions and the fact that testing for GMOs is required under the organic regulations whether it be in response to a contamination event or a complaint (§ 205.670(b)), or whether it be part of a certifying agent's periodic testing residue plan (§ 205.670(c)).

Providing NOP with a recommendation for further guidance on testing falls directly under the specific responsibilities of NOSB outlined in OFPA starting at section 2119(k):

5. PRODUCT RESIDUE TESTING.—The Board shall advise the Secretary concerning the testing of organically produced agricultural products for residues caused by unavoidable residual environmental contamination.

This approach will assist certifiers and industry with a tool that supports a process-based standard, it will increase knowledge about GE contamination, and it will stimulate action and further development of mitigation measures. We are not suggesting this replace the effort of gathering information to better understand the problem of unintended GE presence or the looming topic of setting control limits. We are suggesting a recommendation we feel NOP is best suited to respond to (guidance on GE testing for certifiers and industry) vs. action that is best suited for research conducted by a third-party entity outside of the certification system.

## Conclusion

The use of excluded methods is prohibited in organic production and handling. The Organic Trade Association is committed to actions that keep genetically modified organisms out of organic livestock feed, seed, crops, food and fiber. We continue to be extremely supportive of moving recommendations forward to NOP that will improve the practices to accomplish this goal. In the name of continuous progress, we encourage NOSB to focus on drafting proposals that have the best chance of successfully moving through the regulatory system at this time.





On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard  
Vice President, Regulatory and Technical Affairs  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Avenue, SW  
Room 2642-So., Ag Stop 0268  
Washington, DC 20250-0268

**Docket:** AMS-NOP-18-0071

**RE: Materials Subcommittee –Assessing Cleaning and Sanitation Materials Used in Organic Crop, Livestock and Handling (Discussion)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Materials Subcommittee’s Discussion Document on Assessing Cleaning and Sanitation Materials Used in Organic Crop, Livestock and Handling. The subcommittee is inviting discussion on a new system for reviewing sanitation and disinfection materials in organic production and processing.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

### **Summary**

- ✓ We support the Subcommittee’s intended outcomes for this work agenda item: to enable consistent reviews of these materials and to provide a comprehensive toolbox of food safety options for organic producers.
- ✓ We have questions about how a new “system” or “framework” for reviewing sanitizers fits in to the larger existing context and process for NOSB to evaluate substances under OFPA and NOP requirements.
- ✓ We ask that NOSB withdraw its request for the Technical Review because the scope of work is unclear and stakeholders have not yet had an opportunity to weigh in on this new concept of sanitizer review.
- ✓ Grouping sanitizers by active ingredient and/or function could be a helpful exercise in assessing whether alternatives are available, and will support the Subcommittee’s stated goal to “identify materials needed to fill potential gaps in organic crop production, livestock health, and food safety.”

**We offer the following more detailed comments:**

## **Background**

Substances for cleaning, sanitation, and disinfection are listed on the National List across the crop, livestock, and handling scopes, and are reviewed by NOSB when these substances are petitioned and/or are undergoing Sunset Review. Public commenters and NOSB members have expressed continued interest in learning more about antimicrobials and the range of available products that are both effective and most appropriate for use in organic production and handling. The Organic Trade Association agrees.

It is critical that organic producers and handlers have a tool kit of antimicrobials that will allow them to fully comply with all food safety requirements and have the ability to rotate among several materials to reduce the incidence of microbial resistance. It is also critical that the National List continues to represent the best and least-toxic technology our food system has developed. For this reason, the Organic Trade Association continues to be supportive of NOSB's work agenda item to develop questions to assess the essentiality of sanitizer (antimicrobial) materials.

## **Intended outcomes of NOSB's "system" for reviewing sanitizers**

The discussion document<sup>1</sup> presented at this spring 2019 meeting describes the Subcommittee's intent to develop "a **system to assess sanitizers for essentiality** as well as evaluate them under the OFPA and NOP regulatory criteria for the National List." According to the discussion document, this work agenda item is intended to "assist the NOSB Crops, Livestock, and Handling Subcommittee to **generate consistent reviews** when addressing the possible placement of sanitation materials on the National List." The subcommittee also states that, "**Our goal is not to limit these tools. This review could help identify materials needed to fill potential gaps in organic crop production, livestock health, and food safety.**"

The discussion document also acknowledges that NOSB has requested a Technical Review to provide "information on the essentiality and appropriateness for these types of materials in a variety of situation;" "reference and information to develop a framework and questions for reviewing sanitation and disinfection materials;" and "a broad scope of questions to consider for such materials." The Technical Review is intended to be used as a reference for NOSB members to "**enable consistent reviews of these materials and provide a comprehensive toolbox of food safety options for organic producers.**"

We support the intended outcomes of this effort: collecting information and references; enabling more consistent reviews; and filling gaps in food safety tools. These outcomes will support continuous improvement in the regulatory approval of more effective and less toxic sanitizers that are needed to ensure safe production and processing of organic foods. However, we have questions about how this new "system" (which is also referred to as a "framework" or "methodology" in the document) for reviewing sanitizers fits in to the larger existing context and process for NOSB to evaluate substances under the Organic Foods Production Act (OFPA) and National Organic Program (NOP) requirements. The Subcommittee has not described how the system will work or how it will impact existing NOSB policies and procedures.

Furthermore, we are concerned that NOSB moved to request a Technical Review for a work agenda item that is in such an early conceptual stage and without first receiving public comment on the concept itself.

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<sup>1</sup><https://www.ams.usda.gov/sites/default/files/media/MSAssessSanitizerFoodLivestockWebApril2019.pdf>

The scope of work for the Technical Review, as described in the discussion document, is unclear. It also appears to defer to the third party technical reviewers to develop evaluation criteria on behalf of the Board which would not be appropriate. **For these reasons, we ask that NOSB withdraw its request for the Technical Review described in the discussion document.** We believe that more clarity is needed from NOSB on several aspects of this new concept of sanitizer review, and stakeholders need the opportunity to weigh in on the concept details. This information exchange is essential to ensuring that a future Technical Review will address a clear and appropriate scope of work, resulting in a better technical resource for current and future NOSB members.

#### **“Evaluation criteria” for reviewing sanitizer materials**

The Subcommittee’s discussion document identifies a list of 16 “evaluation criteria” that could be included in the new system/framework for reviewing sanitizers. It is not explained how these criteria will fit in to the Subcommittee’s vision for a system of reviewing sanitizers, nor how these criteria align with the existing requirements of OFPA or the NOP.

**Regardless of the type of material (sanitizer or not), NOSB must conduct its evaluation of substances for National List in accordance with OFPA (7 USC 6517 and 6518).** Part 6517 includes the guidelines for the National List. Under these guidelines, the National List may provide for the *allowance of a synthetic substance only if* use of the substance “(i) would not be harmful to human health or the environment; (ii) is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products; and (iii) is consistent with organic farming and handling”, and the National List may provide for the *prohibition of a non-synthetic substance only if* use of the substance “(i) would be harmful to human health or the environment; and (ii) is inconsistent with organic farming or handling, and the purposes of this chapter (7 USC 6517(c).” In Part 6518, OFPA identifies seven criteria that the NOSB must consider in its evaluation of substances: “1. the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems; 2. the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment; 3. the probability of environmental contamination during manufacture, use, misuse or disposal of such substance; 4. the effect of the substance on human health; 5. the effects of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock; 6. the alternatives to using the substance in terms of practices or other available materials; and 7. its compatibility with a system of sustainable agriculture.” In developing recommendations for substances on the National List, NOSB is statutorily required to evaluate substances based on the evaluation criteria and the guidelines specified in OFPA. Processing aids or adjuvants are subject to additional criteria set out in the NOP regulations 7 CFR 205.600(b).

In applying the statutory and regulatory criteria to specific substances undergoing review by NOSB, it is reasonable to expect that NOSB may need to develop more specific questions to be asked of petitioners and/or of technical reports to ensure that NOSB has sufficient information to conduct its review and develop its recommendation. Such internal evaluation tools can have a role in supporting consistency in the depth of analysis, technical information, and application of the OFPA requirements. However, it is critical that any such internal evaluation tools align with the existing statutory requirements of OFPA and regulatory requirements of NOP, and do not conflict or distract from these requirements.

**As the Subcommittee continues to develop its new concept of reviewing sanitizers, it must make clear and concerted efforts to frame the system within the context of OFPA and the NOP regulations.** Actions to support this effort may include:

- Develop a purpose statement that identifies evaluation criteria as an internal tool to support review under OFPA and NOP.
- For each evaluation criteria, identify the specific OFPA statutes and/or 7 CFR 205.600 regulation for which the evaluation criteria is intended to help address. Any criterion that does not help determine compliance with OFPA or 7 CFR 205.600 should be eliminated.
- Develop a disclaimer statement that acknowledges that the Subcommittee's list of evaluation criteria is not a substitute for OFPA or NOP. NOSB members must be free to interpret the statutory and regulatory criteria, and should not be limited to only the questions/criteria included in the internal evaluation tool.
- Consider choosing a different name other than "evaluation criteria." That phrase is used in the heading of 7 CFR 205.600 and refers to specific regulatory and statutory requirements. NOSB must avoid any confusion between the Subcommittee's concepts and the requirements of OFPA and NOP.

**The Subcommittee should consider whether the evaluation criteria described in this discussion document should be applicable for all materials, and not just for sanitation materials.** Neither OFPA nor the NOP regulations include any criteria unique to sanitizers. Therefore, it may not be appropriate to impose a unique set of evaluation tools for these materials when *all* materials must be evaluated under the same set of statutory and regulatory criteria. If the Subcommittee's list of evaluation criteria is only used for sanitizer materials, it could actually contribute to *inconsistency* in review of sanitizers compared to other materials. This would upend the ultimate goal of NOSB to bring more consistency to the review of materials. Furthermore, if this evaluation system is limited only to sanitizers, NOSB would need to develop clear definitions for the terms (cleaner, sanitizer, and disinfectant) and be able to parse out which materials are reviewed under this system. This could be difficult especially when certain sanitizers are classified as pesticides within certain regulatory schemes.

#### **"Classification" of sanitation materials by active ingredients**

The Subcommittee's document includes a list of 18 active ingredients under which petitioned or sunset materials could be classified. The Subcommittee would use these classifications to compare materials by function, which will "help in determining which are unique."

Grouping sanitizers by active ingredient and/or function, and conducting a gap analysis of materials within and among each group could be a helpful exercise to support NOSB's evaluation of "the alternatives to using the substance in terms of practices or other available materials (7 USC 6518(m)(6))" and whether the substance "is necessary to the production or handling of the agricultural product because of the unavailability of wholly natural substitute products (7 USC 6517(c)(2)(a))." This exercise will support NOSB's stated goal of this evaluation framework to "help identify materials needed to fill potential gaps in organic crop production, livestock health, and food safety."

The Subcommittee may want to consider choosing a different term for this list of active ingredients other than "classification." That term is used to refer to the determination of a substance as synthetic or non-synthetic, and/or agricultural or non-agricultural, and NOSB must avoid any confusion between this internal tool and the regulatory definitions.

### **Discussion Questions**

1. *Should the “evaluation criteria” list noted above be modified, consolidated, or shortened; are there additional items needed?*

Please see above for comments regarding the “evaluation criteria” for reviewing sanitizer materials

2. *Should the “materials classified by their active ingredients” list noted above be modified, consolidated, or shortened; are there additional items needed?*

Please see above for comments regarding the “classification” of sanitizer materials by active ingredient

3. *Do you have additional suggestions for the development of this framework?*

Please see above for comments regarding additional suggestions for developing this framework.

### **Conclusion**

Although the Organic Trade Association continues to be supportive of NOSB’s work agenda item to develop questions to assess the essentiality of sanitizer (antimicrobial) materials, it is essential that such internal evaluation tools are clearly aligned with the statutory and regulatory requirements of OFPA and the NOP. Additional clarifications from NOSB are needed to ensure that these type of internal evaluation tools do not distract from OFPA and NOP requirements, and that consistency is maintained across NOSB’s review of substances for the National List. We also ask that NOSB withdraw its request for the Technical Review because the scope of work is unclear and stakeholders have not yet had an opportunity to weigh in on this new concept of sanitizer review.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Johanna Mirenda  
Farm Policy Director  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association





April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP

**Docket:** AMS-NOP-18-0071

**RE:** Oversight Improvements to Deter Fraud Discussion Document

Dear Ms. Arsenault:

Thank you for this opportunity to provide feedback on the Compliance, Accreditation and Certification (CACS) Subcommittee's Discussion Document on Oversight Improvements to Deter Fraud Discussion.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The U.S. Department of Agriculture (USDA), certifiers, inspectors and organic businesses all have a shared role in protecting the integrity of the seal. The ongoing work of the National Organic Program (NOP) to strengthen the enforcement of the organic standards and to deepen the rigor of oversight across the supply chain is critical to protecting organic integrity and ensuring a level playing field for all organic market participants – in the U.S. and abroad. The integrity of the organic certification process from farm to table is the lifeblood of the organic industry.

The Organic Trade Association appreciates the summary the CACS has provided and the list of actions that will build a better compliance and enforcement system. The Organic Trade Association has identified fifteen critical action areas and ranked them according to the level of impact we believe each will have in increasing organic integrity. Although we have provided a ranking, we want to emphasize that they are all extremely important and we ask NOSB to please urge NOP to take action on each one.

In addition to the fifteen critical actions prioritized below, we are including the enforcement and oversight legislative text from the 2018 Farm Bill in addition to the conference report language (Appendix B & C). The 2018 Farm Bill gives USDA's National Organic Program new authorities to carry out compliance and enforcement actions in the U.S. and abroad. We urge NOSB and NOP to focus time and energy on figuring out ways to best maximize those authorities. There are new avenues and tools now available that did not exist when NOSB started its response to NOP's 2017 memo.

**Summary of the Organic Trade Association's top priorities:**

1. **Excluded Operations:** Limit the types of operations that may be excluded from certification. Specifically, require certification of each producer, handler and handling operation in the supply chain that is producing or handling products sold, labeled, or represented as "100 percent organic,"

“organic,” or “made with organic (specified ingredients or food group(s)).” Exclusion from certification should be very restricted and may be granted only for transporters, storage facilities and retail food establishments that meet the conditions and regulatory compliance requirements detailed in our comments below.

2. **Organic Integrity Database:** 1) Require Accredited Certifying Agents (ACAs) to report aggregate production area certified by crop and location at least on an annual basis to the Organic Integrity Database. Currently there are no means to accurately calculate organic acreage and/or yield estimates on a country-by-country basis; and 2) require ACAs to update the OID within 72 hours when an operation surrenders its certification, or its certification is suspended or revoked.
3. **Complaint & Alert System:** 1) Create a risk assessment process for prioritizing complaints; 2) improve the timing and communication around NOP’s complaint system; and 3) develop a public alert system that identifies products or regions where heightened vigilance is needed.
4. **Organic Identification:** 1) Require all documentation associated with NOP certified product to include identification of organic status; and 2) require all non-retail containers and packaging to include identification of the product as organic.
5. **Testing:** 1) Update NOP’s Guidance on Residue Testing (NOP 2610, 2611, 2613) to gain better consistency and bring testing methodology up to speed with industry standards and testing technology; and 2) increase required use of testing for imports and other high-risk products and/or regions.
6. **Grower Groups:** Formally respond to the National Organic Standards Board (NOSB) Recommendations on Grower Groups and conduct rulemaking to ensure consistent oversight and enforcement of group operations.
7. **Inspector and Certifier Oversight (including Satellite Offices):** 1) Increase oversight of certifiers, including satellite offices domestically as well as in foreign countries, which should be required to be audited on an annual basis; 2) Develop more robust auditing of ACAs with increased attention on whether a certifier’s process and qualifications are sufficient to verify compliance and detect fraud.
8. **Equivalency and Recognition Arrangements:** 1) *Terms and conditions of equivalency arrangements:* Prioritize competency of oversight and data transparency followed by differences in regulations and materials; 2) *Communication:* Improve communications with the enforcement authorities of trading partners, certification bodies in regions and countries covered by equivalency arrangements and recognition agreements, and other institutions that protect organic integrity; and 3) *Follow-up:* On recognition agreements, ensure that the governmental authorities, in fact, are implementing the NOP rule including associated guidance and policy.
9. **Inspectors (Qualifications, Training and Field Evaluations):** 1) Improve qualifications and training of inspectors and ACAs to monitor, detect and address fraud; and 2) Establish minimum requirements for qualifications and initial and continuing training.



10. **Import Certificates:** 1) Implement a system that collects a greater amount of data, including tracing the original product to its origin; and 2) Improve online access to electronic import certificate system.
11. **Updates to Non-compliances and Appeals Process:** Expedite the NOP appeals process such that that appeals are reviewed and responded to in a timelier manner.
12. **Unannounced Inspections:** Require certifying agents to conduct unannounced inspections on at least 5% of certified clients. Additional unannounced inspections should be conducted as needed in response to complaints and investigations. The cost of unannounced inspections should be factored into the certifier's fee structure. Additionally, require certifiers to report to NOP annually on their programs, success rate and compliance with the minimum requirement.
13. **10-Digit HT Codes:** Prioritize increasing the number of 10-digit statistical breaks for organic products in the harmonized tariff schedule and *require* the use of the 10-digit code when it exists. Use of an organic 10-digit statistical breakout for imported organic product (if one exists) ensures accurate accounting of products entering the United States. This information is critical to understanding what products are entering the U.S. and from which countries. It is the only U.S. government produced, year-round, public data set available on the topic. Without increased number of codes and their compulsory use by industry, there is no reliable/consistent baseline for understanding volumes, prices, and origins of imported organic products. The non-use of the code should not disqualify the product as organic. However, this could prompt a mandatory test.
14. **Federated Organic Certificates:** Consider a narrower and more easily-implementable solution that will help deter fraudulent certificates. Until the Organic INTEGRITY Database is reliably providing accurate and current information for certified operations, federated organic certifications should not be mandatory.
15. **Fumigation Notifications:** Continue to increase coordination and access to available data cross border documentation systems administered across other agencies including U.S. Customs and Border Patrol (CPBs) Automated Commercial Environment (ACE), and Phytosanitary certificates. This includes notifying NOP when imported agricultural products are treated with NOP-prohibited substances at U.S. ports of entry. Notifications must include the crop/product, name of the associated company, the substance used, and information must be made available to ACAs.

**We offer the following more detailed comments**

### **EXCLUDED OPERATIONS**

In #3 of the Discussion Document the CACS references "closing the loophole which allows uncertified handlers to both buy/sell organic products, as well as to physically take possession." This topic involves an examination of the types of operations that should be required to be certified and why.

### ***Which types of excluded operations should be required to be certified and why?***

The Organic Trade Association prioritized several legislative changes for the 2018 Farm Bill to give NOP the tools it needs to prevent fraud. One of our top priorities most relevant to the role of uncertified operations in the supply chain is the section in the Organic Farmer and Consumer Protection

Act (OFCPA) that was signed into law in December 2018, which calls for a modification to the regulations to limit the type of operations that are excluded from certification under 7 CFR §205.101. The language reads:

Farm Bill 2018 – Sec. 10104

#### ORGANIC CERTIFICATION

Exclusions from certification. Not later than 1 year after the date of enactment of this Act, the Secretary shall issue regulations to limit the type of organic operations that are excluded from certification under section 205.101 of title 7, Code of Federal Regulations, and from certification under any other related sections under part 205 of title 7, Code of Federal Regulations.

The Organic Trade Association believes that each **producer, handler and handling operation** in the organic supply chain that is producing, handling or selling products sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified. In other words, every organic ingredient and every organic product must be handled by a certified operation from farm to retailer. The opportunity to be excluded from certification should be very limited, clearly stated and based on the scope and activity of the operation.

Uncertified entities in the supply chain that are handling organic products pose a major risk of fraud because they are operating outside of the certification system and accordingly are not subject to annual on-site audits. This results in an interruption or break in an otherwise tightly linked supply chain, and creates an opportunity for unverified activity and ultimately fraudulent behavior. Furthermore, the exclusion from certification under § 205.101(b)(1) is no longer appropriate considering the complexity of today’s organic supply chain and the global scale and growth of the sector. The practice of a buyer accepting an organic certificate from a supplier, with the expectation that it represents complete supply chain certification back to the farm, can only be valid if each entity in the supply chain is certified.

The following chart reflects operations that are ***commonly considered “excluded”*** but for which we believe certification should be required. Our comments below offer further detail.

Certification Required	**Certification may not be required
Brokers (excluding customs brokers*)	Retail Food Establishments (as described under 205.101(a) and (b))
Importers	***Transporters
Traders	****Storage Facilities that do not sell, process, package, label
Wholesalers	****Distribution Centers that do not sell, process, package, label
On-line auctions	
Agricultural Ports	

\* Because of the complexity involved with importing and exporting goods, many companies use customs brokers to act as their agents. Customs brokers clear shipments of imported goods prepare required documentation for export shipments and collect duties and taxes. They act as an intermediary between importers and the government. They are paper pushers only and should not be subject to certification.

\*\*Depending on scope and activity – see our comments below

\*\*\*Operation that transports (this carve out is based on OFPA definitions) – if it does not handle (sell, process or package) and certified organic product is transported from a certified operator to another certified operator or final retailer

\*\*\*\*Must receive certified organic products in wholesale or retail containers (enclosed in a sealed, tamper-proof and properly labeled container) and ship in the same wholesale or retail container without opening, reconstituting, altering, splitting, repackaging, processing or relabeling the products.

The Organic Trade Association believes that eliminating the exclusion from certification for uncertified entities that handle (sell, process, package) organic product, including agricultural ports, commodity brokers, importers, wholesalers, commodity traders and on-line auctions, regardless of whether they take physical possession of the product, is the single-most important action that can be taken to increase the integrity in the global organic control systems and create a level playing field for all organic operations.

### ***Should any of the current exclusions in the USDA organic regulations remain in place?***

Yes. However, the Organic Trade Association urges NOP to focus on “who may be excluded” rather than “who should be certified.” We urge NOP to first communicate that everyone in the supply chain producing and/or handling organic products (grow, sell, process, package, label) must be certified, and then communicate the very limited and restricted exception to the Rule.

In short, an exception to the rule may apply *only* to:

1. **Exempt operators** meeting the conditions and requirements of 205.101(a). Please note that the Organic Trade Association’s is focused on limiting the types of operations that may be ***excluded***. Our legislative efforts are not aimed at ***exempt*** operations.
2. **Retail food establishments** and **storage facilities** that meet the conditions and requirements of § 205.101(b) as described in our comments below;
3. **Transporters**, provided: 1) they do not sell, process, or package; 2) the activity is limited to the delivery of certified organic crops or livestock from one certified entity to another; and 3) they are operating in compliance with NOP Guidance 5031 (Certification Requirements for Handling Unpackaged Organic Products).

In all cases above, the regulations need to be revised to clarify the conditions and regulatory provisions that must be met by exempt and excluded operations, particularly as it relates to commingling and contamination prevention, labeling and record keeping.

### **Retail Food Establishments**

The Organic Trade Association strongly advocates for voluntary certification of **retail food establishments**. Retailers represent the final interface with consumers in the organic supply chain, and it is crucial that organic integrity in merchandising, handling and marketing be vigilantly maintained. While we strongly advocate for voluntary certification of retailers, we support retaining the current exclusion (and exemption) for retail food establishments, ***provided*** NOP:

1. Swiftly act on NOSB’s 2014 recommendation titled “Clarification and Guidance on Retail Compliance and Certification.” This recommendation (unanimously passed) requests that NOP provide clear general education and guidance on organic compliance to the retail sector and clarify specific sections of the Rule as it applies to retail food establishments.

2. Revise the regulations to clarify that all retail food establishments that are either exempt and/or excluded from certification must still comply with prevention of contact with prohibited substances as set forth in §205.272, the labeling provisions of §205.310 and record keeping as described in §205.101(c).
3. Clarify the definition of a “retailer” as used in the NOP Town Hall Webinar. One of the retail areas NOSB requested clarification on in the 2014 recommendation is the function of on-line retailers. We understand that the early drafted regulations and the exemption and exclusions provided for retail food establishments may not have had on-line retailers in mind at the time the regulations were drafted. The regulations are out of date in this area and the Organic Trade Association views guidance in this area as a top priority.

The Organic Trade Association believes that focused education, guidance and outreach to the retail sector will help improve compliance and regulation, foster consistency across certified and non-certified operations, and promote consumer confidence in the USDA organic label.

### **Storage Facilities / Distribution Centers**

Under conditions that need to be clearly spelled out in the organic regulations and guidance (see our suggested revisions below), **storage facilities that store and/or distribute** may be excluded from certification provided they are covered under the certified operation’s Organic System Plan that is responsible for the organic product(s). Additionally, documentation attesting to contamination/commingling prevention and record keeping practices should be maintained in the OSP *and* on-site at the storage facility location. **See Appendix D – Independent Storage Information Sheet.**

The organic regulations in combination with guidance must make it abundantly clear that an excluded storage facility or distribution center **must receive certified organic products in wholesale or retail containers (enclosed in a sealed, tamper-proof and properly labeled container) and ship/distribute them in the same wholesale or retail container without opening, reconstituting, altering, repackaging, splitting, processing or relabeling the products.**

Storage or distribution centers that are performing secondary packaging on organic products must be certified.

**Note:** The term “properly labeled” refers to a NOP certified product that is labeled in accordance with the labeling requirements of the organic regulations *in addition* to identification of its organic status (see our comments below on page 13 - ORGANIC IDENTIFICATION ON DOCUMENTS AND LABELS).

For storage facilities (and any other excluded operation covered under 205.101(b)), a regulatory revision providing more specificity on the meaning of “packaged or otherwise enclosed in a container” is needed.

The Organic Trade Association recommends the following:

#### **§ 205.101 (b)(1) Exclusions:**

- (i) Are packed and shipped by a certified operation and remain packaged or otherwise enclosed in a sealed, tamper-proof and properly labeled container prior to being received or acquired by the storage operation; and

- (ii) Remain in the same package or container and are not otherwise ~~processed~~ handled while in the control of the handling operation.

The term “processed” in (ii) is replaced with “handled” to include “***sell, process and package.***”

**§ 205.2 (Terms Defined) - Handle.** To sell, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

We also urge NOP to clarify that storage facilities and distribution centers that **ALWAYS MEET THESE CONDITIONS** are excluded from the requirements of this part, except:

- The requirements for prevention of commingling and contact with prohibited substances as set forth in §205.272; and
- Records sufficient to 1) prove that ingredients/products identified as organic were organically produced and handled; 2) ensure traceability; and 3) document procedures for contamination/commingling prevention.

Furthermore, records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State organic programs' governing State official access to these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

### **Transporters**

Given the NOP definition of a “handler,” an exception to certification may be given to an **operation that “transports,”** provided they do not handle (sell, process or package) organic products and the product(s) are delivered directly from one certified operation to another certified operation or to the final retailer. In all instances, the certified operation responsible for the organic product(s) must disclose all activity in the Organic System Plan and maintain compliance with the organic regulations, including records, audit trail and traceability of the product(s).

Accordingly, we support the guidance pasted below related to transporters/transportation in NOP Guidance 5013. However, it should apply to unpackaged **and** packaged products.

#### **NOP Guidance 5031**

##### **4.2 An operation that transports unpackaged organic products does not need to obtain certification if it does not handle (i.e., sell, process, or package) organic products.**

The certified organic operation responsible for the organic products that are transported must:

- Maintain records in sufficient detail as to be readily understood and audited;
- Maintain the audit trail and traceability of organic products;
- Prevent commingling and contamination of the certified organic products during transportation;
- Fully describe the transportation practices in the organic system plan; and
- Ensure that the transportation records for organic products are available for inspection.



**Examples** of operations that do not need to obtain certification include:

- Transportation companies that move certified organic hay or straw (wrapped or unwrapped) or milk from a certified organic farm to a certified organic buyer or processing facility;
- Transportation companies that transport certified organic grain from certified operations to a certified handling facility; and
- Transportation companies that move certified organic livestock from a certified organic farm to a certified organic slaughter facility.

**4.3 An operation that handles unpackaged organic products (other than transporting), and is not an exempt or excluded handling operation, must be certified.**

**Examples** of operations that handle unpackaged organic products and must be certified:

- Operations that handle certified organic hay or straw (wrapped or unwrapped) by combining or splitting loads or lots;
- Operations that handle unpackaged grain, including combining or splitting loads or lots, package, or otherwise handle the product other than for transport; and
- Fruit and vegetable wholesalers that package or label containers of certified organic produce for sale as organic.

**4.4 Additional requirements**

All handling operations, whether certified or not, must prevent commingling with non-organic products and contact with prohibited substances. (See § 205.272.)

Handlers that handle unpackaged organic products must maintain adequate records.

**Examples** of records documenting compliance with the USDA organic regulations:

- Clean truck affidavits, records of cleaning and sanitizing materials, and procedures used to clean trucks;
- Bills of lading, manifests, transaction certificates, shipping records, delivery records, invoices, lot numbers, and other audit trail documents; and
- Records documenting the audit trail, chain of custody, tanker seals, wash tags, truck and trailer numbers.

The Organic Trade Association, however, **DOES NOT** agree with the following example in section 4.1 of NOP 5031. The Organic Trade Association urges NOP to require the following operations to be certified and strike this portion from **NOP Guidance 5031**:

**NOP Guidance 5031 - Section 4.1**

**Examples** of operations that are excluded and do not need to be certified:

- Wholesale distributors, brokers, and traders that sell boxed or otherwise sealed containers of certified organic products (e.g., sealed tote bags, 55-gallon juice drums, boxed cereal, milk in cartons);
- Produce handlers who do not open, repack, trim, or relabel certified organic products (e.g., bagged salad greens, boxed produce).

## ***Regulatory analysis; potential options for change and nuances to note***

### **Goal:**

1. Revise the regulations to require every handler and every handling operation in the organic supply chain to be certified. Every organic ingredient and every organic product must be handled (sell, process, package, label) by a certified operation, with very limited exception.
2. Revise the regulations to provide exceptions to certification for: 1) exempt operations as described in 205.101(a); 2) storage or distribution facilities (used only for wholesale or retail packaged product); 3) retail food establishments (exempt and excluded); and 4) transporters.

**Analysis of NOP Handling Definitions:** The regulations require each “production” or “handling operation” or specified portion of a “production” or “handling operation” to be certified. The definition of “**handling operation**” is problematic because it does not capture the activity of “**selling**” as does the definition of “**handle**.” All three definitions (handle, handler and handling operation) are in OFPA and cannot be changed.

**Current NOP definition of Handle:** To **sell**, process, or package agricultural products, except such term shall not include the sale, transportation, or delivery of crops or livestock by the producer thereof to a handler.

**Current definition of Handling Operation:** Any operation or portion of an operation (except final retailers of agricultural products that do not process agricultural products) that receives or otherwise acquires agricultural products and processes, packages, or stores such products.

### **Excluded Operations: Recommended Change #1:**

**§205.100 What has to be certified** could be revised to specify **handlers and** handling operations in order to capture the activity of “selling”:

#### **§205.100 What has to be certified.**

- (a) Except for operations exempt or excluded in §205.101, **each production or handling operation or specified portion of a production or handling operation or handler that produces or handles crops, livestock, livestock products, or other agricultural products** that are intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” must be certified according to the provisions of subpart E of this part and must meet all other applicable requirements of this part.

**Note:** The definition of “**handle** includes” the term **process**. The definition of *processing* is as follows:

**Processing.** Cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, extracting, slaughtering, cutting, fermenting, distilling, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing and includes the packaging, canning, jarring, or otherwise enclosing food in a container.

**Clarification is needed:** Storage facilities commonly freeze and/or chill packaged and sealed products. There needs to be an exception made for “holding<sup>1</sup>” for safe or effective storage (aeration, cooling, freezing) provided it does not involve prohibited inputs/materials/practices and provided it does not transform a raw agricultural commodity into a processed food. Such storage activities should not require certification provided the excluded storage facility receives certified organic products in wholesale or retail containers (enclosed in a sealed, tamper-proof and properly labeled container) and distributes the products in the same wholesale or retail container without opening, reconstituting, altering, repackaging, processing or relabeling the products.

### **Excluded Operations: Recommended Change #2:**

**§ 205.101(b)(1) Excluded Operations** could be revised to cover the compliant activity performed by storage facilities *only* (receiving, storing and shipping) and to expand the compliance requirements as we have suggested (contamination prevention, labeling, record keeping and OSP disclosure). All other handlers and handling operations (excluding retail food establishments and transporters meeting the terms of the regulation and guidance) must be certified.

§ 205.101 (b)(1) Exclusions: A handling operation or portion of a handling operation that is engaged in the act or process of storing agricultural products is excluded from the requirements of this part, except for the requirements for the prevention of commingling and contact with prohibited substances as set forth in §205.272 with respect to any organically produced products, if such operation or portion of the operation only sells stores and distributes organic agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s))” that:

- (i) Are packed and shipped by a certified operation and remain packaged or otherwise enclosed in a sealed, tamper-proof and properly labeled container prior to being received or acquired by the handling operation; and
- (ii) Remain in the same package or container and are not otherwise processed handled while in the control of the handling operation.

This section of the rule also needs to be revised to specify that, in addition to the requirements for the prevention of contact with prohibited substances as set forth in §205.272, storage facilities are required to meet all applicable labeling requirements of the organic regulations as well as the record keeping requirements as described in §205.101(c).

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<sup>1</sup> FDA Definition of “Holding” for Registration of Food Facilities (21CFR1.227) - *Holding* means storage of food and also includes activities performed incidental to storage of a food (e.g., activities performed for the safe or effective storage of that food, such as fumigating food during storage, and drying/dehydrating raw agricultural commodities when the drying/dehydrating does not create a distinct commodity (such as drying/dehydrating hay or alfalfa). Holding also includes activities performed as a practical necessity for the distribution of that food (such as blending of the same raw agricultural commodity and breaking down pallets), but does not include activities that transform a raw agricultural commodity into a processed food as defined in section 201(gg) of the Federal Food, Drug, and Cosmetic Act. Holding facilities could include warehouses, cold storage facilities, storage silos, grain elevators, and liquid storage tanks.



Additionally, storage and distribution centers must be covered under the certified operation's Organic System Plan that is responsible for the organic product(s).

**NOTE: It is important to recognize the inconsistency in the existing regulations for exempt vs. excluded operations.** The common practice or interpretation is that the contamination/commingling prevention, labeling and record keeping provisions apply to all exempt and excluded operations. While the Organic Trade Association strongly supports this practice, it is not reflected in the Rule. The charts below reflect the provisions that apply to each exemption or exclusion:

**Exemptions – 205.101(a) (vs. Exclusions)**

- (a)(1) Production or handling operation - \$5000 gross or less
  - Applicable regulations
  - Labeling (205.310)
- (a)(2) Retail establishment that handles but does not process
  - Labeling (205.310)
- (a)(3) Handling operation or portion that handles “less than 70% organic”
- (a)(4) Handling operation that only identifies organic in the ingredient statement
  - Contamination prevention
  - Labeling of 205.305 and 205.310
  - **Record keeping in 205.105(c)**

**205.101 Exclusions (vs. Exemptions)**

- (b)(1) Handling operation or portion of a handling operation
  - **Are packaged or otherwise enclosed in a container** prior to being received or acquired by the operation; and
  - Remain in the same package or container and are **not otherwise processed** while in the control of the handling operation.
    - Contamination prevention
    - Labeling provisions of 205.310
- (b)(2) Retail food establishment that processes, on-site, raw and ready to eat food
  - Contamination prevention
  - Labeling provisions of 205.310

**IMPORTANT:** The current requirement to maintain records applies to EXEMPT operations only. As per the Organic Foods Production Act, the record keeping requirements should apply to all exempt **and** excluded operations.

**7 CFR 205 - Exemptions and exclusions (205.101(c))**

Records to be maintained by **exempt** operations. (1) Any handling operation exempt from certification pursuant to paragraph (a)(3) or (a)(4) of this section must maintain records sufficient to:

Prove that ingredients identified as organic were organically produced and handled; and

(ii) Verify quantities produced from such ingredients.

(2) Records must be maintained for no less than 3 years beyond their creation and the operations must allow representatives of the Secretary and the applicable State or governing State official access to

these records for inspection and copying during normal business hours to determine compliance with the applicable regulations set forth in this part.

### **Organic Foods Production Act**

§6519. Recordkeeping, investigations, and enforcement

#### **(a) Recordkeeping**

##### **(1) In general**

Except as otherwise provided in this chapter, each person who sells, labels, or represents any agricultural product as having been produced or handled using organic methods shall make available to the Secretary or the applicable governing State official, on request by the Secretary or official, all records associated with the agricultural product.

The Organic Trade Association urges NOP to revise the regulations so that all operations, exempt or excluded, from certification must still comply with:

- The requirements for the prevention of contact with prohibited substances as set forth in §205.272;
- The labeling provisions of §205.310;
- Record keeping as described in §205.101(c)

#### ***What impact will these changes have?***

The Organic Trade Association recognizes that handlers currently conducting business as “excluded operations,” such as commodity brokers, traders and wholesalers, will need to become certified. We believe that fraud in the industry poses a far greater risk to the success of the organic marketplace than any impact this change may have, and acknowledge that a trade-off must be made to ensure organic integrity throughout the supply chain and maintain consumer trust in the label. Where ill-intended actors are involved, certification and the oversight of certifying bodies mitigate risk of fraudulent action and create a more robust paper trail for investigating concerns and holding accountable bad actors. Furthermore, revising the regulations, as we have suggested, will help clarify and reinforce the existing requirements for organic operations and support the process for ACAs to verify compliance with the current organic standards. As a result, there will be increased consistency among ACAs in their verification process and increased scrutiny by certified businesses of their supply chains.

#### **ORGANIC INTEGRITY DATABASE (INCREASED REPORTING OF ACREAGE)**

Increased reporting of organic acreage to the organic INTEGRITY database is a top priority that will help address full supply chain traceability from farm to table.

The Organic Trade Association believes that NOP **requiring** ACAs to report aggregate production area certified by crop and location on an at least an annual basis to the Organic INTEGRITY Database is the second-most important action that can be taken to increase the integrity in the global organic control systems. Currently there are no means to accurately calculate organic acreage and/or yield estimates on a country-by-country basis. Although the database can accept acreage data from certifiers, not all certifiers report acreage to the database. This should be considered minimum required data. Currently, acreage data is available for less than 30% of organic operations in the U.S. and 0% in high-risk regions. As a result, there are no means to accurately calculate organic acreage and/or yield estimates on a country-by-country basis. This hinders the ability of NOP, the State Organic Program, and certifiers to evaluate the total

volume of organic product coming from any given region and accordingly detect whether fraud is occurring.

The Organic Trade Association also urges NOP to require global use of the Organic INTEGRITY Database. If global use is not possible, then we recommend investment into the development of some additional system that gives organic operations and certifying agents access to the same type of information about certified operations around the world that are operating under equivalency arrangements or recognition agreements and selling product into the United States. The system should include operations in equivalent countries eligible to export to the U.S. as organic and operations certified to the USDA regulations by a certifier operating under a recognition agreement.

Finally, the Organic Trade Association urges NOP to require ACAs to update the Organic INTEGRITY Database within 72 hours when an operation surrenders its certification, or its certification is suspended or revoked.

As we move ahead and work to update and improve the Organic INTEGRITY Database, the Organic Trade Association asks that members of the organic trade be included in **OID User Groups**. Feedback from organic industry members that regularly use the Organic INTEGRITY Database - in addition to certifiers – will be incredibly valuable in enhancing a user-friendly database with increased functionality.

See our additional comments on the Organic INTEGRITY Database on page 21 as it relates to Federated Organic Certificates.

### **ORGANIC IDENTIFICATION ON DOCUMENTS AND LABELS**

The Organic Trade Association views work in this area as a significant opportunity for improving oversight of the organic supply chain and ensuring strong enforcement of organic regulations.

Note: Throughout these comments, we use the term “organic identification” to refer to the use of the term “organic” to identify a product as organic. We are not referring to any numbers or codes used by NOP for identifying organic operations.

**Organic identification should be a baseline requirement for any and all documentation, labels, and other related items for an organic product and its supply chain.** This includes all transaction documents and all product labels, including both retail and non-retail. This information is essential for connecting physical product to its organic certificate and other relevant documentation, which is critical for ensuring organic status of the product and being able to conduct traceability audits. In order to fulfill this expectation, we recommend the following new requirements:

1. **Require all documents used to document an organic transaction to include organic identification.** Any operation that is creating documentation to be used in an organic transaction (e.g., receipts, invoices, transaction certificates, bills of lading, and any other transfer documents) must include information such that it can be connected to the organic product to which the documentation pertains. The organic status of a product should be explicitly required and recorded on the title of transfer documents. The recordkeeping requirements in § 205.103 may be the appropriate place to codify this requirement.

2. **Require all packaging of certified products to include organic identification, including non-retail containers.** Identification of organic products as organic is essential and should not be optional in any scenario. Having products that are organic but not labeled as such creates a vulnerability in the organic supply chain that can be addressed through mandatory organic identification requirements. The labeling requirements in § 205.303 should be revised to *require* identification of the product as organic instead of having this as an optional piece of information. (See Appendix A for suggested regulatory changes.)
3. **Organic identification is especially important on non-retail containers given the expectation that such product will be transferred and/or repackaged.** The labeling requirements in § 205.307 should be revised to *require* non-retail containers to display identification of the product as organic and the production lot number of the product in all instances. (See Appendix for suggested regulatory changes.)

Additional best practices may be provided to certifiers and certified operators through guidance or instruction in the NOP Handbook to further ensure that enough information is provided for transparency of organic status and traceability of the supply chain. For example, non-retail labels should ideally also identify the last certified organic operation that handled the product. This would allow the certificate of the last handler to be matched to the physical product identified as having been handled by that operation.

### **GROWER GROUPS**

The certification of grower groups was one of the topics presented at the July 2018 NOP Town Hall on Enforcement Rulemaking and it is a topic that our Global Organic Supply Chain Integrity (GOSCI) Task Force identified as a significant area that presents vulnerability to fraud. In the NOP Town Hall, NOP asked for feedback on “What specific practices might NOP consider for Grower Groups that are not already addressed by the 2002 and 2008 NOSB recommendations?” We offer the following comments to NOSB to include in a recommendation to NOP.

Under Policy Memo 11-10, NOP allows the certification of grower groups using the policies identified in the 2002 and 2008 NOSB recommendations. OTA supports NOP’s intent to formalize these policies through rulemaking because it will ensure consistent oversight and enforcement of group operations. Some aspects of group operations present inherent vulnerabilities, and therefore must be overseen by clear and enforceable regulations. Group operations, by virtue of being a collection of many production units, produce a disproportionately large amount of product compared to single operations. Products produced by group operations have historically been high-value imported products such as coffee, cocoa, tea, spices, and tropical fruits. Furthermore, compliance of group operations is primarily overseen by the group’s own Internal Control System. For all of these reasons, rulemaking related to group operations is critical for strengthening oversight of organic production.

To ensure organic integrity, NOP regulations (with accompanying guidance and/or instructions as appropriate) should address the following points about the certification of group operations:

- **Terms defined:** A definition for group operations should be included in the regulations. The definition should specify that a group operation is a single legal entity wherein multiple producers are overseen by an internal control system. OTA suggests using the term “*Group Operation*”

rather than “*Grower Group*” to avoid using the term “*grower*” that is not defined or used elsewhere in the regulations.

- ***Criteria for an operation to qualify for group certification:*** Group certification has proven to be an essential certification tool for production of certain organic crops by smallholders in developing countries who otherwise would not have the means to obtain organic certification independently. However, the privilege of foregoing the requirement for individual certification of each group members is one that must be restricted to very specific and limited circumstances to ensure organic integrity. Operations must be required to meet very clear and distinct criteria to qualify for group certification.

The criteria for an operation to qualify for group certification shall maintain the existing scale-neutrality of the NOP regulations, and not introduce any bias towards a particular scope or scale or location of production. Rather, the criteria themselves shall regulate whether a particular operation may qualify for group certification. Therefore, it is critical that the criteria are clear and specific enough to appropriately limit operations that may qualify for group certification and not result in unintended consequences that would reduce our ability to enforce organic integrity.

Criteria for an operation to qualify for group certification should include (but are not limited to):

- o The group is established under a single legal entity.
- o Organic products produced by the group are sold only through the group’s legal entity under the group’s organic certification.
- o The group sells only organic products produced by the group. Spot purchasing of outside products and re-selling through the group is prohibited.
- o Individual group members must not hold independent organic certification outside of the group.
- o Individual group members must not sell any organic products outside of the group.
- ***Organic System Plan for Group Operations:*** NOP Handbook should be updated with templates and forms specific to group operations. These additional resources will assist certifiers in collecting appropriate and sufficient information from operations applying for group certification.
- ***Internal Control System (ICS):*** A strong and effective internal control system is critical for a group operation to maintain compliance. As such, NOP should specify the required elements of an internal control system that must be developed and maintained by group operations.
  - o *Internal Surveillance of group members by the ICS:* Guidance and/or instruction are needed for ICS personnel to conduct internal surveillance of group members. Each ICS inspector should be approved by the certifier. Certifiers should provide training to ICS inspectors.
  - o *Internal Sanctions of group members by the ICS:* Guidance and/or instruction is needed for ICS personnel to issue internal sanctions to group members.
- ***Recordkeeping by group operations:*** As already required by §205.103, records must be adapted to the particular business that the certifier operation is conducting. Group operations are likely to require additional unique recordkeeping systems that are adapted to the group and its internal



control system and encompass all group members and production units. Records to be kept by the individual member and records to be kept by the ICS shall be specified.

As with any certified operation, the existing requirements for recordkeeping, lot tracking, and traceability shall be followed. In addition, the group operation's traceability system shall allow product to be traceable back to the individual group member.

- ***Inspections by the certifier:*** For group operations, the certifier is required to inspect the adequacy of the ICS as well as a meaningful sample of group members. This form of oversight and inspection is very different from a typical operation, and therefore certifiers need clear expectations and instructions for conducting inspections in a manner that ensures organic integrity and strong enforcement. In particular, instructions are needed for certifiers to verify compliance of internal control systems and to select group members to inspect.
  - o *Inspecting the ICS:* Guidance and/or instruction is needed for conducting inspections of internal control systems. Such information should include the documentation that is required from operators and how to verify the compliance of the documentation and the intended practices.

Clarification is also needed around the expectations for issuing noncompliances to group operations, and how the ICS's practice of issuing internal sanctions translates to noncompliance of the group by the certifier.
  - o *Selecting members to inspect:* Guidance and/or instruction are needed for determining the sample size and composition of members to be inspected. Such selection methodology shall include risk-based selections as well as random selections. High-risk group members shall be inspected and shall include members for which the ICS issued internal sanctions related to prohibited materials and/or audit train exercises.

Clarification is also needed around the inspection requirements for group members during an initial inspection of a new group operation, versus the inspection requirements of a new group member added to an existing certified group operation.
  - o *Inspector Qualifications:* Inspections of group operations are uniquely complex and must be conducted by an inspector qualified for such inspections. Mass balance audits are particularly critical for group operations and may be highly complex.

### **INSPECTOR AND CERTIFIER OVERSIGHT (SATELLITE OFFICES)**

The Organic Trade Association recognizes a strong need to increase oversight of certifiers. In general, there is a need for a more robust auditing of ACAs with increased attention on whether a certifier's process and qualifications are sufficient to verify compliance and detect fraud. There is significant attention being placed on the performance and qualifications of certifiers and inspectors. However, from an oversight perspective, we argue that even greater emphasis needs to be placed on the performance of USDA auditors and oversight effectiveness. With this in mind, we have identified three critical areas where increased attention is needed as it directly relates to organic fraud prevention: 1) satellite offices; 2) certifier-to-certifier responsiveness; and 3) risk-based accreditation.

#### ***Satellite Offices***

The ability to provide direct accreditation oversight in a timely manner should be the highest priority for foreign satellite offices. As the current system stands, when a certification decision is made at an operation's headquarters, satellite offices are not required to have direct visits or to be directly accredited.

This allows an easier entry of organic fraud into the supply chain, such as the recent fraudulent grain imports from Turkey.

The Organic Trade Association recognizes a potential objection that may be raised with regards to “national treatment.” Namely, the idea that if requirements are imposed on an agency in another country, then it must apply to U.S. entities as well. This creates, according to the WTO, the precedence to a non-tariff barrier to trade. Bearing in mind this concern, we propose the following ideas to improve timely oversight while not conflicting with any trade requirements: 1) eliminate the reference to “foreign” satellite offices; 2) clarify and make readily available the definition and characteristics of a satellite office, and; 3) avoid national treatment by applying the same rules to all offices regardless of location.

### ***Certifier-to-Certifier Responsiveness***

The Organic Trade Association continues to hear complaints that accredited certifiers based overseas are not sending requested information to U.S.-based accredited certifiers. Auditing paperwork prior to *export* is essential. Therefore, it is critical that ACAs are responsive to one another, and send the requested documentation needed to audit and verify shipments before they arrive at the port of entry. From a HACCP point of view, a primary critical control point is the **port-of exit**. Verifying the organic product before it leaves the country of origination is the only viable way of assuring an audit of a product back to the field. The development of an NOP pre-clearance program to validate product legitimacy prior to export, prioritizing highest risk geographies for program build-out, is another advisable step for addressing the port-of-exit critical control point. An NOP directive to overseas accredited certifiers that they **MUST** send the information requested by U.S.-based accredited certifiers is needed. Timing should be prescribed.

### ***Risk-based accreditation***

Competent and consistent application of USDA’s organic regulations by certifying agents is critical to the success of NOP as is NOP’s responsibility to ensure adequate oversight of each certifying agent. Both are principal factors to protecting organic integrity. As we know, the complexity of each organic operation and the depth of its supply chain vary significantly as do the type and number of factors that create and/or elevate the risk of fraud. It is the responsibility of NOP to assess whether a certifying agent should be authorized to certify farms and businesses to the USDA organic regulations and determine the level of oversight needed to ensure that certifiers are adequately fulfilling their responsibilities.

Given the range of risk factors that contribute to potential fraud, the Organic Trade Association fully supports the concept of risk-based accreditation oversight and the development of criteria to use to guide the process. We agree with the criteria presented in NOSB’s proposal from the fall 2018 meeting titled **“Developing Criteria for Risk-Based Accreditation Oversight,”** and offer the following suggestions/comments:

1. In general, the Organic Trade Association finds the NOSB proposal to be a good start and it addresses many of the known risk factors for fraud. We are advocating for increased levels of performance within the recommended suggestions to increase the effectiveness of the efforts and improve measures of expected outcomes. While identifying risk factors, the proposal appears to only recommend additional actions for accreditors to take when auditing or considering a first application for a certifier with elevated risk factors, rather than requiring adherence to the recommended mitigation activities. Further, the recommended risk mitigation actions are not

detailed enough, nor do they provide guidance on if or when the outcomes of the mitigating measures would warrant a finding of non-compliance or prevent a certifier from achieving accreditation. Perhaps these are meant to be next steps in the process. If so, the proposal should indicate as much.

2. As stated in the proposal, the risk factors are unranked. However, some factors appear to be of much higher risk than others, and we can assume that risk increases depending on the accumulative number of factors that may be in play. For example, a certifier that employs or contracts with inspectors or reviewers new to certification and the organic sector is common. Given appropriate oversight by senior inspectors/reviewers, this factor likely does not pose a huge area of risk. However, this factor combined with one or more of the others will have a different outcome. It may be helpful for NOSB and/or NOP to create a risk matrix defining the level of risk by considering a category of probability or likelihood against a category of consequence severity. This would be a helpful mechanism to increase visibility of risks and assist management of decision-making.
3. NOP and the Accredited Certifiers Association conduct annual certifier trainings around the United States. The NOP annual training is a key opportunity for certifying agents to receive timely information highlighting areas needing performance improvement, and helps maintain certifier consistency with respect to decision-making. The Organic Trade Association believes that attendance is critical, and the trainings should be mandatory. Therefore, moving forward, we believe missing one or more of the NOP annual trainings is a factor that could contribute to a higher risk of fraud. We recommend adding the following risk factor:
  - Certifier misses one or more of the NOP annual trainings
    - Include evaluation of whether the appropriate staff are attending the training
    - Include evaluation of whether the information received at the training is being adequately disseminated to certifier and inspector personnel

## **EQUIVALENCY AND RECOGNITION AGREEMENTS**

There are currently multiple bilateral and unilateral organic equivalency arrangements in play between the U.S. and our larger trading partners. These equivalency arrangements are key factors in facilitating trade, yet they also strengthen government to government relationships. At this point in time, there are major agreements up for renewal or that are being revised. Historically, the primary method of considering equivalency was through overcoming barriers to differences in practice standards and national list allowances. Now there is a larger consideration of oversight and integrity at the center of these discussions. From the trade side, there is increasing skepticism from the private sector that we are losing data transparency. A solution to mitigate these concerns would be to require other countries maintain a comparable certified organic database to our own. Under equivalency arrangements, there are no requirements outside of import certificates. Therefore, regarding the terms and conditions of equivalency arrangements, the current priorities should focus on compliance oversight by ensuring a competent authority and greater transparency of data.

Separately, communications must be improved between enforcement authorities of trading partners and certification bodies in countries covered by equivalency arrangements and recognition agreements. Ensuring honest and timely communications between these bodies will help achieve the broader goal of



oversight and integrity as equivalency arrangements are discussed for renewal. Lastly, regarding recognition agreements, there must be an oversight process to ensure that governmental authorities are in fact implementing the NOP rule including associated guidance and policy. All equivalency arrangements should be based on systems of comparable rigor and standards, and this follows for continuous compliance assessment. The integrity of the compliance system is pivotal to ensuring the continued success of equivalency arrangements and recognition agreements.

### **IMPORT CERTIFICATES**

As equivalency arrangements were signed, other countries have required export transaction-based documentation, and we have required other countries to present us with an import certificate. Recently, the E.U. has implemented a new technology for import certificates, reducing the utility burden with non-perishable items at the border. The Organic Trade Association is appreciative of NOP's new optional electronic system for imports. There is potential to have this online system account for more than just import transactions, such as greater product traceability from the point of origin to its final point of delivery. This traceability would greatly improve verification of the supply chain and further actions to generate data under equivalency arrangements. However, there are technological barriers that present difficulty when using the system. For example, industry feedback indicates that the program only works with select internet browsers. As with all new technology, testing will be critical for success of the system.

### **UPDATES TO NONCOMPLIANCE AND APPEALS PROCESS**

The process for noncompliance and appeals was one of the topics presented at the NOP Town Hall on Enforcement Rulemaking. Specifically, NOP asked for feedback on "Which parts of the noncompliance and appeal process might NOP need to further clarify?"

In terms of the **noncompliance** process, OTA supports an interpretation of the current regulations that allows correction of minor or administrative non-compliances during the adverse action process to suffice for resolving the noncompliance, even if the issue has advanced to the proposed suspension stage. Examples of minor or administrative noncompliance include: late payment of invoices, late submission of documentation. The use of time, funds, and other resources by certifiers to carry out the noncompliance process for these minor issues that have already been corrected is unnecessary, when these resources could be directed towards major noncompliance and other investigations to assure organic integrity. This interpretation can be implemented through updated training from NOP staff to certifiers.

In terms of **appeals**, OTA sees a need for the process to be expedited such that appeals are reviewed and responded to in a timelier manner. As currently administered, the appeals process takes too long. It can take up to a year for NOP to evaluate and respond to an appeal. When an appeal is denied and the appellant requests a hearing, it can take an additional year or more to reach a final outcome. This multi-year process is unacceptable, especially considering that the operator is still certified and able to sell products as organic throughout the entire appeals process. It is essential that NOP strike a balance between due process and efficiency to minimize the amount of time that operations are able to sell product as organic while under an adverse action. To do so, OTA strongly encourage NOP to staff itself appropriately so that NOP can respond to appeals in a timely manner (ideally, within 6 months).

## **INSPECTOR QUALIFICATIONS**

Inspector qualifications were one of the topics presented at the NOP Town Hall on Enforcement Rulemaking. Specifically, NOP asked for feedback on “What should the minimum qualifications and training requirements be for organic inspectors?”

Improvement in qualifications and training of inspectors are key steps in improving a certifier’s ability to monitor, detect and address fraud. OTA supports NOP’s effort to establish minimum requirements for qualifications and initial and continuing training. We support the criteria and qualifications laid out in the NOSB Recommendation Inspector Qualifications<sup>2</sup>, as well as the ACA’s Guidance on Inspector Qualifications<sup>3</sup>.

Training of inspectors should be a top priority in ensuring that inspectors are knowledgeable and capable of conducting a rigorous on-site inspection. Critical aspects of inspector training that related to enforcement and fraud detection include: **mass balance audits**, **traceability audits**, and **investigative techniques**. NOP should work closely with the IOIA, ACA, and other qualified organizations to develop training on these skills. On-site shadowing of inspections with an expert mentor inspector should also be a mandatory part of inspector training.

Under NOP’s general requirements for accreditation (§205.501), certifiers are required to "Ensure that its responsibly connected persons, employees, and contractors with inspection, analysis, and decision-making responsibilities have sufficient expertise in organic production or handling techniques to successfully perform the duties assigned." As such, it is the certifier’s responsibility to ensure that inspectors are qualified to conduct the inspections for which they are assigned. It is also NOP’s responsibility though its accreditation oversight to ensure that certifiers have systems in place to properly evaluate the qualifications of inspectors and ensure that operations are being inspected by an inspector that is appropriately qualified and trained to inspect that particular type of operation.

OTA supports a **licensing system** as a means for inspectors to demonstrate that an inspector is qualified and experienced with the types and scale of operations they are inspecting. A licensing system should ensure inspectors have achieved a baseline understanding of the requirements and process unique to organic certification, and must provide a mechanism for preventing inspectors from inspecting operations for which they do not have adequate expertise and experience. A licensing system can ensure that regardless of the certification body, inspector, or employment status, all inspectors meet a threshold requirement. Such licenses should be issued by organizations that have obtained an appropriate ISO accreditation.

## **UNANNOUNCED INSPECTIONS**

OTA supports a regulatory amendment that codifies the requirement for certifiers to conduct unannounced inspections of at least 5% of operations per year. Additional unannounced inspections shall be conducted as needed in response to complaints and investigations.

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<sup>2</sup> <https://www.ams.usda.gov/sites/default/files/media/CACSIInspectorqualificationsApril2018.pdf>

<sup>3</sup> <https://www accreditedcertifiers.org/wp-content/uploads/2018/02/ACA-Guidance-on-Inspector-Qualifications-with-IOIA-Evaluation-Checklist.pdf>



OTA does not take issue with the current NOP Instruction 2609 that allow certifiers to “charge an operation for unannounced inspections as long as the fees are clearly disclosed to all certified operations.” Certifiers must clearly disclose to their clients their protocols for unannounced inspections and their fees, should they decide to charge their clients. Many certifiers have integrated the costs for unannounced into their baseline certification fee.

### **FEDERATED ORGANIC CERTIFICATES**

OTA supports NOP’s movement towards the use of federated organic certificates (i.e., organic certificates generated within the Organic INTEGRITY database.) The use of federated organic certificates will bring many benefits to the organic sector. Primarily, the certificate will link to the specific relevant certified operation within the Organic INTEGRITY Database. Also, the use of federated organic certificates will bring consistency across certificates used by certifiers, so it is easier to identify a valid certificate and identify fraudulent designs. Additional benefits may be gained by linking aspects of the NOP federated organic certificate system to the EU Trade Control & Expert System (TRACES). It is important that federated organic certificates refrain from including any confidential or sensitive business information.

However, we see significant challenges if certifiers were to be mandated to use only federated organic certificates generated from the Organic INTEGRITY Database. At this point, certifiers are only required to update information in the database once per year, whereas the status of a certified operation’s scope, certified products, and other details may change much more often. It would be unwise to require certifiers to generate certificates from a database of outdated information. Until the Organic INTEGRITY Database is reliably providing accurate and current information for certified operations, federal organic certifications should not be mandatory. Certifiers also need time to fully adopt the taxonomy set by NOP for identifying specific certified organic products covered by the organic certificate.

Instead of moving directly to mandatory federated organic certificates, OTA suggests NOP consider a step-wise approach, with narrow and easily implementable solutions that can be achieved in the short-term to help deter fraudulent certificates. For instance, requiring a common design feature or code will help to support the end goal of increasing consistency among certificates without overburdening certifiers. At the very least, the operation’s ten-digit NOP Operation ID should be required to appear on the certificate so that the operation can easily be connected to its specific relevant entry in the Organic INTEGRITY database. These solutions can be effective in the short term while more significant updates to the Organic INTEGRITY Database are implemented by NOP, and standardization of product taxonomy are implemented by certifiers to populate the database with consistent terminology.

### **Conclusion**

The Organic Trade Association thanks the National Organic Standards Board for reaching out to the organic sector and requesting feedback on priorities and where to best focus funds and enforcement activities.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for your commitment to protecting organic integrity.

Respectfully submitted,

Gwendolyn Wyard  
Vice President, Regulatory and Technical Affairs

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

## **Appendices**

**Appendix A** – Organic Identification on Documents and Labels

**Appendix B** – 2018 Farm Bill: Legislative text on enforcement and oversight

**Appendix C** – 2018 Farm Bill Conference Report

**Appendix D** - OTCO Independent Storage Information Sheet

## **APPENDIX A: ORGANIC IDENTIFICATION ON DOCUMENTS AND LABELS**

OTA's Enforcement Rulemaking task force began to discuss specific regulatory changes that could be effective to implement our suggestions related to organic identification on retail and non-retail labels. Our current thinking is provided below (underlined = new text; ~~strikethrough~~ = deleted text):

### **§205.303 Packaged products labeled “100 percent organic” or “organic.”**

(a) Agricultural products in packages described in §205.301(a) and (b) may display, on the principal display panel, information panel, and any other panel of the package and on any labeling or market information concerning the product, the following:

(1) ~~The term, “100 percent organic” or “organic,” as applicable, to modify the name of the product;~~

(2) For products labeled “organic,” the percentage of organic ingredients in the product; (The size of the percentage statement must not exceed one-half the size of the largest type size on the panel on which the statement is displayed and must appear in its entirety in the same type size, style, and color without highlighting.)

(3) The term, “organic,” to identify the organic ingredients in multiingredient products labeled “100 percent organic”;

(4) The USDA seal; and/or

(5) The seal, logo, or other identifying mark of the certifying agent which certified the production or handling operation producing the finished product and any other certifying agent which certified production or handling operations producing raw organic product or organic ingredients used in the finished product: Provided, That, the handler producing the finished product maintain records, pursuant to this part, verifying organic certification of the operations producing such ingredients, and: Provided further, That, such seals or marks are not individually displayed more prominently than the USDA seal.

(b) Agricultural products in packages described in §205.301(a) and (b) must display:

(1) The term, “100 percent organic” or “organic,” as applicable, to modify the name of the product; except when the USDA seal is displayed on the principal display panel.

(24) For products labeled “organic,” identify each organic ingredient in the ingredient statement with the word, “organic,” or with an asterisk or other reference mark which is defined below the ingredient statement to indicate the ingredient is organically produced. Water or salt included as ingredients cannot be identified as organic.

(32) On the information panel, below the information identifying the handler or distributor of the product and preceded by the statement, “Certified organic by \* \* \*,” or similar phrase, identify the name of the certifying agent that certified the handler of the finished product and may display the business address, Internet address, or telephone number of the certifying agent in such label.

**§205.307 Labeling of non-retail containers used for only shipping or storage of raw or processed agricultural products labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)).”**

(a) Non-retail containers of organic products used only to ship or store raw or processed agricultural product labeled as containing organic ingredients may display the following terms or marks:

~~(1) The name and contact information of the certifying agent which certified the handler which assembled the final product;~~

~~(2) Identification of the product as organic;~~

~~(13) Special handling instructions needed to maintain the organic integrity of the product;~~

~~(24) The USDA seal;~~

~~(35) The seal, logo, or other identifying mark of the certifying agent that certified the organic production or handling operation that produced or handled the finished product.~~

(b) Non-retail containers of organic products used to ship or store raw or processed agricultural product labeled as containing organic ingredients must display

(1) identification of the product as organic;

(2) name and contact information of the handler which assembled the final product;

(3) name and contact information of the certifying agent which certified the handler which assembled the final product; and

(4) the production lot number of the product if applicable.

(c) Shipping containers of domestically produced product labeled as organic intended for export to international markets may be labeled in accordance with any shipping container labeling requirements of the foreign country of destination or the container labeling specifications of a foreign contract buyer: Provided, That, the shipping containers and shipping documents accompanying such organic products are clearly marked “For Export Only” and: Provided further, That, proof of such container marking and export must be maintained by the handler in accordance with recordkeeping requirements for exempt and excluded operations under §205.101.

## Attachment B

### Farm Bill 2018 - Sec. 10104.

#### Organic certification

- (a) Exclusions from certification. Not later than 1 year after the date of enactment of this Act, the Secretary shall issue regulations to limit the type of organic operations that are excluded from certification under section 205.101 of title 7, Code of Federal Regulations, and from certification under any other related sections under part 205 of title 7, Code of Federal Regulations.
- (b) Definitions. Section 2103 of the Organic Foods Production Act of 1990 ([7 U.S.C. 6502](#)) is amended--
  - (1) in paragraph (3)--
    - (A) by striking "The term" and inserting the following:
      - "(A) In general. The term"; and
      - (B) by adding at the end the following:
        - "(B) Foreign operations. When used in the context of a certifying agent operating in a foreign country, the term "certifying agent" includes any person (including a private entity)--
          - "(i) accredited in accordance with section 2115(d); or
          - "(ii) accredited by a foreign government that acted under an equivalency agreement negotiated between the United States and the foreign government from which the agricultural product is imported.";
          - (2) by redesignating paragraphs (13) through (21) as paragraphs (14) through (22), respectively; and
          - (3) by inserting after paragraph (12) the following:
            - "(13) National organic program import certificate. The term "national organic program import certificate" means a form developed for purposes of the program under this title--
              - "(A) to provide documentation sufficient to verify that an agricultural product imported for sale in the United States satisfies the requirement under section 2115(c);
              - "(B) which shall include, at a minimum, information sufficient to indicate, with respect to the agricultural product--
                - "(i) the origin;
                - "(ii) the destination;
                - "(iii) the certifying agent issuing the national organic program import certificate;
                - "(iv) the harmonized tariff code, if a harmonized tariff code exists for the agricultural product;
                - "(v) the total weight; and
                - "(vi) the organic standard to which the agricultural product is certified; and
              - "(C) that is not more than otherwise required under an equivalency agreement negotiated between the United States and the foreign government.".
    - (2) by redesignating paragraphs (13) through (21) as paragraphs (14) through (22), respectively; and
    - (3) by inserting after paragraph (12) the following:
      - "(13) National organic program import certificate. The term "national organic program import certificate" means a form developed for purposes of the program under this title--
        - "(A) to provide documentation sufficient to verify that an agricultural product imported for sale in the United States satisfies the requirement under section 2115(c);
        - "(B) which shall include, at a minimum, information sufficient to indicate, with respect to the agricultural product--
          - "(i) the origin;
          - "(ii) the destination;
          - "(iii) the certifying agent issuing the national organic program import certificate;
          - "(iv) the harmonized tariff code, if a harmonized tariff code exists for the agricultural product;
          - "(v) the total weight; and
          - "(vi) the organic standard to which the agricultural product is certified; and
        - "(C) that is not more than otherwise required under an equivalency agreement negotiated between the United States and the foreign government.".
- (c) Accreditation program. Section 2115 of the Organic Foods Production Act of 1990 ([7 U.S.C. 6514](#)) is amended by striking subsection (c) and inserting the following:
  - "(c) Additional documentation and verification. The Secretary, acting through the Deputy Administrator of the national organic program established under this title, has the authority, and shall grant a certifying agent the authority, to require producers and handlers to provide additional documentation or verification before granting a certification under section 2104, in the case of a compliance risk with respect to meeting the national standards for organic production established under section 2105, as determined by the Secretary or the certifying agent.
  - "(d) Accreditation of foreign organic certification program.



- "(1) In general. For an agricultural product being imported into the United States to be represented as organically produced, the Secretary shall require the agricultural product to be accompanied by a complete and valid national organic import certificate, which shall be available as an electronic record.
  - "(2) Tracking system.
    - "(A) In general. The Secretary shall establish a system to track national organic import certificates.
    - "(B) Integration. In establishing the system under subparagraph (A), the Secretary may integrate the system into any existing information tracking systems for imports of agricultural products.
  - "(e) Duration of accreditation. An accreditation made under this section--
    - "(1) subject to paragraph (2), shall be for a period of not more than 5 years, as determined appropriate by the Secretary;
    - "(2) in the case of a certifying agent operating in a foreign country, shall be for a period of time that is consistent with the certification of a domestic certifying agent, as determined appropriate by the Secretary; and
    - "(3) may be renewed."
- (d) Requirements of certifying agents. Section 2116 of the Organic Foods Production Act of 1990 ([7 U.S.C. 6515](#)) is amended--
  - (1) in subsection (i)--
    - (A) in paragraph (1), by inserting "or an entity acting as an agent of the certifying agent" after "a certifying agent";
    - (B) by redesignating paragraph (2) as paragraph (3); and
    - (C) by inserting after paragraph (1) the following:
      - "(2) Oversight of Certifying Offices and Foreign Operations.
        - "(A) In general. If the Secretary determines that an office of a certifying agent or entity described in paragraph (1) is not complying with the provisions of this title, the Secretary may suspend the operations of the certifying agent or the noncompliant office, including--
          - "(i) an office operating in a foreign country; and
          - "(ii) an office operating in the United States, including an office acting on behalf of a foreign-domiciled entity.
        - "(B) Process for resuming operations following suspension. The Secretary shall provide for a process that is otherwise consistent with this section that authorizes a suspended office to resume operations."; and
      - (2) by adding at the end the following:
        - "(j) Notice. Not later than 90 days after the date on which a new certifying office performing certification activities opens, an accredited certifying agent shall notify the Secretary of the opening."
- (g) Investigations. Section 2120(b) of the Organic Foods Production Act ([7 U.S.C. 6519\(b\)](#)) is amended by adding at the end the following:
  - "(3) Information sharing during active investigation. In carrying out this title, all parties to an active investigation (including certifying agents, State organic certification programs, and the national organic program) shall share confidential business information with Federal Government officers and employees involved in the investigation as necessary to fully investigate and enforce potential violations of this title."
- (h) Data organization and access. Section 2122 of the Organic Foods Production Act of 1990 ([7 U.S.C. 6521](#)) is amended by adding at the end the following:
  - "(c) Access to data documentation systems. The Secretary shall have access to available data from cross-border documentation systems administered by other Federal agencies, including the Automated Commercial Environment system of U.S. Customs and Border Protection.
  - "(d) Reports.
    - "(1) In general. Not later than March 1, 2020, and annually thereafter through March 1, 2023, the Secretary shall submit to Congress, and make publicly available on the website of the Department of Agriculture, a report describing national

- organic program activities with respect to all domestic and overseas investigations and compliance actions taken pursuant to this title during the preceding year.
  - "(2) Requirements. The data described in paragraph (1) shall be broken down by agricultural product, quantity, value, and month.
  - "(3) Exception. Any data determined by the Secretary to be confidential business information shall not be provided in the report under paragraph (1).".
- (i) Organic agricultural product imports interagency working group. The Organic Foods Production Act of 1990 is amended by inserting after section 2122 ([7 U.S.C. 6521](#)) the following:
  - "Sec. 2122A.

Organic agricultural product imports interagency working group

- "(a) Establishment.
  - "(1) In general. The Secretary and the Secretary of Homeland Security shall jointly establish a working group to facilitate coordination and information sharing between the Department of Agriculture and U.S. Customs and Border Protection relating to imports of organically produced agricultural products (referred to in this section as the "working group").
  - "(2) Members. The working group--
    - "(A) shall include--
      - "(i) the Secretary (or a designee); and
      - "(ii) the Secretary of Homeland Security (or a designee); and
    - "(B) shall not include any non-Federal officer or employee.
  - "(3) Duties. The working group shall facilitate coordination and information sharing between the Department of Agriculture and U.S. Customs and Border Protection for the purposes of--
    - "(A) identifying imports of organically produced agricultural products;
    - "(B) verifying the authenticity of organically produced agricultural product import documentation, such as national organic program import certificates;
    - "(C) ensuring imported agricultural products represented as organically produced meet the requirements under this title;
    - "(D) collecting and organizing quantitative data on imports of organically produced agricultural products; and
    - "(E) requesting feedback from stakeholders on how to improve the oversight of imports of organically produced agricultural products.
  - "(4) Designated employees and officials. An employee or official designated to carry out the duties of the Secretary or the Secretary of Homeland Security on the working group under subparagraph (A) or (B) of paragraph (2) shall be an employee or official compensated at a rate of pay not less than the minimum annual rate of basic pay for GS-12 under [section 5332 of title 5, United States Code](#).
- "(b) Reports. On an annual basis, the working group shall submit to Congress and make publicly available on the websites of the Department of Agriculture and U.S. Customs and Border Protection the following reports:
  - "(1) Organic trade enforcement interagency coordination report. A report--
    - "(A) identifying existing barriers to cooperation between the agencies involved in agricultural product import inspection, trade data collection and organization, and organically produced agricultural product trade enforcement, including--
      - "(i) U.S. Customs and Border Protection;
      - "(ii) the Agricultural Marketing Service; and
      - "(iii) the Animal and Plant Health Inspection Service;
    - "(B) assessing progress toward integrating organic trade enforcement into import inspection procedures of U.S. Customs and Border Protection and the Animal and Plant Health Inspection Service, including an assessment of--

- "(i) the status of the development of systems for--
        - "(I) tracking the fumigation of imports of organically produced agricultural products into the United States; and
        - "(II) electronically verifying national organic program import certificate authenticity; and
      - "(ii) training of U.S. Customs and Border Protection personnel on--
        - "(I) the use of the systems described in clause (i); and
        - "(II) requirements and protocols under this title;
    - "(C) establishing methodology for ensuring imports of agricultural products represented as organically produced meet the requirements under this title;
    - "(D) recommending steps to improve the documentation and traceability of imported organically produced agricultural products;
    - "(E) recommending and describing steps for--
      - "(i) improving compliance with the requirements of this title for all agricultural products imported into the United States and represented as organically produced; and
      - "(ii) ensuring accurate labeling and marketing of imported agricultural products represented as organically produced by the exporter; and
    - "(F) describing staffing needs and additional resources at U.S. Customs and Border Protection and the Department of Agriculture needed to ensure compliance.
  - "(2) Report on enforcement actions taken on organic imports. A report--
    - "(A) providing detailed quantitative data (broken down by agricultural product, quantity, value, month, and origin) on imports of agricultural products represented as organically produced found to be fraudulent or lacking any documentation required under this title at the port of entry during the report year;
    - "(B) providing data on domestic enforcement actions taken on imported agricultural products represented as organically produced, including the number and type of actions taken by United States officials at ports of entry in response to violations of this title;
    - "(C) providing data on fumigation of agricultural products represented as organically produced at ports of entry and notifications of fumigation actions to shipment owners, broken down by product variety and country of origin; and
    - "(D) providing information on enforcement activities under this title involving overseas investigations and compliance actions taken within that year, including--
      - "(i) the number of investigations by country; and
      - "(ii) a descriptive summary of compliance actions taken by certifying agents in each country."
- (j) Authorization of appropriations for national organic program. Section 2123 of the Organic Foods Production Act of 1990 ([7 U.S.C. 6522](#)) is amended--
  - (1) by striking the section heading and inserting "Funding";
  - (2) in subsection (b), by striking paragraphs (1) through (7) and inserting the following:
    - "(1) \$ 15,000,000 for fiscal year 2018;
    - "(2) \$ 16,500,000 for fiscal year 2019;
    - "(3) \$ 18,000,000 for fiscal year 2020;
    - "(4) \$ 20,000,000 for fiscal year 2021;
    - "(5) \$ 22,000,000 for fiscal year 2022; and
    - "(6) \$ 24,000,000 for fiscal year 2023."; and
    - (3) by striking subsection (c) and inserting the following:
      - "(c) Modernization and improvement of international trade technology systems and data collection.

- "(1) In general. The Secretary shall establish a new system or modify an existing data collection and organization system to collect and organize in a single system quantitative data on imports of each organically produced agricultural product accepted into the United States.
  - "(2) Activities. In carrying out paragraph (1), the Secretary shall modernize trade and transaction certificates to ensure full traceability to the port of entry without unduly hindering trade or commerce, such as through an electronic trade document exchange system.
  - "(3) Access. The single system established under paragraph (1) shall be accessible by any agency with the direct authority to engage in--
    - "(A) inspection of imports of agricultural products;
    - "(B) trade data collection and organization; or
    - "(C) enforcement of trade requirements for organically produced agricultural products.
  - "(4) Funding. Of the funds of the Commodity Credit Corporation, the Secretary shall make available \$ 5,000,000 for fiscal year 2019 for the purposes of--
    - "(A) carrying out this subsection; and
    - "(B) maintaining the database and technology upgrades previously carried out under this subsection, as in effect on the day before the date of enactment of the Agriculture Improvement Act of 2018.
  - "(5) Availability. The amounts made available under paragraph (4) are in addition to any other funds made available for the purposes described in that paragraph and shall remain available until expended."
- (k) Trade savings provision. The amendments made by subsection (i) shall be carried out in a manner consistent with United States obligations under international agreements.

## **Attachment C – Farm Bill 2018 Conference Report**

The House bill directs the Secretary of Agriculture (the "Secretary") to issue regulations to limit the type of organic operations that are excluded from certification. The bill further requires the Secretary to modernize trade tracking and data collection systems, including full traceability, as well as a report to Congress regarding investigations and compliance actions. It authorizes the Secretary to oversee and approve a certifying agent in a foreign country and provides for annual certification.

The House bill authorizes sharing of certain information during an investigation. It also authorizes a certifying agent to require additional information from a producer and handler under certain circumstances, and authorizes access to cross border documentation systems. The section requires the \$5 million of CCC funds provided be available for modernization of trade and data collection and to maintain current database and technology upgrades. (Section 9006)

The Senate amendment directs the Secretary to issue regulations to limit the type of organic operations that are excluded from certification, amends the definition of "certifying agent", and defines the term "national organic program import certificate". The amendment requires an import certification for imports represented as organic in the U.S. It further requires the Secretary to establish a tracking system, modernize trade tracking and data collection systems, including full traceability, and provide a report to Congress on organic imports. It authorizes the Secretary to oversee a certifying agent in a foreign country and provides the certification be for a period of time consistent with the certification of a domestic certifying agent.

The Senate amendment authorizes sharing of certain information during an investigation and for the review of an accreditation of an agent in a foreign country and provides access to cross border documentation systems. It authorizes an organic agricultural product imports interagency working group. The section requires \$5 million of CCC funds be provided for data collection. Finally, the section requires certain provisions be carried out in a manner consistent with all trade obligations. (Section 10104)

The Conference substitute adopts the Senate provision with an amendment providing for the oversight of foreign and domestic certifying offices as well as notice and process regarding new and suspended certifications. The amendment also adopts the House provision regarding additional documentation and verification.

The Managers recognize that fraudulent organic imports have the potential to unfairly damage the reputation of the National Organic Program's (NOP) organic certification system and undercut domestic sales of certified organic products. Therefore, the Managers agreed to provisions from both the House-passed bill and Senate Amendment that are intended to provide the Secretary with better data, information-sharing and clarity of authority to identify and prevent known compliance risks to the NOP, particularly those imported from certifiers, handlers, or producers not accredited or certified by USDA or covered under an organic equivalency agreement. The Managers intend for these measures to be consistent for all products covered under the NOP. The Managers adopted and are applying a trade savings provision to ensure USDA implementation does not inhibit trade in organic agricultural products that are otherwise certified and following NOP standards, as well as other trade protocols.

### **Attachment C – Farm Bill 2018 Conference Report continued....**

The Managers encourage improved coordination between Federal agencies that oversee import protocols and agencies responsible for organic certification and enforcement in order to ensure information sharing and response in cases of potential fraud. Since the NOP is a marketing and process-oriented program, the Managers provide funding for the Secretary to establish and utilize more modern systems and method to share data with other agencies both within USDA, between the Animal and Plant Health Inspection Service (APHIS), AMS, and Foreign Agricultural Service (FAS), as well as outside of USDA, particularly U.S. Customs and Border Protection. In addition, the Conference Substitute adopts a provision authorizing the Secretary to require producers and handlers of imported organic products, in cases of a known NOP compliance risk, to provide additional documentation, including an NOP import certificate, as long as this additional information is not more than is otherwise required under an equivalency agreement negotiated between the United States and the foreign government. The Managers codified the oversight authority of the Secretary to accredit certifying agents operating in a foreign country as well as certifying offices and foreign operations located within the United States. The Managers intend for the Secretary to implement these measures to be consistent with such standards and information as are required for domestic producers and handlers within the NOP.





# INDEPENDENT STORAGE INFORMATION SHEET

# ISIS

Electronic versions available at [www.tilth.org](http://www.tilth.org)

Page 1 of 2

**Operation Name:** \_\_\_\_\_ **Date:** \_\_\_\_\_

- ▶ The manager of the storage facility must answer the questions below.
- ▶ Copies of the Independent Storage Information Sheet (this form) must be kept by both the OTCO certified operation and the storage facility.

The National Organic Standards section 7CFR205.101(b)(1) allows organic operations to store products at non-certified facilities as long as the products are packaged or otherwise enclosed in a container prior to being received or acquired, the organic products remain in the same package or container, and the products are not repacked or re-labeled while in the control of the storage operation.

## 1.1 STORAGE LOCATION

Name of Facility:

Manager or Owner:

Phone:

Fax:

Email(s):

Physical Address:

City:

State:

Zip:

Country:

## 1.2 STORAGE ACTIVITIES

- 1) Does the storage facility implement necessary measures to protect the organic product from contacting prohibited substances such as pesticides?  
☐ Yes ☐ No
- 2) Does the OTCO certified operation retain ownership of the product during storage?  
☐ Yes ☐ No
- 3) Is the organic product packaged or enclosed in a container prior to being received and does it remain in that enclosed container during storage?  
☐ Yes ☐ No
- 4) Do the appropriate records indicate that the product is "organic"?  
☐ Yes ☐ No
- 5) Are the records detailed enough to disclose description and amounts of organic products transferred, and to link any lot numbers assigned by the OTCO certified operation with tracking numbers or lot numbers assigned at the storage facility?  
☐ Yes ☐ No
- 6) If pesticide fogging is performed or pesticide sprays are applied to areas where packaged or otherwise enclosed organic products are stored, are the organic products removed prior to application or covered with impermeable coverings, or otherwise protected from contacting pesticides and is this documented?  
☐ Yes ☐ No ☐ NA

2525 SE 3rd Street, Corvallis, OR 97333, 503-378-0690 | 1-877-378-0690 | [organic@tilth.org](mailto:organic@tilth.org)



## INDEPENDENT STORAGE INFORMATION SHEET

# ISIS

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Page 2 of 2

7) Does the storage facility further process the organic product, including sorting, culling, icing or hydro cooling?

☐ Yes ☐ No

8) Does the storage facility apply any substance to the organic product or its packaging or container, including water, ethylene or controlled atmosphere treatment?

☐ Yes ☐ No

9) Does the storage facility label or re-label the organic product?

☐ Yes ☐ No

In order to qualify as an Independent Storage Facility and not have to undergo an inspection, the answer to questions 1-6 must be "YES" and questions 7-8 must be "NO". If you answer "YES" to question 9 please contact Oregon Tilth.

---

Name (Facility Manager)

Date

---

Signature

OTCO reserves the right to inspect any facility storing organic product owned by an OTCO certified operation as specified in 7CFR 205.400. If it is determined that the storage operation has misrepresented policies or procedures as stated on this form, or acts in a manner that might jeopardize organic integrity or tracking of the organic product, the OTCO client using the facility will be notified. They will be held responsible for correcting any noncompliance issues according to the timeline set by OTCO.



April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP

**Docket:** AMS-NOP-18-0071

**RE:** Oversight Improvements to Deter Fraud – An Update on the Organic Trade Association’s Organic Fraud Prevention Solutions Program

Dear Ms. Arsenault:

Thank you for this opportunity to update the National Organic Standards Board (NOSB) on the Organic Trade Association’s organic fraud prevention program that was launched March 5. We are excited to share the progress of a private sector initiative designed to complement the work of NOSB, the National Organic Program (NOP) and accredited certifying agencies, and reinforce the organic regulations.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. The Organic Trade Association is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. The Organic Trade Association’s mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

**Organic Fraud Prevention Solutions – Ensuring Global Organic Supply Chain Integrity**

Food fraud, or the act of defrauding buyers of food or ingredients for economic gain, has plagued the food industry throughout history. Although it is not known conclusively how widespread food fraud is in the United States or worldwide, it is now estimated to be a \$50 billion industry for the total food market -- about the same size as the entire 2017 U.S. organic market. Although the act of adulterating food for economic gain dates back to at least the Middle Ages, its presence in the global organic supply chain is more recent, and poses a significant threat to the integrity of the organic brand.

For the past two years, the Organic Trade Association has prioritized significant time and resources into organic fraud prevention solutions that will help mitigate and prevent the occurrence inside and outside of the United States. Our work to address organic fraud is taking place on several fronts ranging from our legislative efforts and Farm Bill priorities, to our member task force action and work with NOSB to shape a major piece of NOP enforcement rulemaking slated for fall 2019, to our major private-sector initiative that has evolved into an industry-wide fraud prevention program that launched on March 5, 2019. The new program is based on the Organic Trade Association’s [Organic Fraud Prevention Guide](#) that provides businesses engaged in organic trade with a risk-based process for developing and implementing an organic fraud prevention plan. It also provides detailed information on what to do when you suspect or detect fraud, and the process for filing a complete and effective complaint to USDA’s National Organic Program. See **Appendix A** to read the [Executive Summary](#) of the Guide.

Before diving into the details of the organic fraud prevention program, let's take a look at the steps taken to get here.

### ***GOSCI Task Force and Best Practices Guide***

In May 2017, the Organic Trade Association convened a Global Organic Supply Chain Integrity (GOSCI) Task force of 48-member companies to develop a best-practices guide to preventing fraud specifically for the organic industry. In an effort to both acknowledge and utilize the extensive fraud prevention strategies already developed by Michigan State Food Fraud Think Tank and the Global Food Safety Initiative (GFSI), the task force adopted a model that highlights the motivation behind fraud (i.e. the root cause) to better understand the detection and prevention activities that need to be developed based on a company's susceptibility or exposure to food fraud risk. The GFSI model is a smart and practical approach because it was built to be a starting point consistent with other quality management practices such as HACCP (Hazard Analysis and Critical Control Points), lending itself to a fraud prevention program that can be adopted into existing internal quality management systems. While the traditional HACCP-type food safety approach is applied at manufacturing steps, food fraud vulnerabilities are company-wide, and must be applied cross-functionally and within the overall organization. The name of the game is to think like a criminal!

The Organic Fraud Prevention Guide developed by the task force is aimed at buyer responsibility and the assessment of factors that create vulnerabilities in an organic supply chain. Accordingly, the Guide provides businesses engaged in the organic trade with a systematic risk-based approach for identifying appropriate fraud mitigation measures, and developing and operationalizing a written Organic Fraud Prevention Plan. It also includes information on what to do when you suspect or detect fraud, along with resources and helpful tools for identifying and deterring fraud.

### ***GOSCI 'Pilot Project'***

Following the creation of the Guide, the trade association launched a pilot program. The pilot was an intensive-focused exercise running from June – September 2018 in which 13 OTA member companies "test drove" in their specific businesses the fraud prevention strategies described in the Guide. Participants concentrated on one product or ingredient, and developed fraud mitigation measures based on the results of a vulnerability assessment that identifies weak points in a supply chain that increase exposure to fraud. Pilot participants informed the final version of the Guide, and helped set the stage for implementing a corresponding program. Collaborating partners in the project included USDA-NOP, the Accredited Certifiers Association (ACA) and NSF International.

### ***Organic Fraud Prevention Solutions***

With a tested and completed fraud prevention guide in hand, the Organic Trade Association has developed an organic fraud prevention program in which organic businesses may voluntarily enroll. The name of the program is *Organic Fraud Prevention Solutions*. The **mission** of the program is to assure the authenticity of organic products by mitigating the occurrence of organic fraud. The **goal** of the program is to establish a framework and formal process for businesses to create continuously improving internal programs for achieving organic integrity throughout their associated supply chains. The program requires training, registration and the development of an organic fraud prevention plan, followed by confirmation by an accredited certifier and public acknowledgment of enrollment on the Organic Trade Association's Find.Organic Business Directory (coming soon). Organic Fraud Prevention Solutions is not a certification or verification program nor is it a product label. Instead, the program serves as a business-to-business

marketing advantage designed to improve internal quality assurance programs. It is also designed to complement and reinforce USDA's organic standards and the work of the accredited certifying agencies.



### ***Why is the program important?***

Organic fraud cannot be tolerated in the organic supply chain, inside or outside the United States. Anytime there is fraud anywhere in organic in the organic system, it takes value out of the organic label. Everyone plays a role in preventing organic fraud. It is critical that organic businesses have robust systems and measures in place that adequately support the promise of providing organic products that people can trust. Organic Fraud Prevention Solutions, as adopted by businesses engaged in organic trade, will become the industry standard reference for excellence and achieving integrity across complex organic global supply chains.

### ***Why should companies enroll?***

To strengthen supplier verification systems and prevent organic fraud. Organic companies that want to prevent organic fraud in their supply chain and be publicly recognized for having implemented an Organic Fraud Prevention Plan need to successfully complete the program. Leadership and commitment from organic businesses will drive adoption of the program. The more companies that join, the stronger the organic supply chain will become.

### ***Who can participate in the program?***

Organic Fraud Prevention Solutions is currently open for pre-enrollment only. To enroll, a company must be an Organic Trade Association member and either certified organic or listed with a USDA recognized Material Review Organization such as OMRI (Organic Material Review Institute). Eligible operations include, farmers, handlers, processors, distributors, traders, retailers and input manufacturers. There are also opportunities for accredited certifiers, consultants and advisors that would like to partner in the program. Enrollment for non-Organic Trade Association members will begin in 2020.

### ***How much time and resources will it take?***

Time and resource commitment depend on the size, scope and complexity of the organic business. The program is designed to foster continuous improvement and provide each company with a reasonable entry point. Companies should expect to form a multi-disciplinary organic fraud prevention team with a designated and qualified lead to carry out a vulnerability assessment. Each company will be required first to perform a prefilter or initial screening assessment followed by a more detailed assessment on high-risk ingredients or products. Quality departments are best positioned to take the lead in conducting the pre-filter and vulnerability assessment, but will be best supported by procurement, legal, and Human Resources. The program requires ongoing annual management.

***What does the enrollment process involve?***

Enrollment initiates the process and signs the eligible company up for the first offered training that will take place in late summer or early fall. The enrollment steps are: 1) pre-enrollment and receipt of the Organic Fraud Prevention Guide; 2) training; 3) registration (fee required); 4) initial screening and vulnerability assessment; 5) vulnerability assessment review; 6) developing and implementing organic fraud mitigation measures; 7) collating an Organic Fraud Prevention Plan; 8) updating your existing Organic System Plan; 9) obtaining confirmation from your certifier; and 10) enrollment completion and public recognition. The process is integrated into the organic certification cycle and maintained annually.

***Why do I need another seal or certification/verification?***

As mentioned earlier, the program is NOT a certification or verification program, and it does not involve a consumer-facing label. The program serves as a business-to-business marketing advantage designed to improve internal quality assurance programs. Companies that successfully complete and maintain annual enrollment will be publicly recognized.

***But wait, isn't enforcement USDA's job?***

USDA's National Organic Program is, in fact, responsible for oversight and enforcement of the organic regulations. However, the Organic Fraud Prevention Solutions is designed to complement and reinforce USDA's organic standards and the work of the accredited certifying agencies.

***Early Adopters of Organic Fraud Prevention Solutions***

USDA certified organic companies that have already enrolled in the program are:

- **Albert Lea Seed House Inc.** (handler, seeds)
- **Ardent Mills** (milling/flour/grain)
- **Bridges Produce, Inc.** (distributor/produce)
- **Coyuchi Inc.** (home textiles, retail, GOTS certified)
- **DFI Organics** (trader, food ingredients)
- **Doudlah Farms** (producer/livestock/eggs)
- **Global Organics Ltd.** (handler/importer)
- **Grain Millers, Inc.** (handler/processor/grains)
- **Grund America** (home textiles, GOTS certified)
- **Handsome Brook Farm** (livestock/eggs)
- **Hibernia Misiones S.A.** (milling/sugar)
- **Ingredion Inc.** (processor/sweeteners, starches, nutrition ingredients)
- **I Was Thinking** (importer/handler/co-packer, grains, seeds, legumes, sweeteners)
- **Lundberg Family Farms** (food manufacturer/grains/rice)
- **Monin, Inc.** (manufacturer/flavors)
- **Mosher Products Inc.** (broker/grain/feeds)
- **Naturepedic Organic Mattresses** (home textiles manufacturer/retailer, GOTS certified)
- **Organically Grown Company** (distributor/produce)
- **Organic Valley CROPP Cooperative** (producer/handler/livestock/dairy/meat)
- **Pipeline Foods, LLC** (handler/supply chain solutions/feed grains/oilseeds)
- **J.M. Smucker Company** (processor/multi-ingredient)
- **Stonyfield** (producer/handler/livestock/dairy)
- **The Forest Farmers** (producer/maple/birch/tree syrups)
- **True Organic Products, Inc.** (manufacturer/fertilizer)





- **Wolf, DiMatteo & Associates** (consultant, pre-enrolled as a Trusted Advisor\*)
- **Miles McEvoy, Lacewing LLC** (consultant, pre-enrolled as a Trusted Advisor\*)

*\* Trusted Advisors are a category of professional that may qualify and partner with Organic Fraud Prevention Solutions and work with enrolled companies to develop an Organic Fraud Prevention Plan. Trusted Advisors are experts in organic certification as well as in conducting vulnerability assessments and organic fraud mitigation plans.*

### ***How do I pre-enroll in the program?***

The most efficient method is to [pre-enroll online](https://ota.com/OrganicFraudPrevention) through the Organic Trade Association's Organic Fraud Prevention Solutions [web page](https://ota.com/OrganicFraudPrevention): <https://ota.com/OrganicFraudPrevention>

### ***In the Media***

Organic Fraud Prevention Solutions is picking up attention in the media. We appreciate the support and encourage everyone to please spread the word!

<https://www.globenewswire.com/news-release/2019/03/06/1748918/0/en/Organic-Trade-Association-launches-Organic-Fraud-Prevention-Solutions-program.html>

<https://www.feednavigator.com/Article/2019/03/20/US-organic-body-launches-fraud-prevention-program>

<https://www.foodbusinessnews.net/articles/13425-smucker-others-join-organic-fraud-prevention-program>

<https://www.foooddive.com/news/organic-trade-group-uses-volunteer-program-to-tackle-fraud/550030/>

<https://associationsnow.com/2019/03/two-years-in-the-making-organic-trade-association-launches-anti-fraud-program/>

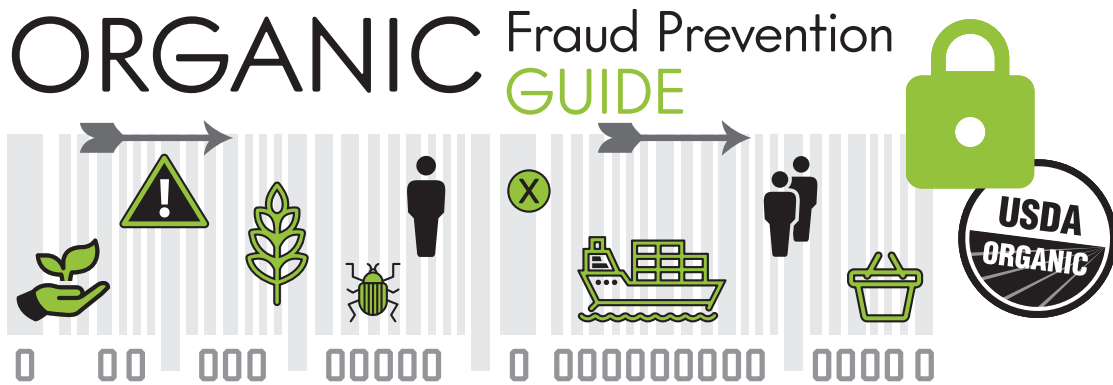
Respectfully submitted,

Gwendolyn Wyard  
Vice President, Regulatory and Technical Affairs

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

**Appendix A** – Organic Fraud Prevention Guide: [Executive Summary](#)

# EXECUTIVE SUMMARY



## ENSURING GLOBAL ORGANIC SUPPLY CHAIN INTEGRITY

**A Guide to Developing an  
Organic Fraud Prevention Plan**



*An Organic Trade Association Resource*

# Ensuring Global Organic Supply Chain Integrity

## I. INTRODUCTION

- A. Purpose of this Guide**
- B. Definition of Organic Fraud**
- C. Structure of the Guide and Summary**

## II. THE ORGANIC SUPPLY CHAIN UNDER THE NATIONAL ORGANIC PROGRAM

- A. Participants, Roles and Responsibilities**
- B. The Certification and Approval Process**
- C. The Organic Supply Chain**
- D. Challenges and Gaps in the Supply Chain**

## III. DEVELOPING AND IMPLEMENTING AN ORGANIC FRAUD PREVENTION PLAN (OFPP)

### **A. Vulnerability Assessment: Identifying Gaps and Weaknesses**

- i. Definitions
- ii. Vulnerability Factors
- iii. Carrying out the Vulnerability Assessment Process
- iv. Using the Organic Vulnerability Assessment Tool
- v. Examples of Medium to High Vulnerabilities

### **B. Mitigation Measures: Designing a Mitigation Strategy**

- i. Create a Supplier Verification Approval Program
- ii. Establish Best Practices for Receiving Organic Ingredients/ Products
- iii. Establish Best Practices for Imports or High-Risk Products
- iv. Establish Best Practices for Ensuring Supply Chain Traceability and Mass Balance
- v. Establish Labeling Best Practices

### **C. Monitoring and Verification: Effectively Implementing Mitigation Measures**

- i. Internal Audits
- ii. Testing: A Tool For Verifying Compliance
- iii. Tracking and Compliance Verification Technologies
- iv. Implementing the Organic Fraud Prevention Plan
  - 1. Effective Training and Communication Strategy
  - 2. Updating the Organic System Plan

# A Guide to Developing an Organic Fraud Prevention Plan

## IV. ALERT SYSTEM – MONITORING AND REPORTING ORGANIC FRAUD

### A. What to Do When You Suspect or Detect Fraud

### B. How to File a Complaint with NOP

- i. Complaint Template

## V. ACKNOWLEDGMENTS AND FURTHER READING

### A. Acknowledgments

- i. Global Organic Supply Chain Integrity Task Force
- ii. USDA National Organic Program
- iii. Food Fraud Think Tank and GFSI Food Fraud Initiative

### B. Resources and Further Reading

- i. Standards
- ii. USDA Guidance Documents / Instruction / Policy
- iii. Self-Assessment Tools
- iv. Alerts and Databases
- v. Testing
- vi. General Resources

## VI. APPENDIX A

### Uncertified Handler Declaration

## VII. APPENDIX B

### Organic Fraud Vulnerability Assessment Tool

## VIII. APPENDIX C

### Complaint Template

## OVERVIEW

The success of the organic sector relies on consumer trust of the United States Department of Agriculture's (USDA) Organic seal. The organic certification system, under the oversight of USDA's National Organic Program (NOP), is designed to deliver organic products that are uniformly certified to a single federal standard by a third-party USDA accredited certifying agent (ACA). Organic certification is also designed to create a linked system of compliance providing complete source-to-sale traceability of organic products and accountability of each operation in the global supply chain. To date, the organic label remains the only regulated eco-claim with third-party certification, federal oversight and enforcement.

Recent activities and USDA investigations have revealed products fraudulently labeled as organic and gaps in the complex organic supply chain, specifically as it relates to organic imports. Compromised supply chains due to fraud can erode consumer trust in the integrity of the organic brand. Strong action is needed to improve the effectiveness of controls throughout the organic product supply chain. In addition to the number of steps currently being taken to strengthen NOP oversight of imported organic products, further actions include oversight and training of ACAs, improved collaboration with other agencies to better oversee organic products at U.S. Ports of Entry, and encouraging the private sector to be proactive and take responsible steps for improving systems that will help mitigate and avoid the risk of fraud.

Everyone has a role in organic fraud prevention. It is critical that producers, handlers, processors, distributors, traders and holders of organic brands have systems and measures in place that adequately support the promise of providing organic food that people can trust. This Best Practices Guide, as adopted by businesses engaged in organic trade, will become the industry standard reference for achieving integrity across complex organic supply chains.

### Purpose of the Best Practices Guide

The purpose of this Guide is to provide businesses engaged in the organic trade with a risk-based approach for developing and implementing a written Organic Fraud Prevention Plan (OFPP) to assure the authenticity of organic products by minimizing vulnerability to organic fraud and mitigating the consequences of occurrence.

By outlining systematic approaches to the organic certification process and verification procedures carried out by ACAs and certified operations, the Guide's recommended practices are intended to establish an industry standard for businesses to create continuously improving internal programs and processes for achieving organic integrity throughout their associated supply chains.

### DEFINITION OF ORGANIC FRAUD

For the purposes of this Guide, organic product fraud can be defined as an intentional misleading or deceptive action carried out for illicit financial gain. Fraudulent acts may include adulteration, substitution, falsified records and the deliberate mislabeling of goods, as well as false statements made on applications, organic system plans, and during

inspections. Of primary concern are intentional and economically motivated substitutions and the fraudulent mislabeling of organic products, including fabrication of fraudulent organic certificates. Such misrepresentation may occur at any point along the value chain from the product source to selling point.

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## STRUCTURE OF THE BEST PRACTICES GUIDE

**This booklet presents a systematic approach to developing and operationalizing a written organic fraud prevention plan that can be summarized by a five-step process:**

- Conduct a vulnerability assessment, including
  - Know your products and risks (history, economic and geographical factors)
  - Know your suppliers (manufacturer, broker, certified/uncertified, history)
  - Know your supply chain (length, complexity, supply and demand)
  - Know your existing verification measures and identify the gaps
- Design and implement internal mitigation measures including a robust supplier approval program that involves internal audits and second-party supplier audits
- Ensure practices are effective through monitoring practices and verification tools such as internal audits and control testing
- Document the vulnerability assessment, mitigation measures and monitoring practices in an Organic Fraud Prevention Plan
- Integrate mitigation measures into the Organic System Plan (OSP)

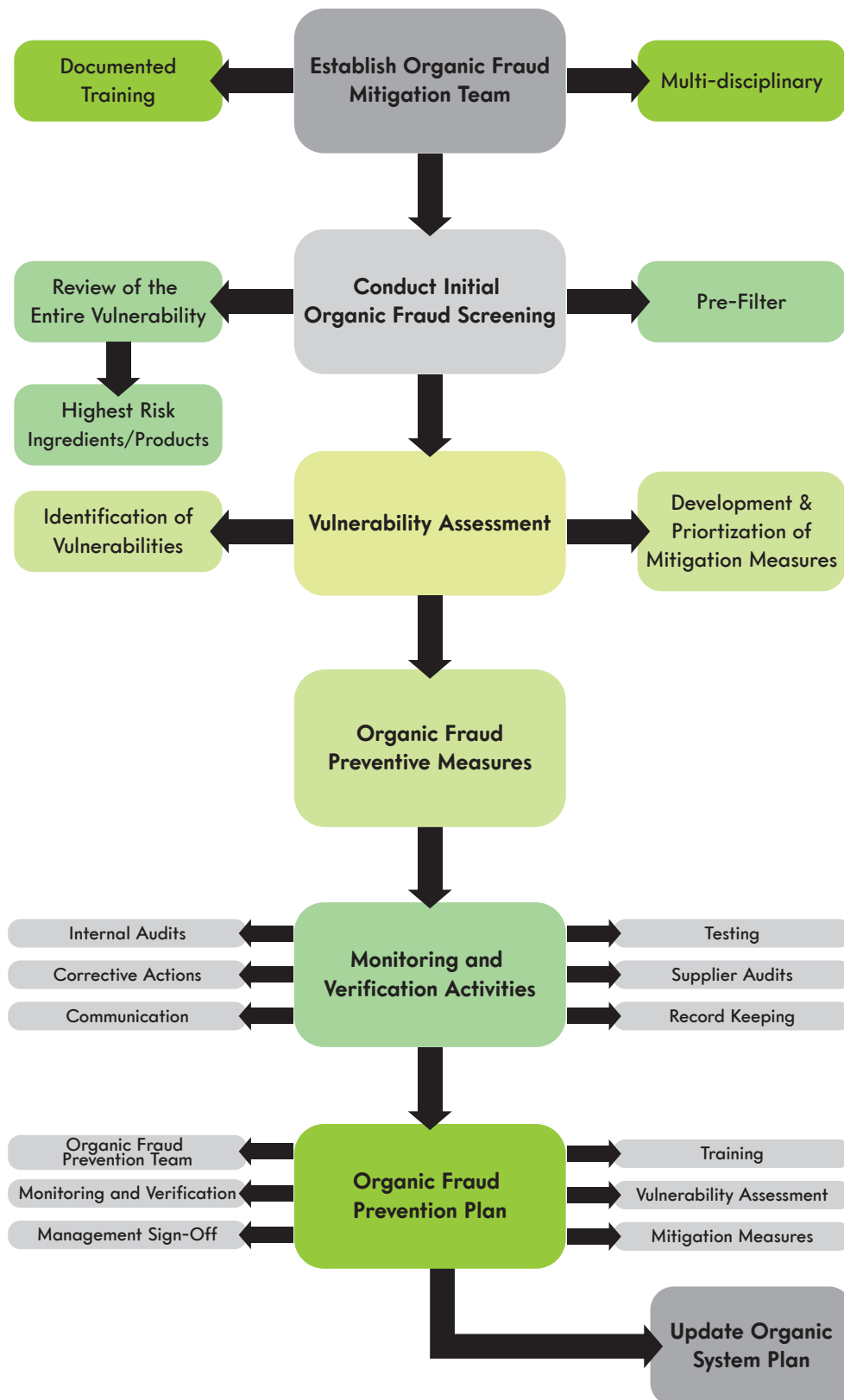
### **In Summary, this Guide:**

- Provides businesses engaged in organic trade with a risk-based approach for developing best practices for improving the resilience and overall integrity of global organic supply chains
- Is intended for individual businesses engaged in the selling, buying, producing, processing or packaging of certified organic products
- Provides background on the participant's responsibilities and organic requirements for a simple and complex organic supply chain
- Aims to set a standard industry practice that complements and reinforces the organic certification process and verification procedures carried out by ACAs and MROs as authorized by USDA-NOP
- Presents a process for carrying out a vulnerability assessment to design and implement appropriate mitigation practices that can be integrated into the annual organic certification system
- Provides guidance on developing and implementing a written organic fraud prevention plan to assure the authenticity of organic products by minimizing vulnerability to organic fraud and mitigating the consequences of occurrence
- Recommends monitoring procedures and verification tools that will ensure the practices and procedures are effectively implemented
- Includes detailed information on what to do when you suspect or detect fraud and the process for filing a complaint to the National Organic Program
- Provides additional resources and helpful tools for identifying and or deterring fraud.





## DEVELOPING AN ORGANIC FRAUD PREVENTION PLAN



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## DEFINITIONS

### **Mitigation Measure:**

Measure taken to decrease vulnerability to organic fraud in a given supply chain.

### **Mitigation Strategy:**

Selected set of mitigation measures aimed at preventing food fraud in a given supply chain that are incorporated into the Organic Fraud Prevention Plan.

### **Organic Critical Control Points (OCCP):**

A step or procedure at which controls can be applied to prevent the organic integrity of an organic ingredient or product being compromised. Control points are essential components of an Organic System Plan, and identify the places in a product process flow or in the supply chain where the organic integrity of a product could be compromised.

### **Organic Fraud:**

For the purposes of this Guide, organic product fraud can be defined as an intentional misleading or deceptive action carried out for illicit financial gain. Fraudulent acts may include adulteration, substitution, falsified records and the deliberate mislabeling of goods, as well as false statements made on applications, organic system plans, and during inspections. Of primary concern are intentional and economically motivated substitutions and the fraudulent mislabeling of organic products, including fabrication of fraudulent organic certificates. Such misrepresentation may occur at any point along the value chain from the product source to selling point.

### **Organic Fraud Prevention Plan:**

A company plan that documents the vulnerability assessment, mitigation measures and verification procedures that will be performed and maintained to verify that the plan is effectively implemented.

### **Organic System Plan:**

A plan of management of an organic production or handling operation that has been agreed to by the producer or handler and the certifying agent, and that includes written plans concerning all aspects of agricultural production or handling described in Title 7 CFR 205 (National Organic Program Regulations.)

### **Vulnerability Assessment (or vulnerability characterization):**

Within a food fraud management system, the step aimed at reviewing and assessing various factors that create vulnerabilities in a supply chain (i.e. weak points where fraud has greater chances to occur).

- Note: A *vulnerability* is a weakness or gap in protection efforts. *Risk* – The potential for loss, damage or destruction of an asset as a result of a threat exploiting a *vulnerability*. *Risk* is the intersection of assets, threats, and *vulnerabilities*.

The Organic Trade Association has developed the **Organic Fraud Prevention Solutions** private-sector program to help protect your business, and grow consumer confidence in organic.



**Organic Fraud Prevention Solutions** improves your internal quality assurance programs.

- ✓ It helps **prevent organic fraud** in your supply chain
- ✓ It provides a **business-to-business marketing advantage**

The program provides step-by-step training and resources.

- ✓ Identify **weaknesses** and gaps
- ✓ Design internal **mitigation** measures
- ✓ Implement **monitoring** and verification tools
- ✓ Update your **Organic System Plan**

The program complements and reinforces the U.S. Department of Agriculture's Organic standards and the work of the accredited certifying agencies.

- ✓ It is a quality assurance program, **not a certification** or verification program

**Organic Fraud Prevention Solutions** is designed and tested by the organic sector. It minimizes vulnerabilities for organic farmers, handlers, traders, processors, distributors and retailers.

**Organic Fraud Prevention Solutions** is open for enrollment\*

- ✓ Be **publicly recognized** as an Organic Fraud Prevention Solutions enrollee
- ✓ Receive the comprehensive Organic Fraud Prevention **Best Practices Guide**
- ✓ Secure your **training slot** (free to Organic Trade Association members)
- ✓ Receive **business-critical updates** on program developments and fraud news

*An Organic Trade Association Resource*

\*Pre-enrollment is available for Organic Trade Association members. All program participants must be certified organic or listed by a USDA recognized Material Review Organization.

**Learn More: [OTA.com/OrganicFraudPrevention](http://OTA.com/OrganicFraudPrevention)**



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ExecSum Rev 01

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April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Avenue, SW  
Room 2642-So., Ag Stop 0268  
Washington, DC 20250-0268

**Docket:** AMS-NOP-18-0071

**RE: Livestock Subcommittee – Use of Excluded Method Vaccines in Organic Livestock Production (Discussion)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Discussion Document on Use of Excluded Method Vaccines in Organic Livestock Production. The subcommittee is inviting discussion on three possible regulatory solutions regarding the use of vaccines produced through excluded methods.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Organic Trade Association is committed and actively engaged in fighting the proliferation of GMOs to protect organic agriculture and trade, and preserve farmer and consumer choice. We do not in any way support the use of excluded methods in the production of organic seeds, crops, ingredients or other production methods. However, we do acknowledge that the regulations currently provide for one narrow exception to the prohibition on excluded methods—GMO vaccines—provided they are approved in accordance with § 205.600(a). We also acknowledge that GMO vaccines have been allowed since at least 2002. Therefore, we believe that any recommendation that is approved needs to completely and accurately assess the impact it would have on animal and human welfare and the organic livestock sector in general.

**Summary**

- ✓ We support NOSB's work towards a recommendation for vaccines that stands against the proliferation of GMOs in organic, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology.
- ✓ We acknowledge and appreciate the tremendous amount of work that NOSB has put forth on this issue.
- ✓ There are positive aspects to all of the regulatory solutions. However, within the limited comment period, OTA was not able to conduct a complete and thorough evaluation of the options or fully engage our membership to the extent needed to endorse any one specific option.

We offer the following more detailed comments:

### **OTA Position GMO Vaccines (“Vaccines made with excluded methods”)**

OTA is committed and actively engaged in fighting the proliferation of GMOs to protect organic agriculture and trade, and preserve farmer and consumer choice. We do not in any way support the use of excluded methods in the production of organic seeds, crops, ingredients or other production methods. However, we do acknowledge that the regulations currently provide for one narrow exception to the prohibition on excluded methods—GMO vaccines—provided they are approved in accordance with §205.600(a).

We acknowledge that GMO vaccines have been allowed since at least 2002. Due to the lack of information or guidance about how to identify a GMO vaccine, certified livestock operations, with approval from their certifier, have chosen vaccines based upon effective disease prevention and not based on its GMO status. While not every certifier is allowing GMO vaccines and some certified operations have internal policies that do not allow for their use, generally speaking they have been allowed.

We acknowledge that some vaccines are only available in GMO form, and that prohibition of those vaccines would have significant impact on the organic livestock sector. For example, as described in OTA’s comments to NOSB in 2012, the large majority of organic poultry operations are using *Salmonella* vaccines as part of their preventive disease control program given the requirements to prevent *Salmonella* under the FDA Egg Safety Rule, and the only available vaccine for live *Salmonella typhimurium* (ST) is genetically engineered. Some state laws even require operators to administer certain vaccines (including GMO vaccines) for the prevention of certain animal diseases. Furthermore, as reported by NOSB in its 2009 Recommendation, the market for GMO vaccines is growing exponentially as a result of changing field conditions and technologic advances in production.

While OTA does not promote the use of GMO vaccines, it’s also unacceptable to move forward with a recommendation that prohibits use of GMO vaccines for preventive control if there is no conventionally produced alternative. We do not believe that organic producers should be at a disadvantage when it comes to providing adequate health care to their livestock. Vaccines are an integral part of a preventive livestock health care plan. Therefore, we support NOSB’s work towards a recommendation for vaccines that stands against the proliferation of GMOs in organic, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology.

### **Background**

Uncertainty has existed about the status of vaccines made from excluded methods (i.e. genetic engineering) that are permitted, which has caused inconsistencies between certifiers in what vaccines are allowed to be used in organic livestock production. Excluded methods are prohibited under §205.105(e) *except for vaccines*, provided that the vaccines are approved in accordance with §205.600(a) (i.e., reviewed in accordance with OFPA’s National List Criteria at 7 U.S.C. 6517 & 6518). Vaccines are listed on the National List under §205.603(a)(4). However, the listing which reads “Biologics—vaccines” does not specifically reference those from excluded methods. NOP’s 2010 position<sup>1</sup> (supported by the legal opinion of the USDA’s Office of General Counsel) is that GMO vaccines are allowed only if they are

<sup>1</sup><https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Response%20to%20Rec%20from%20April%202010%20Meeting.pdf>



approved according to §205.600(a), and that NOSB still needs to review vaccines from excluded methods under the provisions of §205.600(a). The preamble to the NOP final rule supports this position by explaining that §205.105 was structured so that vaccines produced using excluded methods could only be used if they are affirmatively included on the National List. Therefore, the current exception at §205.105(e) to allow vaccines made with excluded methods only applies to those that are reviewed according to §205.600(a).

NOSB's work to accomplish the task of reviewing vaccines made with excluded methods under the provisions of §205.600(a) and to prepare for an affirmative decision to include vaccines made with excluded methods on the National List (if/as appropriate) has been extensive, and includes the following milestones:

- Requested development of a Technical Review<sup>2</sup> on vaccines made with excluded methods which used the criteria found at 7 USC 6517 and 6518 (as required by §205.600(a)).
- Convened a Working Group of NOSB, NOP, and staff from the Center for Veterinary Biologics (CVB) division of the Animal Plant and Health Inspection Service (APHIS) to develop information about the use and identification of vaccines made with excluded methods to support the NOSB's review of vaccines from excluded methods according to §205.600(a). The Working Group presented an Interim Report<sup>3</sup> to the NOSB Livestock Subcommittee (February 5, 2013).
- Presented a comprehensive overview and recommendation<sup>4</sup> on vaccines from excluded methods (August 2014), thereby responding to NOP's request for NOSB to review vaccines from excluded methods in accordance with §205.600(a). NOSB unanimously passed this recommendation in October 2014, and requested that NOP utilize the information within the NOSB recommendation to provide Guidance to NOSB, certifiers, and MROs on the use of vaccines made with excluded methods in organic livestock production.

NOP has not been able to act on the NOSB's recommendation because of the following challenges cited in the April 2019 NOSB Meeting Materials: "having an updated definition of excluded methods that determines if new technologies were to be excluded methods for organic, having a clear understanding if there were non-excluded method vaccine equivalents to excluded method derived vaccines and how to provide for use of excluded method vaccines if there was an emergency when only an excluded method vaccine could address the problem in a timely way."

The current NOSB Livestock Subcommittee believes these issues have been clarified, and is ready to address the issue through a regulatory solution that will clarify the allowance of vaccines from excluded methods. The Subcommittee states it is committed to finding a pragmatic way to stand against the pervasive use of excluded methods in organic agriculture and foods, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology.

<sup>2</sup><https://www.ams.usda.gov/sites/default/files/media/Vaccines%20from%20Excluded%20Methods%20report%202011.pdf>

<sup>3</sup><https://www.ams.usda.gov/sites/default/files/media/LSInterimReportVaccineswithExcludedMthdsApr2013.pdf>

<sup>4</sup><https://www.ams.usda.gov/sites/default/files/media/NOP%20Livestock%20Vaccines%20from%20Excluded%20Methods.pdf>

### **Three Regulatory Solutions:**

In the Subcommittee's discussion document<sup>5</sup>, three possible regulatory solutions are presented to the public for feedback.

- **Option #1: Follow the requirements of §205.105(e) and start reviewing known excluded method vaccines for individual placement on the National List.**

Under this option, individual vaccines made from excluded methods will need to be petitioned to NOP, reviewed by NOSB, and placed on the National List via NOP rulemaking.

- **Option #2: Approve all vaccines produced through excluded methods as a “class” of vaccines and place this class of vaccines on §205.603(a)(4).**

Under this option, vaccines made from excluded methods would be allowed without further review or restriction. (Note: A more streamlined way to implement this option would be to amend §205.105(e) to remove the phrase, “Provided, That, the vaccines are approved in accordance with §205.600(a).”)

- **Option #3: Change §205.105(e) to read as follows: *(e) Excluded methods, except for vaccines: Provided, That, there are no commercially available vaccines that are not produced through excluded methods to prevent that specific animal disease or health problem.***

Under this option, vaccines would not need to be individually reviewed by NOSB, but certifiers will need to conduct reviews to determine if the vaccine is made from excluded methods and whether the commercial availability restriction would apply.

### **Feasibility of identifying a vaccine as being made from excluded methods**

Options #1 and #3 are both contingent upon the ability to identify if a vaccine is made from excluded methods. For Option #1, this information is necessary to determine if the vaccine needs to be petitioned for inclusion on the National List. For Option #3, this information is necessary to determine if the vaccine is subject to a commercial availability restriction.

The main barrier to previous attempts to identify a vaccine as being made from excluded methods was that the current regulatory definition for “excluded methods,” on its own, is inadequate to clarify methods relevant to vaccine manufacturing. In the past several years, NOSB has conducted extensive work on excluded methods terminology, with a breakthrough recommendation passed in fall 2016 that includes a set of supplemental definitions, criteria for review of new technologies, and a list of technologies that have been determined to be an excluded method. This recommendation, along with subsequent recommendations that continue to clarify new terms and technologies, will greatly improve the efforts of the organic industry to determine whether a vaccine manufacturing method should be classified as excluded. Although there may be some outstanding “to be determined” technologies that are relevant to vaccines, there is at least a set of criteria and a process for NOSB to conduct the evaluation and make a determination. For example, transposons (used in animal vaccines) are listed as “to be determined,” and two forms of transposons are included in the spring 2019 NOSB agenda for determination. It is important

<sup>5</sup> <https://www.ams.usda.gov/sites/default/files/media/LSVaccinesExcludedMethodsDDWebApril2019.pdf>

for the NOSB Recommendations on Excluded Methods Terminology to be formalized as NOP Guidance so that this valuable information can become an official resource to support efforts to identify if a vaccine is made from excluded methods.

Another barrier to previous attempts to identify a vaccine as being made from excluded methods was the challenge of obtaining information about a vaccine's manufacturing process in order to evaluate whether the process involves an excluded method. Vaccine manufacturers may not be able to disclose manufacturing information due to patent protections or other need to maintain confidential business information. This will remain a challenge going forward.

For vaccines whose manufacturing process cannot be obtained, there are very limited options for determining if the vaccine is made with excluded methods. According to the 2014 NOSB Recommendation, if an APHIS-registered vaccine label uses the terms "Subunit," "Vector," or "Chimera," one can reliably identify that vaccine as being made with an excluded method. The resources appear to end there. APHIS product codes are not reliable for determining whether a vaccine was made using technologies that would be considered excluded methods under the NOP regulatory definition.

If Options #1 or #3 are pursued, the industry will face challenges in positively identifying whether a vaccine is made with excluded methods due to the challenges of obtaining sufficient information about the vaccine manufacturing process in order to conduct the evaluation of the vaccine against the NOP definition and NOSB recommendations for excluded methods terminology. Additional guidance will need to be developed that provides certified operators and certifiers with instructions on how to identify vaccines made from excluded methods. There may be cases where this challenge is unsurmountable, and a vaccine will default to being classified as an excluded method due to a lack of information to prove otherwise.

### **Feasibility of evaluating commercial availability of vaccines *not* from excluded methods**

Option #3 is contingent upon the ability to identify if a vaccine is made from excluded methods (as described above), and also the ability to identify if an alternative version *not made from excluded methods* is commercially available to prevent that specific animal disease or health problem.

Commercial availability restrictions are not new to the regulations (definition at §205.2; restrictions on seeds and planting stock at §205.204(a)(1); restriction on yeast in products for human consumption at §205.605(b); restrictions on non-organic agricultural minor ingredients at §205.606). However, such restrictions are based on commercial availability of organic forms, which can be clearly verified by an organic certificate. Operators that are responsible for conducting a commercial availability search for organic forms have a clear method of determining whether a form is organic or not, and can document their search for verification by their certifier. On the other hand, a commercial availability search for forms *made with excluded methods* is an exercise that will be new to the organic regulatory scheme. If operators are required to conduct their own search for vaccines made without excluded methods, it will be a complex and technical process of attempting to identify individual vaccines as being made from excluded methods, which involves several challenges (as described above). If Option #3 is pursued, operators will be challenged to conduct their own commercial availability searches for vaccines made without excluded methods. Additional guidance will be needed to support operators in this effort.

Operators and certifiers alike may be challenged in conducting commercial availability searches for custom vaccines and combination vaccines (multiple vaccines are often combined into one dosage / multi-disease vaccine packages). However we anticipate that certifiers can adapt existing policies they may have in place for custom/combination inputs already subjected to commercial availability restrictions (e.g. seeds; colors).

In the Subcommittee's discussion document, two questions related to commercial availability are presented to the public for feedback.

- *What type of documentation would be used to prove non-commercial availability of vaccines produced without excluded methods?*

Operators that use a vaccine made with excluded methods would need to document their effort to search for vaccines made *without* excluded methods in appropriate form, quality, or quantity to fulfill the intended function (i.e. is specific to an animal disease or health problem). Certifiers are the ultimate decision makers of whether an operator's commercial availability documentation is sufficient. We anticipate that certifiers could adapt existing documentation requirements for other inputs already subjected to commercial availability restrictions (e.g. seeds; substances on §205.606).

- *When reviewing vaccines under commercial availability, are there special issues that should be considered?*

See above.

### **Other considerations for the use of vaccines**

*Federal or state mandated vaccinations:* Some organic operations may be subject to federal or state mandated vaccinations. It is important that organic operations are not mandated to use vaccines that could jeopardize their organic certification status.

- Option #3 may not be a viable option for accommodating federal or state mandated vaccines. For example, if a mandated vaccine is made from excluded methods, an organic operation would need to demonstrate commercial unavailability of alternative vaccines not made from excluded methods in order to comply with the mandate. The state or federal agency may or may not approve use of the non-excluded method alternative.
- Option #2 is the most preferable option for accommodating federal or state mandated vaccines. Under this option, organic operations would have a level playing field with conventional operators to use the vaccines as required by federal or state mandates.

*Timeliness of approval:* In order for vaccines to be an effective preventive health care tool, livestock operations need approved access to such tools in a timely manner so that animals can be vaccinated at the appropriate time to protect against disease. Timely approval is important for the use of newly developed vaccines and/or vaccines that are needed as an emergency response.

- Option #1 is not a viable option for accommodating the timely use of a new vaccine because it would involve the time-consuming process of NOSB review and NOP rulemaking (which may take years) to provide for the allowance of a new vaccine.
- Option #2 is the most viable option for accommodating the timely use of a new vaccine and/or a vaccine needed for an emergency response, because the operator could use any vaccine without needing to evaluate whether the vaccine was made with excluded methods, or to conduct a commercial availability search for non-GMO alternatives, or to go through the NOP rulemaking process.

*Economic impact analysis:* In the NOP's 2010 memo<sup>6</sup>, NOP suggested that the Board include in its review an assessment of the economic impact of using commercial availability criteria for non-GMO vaccines. This assessment has not been conducted, and we believe this is an area that needs considerably more work if Option #3 is pursued.

### **Preferred Options (Summary)**

All of the regulatory solutions presented in the discussion document are effective in standing against the proliferation of GMOs in organic, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology. Additionally, all of the options will level the playing field of certified livestock operations by ensuring that all certifiers are following a consistent practice in reviewing and allowing vaccines from excluded methods. These options also do not preclude the option of submitting petitions to the National List to prohibit individual vaccines that may not comply with National List criteria. For these reasons, there are positive aspects to all of the regulatory solutions.

Option #1 is not a preferred option, primarily due to inability to accommodate the timely use of a new vaccines, which would prevent operators from providing full and comprehensive preventive care for organic livestock.

Option #2 is preferable in terms of accommodating the timely use of a new vaccine, and emergency use of vaccines, and accommodating federal or state mandated vaccinations, while also eliminating the challenge of identifying vaccines as being made with excluded methods (which may be an unsurmountable challenge in some cases).

Option #3 is not a preferred option in terms of accommodating federal or state mandated vaccinations, and also involves the challenges of needing to identify vaccines as being made with excluded methods (which may be an unsurmountable challenge in some cases), and also needing to determine if alternative versions not made from excluded methods are commercially available to prevent that specific animal disease or health problem. However, there are positive considerations for this option. This option makes it incumbent upon organic producers to seek out and use non-GMO vaccines before those made by excluded methods can be used, which aligns with an underlying premise of organic to avoid GMOs. It is unclear at this time whether this option is feasible given the aforementioned challenges.

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<sup>6</sup><https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Response%20to%20Rec%20from%20April%202010%20Meeting.pdf>

### **Conclusion**

We support NOSB's work towards a recommendation for vaccines that stands against the proliferation of GMOs in organic, while being practical in accepting the fact that some necessary vaccines are only available using excluded method technology. While OTA does not promote the use of GMO vaccines, it's also unacceptable to move forward with a recommendation that prohibits use of GMO vaccines for preventive control if there is no non-GMO alternative. The options presented in the discussion document are effective to meet this goal, although each option presents unique challenges and considerations. Within the limited comment period, OTA was not able to conduct a complete and thorough evaluation of the options or fully engage our membership to the extent needed to endorse any one of the specific options. However, we look forward to continuing to explore these options with our members, and will be in a better position to comment on a more specific proposal on this topic should it be presented in the fall.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink that reads "Johanna Mirenda".

Johanna Mirenda  
Farm Policy Director  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association





April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Avenue, SW  
Room 2648-So., Ag Stop 0268  
Washington, DC 20250-0268

**Docket:** AMS-NOP-18-0071

**RE: Livestock Subcommittee – 2021 Sunset Reviews**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2021 Sunset Review.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering each livestock production material scheduled for review as part of the 2021 Sunset Review cycle. Materials placed on the National List for use in organic livestock production should remain on the National List if: 1) they are consistent with organic farming; 2) they are still necessary to the production of the agricultural product because of the unavailability of wholly natural substitute products in organic production; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517] National List). Furthermore, decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at-large. It's critical that NOSB hear from certified farmers on whether these inputs are consistent with and necessary for organic production, or whether there are other effective natural or organic alternatives available.

#### **About OTA Sunset Surveys**

OTA is submitting results to our Sunset Surveys created for each input under review as part of the 2021 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input. See Appendix A for a sample survey. Our surveys do not address information regarding the impacts on human health or the environment.

The surveys are open to any NOP certified organic operation. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) and the Organic Materials Review Institute (OMRI) to distribute the survey to all of their clients as well as to targeted clients they

know are using the inputs under review. OTA also worked through its Farmers Advisory Council<sup>1</sup> to help assist in distribution to NOP certified farmers.

### **Results of OTA Sunset Surveys**

OTA has received 2 responses on our 2021 Livestock Sunset Surveys. Below is a summary of the feedback received via OTA's Sunset Surveys to date.

#### **§205.603 – Synthetic substances allowed for use in organic livestock production.**

Substance	# of responses	Summary of responses	Average rating of Necessity (from 1 to 5, with 1 being "unnecessary" and 5 being "critical /would leave organic without it")
Atropine	0		
Hydrogen Peroxide	0		
Iodine	0		
Magnesium sulfate	0		
Fenbendazole	0		
Moxidectin	0		
Peracetic acid	0		
Xylazine	0		
Methionine	2	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used to provide an essential amino acid to organic poultry</li> <li>- Used to ensure proper growth and production of organic poultry</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Outdoor access can provide some of the methionine need, but in climates where insects are not naturally occurring year round, it is challenging to get enough methionine into the diet without supplementation.</li> <li>- Over-feeding protein can lead to too much nitrogen in the manure which contribute to nitrogen runoff challenges</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Reduced egg production</li> <li>- Decreased broiler growth</li> <li>- Unhealthy/dead chickens</li> <li>- Would leave organic production</li> </ul>	<b>5</b>
Trace minerals	0		
Vitamins	0		

<sup>1</sup> OTA's Farmers Advisory Council was established in 2013 to formalize two-way communication between OTA and member producers as well as regional organic producer organizations across the United States. Through dialog and input, FAC gives organic farmers a voice to directly influence OTA's policy and provides an avenue for OTA to share information and advocacy work with this stakeholder group.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Johanna Mirenda  
Farm Policy Director  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

## Appendix A – Sample Survey for Crop and Livestock Inputs

1. Please describe the types of organic products produced or handled on your operation:
2. How many states are your products sold in? Are they exported to other countries?
3. How many years has your operation been certified organic?
4. Which organic products do you use the substance on/for? (e.g., lettuces, fruit trees, broiler chickens)
5. What function does the substance provide and why is it necessary? (e.g., to control a specific pest or disease, sanitation, etc.)
6. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)
7. Have you tried using any *natural substances* as an alternative to the substance? (e.g., natural oils instead of synthetic pesticides) If so, please describe the availability and efficacy of the alternative substances:
8. Are there any other *management practices* that would eliminate the need for the substance? (e.g., hand weeding instead of using an herbicide; or using a particular harvesting practice to avoid a disease instead of using a fungicide). If so, please describe the efficacy of the alternative management practices:
9. Describe the effects to your operation if you were to no longer be allowed to use this substance in organic production:
  - Agronomic effects (effects to health of crops or livestock):
  - Environmental effects (effects to environment if the substance was no longer allowed; effects to environment from potential alternatives):
  - Economic effects (effects to economic health of your operation):
10. On a scale from 1 to 5 stars, rate the overall necessity of this substance for your organic operation:

Unnecessary (don't need it  
at all)

Neutral (nice to have but  
could live without it)

Critical (would leave organic  
without it)





April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP

**Docket:** AMS-NOP-18-0071

**RE: Pullulan Petition (Proposal)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Handling Subcommittee's Proposal on the Pullulan Petition. The purpose of submitting this petition is to: 1) protect the production and availability of USDA-NOP "made with" certified encapsulated dietary supplements; and 2) support the commercial development of certified organic Pullulan.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

### Summary

The Organic Trade Association strongly supports the Handling Subcommittee's proposal to add Pullulan to the National List at 205.605(a). We support the subcommittee's recommendation and we urge the full Board to pass the recommendation at the Spring 2019 meeting in order to bring Pullulan under the strict review of NOSB and the National List Sunset process, and allow for the on-going availability of USDA-NOP certified vegetarian encapsulated dietary supplements labeled "made with organic (specified ingredients or food group(s))."

The Organic Trade Association is the petitioner of this material. The petition was submitted on behalf of our organic trade members that are manufacturing and selling USDA-NOP certified dietary supplements that utilize Pullulan-based (vegetarian) capsules. The petition is for the *continued* allowance of non-organic Pullulan used in dietary supplements labeled "**made with organic (specified ingredients or food group(s)).**" The only alternative is a gelatin capsules (animal based), which is not appropriate for vegetarian products and may cause issues among kosher and halal consumers.

Pullulan is a product of microbial fermentation. It utilizes primarily agricultural source materials for its production, but it is a polysaccharide that is secreted extracellularly by the organism *Aureobasidium pullulans* into a culture medium from which it is then recovered and purified. From this perspective and using NOP's Classification of Materials Guidance (NOP 5033), it should be classified as non-agricultural.

The petition was submitted in response to accredited certifying agents reclassifying Pullulan as "non-agricultural" in accordance with NOP's Classification of Materials Guidance released in late 2016. Since

the early 2000s, certifying agents have allowed its use in encapsulated dietary supplements certified to the **“made with” product category**. This allowance has significantly contributed to the growth of NOP certified dietary supplements. As a **non-agricultural** substance, Pullulan must now appear on the National List. If Pullulan is not placed on the National List, the continued allowance of NOP certified **vegetarian** encapsulated supplement products will no longer be possible. Without its continued allowance and without an alternative vegetarian option, we estimate the economic impact to the organic dietary supplement sector would be over \$825 million. The damage would also extend to the entire organic raw material supply chain that fills the capsules, hurting organic herb farmers and handlers throughout the world.

Adding Pullulan to the National List is a timely and important action that will quickly address a new interpretation made by several accredited certifying agents in response to NOP’s Classification of Materials Guidance (NOP 5033). Adding Pullulan to the National List will prevent widespread disruption and economically significant damage to the organic supplements sector and its raw material supply chain, and it will support the commercial development of certified organic Pullulan that is highly sought by the supplement sector.

**We offer the following more detailed comments:**

### **Background**

Pullulan is a natural extracellular polysaccharide excreted by the yeast-like fungus *Aureobasidium pullulans*. It is not genetically modified, and it is commercially produced by a non-pathogenic and non-toxicogenic strain of the organism using a liquid starch syrup as the fermentation substrate. Pullulan can be made into very thin films with high tensile strength and stability over a range of temperatures, making it an ideal material to be used in the manufacture of empty capsules for encapsulating dietary supplements or as a coating for dietary supplement tablets.

Encapsulation of organic raw materials and active blends is essential to the handling of dietary supplements because it allows the delivery of materials without the use of excipients, and without the risk of damaging those materials through tablet compression. It also allows controlled dosage, which bulk powders do not, and the lack of heat used during processing helps preserve the bioavailability of the active compounds.

Encapsulated vegetarian dietary supplements certified under USDA’s National Organic Program (NOP) rely on the use of Pullulan as the primary ingredient in the capsule. For dietary supplements, the capsule is considered an “ingredient” and must either be “certified organic,” or comprised of ingredients compliant with the National List of Allowed and Prohibited Substances. The capsule, as an ingredient, also is counted in the weight of the total encapsulated product when calculating the organic percentage. The weight of a capsule always exceeds 5% so any encapsulated product utilizing a non-organic capsule will only qualify for the “made with” labeling category. For an encapsulated product to be certified and labeled as “organic,” an organic capsule would need to be used.

Since the early 2000s, accredited certifying agents have classified Pullulan as **“agricultural”** and allowed its use only in encapsulated dietary supplements certified to the **“made with” product category**. This allowance has significantly contributed to the growth of NOP certified dietary supplements. Currently,

certified organic Pullulan is commercially unavailable in North America, and there are no other NOP compliant vegetarian options available. Gelatin capsules, while allowed under NOP, present consumer acceptance and GMO challenges.

In late 2016, NOP released a guidance document (NOP 5033) on the Classification of Materials. This document assists the National Organic Standards Board (NOSB), accredited certifying agents, and the organic industry in making ‘Agricultural’ vs. ‘Non-agricultural’ and ‘Synthetic’ vs. ‘Non-synthetic’ determinations. Given the information contained in the NOP guidance document, accredited certifying agents are now in general agreement that Pullulan should be classified as a “**non-agricultural, non-synthetic**” substance, and accordingly must appear on the National List at §205.605 to be allowed in NOP certified products.

In response to this new interpretation, we are requesting that Pullulan be added to the National List so that it may *continue* to be allowed as an ingredient in capsules for dietary supplements labeled “made with organic (specified ingredients or food group(s)).”

**IMPORTANT CLARIFICATION:** Please note that we are intentionally limiting the petitioned allowance of non-organic Pullulan to dietary supplements certified to the “made with” category. Any encapsulated dietary supplement sold or labeled as “certified organic (95% +)” will still need to use certified organic Pullulan. Although organic Pullulan-based capsules are not commercially available in North America, development is underway and they should be available in the future. The end goal is the development and use of organic Pullulan. The organic supplement sector is highly motivated to use organic Pullulan because it is the only way these products can qualify for the USDA Organic seal.

**Pullulan should be classified as a non-synthetic, non-agricultural substance, as per NOP’s Classification of Materials guidance document (NOP 5033), and placed on the National List at 205.605(a).**

Pullulan is a product of microbial fermentation. It utilizes primarily agricultural source materials for its production but it is a polysaccharide secreted extracellularly by the organism *Aureobasidium pullulans* into a culture medium from which it is then recovered and purified. Historically, at the certifier level, Pullulan was thought to be a fermentation product made from plant material and considered agricultural, since the large majority of its production is based on plant starch (starch syrup, the substrate that feeds the microorganism). Additionally, some view (and continue to view) fermentation products in general to be agricultural, especially since they could be certified organic if organic substrate is used along with processing aids on the National List. In this particular case, “organic” pullulan is under development, so it begs the question of how Pullulan can be classified as “non-agricultural” yet still be certified to a regulation that certifies **agricultural** products. This is a long-running debate, but thankfully one that NOP has formally weighed in on via the Classification of Materials Guidance (NOP 5033), as informed by years of NOSB deliberations and public comment. Based on the NOP Classification of Materials Guidance and relevant Decision Trees, we believe that Pullulan should be classified as **non-agricultural** and **non-synthetic** because it is a product of a microorganism, rather than a crop or livestock.

See **Appendix A** for a guided tour of Pullulan through NOP’s Decision Tree for Classification of Agricultural and Non-agricultural Materials (5033-2).





## **Organic Pullulan is NOT available for use in North America**

Organic Pullulan-based capsules are not commercially available for use in North America. A quick Internet search for organic Pullulan will produce results reflecting the availability from Bright Pharma Caps, Inc., JC Bright. However, Capsugel® is the owner of U.S. patents covering Pullulan capsules. Capsugel® sued JC Bright for patent infringement and false advertising related to JC Bright's sale of Pullulan capsules. Capsugel® obtained a consent judgment barring JC Bright from selling infringing organic and non-organic capsules. At this time, we are not aware of a legitimate source of Pullulan capsules in the U.S. other than Capsugel®

Because Pullulan is made via a fermentation utilizing agricultural source material, the manufacturing of **organic** Pullulan is possible and development is underway. Capsugel® is in the process of ramping up scale to meet the demand, and the availability of organic Pullulan for the U.S. market should occur in the near future. However, in the interim, no other vegetarian option that we are aware of is available. As mentioned earlier, the organic sector is motivated to use Organic Pullulan. Once it becomes available, we expect that companies selling products in the “made with organic” category will reformulate with organic pullulan capsules and move the product line to the USDA organic label.

## **The only National List alternatives are animal-based and not acceptable to vegetarians**

Gelatin-based capsules, informally called gel caps or gelcaps, are composed of gelatin **manufactured** from the collagen of animal skin or bone. Gelatin is listed on § 205.606 of the National List and may be used as an ingredient in gelatin capsules for dietary supplements, provided they are non-GMO and not available in organic form. However, because gelatin capsules are animal based and not appropriate for vegetarian products, they may cause issues among kosher and halal consumers.

## **If Pullulan is not placed on the National List, the continued allowance of NOP certified vegetarian encapsulated supplement products will not be possible**

It is critical to understand that non-organic Pullulan is not being used in “certified organic” encapsulated supplements. The weight of a non-organic capsule exceeds the 5% non-organic allowance in a product labeled as “organic.” The allowance of non-organic Pullulan-based capsules, previously and going forward, is only in products labeled as “**made with organic (specified ingredients or food group(s)).**”

If Pullulan is not placed on the National List, the continued allowance of NOP certified vegetarian encapsulated supplement products will not be possible. As reported in the petition, the 2018 forecast for Pullulan capsules, the only capsule currently allowed in the “made with organic” category, was accurately reported at approximately 2.5 billion capsules. A conservative estimate of \$10 per bottle of 30 would represent an economic value of over \$825 million. Without the continued allowance of Pullulan, not only will there be a devastating economic impact to the organic dietary supplement sector but to the entire organic raw material supply chain that fills the capsules, including organic herb farmers throughout the world.

The addition of Pullulan at §205.605(a) will be **critical** to maintain the status of NOP certified encapsulated supplements. Notably, there is no other alternative for a vegetarian, organic-compliant

capsule. Thus, companies would be forced to either lose organic certification without changing their formula, or switch to a (non-vegetarian) gelatin capsule.

### Conclusion

The Organic Trade Association thanks the Handling Subcommittee for carefully considering the Organic Trade Association's petition to add Pullulan to the National List at 205.605(a) as a non-agricultural, non-synthetic substance that may be used in encapsulated dietary supplements labeled "**made with organic (specified ingredients or food group(s)).**"

Adding Pullulan to the National List is a timely and important action that will:

- ✓ Quickly address a new interpretation made by several accredited certifying agents in response to NOP's Classification of Materials Guidance (NOP 5033);
- ✓ Prevent widespread disruption and economically significant damage to the organic supplements sector and its associated organic supply chain;
- ✓ Bring the allowance of non-organic Pullulan under strict review of NOSB and the National List Sunset process;
- ✓ Support the commercial development of certified organic Pullulan that is highly sought by the supplement sector.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Gwendolyn Wyard  
Vice President, Regulatory and Technical Affairs  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

**Appendix A:** A guided tour of Pullulan through NOP's Decision Tree for Classification of Agricultural and Non-agricultural Materials (5033-2).

**1. Is the substance a mineral or bacterial culture as included in the definition of "non-agricultural substance" at section 205.2 of the USDA organic regulations?**

No. Pullulan is not a bacterial culture. Pullulan is best described as a microbial metabolite that is isolated from a culture medium or fermentation broth. It is a polysaccharide that is secreted extracellularly by the organism *Aureobasidium pullulans* into a culture medium from which it is then recovered and purified.

YES = Non-agricultural

No = Question Go to Question #2

**2. Is the Substance a microorganism (e.g., yeast, bacteria, fungi) or enzyme?**

No, Pullulan is not a microorganism. It is the product of a microorganism. More specifically, it is a microbial metabolite of a yeast-like fungus.

Yes = Non-agricultural

No = Go to Question #3

**3. Is the substance a crop or livestock product derived from crops or livestock?**

No, Pullulan is derived from a microorganism utilizing crop material as the substrate.

Yes = Go to Question #4

No = Non-agricultural

**GO TO SYNTHETIC / NON-SYNTHETIC DECISION TREE QUESTIONS:**

**Has the substance been processed to the extent that its chemical structure has been changed?**

No. At the completion of the fermentation process for Pullulan, the resulting broth consists of microbial cells and cellular debris, as well as the extracellular metabolites produced and excreted during the fermentation (e.g., pullulan). The microbial cells and cellular debris are first removed by microfiltration. The cell-free filtrate is then heat-sterilized.

The filtrate is then purified by a deionization process using an ion exchange resin to remove the salt and protein contaminants<sup>1</sup>. The deionized solution is concentrated to a solids content of about 12%, treated with activated carbon to remove pigments and other impurities by adsorption, and filtered using diatomaceous earth as a filter aid.

The filtrate is concentrated by evaporation to a solids content of about 30% and dried in a drum dryer. The dried pullulan is pulverized to a specified particle size and packed in sterilized polyethylene bags.

Pullulan is produced through a naturally occurring biological process (fermentation) and does not undergo a chemical change at any stage of the extraction or purification process. The purified substance is non-synthetic and has not been altered into a form that does not occur in nature. The processing aids used in the purification process are removed from the final substance such that they have no technical or functional effect in the final product. Furthermore, the microorganism as well as the substrate is not genetically modified and there are no ancillary substances added.

<sup>1</sup> Please note that some manufacturing descriptions found in research articles indicate that an additional step may be utilized prior to deionization using ion-exchange chromatography in which the filtrate is treated with an organic solvent (e.g., alcohol) to precipitate the pullulan. However, we have confirmed that Hayashibara Company's manufacturing process does not use this step, and no organic solvents are used during their production.

**Is the chemical change a result of naturally occurring biological processes such as fermentation or use of enzymes; or a result of mechanical/physical/biological process described under section 205.270(a)?**

N/A - Pullulan does not undergo a chemical change.

Based on the Classification of Materials Guidance and relevant Decision Trees, we believe that Pullulan is best classified as **non-agricultural** and **non-synthetic**.

We acknowledge that the Guidance does not perfectly address the spectrum of products produced via microbial fermentation. There is one question that asks if the substance is a bacterial culture and one that asks if the substance is a microorganism. The Decision Tree lacks a question about whether the substance is a product of a microorganism. In the Classification Guidance, wine is used as an example, and is classified as “agricultural” with the following explanation:

“Substance is a product of a microorganism and produced from agricultural media.”

A similar argument could be made for Pullulan. However, wine retains a large amount of the “agricultural media” in the finished product while Pullulan is recovered from the agricultural media and purified. The production of Pullulan is more analogous to citric acid or xanthan gum, both of which are classified as “non-agricultural” and appear on § 205.605(a) of the National List.

The use of the 5033-2 Decision Tree, when applied to fermentation by-products, does present some challenges. However, if there is uncertainty or lack of agreement about the agricultural/non-agricultural status of Pullulan, the Organic Trade Association would prefer to see Pullulan go through the NOSB process, be placed on the National List, and brought under the five-year Sunset Review cycle.

To address the concept that Pullulan could be both “non-agricultural” AND certified organic, please refer to **NOP Guidance 5033**:

**Section 4.4 - Eligibility for Organic Certification:**

This guidance does not determine the eligibility of a substance for organic certification. If a substance contains or is made up of agricultural ingredients and can meet the USDA organic production, handling, processing and labeling standards, it may be eligible to be certified under the USDA organic regulations.



April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP

**Docket:** AMS-NOP-18-0071

**RE: Celery Powder (Sunset 2021)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the 2021 Sunset Review of celery powder listed on 205.606 of the National List (7 CFR § 205.606 - non-organically produced agricultural products allowed as ingredients in or on process products labeled as organic).

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Organic Trade Association supports the continued listing of celery powder on the National List due to the fact that it is an essential ingredient used in processed organic meat products, and an organic alternative is not commercially available. Celery powder has been in use for over a decade as a "curing" agent in certain processed meat products as an alternative to sodium and potassium nitrate and nitrite. Since 2007, conventionally grown celery powder has been allowed for use in certified organic meat products. During this time, the organic processed meat industry has grown to an estimated \$150 million. As the demand for organic processed meats increases, the organic industry wants to replace the use of conventional celery powder with an organic alternative.

The Organic Trade Association is committed to help the industry innovate and proactively take steps to make this happen. In response to the information being requested and to help inform the fall 2019 review and vote on whether to relist celery powder for an additional five years, we offer the following comments.

**NOSB questions:**

***1. Is non-organic celery powder still essential for the production of ORGANIC processed meats?***

Yes. Celery powder continues to be the only natural source of nitrate allowed as a curing agent in processed certified organic meat. Organic forms of celery powder that meet the required functionality for processed organic meats are not commercially available, and we are not aware of other organic crops that can deliver the same attributes. Celery powder is being used by many organic meat and poultry processors producing organic meat products where the synthetic chemicals, nitrate and nitrite, are not permitted. If celery powder is removed from the National List, organic bacon and other cured organic meats will cease to exist. This would have a devastating impact on an already struggling organic livestock sector and its associated supply chain. Retaining celery

powder on the National List until an organic alternative is commercially available is important to organic livestock producers and it is important for consumers that choose to support organic practices.

Celery powder contains natural forms of nitrate that are converted to nitrite when added to meat, which, in turn, function as a curing agent for products such as organic ham, hot dogs and bacon. Additionally, “pre-converted” forms are used where an incubation with a nitrate reducing bacterium produces celery powders that are high in nitrite. The use of celery powder eliminates the need for conventional purified nitrate and nitrite curing ingredients. The essential function of nitrate/nitrite in processed meats is most importantly related to food safety with antimicrobial properties versus *Clostridium botulinum* and *Listeria monocytogenes* which are very important for protection of public health. Additionally shelf life is improved. Historically, manufacturers struggled to develop traditionally cured products such as ham, bacon and hot dogs that were accepted by consumers without nitrate from either natural or synthetic sources. These products failed the consumer testing, and consumers were not willing to pay more money for lower quality products. Celery powder was placed on the National List to fill a void while the organic sector ramped up organic meat production, and organic forms of celery powder were developed by manufacturers of natural celery powder.

The goal continues to be the commercial availability of organic celery powder. While the organic industry would like to see non-organic celery powder removed from the National List, an appropriate and effective alternative needs to be commercially developed first. The original petition for celery powder foresaw no difficulty in the future production of an organic version. To date, however, a viable, functional version has not been successfully developed. There are several technical and production issues that have proven to be barriers. For example, some of the alternative varieties that achieve the necessary nitrate levels impart too strong of a flavor in the meat products and would not be acceptable to consumers. Other factors include harvest and post-harvest conditions and the time and distance between harvest and processing, and how those variables impact nitrate level retention. The organic meat market also continues to be relatively small.

The greatest barrier perhaps is our ability to secure the additional funding we have been requesting to continue the research needed to address standardization of nitrogenous compounds in appropriate organic celery and/or other crop varieties and the time needed to complete extensive commercial testing on the potential alternatives that are being trialed. See Question #3 below.

2. ***Compared with growing celery for vegetable production, is increased use of synthetic nitrogen fertilizers required to produce source plants with enough nitrate for celery powder production?***  
The Organic Trade Association does not have this data. Regardless of the answer, we believe that the organic sector should be working toward developing an organic alternative that is consistent with organic principles. Our focus is on finding a solution that works in an organic production system, rather than gathering information on current conventional practices. The research driven by the Organic Celery Powder Working Group is focusing on organic variety selection and understanding the post-harvest impacts. If additional N is needed to produce organic source plants with enough nitrate for meat curing it should be done in an environmentally friendly way that supports organic principles (and complies with organic regulations). Regardless, the fate of excess



N is the same whether it is organic or synthetic. We are no better off unless we find an alternative systems-based strategy rather than input substitution, and that has been our approach.

**3. *Since 2015, what progress has been made on the production of organic celery for powder production?***

In the fall of 2015, the Organic Trade Association in collaboration with The Organic Center (TOC) convened the “National List Innovation Working Group” consisting of members interested in investing in applied research to identify alternatives to materials currently on the National List including organic, natural, or more compatible synthetics. The Working Group topics and participants vary, based on the needs and projects identified by the organic sector. Participants are investors in the development of alternatives, or by invitation of investors working in collaboration with public and private research institutions and extension personnel.

The first project (initiated by the Celery Powder Working Subgroup) was to find an organic alternative to non-organic celery powder. To begin to address the issues, the Working Group focused the first six months on establishing research partners, identifying funding opportunities and working in collaboration with the University of Wisconsin on the submission of a proposal for an Organic Research and Extension Initiative (OREI) planning grant. The planning grant proposal, submitted in early March 2016 and awarded later that year, helped to develop the roadmap of integrated research and extension activities needed to adequately address and overcome production challenges. An additional proposal to Farmers Advocating for Organics (FAFO) was also awarded.

The money from the OREI planning grant was used to identify the needed partners, crops, data and research questions that, in turn, informed the full \$2 million OREI grant that was applied for on January 19, 2017, and again in 2018. It was also used to fund the national stakeholder meeting held at the EcoFarm conference in, Asilomar, CA, in 2017. The FAFO grant money funded initial varietal testing in organic celery crops and broader testing of production-scale organic celery that were harvested in fall 2016. Unfortunately, both OREI funding proposals were not accepted, slowing research progress down in 2018.

Despite the setback, the efforts continue, not only for celery powder but for solutions that could potentially benefit all of agriculture. The working group research project sets out to identify potential varieties of organic crops that would meet the chemical specification needed for curing, while being easily incorporated into current crop rotation systems. It will also identify potential management protocols that need to be developed to achieve target nitrate levels in the curing crop to produce the required shelf life, prevent bacteria in the cured meat, and produce the desired flavor, color and texture in food. The project also aims to identify crops which could act as an incentive for expanding organic acreage, given the economic opportunity to partner with contractors that produce curing agents for organic processed meat products. Additionally, the project is investigating potential challenges and pitfalls associated with the production of a high nitrate crop, such as environmental concerns for run-off and excess nutrient leaching.

Identifying solutions for the organic processed meat industry’s need for a curing powder is extremely complex, and the timeline to develop an effective organic alternative does not happen overnight. It requires a very deliberate and well-researched road forward, it takes a multiregional,

multi-stakeholder coordinated effort, it requires substantial funding and it relies on consumer demand. Although the lack of funding has put the project behind schedule, we believe significant progress is being made and that the commitment and organization of the Celery Powder Working Group and our research partners has presented a solid model on how to best carry out the process for developing alternatives to a National List material. **See Attachment A.**

The Organic Center in partnership with the University of Wisconsin plans to submit an OREI proposal one last time. We will also be looking to other funding avenues and calling on industry to further invest in the development of an organic alternative to natural celery powder.

**4. *Are there strategies to produce organic celery powder that is standardized to consistently meet safety and other requirements of the meat processing industry? If not, is enough organic celery being produced to support the meat industry, why not?***

Yes, innovative strategies are underway. However, more research is needed in order to adequately answer this question. To the best of our knowledge, the organic celery grown in the United States is not grown for use as a natural curing agent. It is grown for fresh vegetable consumption, as a nutritional juice or supplement, or for seasoning. The varieties used for culinary and nutritional consumption are not the same as the ones used to produce nitrite. The question is whether there is enough organic celery of the correct variety being produced to support the meat industry. As far as we know, very little organic celery is being grown at commercial scale for the meat industry, but research efforts and trials are underway.

**5. *Are there commercially available agriculturally produced alternatives to celery powder? What is your experience with them? Are they organic? Does their use vary by application? Are they more effective in one application compared to another?***

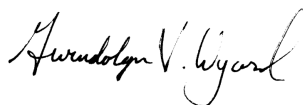
There are other vegetables and minerals which contain natural nitrates including beets, Swiss chard, spinach and sea salt. Although each has its benefits and challenges, none are an identical equivalent to natural celery powder in quality, form and function. The most promising of the potential alternatives that we are aware of is Swiss chard. More research and testing are needed.

**6. *What is the latest information on the human health risks of nitrate and nitrites present in processed meats from either synthetic or plant-based sources?***

To the best of our knowledge, the source of the nitrate/nitrite (synthetic vs. plant-based) does not make a difference. Nitrate and nitrite are simple inorganic ions and the source has no impact on the chemical properties. See the attached research article by King et. al. with respect to on set of food safety parameters (**Attachment B**). We have also attached several other papers representing the latest information about nitrate/nitrite and human physiology (**See the list of references below**). Based on our review, we are unaware of any new information since the last Sunset Review. We would like to defer to the expert panel to answer this question completely.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Gwendolyn Wyard  
Vice President, Regulatory and Technical Affairs  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

**Attachment A: Developing Natural and Organic Alternatives**

**Attachment B:** King, A. M., K. A. Glass, A. L. Milkowski and J. J. Sindelar (2015). "Comparison of the Effect of Curing Ingredients Derived from Purified and Natural Sources on Inhibition of *Clostridium perfringens* Outgrowth during Cooling of Deli-Style Turkey Breast." Journal of Food Protection **78**(8): 1527-1535.

**Additional Helpful References**

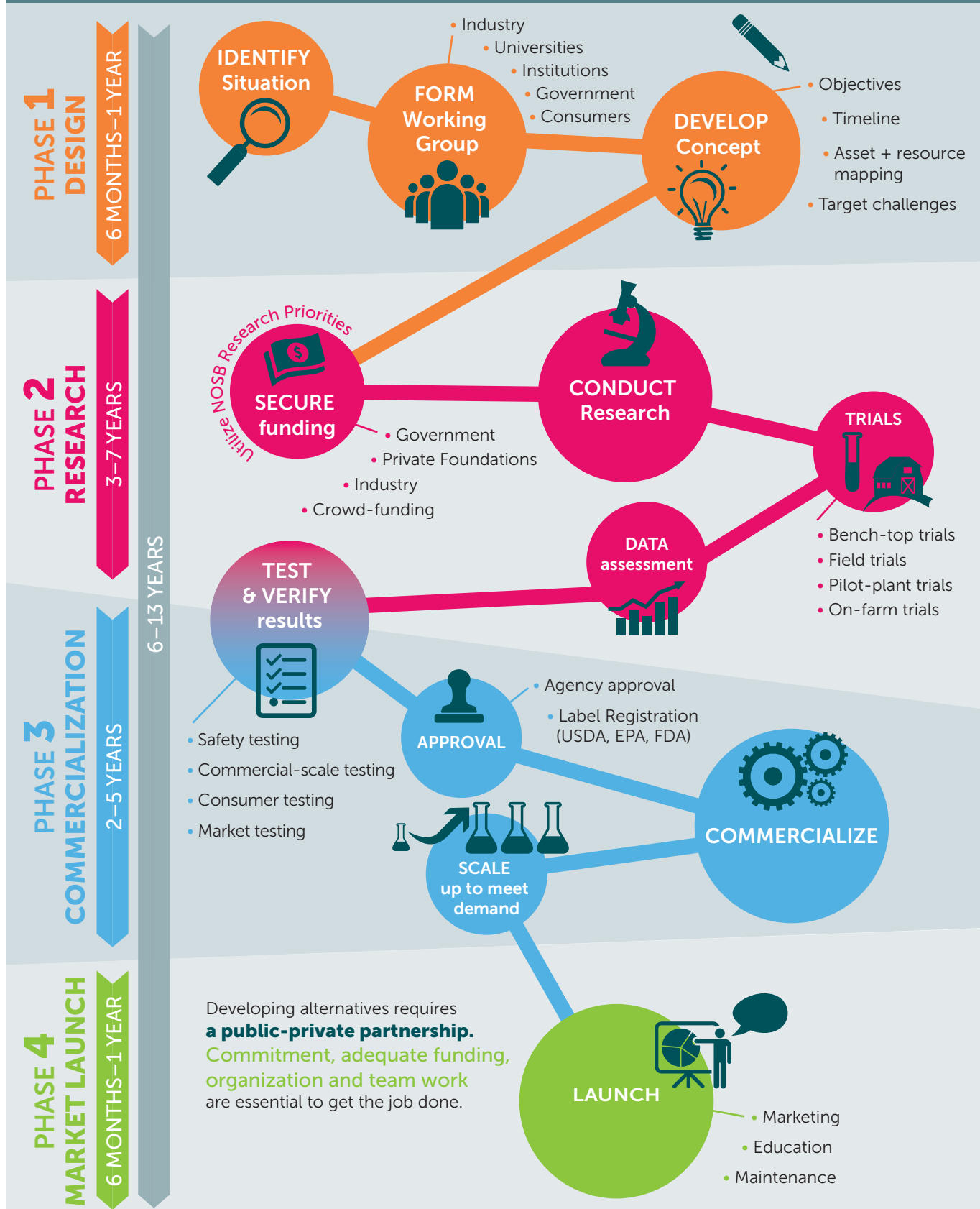
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# A model for developing ORGANIC AND NATURAL INPUTS for use in organic food and farming



## Attachment B

Journal of Food Protection, Vol. 78, No. 8, 2015, Pages 1527–1535

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# Comparison of the Effect of Curing Ingredients Derived from Purified and Natural Sources on Inhibition of *Clostridium perfringens* Outgrowth during Cooling of Deli-Style Turkey Breast

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MS 14-491: Received 13 October 2014/Accepted 27 March 2015

## ABSTRACT

The antimicrobial impact of purified and natural sources of both nitrite and ascorbate were evaluated against *Clostridium perfringens* during the postthermal processing cooling period of deli-style turkey breast. The objective of phase I was to assess comparable concentrations of nitrite (0 or 100 ppm) and ascorbate (0 or 547 ppm) from both purified and natural sources. Phase II was conducted to investigate concentrations of nitrite (50, 75, or 100 ppm) from cultured celery juice powder and ascorbate (0, 250, or 500 ppm) from cherry powder to simulate alternative curing formulations. Ground turkey breast (75% moisture, 1.2% salt, pH 6.2) treatments were inoculated with *C. perfringens* spores (three-strain mixture) to yield 2.5 log CFU/g. Individual 50-g portions were vacuum packaged, cooked to 71.1°C, and chilled from 54.4 to 26.7°C in 5 h and from 26.7 to 7.2°C in 10 additional hours. Triplicate samples were assayed for growth of *C. perfringens* at predetermined intervals by plating on tryptose-sulfite-cycloserine agar; experiments were replicated three times. In phase I, uncured, purified nitrite, and natural nitrite treatments without ascorbate had 5.3-, 4.2-, and 4.4-log increases in *C. perfringens*, respectively, at 15 h, but <1-log increase was observed at the end of chilling in treatments containing 100 ppm of nitrite and 547 ppm of ascorbate from either source. In phase II, 0, 50, 75, and 100 ppm of nitrite and 50 ppm of nitrite plus 250 ppm of ascorbate supported 4.5-, 3.9-, 3.5-, 2.2-, and 1.5-log increases in *C. perfringens*, respectively. In contrast, <1-log increase was observed after 15 h in the remaining phase II treatments supplemented with 50 ppm of nitrite and 500 ppm of ascorbate or ≥75 ppm of nitrite and ≥250 ppm of ascorbate. These results confirm that equivalent concentrations of nitrite, regardless of the source, provide similar inhibition of *C. perfringens* during chilling and that ascorbate enhances the antimicrobial effect of nitrite on *C. perfringens* at concentrations commonly used in alternative cured meats.

*Clostridium perfringens* is a gram-positive, nonmotile, anaerobic bacillus with square ends that forms heat stable spores (14). This organism is one of the most widely distributed bacteria and has been isolated from soil, water, intestines, food, and air. To develop illness, a person must consume 10<sup>8</sup> to 10<sup>9</sup> vegetative cells. Upon exposure to the gastrointestinal environment, cells sporulate and release an enterotoxin, causing symptoms that include abdominal pain, nausea, and diarrhea but that generally subside after 1 to 2 days (8, 14). Although foodborne illness caused by *C. perfringens* results in very few hospitalizations or deaths, it causes an estimated nearly 1 million cases of illness in the United States each year (27).

As a ubiquitous organism, *C. perfringens* is often a component of the normal intestinal microflora of healthy animals and humans, which can lead to contamination of meat products due to fecal cross-contamination during processing. In one U.S. study (37), 1.6% of raw whole muscle and 48.7% of raw ground or emulsified meats were

positive for the presence of *C. perfringens*, and 5.3% of the ground or emulsified samples were positive for *C. perfringens* spores. Cooked meat provides a very suitable growth environment in which *C. perfringens* can have a remarkably short generation time of less than 10 min at 43 to 47°C; in general, growth can occur at 12 to 50°C (29).

To mitigate the risk of *C. perfringens* germination and outgrowth during cooking and chilling in meat products, the U.S. Department of Agriculture (USDA) Food Safety Inspection Service (FSIS) has established controlled chilling procedures (43), and performance standards have been published in Appendix B of the FSIS *Performance Standards for the Production of Certain Meat and Poultry Products* (42). Appendix B states that maximum internal temperatures of uncured products shall not remain between 54.4°C (130°F) and 26.7°C (80°F) for more than 1.5 h nor between 26.7°C (80°F) and 4.4°C (40°F) for more than 5 h. Cured products, defined as those with a minimum 100 ppm of ingoing nitrite, are allowed a longer chilling period. According to Appendix B, maximum internal temperatures of these products must not remain between 54.4°C (130°F) and 26.7°C (80°F) for greater than 5 h nor between 26.7°C (80°F) and 7.2°C (45°F) for an

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additional 10 h. These chilling requirements were designed to limit outgrowth of *C. perfringens* to a maximum 1-log increase during postthermal processing cooling.

Traditionally, cured meats have been prepared using sodium nitrite, which has been well documented to affect *C. perfringens* outgrowth (22, 25, 26). In one study (26), pork was cured with various concentrations of nitrite, inoculated with 11 spores per gram *C. perfringens*, and held at 1 to 4°C for 2 weeks, 13°C for 2 weeks, and 26°C for 6 weeks, and *C. perfringens* was enumerated after 4, 6, 8, and 10 weeks. Higher concentrations of nitrite decreased the percentage of inoculated spores recovered from the treatments. After 10 weeks, in treatments with 0, 50, 100, 150, and 200 ppm of sodium nitrite, 38.0, 12.0, 5.4, 3.6, and 0.9% of inoculated spores, respectively, were recovered. Thus, currently used concentrations (maximum allowed) of sodium nitrite in the United States, 156 ppm for comminuted products and 200 ppm for immersion cured, massaged, or pumped products regulated by the USDA, are well supported and representative of concentrations needed to provide effective control of *C. perfringens*, and published reports support recommendations for this generally used concentration near the maximum allowable ingoing concentrations (41).

Because of increased consumer demand for preservative-free “clean label” processed meat options, alternative cured meats are widely available and are produced without direct addition of purified (or synthetic) sodium nitrite, which is considered a preservative. Alternative cured meats can be made with natural sources of nitrite, such as that derived by using specific starter cultures, such as *Staphylococcus carnosus*, to reduce naturally occurring nitrate in celery powder (30, 32). However, these processing techniques result in lower concentrations of nitrite in these products than in traditionally cured meats (30). Because of nitrite’s contribution to food safety, these lower concentrations prompt the question of whether alternative cured products are equivalent to their traditionally cured counterparts from a microbiological safety perspective. In a study of commercially prepared alternative cured, natural, and organic samples, Jackson et al. (16) reported decreased *C. perfringens* inhibition in 7 of 10 frankfurter brands, six of seven ham brands, and four of nine bacon brands relative to traditionally cured controls. However, the nitrite concentrations measured at the time of testing were variable (e.g., <1 to >65 ppm of residual nitrite in two brands of commercial frankfurters). This variation could be explained by differences among manufacturers in the initial amount of nitrite added to the formulation or the age of the products at the time of testing, as differences in nitrite concentrations during the storage shelf life would be expected as the nitrite depletes over time. Similar results have been observed for *Listeria monocytogenes* growth and *Clostridium botulinum* growth and toxin production in alternative cured meats compared with controls traditionally cured with purified sodium nitrite (28, 44). In none of these studies was an attempt made to standardize the nitrite concentrations or to add cure accelerators to the formulations incorporating nitrite from natural sources. Currently, products cured with nitrite from natural sources frequently contain less than 100

TABLE 1. Base formulation for manufacture of deli-style turkey breast<sup>a</sup>

Ingredient	%	Amt (g)
Turkey breast	100.0	2,268
Water plus ice (50% + 50%)	20.0	454
Salt	1.4	31.8
Modified food starch	2.0	45.4
Sodium tripolyphosphate	0.4	9.1
Total		2,807.7

<sup>a</sup> Formulated ingredients reported as ingoing percentage based on poultry weight.

ppm of nitrite and do not qualify for the same extended cooling as do meats cured with the direct addition of sodium nitrite (1).

Although recent work suggests that both purified nitrite and nitrite from natural sources have similar antimicrobial activity against *L. monocytogenes* and *C. perfringens* when used at comparable concentrations, equivalency against *C. perfringens* has not been thoroughly evaluated during extended chilling following the guideline in Appendix B (10, 11). The overall objective of this study was to determine the antimicrobial impact of purified nitrite and nitrite from natural sources for the control of *C. perfringens* outgrowth during a 15-h biphasic chilling period in deli-style turkey breast. The objective of phase I was to determine whether purified nitrite and ascorbate and nitrite and ascorbate from natural sources, used at equal concentrations, provided similar inhibition of *C. perfringens*. The objective of phase II was to evaluate the antimicrobial impact of natural nitrite and ascorbate at lower concentrations representative of currently produced alternative cured meats.

## MATERIALS AND METHODS

**Spore preparation.** Three strains of *C. perfringens* (ATCC 13124, 12915, and 12916) were grown individually using a modification of procedures outlined by Kennedy et al. (18) to induce sporulation. To enumerate spores, an aliquot of each strain was heat shocked for 20 min at 75°C to kill vegetative cells, and appropriate serial dilutions were made in 0.1% peptone and plated on tryptose-sulfite-cycloserine agar (TSC; Oxoid Ltd., Basingstoke, UK) without egg yolk. Once agar was solidified, plates were overlaid with 8 to 10 ml of TSC and incubated anaerobically (AnaeroPack System 7.0-liter jar with Pack-Anaero Anaerobic Gas Generating System, Mitsubishi Gas Chemical Co., Tokyo, Japan) for 24 h at 35°C. Spore crops were stored in 0.85% saline at –20°C until spore cocktails were prepared for individual experiments. For each meat inoculation, a fresh inoculum was prepared by mixing equivalent levels of the three strains to provide approximately 2.5 log CFU/g of poultry.

**Meat preparation and inoculation.** Frozen turkey breasts obtained from a commercial supplier were thawed and stored at 2.2 to 4.4°C until used (within 4 days). Turkey was ground through a 4.76-mm-whole-size plate attached to a grinder (model 4732, Hobart Corp., Troy, OH). The base formulation for the model turkey breast is given in Table 1. For each treatment, nonmeat ingredients were dissolved in distilled water. To ensure complete solution in the brine, the ingredients were added in the following order: sodium tripolyphosphate, salt, modified food starch, nitrite, and ascorbate.

TABLE 2. Definitions of treatments used to evaluate the effect of equal concentrations of purified and natural sources of nitrite and ascorbate (cure accelerator) for inhibiting outgrowth of *C. perfringens* during a 15-h cooling period (phase I)

Treatment <sup>a</sup>	Ingredient <sup>b</sup>	
	100 ppm of nitrite	500 ppm of ascorbate
1: uncured	0	0
2: SA	0	0.0547% sodium ascorbate
3: SN	0.16% purified curing salt	0
4: PCN	0.44% cultured celery juice powder	0
5: SN + SA	0.16% purified curing salt	0.0547% sodium ascorbate
6: PCN + CP	0.44% cultured celery juice powder	0.32% cherry powder

<sup>a</sup> Uncured, no nitrite from any source; SN, purified sodium nitrite from curing salt containing 6.25% sodium nitrite; PCN, natural preconverted nitrite from cultured celery juice powder containing 2.25% sodium nitrite equivalent; SA, purified sodium ascorbate from pure chemical source; CP, natural ascorbate from cherry powder containing 12% ascorbate.

<sup>b</sup> Concentration (ppm) added based on concentration provided in ingredient specifications and percentage of formulation on poultry weight basis.

The fresh ground turkey and brine were mixed in a mixer (model AS 200, Hobart Corp.) for 3 min, and then approximately 800 g of batter was removed to be packaged as uninoculated samples to be used for analysis of residual nitrite and proximate composition and temperature monitoring throughout processing. The remaining batter was inoculated with the *C. perfringens* spore mixture to yield approximately 2.5 log CFU/g of poultry.

For each sample, 50-g portions of poultry batter were vacuum sealed in oxygen- and moisture-impermeable bags (3 mil high barrier; oxygen transmission rate of 50 to 70 cm<sup>3</sup>/m<sup>2</sup>, 24 h at 25°C and 60% relative humidity; water transmission rate of 6 to 7.5 g/m<sup>2</sup>, 24 h at 25°C and 90% relative humidity; UltraSource, Kansas City, MO) using a vacuum packaging machine (Multivac AGW, Sepp Haggemuller KG, Wolfertschewenden, Germany). To ensure consistent temperature profiles for all samples, the packages were flattened to approximately 3 mm thickness, similar to procedures reported by Kalinowski et al. (17). Samples were held overnight at 4°C until used for cooking and cooling.

**Ingredients and treatment combinations.** This study was conducted in two phases. Phases I and II comprised 6 and 10 treatments, respectively (Tables 2 and 3). Ingredient concentrations were determined from the manufacturer's specifications provided for that ingredient and calculated based on a sodium nitrite or sodium ascorbate basis to achieve the target concentration in each treatment. In phase I, purified ingredients were sodium nitrite from curing salt (6.25% sodium nitrite, 93.75% sodium chloride; Sure Cure, Excalibur Seasoning Company, Pekin, IL) and sodium ascorbate (Excalibur Seasoning Company). In both phases, natural nitrite was in the form of cultured celery juice powder (2.25% sodium nitrite equivalent; Accel 2000, Kerry Ingredients and Flavours, Beloit, WI), and natural ascorbate was in the form of cherry powder (12% ascorbic acid; VegStable 515, Florida Food Products, Eustis, FL).

**Cooking, cooling, and sampling.** Before cooking, a thermocouple (digital thermometer and type K probe, Thermo Fisher Scientific, Waltham, MA) was inserted into each of three representative packages through a rubber septum to monitor the internal temperature during cooking and cooling. Temperature data loggers (iButton Temperature Logger DS1922T, Maxim Integrated, San Jose, CA) were placed in the incubator and in four uninoculated packages to continuously record ambient air and meat temperatures during cooking and cooling. Packages were attached to removable incubator racks with small binder clips and immersed

in a 75°C water bath until the internal temperature of representative packages reached 71°C, which heat shocked the spores and killed any vegetative cells. The time to target cook temperature (approximately 5 min) was manually recorded. Cooked samples were immediately placed into a programmable air incubator (model BOD50A16 incubator, Revco, Thermo Electron Corp., Asheville, NC; model UP550 program controller, Yokogawa Electric Corporation, Tokyo, Japan) and held at 60°C until all samples were loaded into the incubator (maximum of 20 min). This temperature is outside the growth range for the organism and was manually monitored until cooling began. The incubator cooling program was set to cool the product in a biphasic design that matched the maximum cooling time and temperatures for cured products outlined in FSIS Appendix B (42) (54.4 to 26.6°C over 5 h and 26.6 to 7.2°C over 10 h) (Figs. 1 and 2).

TABLE 3. Definitions of treatments used to evaluate the effect of combinations of natural sources of nitrite and ascorbate (cure accelerator) for inhibiting outgrowth of *C. perfringens* during a 15-h cooling period (phase II)

Treatment <sup>a</sup>	Ingredient <sup>b</sup>			
	ppm		%	
	Nitrite <sup>c</sup>	Ascorbate <sup>d</sup>	PCN	CP
1: 0/0	0	0	0	0
2: 50/0	50	0	0.22	0
3: 50/250	50	250	0.22	0.21
4: 50/500	50	500	0.22	0.41
5: 75/0	75	0	0.34	0
6: 75/250	75	250	0.34	0.21
7: 75/500	75	500	0.34	0.41
8: 100/0	100	0	0.45	0
9: 100/250	100	250	0.45	0.21
10: 100/500	100	500	0.45	0.41

<sup>a</sup> Treatments defined by concentrations of natural nitrite and ascorbate in formulation (ppm of nitrite/ppm of ascorbate).

<sup>b</sup> Concentration (ppm) added based on concentration provided in ingredient specifications and calculated on poultry weight basis.

<sup>c</sup> Naturally generated nitrite from cultured celery juice powder (PCN) containing 2.25% sodium nitrite equivalent.

<sup>d</sup> Natural ascorbate from cherry powder (CP) containing 12% ascorbate.

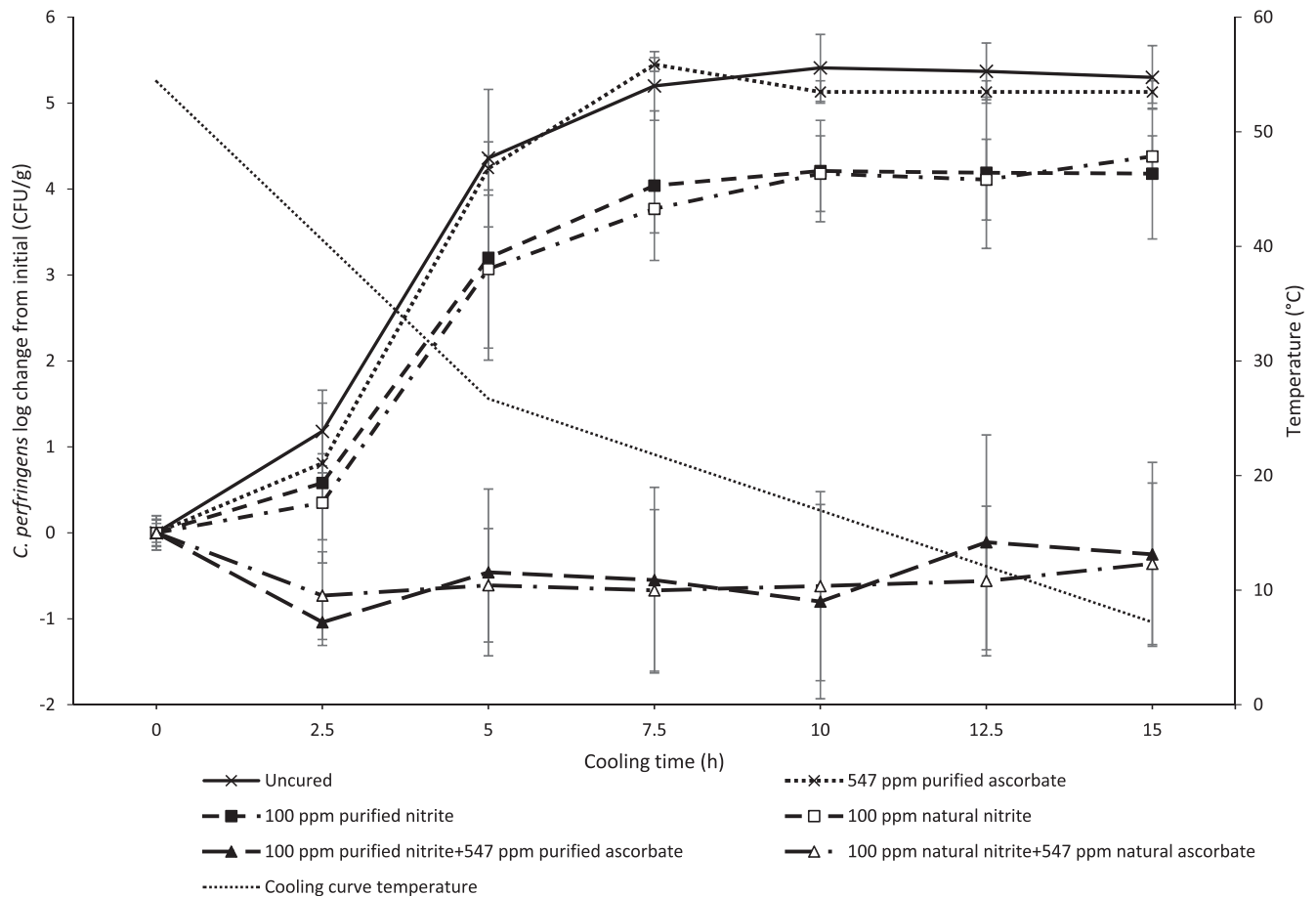


FIGURE 1. Change (sampling point minus initial) in counts of *C. perfringens* during 15 h of cooling of ground turkey breast formulated with purified nitrite or nitrite from cultured celery juice powder plus purified ascorbate or ascorbate from cherry powder (phase I). Data points represent the mean of three independent replications, and error bars represent the standard deviation.

Triplicate samples of each treatment were removed at 0, 2.5, 5, 7.5, 10, 12.5, and 15 h for phase I and 0, 5, 10, and 15 h for phase II. From each 50-g sample, a representative 25-g portion was removed and diluted with 50 ml of Butterfield's phosphate buffer and homogenized for 2 min in a lab blender (Stomacher 400, A. J. Seward, London, UK). Serial dilutions of homogenates were plated onto TSC plates with an 8- to 10-ml TSC agar overlay and incubated anaerobically at 35°C for 24 h. Each set of experiments was replicated three times with different batches of poultry and spore inocula.

**Chemical analysis.** Triplicate uninoculated samples for each treatment were analyzed for moisture (5 h, 100°C vacuum oven method), pH (measured in a slurry prepared by homogenizing 10 g with 90 ml deionized water), NaCl (measured as percentage of  $\text{Cl}^-$ ,  $\text{AgNO}_3$  potentiometric titration; DL22 food and beverage analyzer, Mettler, Columbus, OH), and water activity ( $a_w$ ; AquaLab 4TE water activity meter, Decagon, Pullman, WA) (2, 33). Residual nitrite was analyzed in duplicate uninoculated meat samples from each treatment, which were frozen at -80°C immediately after cooking. A dedicated high-performance liquid chromatography instrument was used to quantify residual nitrite according to modifications of methods previously reported (6, 20). Samples were powdered in liquid nitrogen and stored at -80°C until analysis. Five grams of sample was homogenized with 45 ml of phosphate buffer (100  $\mu\text{M}$ , pH 7.4) and then split into two slurries and centrifuged at  $10,000 \times g$  at 4°C for 5 min (Avanti J-E with JA-25.50 rotor, Beckman Coulter, Indianapolis, IN). After

centrifugation, 400  $\mu\text{l}$  of supernatant from each slurry and 400  $\mu\text{l}$  of methanol were transferred into a 1.5-ml snap cap centrifuge tube. This mixture was vortexed on high speed for 3 to 5 s and allowed to sit at 4°C for at least 10 min to allow the methanol to break down any remaining protein in the sample. The samples were then centrifuged for 8 min at  $13,000 \times g$  at 4°C (Eppendorf model 5424 centrifuge, Brinkmann Instruments, Westburg, NY), and the supernatant was transferred into a new 1.5-ml snap cap tube for quantification using the ENO-20 NOx analyzer (EiCom USA, San Diego, CA). This extraction process yielded four subsamples per treatment, whose residual concentrations were measured using the ENO-20 NOx analyzer and data processor (EPC-500, EiCom USA), and the data were analyzed with PowerChrom (version 2.3, eDAQ, Denistone East, New South Wales, Australia). Analyzer settings were 0.22 ml/min for the reactor pump, 0.66 ml/min for the carrier pump, and an injection volume of 50  $\mu\text{l}$ . Standards were made from purified  $\text{NaNO}_2$  powder diluted with MilliQ water (Millipore, Billerica, MA) into 0, 20, 40, 60, 80, and 100  $\mu\text{M}$   $\text{NaNO}_2$  solutions. Standards and samples were analyzed following the same procedure to determine the concentration of  $\text{NaNO}_2$ .

**Statistical analysis.** Three independent replications were performed for each of the two phases. Data were compared using an analysis of variance and the mixed models procedure of the Statistical Analysis System (SAS Institute, Cary, NC). The model included fixed main effects of treatment (phase I,  $n = 6$ ; phase II,  $n = 10$ ) and replication ( $n = 3$ ). The random effect was the interaction of treatment by replication. All least significant

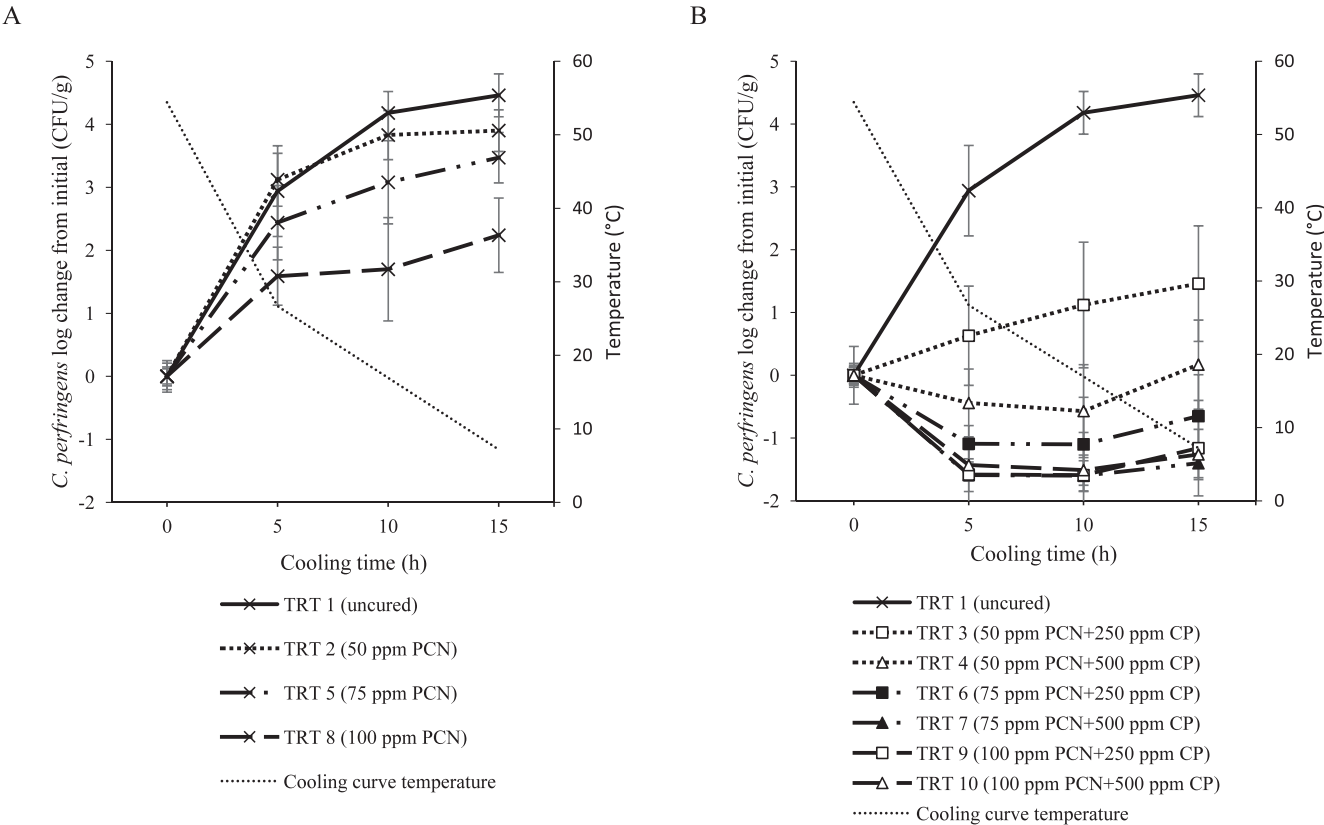


FIGURE 2. Change (sampling point minus initial) in counts of *C. perfringens* during 15 h of cooling of ground turkey breast (phase II). (A) Treatments with natural nitrite from cultured celery juice powder (PCN). (B) Treatments with PCN and natural ascorbate from cherry powder (CP). Data points represent the mean of three independent replications, and error bars represent the standard deviation.

differences were found using the Tukey-Kramer pairwise comparison method with significance determined at  $P < 0.05$ .

### RESULTS AND DISCUSSION

Measurements of moisture, salt, pH, and  $a_w$  confirmed consistency of formulation and manufacturing among treatments. All treatments in phase I had means ( $\pm$  standard deviations) of  $74.2\% \pm 1.8\%$  moisture,  $1.31\% \pm 0.14\%$  NaCl,  $6.31 \pm 0.05$  pH, and  $0.981 \pm 0.003$   $a_w$ . Residual nitrite was analyzed in only the four treatments that included nitrite in the formulations; residual nitrite was  $73.1 \pm 15.7$  and  $78.6 \pm 7.0$  ppm for 100 ppm of ingoing nitrite from purified and natural sources, respectively. When purified or natural sources of ascorbate was added to formulations, the residual nitrite was  $67.8 \pm 17.1$  and  $64.9 \pm 16.3$  ppm, respectively. However, the addition of ascorbate did not reduce ( $P > 0.05$ ) residual nitrite concentrations compared with treatments without ascorbate.

Proximate analyses for phase II treatments were similarly consistent, with  $76.6\% \pm 0.4\%$  moisture,  $1.19\% \pm 0.03\%$  NaCl, pH  $6.22 \pm 0.03$ , and  $0.980 \pm 0.002$   $a_w$ . Phase II results indicated that residual nitrite concentration was dependent upon ingoing nitrite concentration but was not affected by presence or concentration of ascorbate (Table 4). Treatments with 50 ppm of ingoing nitrite had 37.7 to 38.7 ppm of residual nitrite, treatments with 75 ppm of ingoing nitrite had 54.7 to 59.6 ppm of residual nitrite, and treatments with 100 ppm of ingoing nitrite had 77.2 to 80.5 ppm of residual nitrite. The residual nitrite results for

both phases indicated that the cure accelerating function of ascorbate did not have an appreciable effect on nitrite depletion during the time allowed in this product and process. In commercial meat products, less than 50% of the originally formulated nitrite is usually recoverable after thermal processing, and cure accelerators significantly affect residual nitrite concentrations (19, 23, 31). However, in the present study the artificially short time these products were

TABLE 4. Residual nitrite measured in phase II poultry samples containing various concentrations of nitrite from preconverted celery powder and ascorbate from cherry powder

Treatment <sup>a</sup>	Residual nitrite <sup>b</sup>
1: 0/0	NT
2: 50/0	$38.7 \pm 3.2$ c
3: 50/250	$37.9 \pm 3.6$ c
4: 50/500	$37.7 \pm 3.3$ c
5: 75/0	$59.6 \pm 8.9$ B
6: 75/250	$59.1 \pm 6.0$ B
7: 75/500	$54.7 \pm 4.1$ B
8: 100/0	$80.5 \pm 5.0$ A
9: 100/250	$78.9 \pm 6.3$ A
10: 100/500	$77.2 \pm 7.5$ A

<sup>a</sup> Treatments defined by concentrations of natural nitrite from preconverted celery powder and natural ascorbate from cherry powder (ppm of nitrite/ppm of ascorbate).

<sup>b</sup> Values are mean  $\pm$  standard deviation. Means with the same letter are not significantly different ( $P > 0.05$ ). NT, not tested.



exposed to high temperatures for thermal processing (approximately 5 min) limited the extent to which nitrite depletion occurred and minimized the difference in depletion between treatments with ascorbate and those without, which would be more pronounced after a longer commercial cooking process.

Throughout chilling, measurements verified that the maximum range of sample temperatures in the incubator was 3°C, although the temperatures generally were within 1°C. The individual sample temperatures tracked the prescribed chilling curve and target temperature, and all individual samples reached the target temperatures of 26.6°C at  $5.0 \pm 0.26$  h and of 7.2°C at  $15.0 \pm 0.25$  h. Changes in *C. perfringens* populations from the initial level versus temperature over 15 h are shown in Figure 1 (phase D). Approximately 2.5 log CFU/g was recovered after the initial cooking (heat shock) and before chilling. Recovered populations after heat shocking were not different among treatments ( $P > 0.05$ ), indicating the consistency of the inoculation procedure. As expected, the uncured control provided a suitable growth environment for this organism, with a  $4.36 \pm 0.80$ -log increase observed within the first 5 h when the meat temperature was in the known optimal growth range for *C. perfringens*. The treatment containing purified ascorbate in the absence of nitrite supported growth similar to that of the control ( $4.24 \pm 0.31$ -log increase;  $P > 0.05$ ), confirming that ascorbate alone did not inhibit *C. perfringens*. In both treatments containing 100 ppm of nitrite, either purified or from natural sources, but without a cure accelerator, *C. perfringens* grew similarly, and growth was similar to that in the uncured control ( $P > 0.05$ ), with only a slightly greater inhibition (<1-log difference) than in the control. As for the control and ascorbate-only treatments, the majority of growth occurred within the first 7.5 h, with populations remaining relatively unchanged ( $P > 0.05$ ) from 7.5 to 15 h of chilling, when temperatures ranged from 20.2 to 7.2°C according to the chilling cycle. In contrast, the treatments containing 100 ppm of nitrite plus 547 ppm of ascorbate, either purified or from natural sources, limited the outgrowth of *C. perfringens* throughout this chilling period to less than 1 log CFU/g, and final populations were not significantly different from the initial populations ( $P > 0.05$ ). Purified nitrite plus ascorbate and natural nitrite plus ascorbate resulted in decreases of  $0.25 \pm 1.07$  and  $0.36 \pm 0.94$  log CFU/g, respectively. These data confirm that when used at equal concentrations, the purified forms and natural forms of nitrite and ascorbate provided equivalent microbial inhibition ( $P < 0.05$ ). Furthermore, the combination of 100 ppm of nitrite and 547 ppm of ascorbate provided significantly greater inhibition than did 100 ppm of nitrite alone ( $P < 0.05$ ).

Although no differences were observed in the antimicrobial effect of 100 ppm of nitrite and 547 ppm of ascorbate derived from natural or purified sources, further testing was necessary to validate the safety of products made with lower concentrations, which are relevant to current industry practice. Although conventionally cured meats commonly contain both a cure accelerator (e.g., ascorbate or erythorbate) and >100 ppm of sodium nitrite, alternative cured meats

often are made with natural sources of nitrite, which provide <100 ppm of ingoing sodium nitrite, and without a curing accelerator such as ascorbate (32, 34, 35). The hypothesis of phase II of this study was that natural nitrite and ascorbate used at concentrations representative of current alternative curing formulations could inhibit *C. perfringens* outgrowth during the 15-h biphasic chilling process outlined in FSIS Appendix B (42).

Changes in *C. perfringens* populations over time versus temperature are presented in Figure 2, with the 0 value on the y-axis representing the populations recovered after heat shock. Populations of *C. perfringens* after heat shocking were not different among treatments ( $P > 0.05$ ). Results from phase II confirmed a >4-log increase of *C. perfringens* in the uncured control, whereas nitrite alone, although concentration dependent, provided limited additional inhibition of *C. perfringens* outgrowth at 50, 75, or 100 ppm (Fig. 2A). Nitrite had a dose-dependent effect, and as nitrite concentration increased *C. perfringens* growth decreased; however, even 100 ppm of ingoing nitrite alone was insufficient to limit outgrowth to <1 log CFU/g. After 15 h of chilling, growth in the 50 ppm of nitrite treatment was not significantly different from that in the uncured control ( $3.90 \pm 0.33$ -log and  $4.46 \pm 0.34$ -log increases, respectively) ( $P > 0.05$ ). Growth in the 75 ppm of nitrite treatment ( $3.47 \pm 0.40$ -log increase) was significantly less than that in the uncured control ( $P < 0.05$ ) but not different from that in the 50 ppm treatment; whereas growth in the 100 ppm of nitrite treatment ( $2.24 \pm 0.59$ -log increase) was significantly lower than that of the control and the 50 and 75 ppm of nitrite treatments ( $P < 0.05$ ).

Supplementing with 50 ppm of nitrite treatments with 250 ppm of ascorbate increased the inhibition of *C. perfringens* growth compared with the uncured control ( $P < 0.05$ ; Fig. 2B). The only nitrite plus ascorbate treatment that allowed *C. perfringens* growth relative to the initial level was 50 ppm of nitrite plus 250 ppm of ascorbate, which supported a  $1.46 \pm 0.92$ -log increase during the entire chilling period. However, increasing ascorbate concentrations to 500 ppm in combination with 50 ppm of nitrite limited growth to <1 log CFU/g during chilling. The populations of *C. perfringens* decreased in all of the remaining treatments containing  $\geq 75$  ppm of nitrite plus  $\geq 250$  ppm of ascorbate during chilling ( $P < 0.05$ ). *C. perfringens* levels in treatments with 75 ppm of nitrite plus 250 or 500 ppm of ascorbate decreased  $0.65 \pm 0.66$  and  $1.4 \pm 0.23$  log CFU/g, respectively, and levels in treatments with 100 ppm of nitrite plus 250 or 500 ppm of ascorbate decreased  $1.16 \pm 0.76$  and  $1.26 \pm 0.40$  log CFU/g, respectively.

These results confirmed that equivalent concentrations of nitrite, regardless of the source, provided similar inhibition of *C. perfringens* during chilling and that greater inhibition occurred when nitrite was combined with ascorbate. However, these results also suggests that 100 ppm of sodium nitrite alone, excluding a cure accelerator such as ascorbate or erythorbate, may be insufficient to prevent *C. perfringens* outgrowth even when the cooling profile of a high-moisture turkey product meets the extended chilling option of FSIS Appendix B for a cured product.

The Perfringens Predictor model, part of the ComBase online modeling system ([http://modelling.combase.cc/ComBase\\_Predictor.aspx](http://modelling.combase.cc/ComBase_Predictor.aspx)), was used to estimate that an uncured product with pH 6.2 and 1.2% salt at chilling temperatures similar to those used in this study would allow for a 3.8-, 4.7-, and 5-log increase in *C. perfringens* at 5, 7.5, and 15 h of cooling, respectively. Under the same product parameters and chilling profile, the model predicted that a cured product with 100 ppm of ingoing sodium nitrite would support a 2.5-, 3.4-, and 3.6-log increase by 5, 7.5, and 15 h, respectively. The model accurately predicted the observed growth in this study for a product with 6.2 pH, 1.2% salt, and with or without 100 ppm of nitrite but did not take into consideration the synergistic effect of ascorbate during chilling.

The uncured treatment results differed slightly between phase I and phase II, phase I resulting in 0.84-log greater growth than phase II for the uncured product. Similarly, 100 ppm of nitrite alone in phase I treatments permitted 1.94- to 2.14-log greater increases in *C. perfringens* than did 100 ppm of nitrite alone in phase II. Overall, product composition was comparable between the two phases, although a slightly lower pH in phase II (6.2 versus 6.3) could have had a limiting effect on total outgrowth. Gibson and Roberts (9) studied the effects of pH on *C. perfringens* and found that at pH 6.8 and 6.2, growth was observed in 1 week at 15°C in broth, whereas decreasing the pH to 5.6 inhibited growth until 4 weeks. Although chilling procedures in the present study were the same for both phases, heavier loading of the incubator for phase II decreased the rates at which the incubator could remove heat at high temperatures early in the chilling cycle, so that phase II samples took approximately 0.5 h longer to reach 50°C, the reported maximum growth temperature for *C. perfringens* (14). The combination of these two factors of pH and temperature reduction rate may explain the slightly decreased *C. perfringens* growth observed in phase II compared with phase I. However, uncured treatments in both phases allowed substantial *C. perfringens* outgrowth, and 100 ppm of nitrite alone was insufficient in either phase to limit outgrowth to <1 log CFU/g.

Only products cured with the direct addition of purified sodium nitrite currently qualify for the extended cooling option outlined in FSIS Appendix B. Traditional curing formulations normally contain near the maximum allowable ingoing concentration of sodium nitrite (156 to 200 ppm) and almost universally include ascorbate or its stereoisomer, erythorbate, as a cure accelerator. Traditionally, cure accelerators have been utilized for quality impacts, most notably maximizing the usage of added nitrite, increasing the formation of cured pigment, and maintaining cured color during storage (21). Therefore, products that currently qualify for this extended cooling option (15 h) would contain >100 ppm of ingoing nitrite and would likely also include ascorbate or erythorbate near the maximum regulatory limit of 547 ppm; according to the results of the present study, these products could be safely chilled over this 15-h period. However, in alternative cured formulations, ingoing nitrite concentrations are commonly

<100 ppm, and ascorbate (available in a natural form as cherry powder) can often be omitted from products; therefore, formulations without ascorbate may be considered inherently less safe when cooled using this 15-h chilling curve (30).

Although the mechanism of the antimicrobial action of nitrite is not entirely clear, these results confirm previous findings that higher concentrations of nitrite provide a higher protection against pathogen growth (7, 26, 36). However, the minimum nitrite concentration that produces a consistent antimicrobial result is not clearly known. Asan and Solberg (3) reported that nitrite concentrations as low as 25 ppm were inhibitory to *C. perfringens* in broth but only after the combined nitrite and broth were heat sterilized at 121°C for 20 min, a heat treatment that cannot be replicated in a processed meat product to yield a product acceptable to consumers. Redondo-Solano et al. (24) evaluated nitrite concentrations for inhibition of *C. perfringens* in ham during 15 h of exponential chilling between 54.4 and 7.2°C. These authors reported that 100 ppm of sodium nitrite was sufficient to limit *C. perfringens* outgrowth to <1 log CFU/g when packages were heat shocked and cooled 3 h after inoculation, but when held for 24 h before heat shocking and chilling, the same concentrations of nitrite allowed significant outgrowth of approximately 3 log CFU/g. Although product parameters such as moisture, pH, and  $a_w$  were comparable between the ham used by Redondo-Solano et al. and the turkey used in the present study, the difference in cooling methods could explain the contradictory results; exponential cooling would have provided less overall time in the optimum growth range of 43 to 47°C compared with the biphasic linear cooling process used in the present study. To prevent toxin production by *C. botulinum* in frankfurters, Hustad et al. (13) determined that 50 ppm of ingoing nitrite was sufficient. However, Jackson et al. (15) found that *C. perfringens* grew similarly in frankfurters and hams indirectly cured with a natural nitrite source at approximately 50 ppm of nitrite and stored at 20°C for 10 days compared with an uncured control with no nitrite. These results suggest that lower concentrations of nitrite found in alternative cured meat formulations (e.g. 50 or 75 ppm) are effective for inhibiting outgrowth of *C. perfringens* when supplemented with sufficient concentrations of a cure accelerator such as the ascorbate included in the present study.

The synergistic effect of ascorbate and nitrite for inhibiting *Clostridium* growth in meat products is still not clearly understood. In several studies, ascorbate or erythorbate enhanced the antimicrobial effect of nitrite against clostridia (4, 39, 40). Although a direct comparison between treatments with and without nitrite was not made in those studies, in another study (12) large intact hams cured with 200 ppm of sodium nitrite and 540 ppm of sodium erythorbate and then inoculated with *C. perfringens* did not support growth over a chilling curve similar to that used in the present study and even inhibited growth over 23 h of chilling from 54.4 to 7.2°C. In perishable canned cured meats, ascorbate enhanced the antimicrobial impact of both 50 and 156 ppm of sodium nitrite (39). Tompkin (38) investigated the mechanism by which ascorbate enhanced



the effect of nitrite by substituting ingredients that represented each of the individual functions of ascorbate. Specifically, butylated hydroxyanisole and tertiary butylhydroquinone were substituted to test the antioxidant effect, sodium sulfide and cysteine were substituted as reducing agents, and EDTA was tested as a chelating agent. Only EDTA provided inhibition similar to that of ascorbate, leading to the conclusion that the inhibitory effect was not attributed to the reducing capacity or the antioxidant effects of ascorbate. Instead, the hypothesis was that inhibition was due to cell damage by nitric oxide reduced from nitrite, followed by the chelation of a cation essential for recovery by ascorbate. Tompkin et al. (40) reported that 200 ppm of isoascorbate used with 50 ppm of sodium nitrite provided inhibition of *C. botulinum* similar to that provided by 156 ppm of sodium nitrite alone in perishable canned meat. Our results suggest that 50 ppm of sodium nitrite with 250 ppm of ascorbate may be just below the minimum threshold needed to control *C. perfringens* outgrowth in meat products during a 15-h chilling period but emphasize the critical role that ascorbate plays in conjunction with nitrite to prevent *C. perfringens* outgrowth.

Some researchers have concluded that ascorbate and erythorbate do not enhance the antimicrobial activity of nitrite at all (5, 24, 26). Bowen et al. (5) formulated wieners with 0, 15, 30, 50, 100, and 150 ppm of nitrite and 0, 105, and 655 ppm of ascorbate. At 28°C, inoculated *C. botulinum* began to produce toxin by 7 days in wieners with  $\leq 50$  ppm of nitrite, whereas wieners with  $\geq 100$  ppm did not develop toxin within 56 days of testing. No enhancement or detriment to the nitrite effect on toxin prevention was found when ascorbate was included in formulations. Redondo-Solano et al. (24) reported that ham formulated with 547 ppm of erythorbate plus 50 or 100 ppm of nitrite actually supported greater increases of *C. perfringens* than did the same concentrations of nitrite without erythorbate during exponential cooling over 15 h. Variability in meat formulation, such as salt concentration, pH, and  $a_w$ , and differences in cooling procedures could account for the inconsistent conclusions regarding the effect of ascorbate in cured meats; thus, this issue warrants further investigation. These contradictory published results probably have prevented the general industry-wide acceptance of cure accelerators as contributors to a multiple hurdle approach to food safety.

The study confirmed the importance of the concentration of nitrite, not the source, for impacting the microbiological safety of meat products. At equal nitrite concentrations, purified sodium nitrite and nitrite from cultured celery juice powder had an equivalent antimicrobial effect. Because formulations of alternative cured products often contain lower concentrations of natural nitrite than do products conventionally cured by direct addition of purified sodium nitrite, it is critical to evaluate the complete formulation, including concentrations of all curing ingredients, to ensure utmost product safety. These study results also revealed that the inclusion of ascorbate can greatly contribute to product safety with regard to outgrowth of *C. perfringens*. Because ascorbate and erythorbate function in

identical ways, these ingredients could be used interchangeably. Similar to nitrite, both purified and natural sources of ascorbate, when used at equal concentrations, provide the same enhancement of the antimicrobial activity of nitrite. The interaction of the two ingredients is evident in this study, and the true margin of safety at minimum regulatory limits of 100 ppm of ingoing nitrite as the only point of differentiation for chilling requirements is worth reconsidering, because 100 ppm of ingoing nitrite did not limit growth to  $<1$  log CFU/g when used without ascorbate in this study. In this study, combined usage of concentrations of nitrite and ascorbate of 50 and 500 ppm or as low as 75 and 250 ppm, respectively, were effective for controlling the outgrowth of *C. perfringens* during a 15-h cooling period. Although nitrite and ascorbate concentrations are critical for predicting product safety for chilling processed meat products, overall product composition and chilling times and temperatures must also be considered to ensure safe chilling of cured meats.

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April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP

**Docket:** AMS-NOP-18-0071

**RE: Nutrient Vitamins and Minerals (Sunset 2021)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Sunset Review of nutrient vitamins and minerals listed on 205.605(b) (non-agricultural, synthetic) of the National List.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The Organic Trade Association supports the continued listing of nutrient vitamins and minerals on the National List at 205.605(b) (non-agricultural, synthetic) and we strongly support the review of nutrient vitamins and minerals by the National Organic Standards Board (NOSB). Please reference the results of our Sunset Survey 2021 in our separate comments.

NOSB is asking the following questions in this first round of its Sunset Review:

1. Is the current listing meeting the needs of the organic community, certifiers and industry – if not, how should it be revised?
2. How are certifiers currently dealing with non-synthetic nutrient vitamins and minerals?
3. It is speculated that the 2012 rulemaking was stopped due to the impact this change would have on the currently established organic infant formula market which has both established manufacturers and consumers. How should NOSB move this topic forward in light of this issue?
4. Given that added vitamins and minerals need to be listed on ingredient panels, are consumers enabled to make educated purchasing decisions on fortified foods? If not, please explain?

The Organic Trade Association is in a position to address #1 and #3 and provide some thoughts on #2.

Overall, we encourage NOSB and other organic stakeholders to take this Sunset Review opportunity to support the renewal of nutrient vitamins and minerals, as listed, and to urge NOP to continue with its rulemaking process and publish an annotation that is transparent, certifiable and enforceable.

OTA continues to support a listing for Nutrient Vitamins and Minerals that is certifiable, enforceable and captures the intent of the 1995 NOSB recommendation. The organic sector has been fortifying organic

products for many years, and has been doing so in compliance with the NOP regulations and in response to consumer demand. The 1995 NOSB endorsed the fortification of organic foods and put in place a process that was designed to allow for the discriminate use of vitamins, minerals and nutrients that are essential and compatible with organic principles, but unavailable in organic or natural forms. The Organic Trade Association would like to see the organic sector continue to support this intent. However, the current annotation on the listing of nutrient vitamins and minerals (“when used in accordance with 21 CFR 104.20”) is problematic because it is difficult to navigate and does not include several of the nutrient vitamins and minerals that were reviewed and approved by NOSB in 1995. It also does not contain several of the essential vitamins and minerals required in food products today.

Considerable time and energy went into a two-year process that led to a 2012 NOP proposed rule that has yet to be finalized. The 2012 proposed rule was largely based on NOSB discussions and feedback received from the public on the Handling Subcommittee’s March 2011 recommendation (in response to a memo from NOP to NOSB in April 2010), and we believe it most accurately captures the intent of the original 1995 NOSB recommendation:

**Vitamins and minerals identified as essential in 21 CFR 101.9, or as required for infant formula by 21 CFR § 107.100 or 107.1**

There is a long and important history that led to the January 2012 NOP Proposed Rule, and the Organic Trade Association would like to see NOP continue with its rulemaking, including all the nutrients petitioned and passed by the NOSB, and publish an annotation that is transparent, certifiable and enforceable.

**IMPORTANT BACKGROUND**

**In 1995**, the National Organic Standards Board (NOSB) voted to permit the use of synthetic vitamins, minerals and accessory nutrients in organic foods provided their use was appropriate and the nutrients had undergone complete NOSB review via the National List Process. The Board also conducted technical reviews of specific vitamins and minerals [\[1\]](#) and passed the following recommendation:

*Nutrient vitamins and minerals – Determined to be synthetic.* NOSB’s decision is to allow this material for use in organic food processing. *Annotation:* Accepted for use in organic foods for enrichment when required by regulations or recommended by an independent organization.

USDA’s National Organic Program (NOP) Final Rule published on December 21, 2000, did not include the NOSB annotations “when required by regulation” or “recommended by an independent organization.” Instead, NOP decided that the most appropriate reference was the FDA Nutritional Quality Guidelines for Foods found at 21 CFR 104.20.

*§ 205.605(b) Synthetics Allowed:* Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines For Foods.

**In 2006**, NOP received a complaint that substances such as DHA, ARA and taurine were being added to organic infant formula. **In 2007**, NOP clarified that DHA and ARA and other nutrients are allowed in organic foods because 21 CFR 104.20 allows a wide variety of nutrients beyond the vitamin and minerals allowed under § 104.20 and the ones that were reviewed by the 1995 Board.



**In 2010**, after meeting with FDA, NOP released a memo recognizing that its interpretation of FDA's fortification policy was incorrect. The memo clarified the real meaning of § 104.20 and explained that the policy does not include nutrients beyond the ones listed under § 104.20. NOP also recognized that certifiers and certified operations made decisions based on NOP's incorrect interpretation and explained it would be moving forward with draft guidance that would include adequate time for businesses to transition products to comply with the FDA regulations as written.

**In 2012**, NOP issued a proposed rule requesting comments on the following proposed annotation:

*§ 205.605(b) Synthetics Allowed:* "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."

The proposal clarified that the "nutrients" that were not on these CFR sections had to be petitioned.

**In 2011-2013**, many nutrients were petitioned to the National List. A few were recommended to be listed by the NOSB (i.e. Choline and Inositol - for use in infant formula and medical nutritional enteral products, DHA and ARA - not hexane extracted; other ingredients that are agricultural must be organic), but several were not (i.e. lutein, taurine, L-carnitine, lycopene, nucleotides, ascorbyl palmitate, and beta-carotene). It should also be noted that in the last couple years, choline<sup>1</sup> was added to 21 CFR 101.9.

NOP did not finalize the proposed rule, but on **September 27, 2012**, published an Interim Rule, which renewed without change the original listing (21 CFR 104.20).

Upon release of the interim rule, NOP announced "that vitamins and minerals may continue to be added to organic products while the Department continues to clarify which additional nutrients may be added to organic products."

No further NOP rulemaking has occurred to date.

[\[1\]](#) Vitamin A, C, D, E, K, B6, B12, Thiamin, Riboflavin, Niacin, Folate, Biotin, Pantothenic acid, Choline, Inositol, Phosphorous, Magnesium, Zinc, Iodine, Copper, Manganese, Chloride, Sulfur

### **OTA Supports an Annotation that is Certifiable and Enforceable**

The Organic Trade Association believes that we need an annotation that includes CFR references that connect to a clear list of specific vitamins and minerals that are essential. We also believe that revisiting the annotation at the NOSB level is a duplicative effort. USDA's resources are best spent on completing its rulemaking. This includes addressing the nutrients that were petitioned and reviewed by NOSB from 2011 - 2013.

<sup>1</sup> NOSB passed recommendations to add Choline and Inositol at the May 2012 meeting. **Choline chloride** (CAS # 67-48-1) and **Choline bitartrate** (CAS # 87-67-2) for use in infant formula and medical nutritional enteral products. **Inositol** CAS # 87-89-8 (myo-inositol) and 6917-35-7 (non-specific isomer) for use in infant formula and medical nutritional enteral products.



The annotation in the 2012 proposed rule, coupled with nutrients petitioned and passed by the NOSB, offer NOP a concise path forward that reflects consumer preferences, and references distinct lists of essential nutrients found in the FDA Code of Federal Regulations. OTA supports this NOP action because it's consistent with the intent of NOSB's 1995 recommendation on nutrient supplementation of organic foods and will result in a more certifiable and enforceable regulation.

#### **Advocating for use of Natural (Non-synthetic) Vitamins and Minerals**

The Organic Trade Association does not believe that a listing for synthetic vitamins and minerals precludes the use of non-synthetic vitamins or minerals when they are available and compliant with the regulations. OTA continues to favor and advocate for the use of natural and organic alternatives over the use of synthetic. In the case of vitamins, there are some cases where the only form available of a non-synthetic vitamin is one that is produced through fermentation using a genetically modified organism. The certification process ensures that certified operators are only using non-GMO vitamins and minerals; therefore, the only non-GMO compliant option may be the synthetic form. From this perspective, certified operators would need to choose the synthetic version to be in compliance with the regulations. In any case, OTA would like to see operators using organic and/or natural vitamins if they are commercially available and compliant. We believe the most definitive and enforceable mechanism in place to make this happen is the petition process. Companies that offer organic vitamins or natural (organic compliant) vitamins have an opportunity to petition the National List!

#### **Conclusion**

The Organic Trade Association supports the allowance of vitamins and minerals in NOP certified foods and the rational and safe addition of nutrients to foods to preserve a balance of nutrients in the consumer diet. We also support the maximum freedom of choice for organic consumers, and believe that organic products should be nutritionally equal to their conventional counterparts.

As stated at the beginning of our comments, we believe it is important for NOP to complete the rulemaking it started in 2012 and respond to the petitions that were received from 2011 - 2013. We encourage NOSB and other organic stakeholders to take this Sunset Review opportunity to support the renewal of nutrient vitamins and minerals, as listed, and to urge NOP to continue with its rulemaking and publish an annotation that is transparent, certifiable and enforceable.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard  
Vice President, Regulatory and Technical Affairs  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association







April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Avenue, SW  
Room 2648-So., Ag Stop 0268  
Washington, DC 20250-0268

**Docket:** AMS-NOP-18-0071

**RE: Handling Subcommittee – 2021 Sunset Reviews for §205.605 and §205.606**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2021 Sunset Review.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering each handling input scheduled for review as part of the 2021 Sunset Review cycle. Materials that have been placed onto the National List for use in handling should remain on the National List if: 1) they are still essential to and compatible with organic production and handling practices; 2) there are no commercially available alternative materials (natural, organic) or practices; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517 and 6518] National List). Furthermore decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at-large. Furthermore decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at-large. It's critical that NOSB hear from certified handlers on whether these inputs are consistent with and essential to organic handling, or whether there are other effective natural or organic alternatives available.

#### **About OTA Sunset Surveys**

OTA is submitting results to our Sunset Surveys created for each input under review as part of the 2021 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input. See Appendix A for a sample survey. Our surveys do not address information regarding the impacts on human health or the environment.

The surveys are open to any NOP certified organic operation. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) and the Organic Materials

Review Institute (OMRI) to distribute the survey to all of their clients as well as to targeted clients they know are using the inputs under review. OTA also worked through its Farmers Advisory Council<sup>1</sup> to help assist in distribution to NOP certified farmers.

### Results of OTA Sunset Surveys

OTA has received 88 responses on our 2021 Handling Sunset Surveys. Below is a summary of the feedback received via OTA's Sunset Surveys to date.

#### §205.605(a) – Non-synthetic Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).

Substance	# of responses	Summary of responses	Average rating of Necessity (from 1 to 5, with 5 being “critical – would leave organic without it”)
Citric acid	10	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used routinely as a flavor, acidulant, and buffer in a wide variety of organic products (beverages, juices, fruit spreads, yogurt, ice cream and other frozen desserts, cookies, crackers, canned meals, snacks, baking mixes, cereal, granola bars, dressings, refrigerated baked goods, salad dressings, fruit concentrates, frozen potatoes, frozen fruits, canned tomatoes, pasta sauce, soup, gummy candy, fruit snacks, nutritional supplement and more).</li> <li>- Essential for pH control and stability of food products.</li> <li>- Essential for food safety</li> <li>- Essential for gel formation: citric acid is used to adjust the pH of pectin products in order for them to form gels</li> <li>- Essential for stabilizing colors: it is critical that a product has the proper pH to achieve the desired color; i.e. anthocyanins are red at low pH and blue at a high pH.</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Have searched but not found an organic source that supports meets specification requirements in terms of quantity or quality.</li> <li>- No viable alternatives that meet our need to fully acidify certain ingredients while maintaining the sensory attributes and safety of finished products.</li> <li>- Organic lemon juice concentrate can sometimes be a suitable alternative for providing tartness of flavor, but is unsuitable for adjusting pH and can impart undesirable flavors and colors in some applications</li> <li>- No management practices have been identified that could eliminate the need for the substance.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Significant effects to the quality of the organic products (taste, stability, food safety).</li> </ul>	4.5

<sup>1</sup> OTA's Farmers Advisory Council was established in 2013 to formalize two-way communication between OTA and member producers as well as regional organic producer organizations across the United States. Through dialog and input, FAC gives organic farmers a voice to directly influence OTA's policy and provides an avenue for OTA to share information and advocacy work with this stakeholder group.

		<ul style="list-style-type: none"> <li>- Products do not meet customer expectations</li> <li>- Would not be able to safely produce fruit juices.</li> <li>- Reduced production of organic processed products.</li> <li>- Lack of pH control in products can create a food safety risk.</li> </ul>	
Lactic acid	5	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used routinely as a flavor, flavor enhancer, acidulant, buffer, and coagulating agent in a wide variety of organic products (butter, cheese, other dairy products, supplements, cereal, bars, beverages, cookies, condiments, salty snacks, confectionaries, and more).</li> <li>- Essential for pH control of certain products.</li> <li>- Provides longer lasting tartness in confectionary products</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- There are no organic alternatives that are commercially produced.</li> <li>- No management practices have been identified that could eliminate the need for the substance.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Taste, product stability, and food safety would be negatively affected.</li> <li>- Certain products would be unable to be produced in organic form.</li> </ul>	4.3
Calcium chloride	4	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used routinely as a buffer, firming agent in a variety of organic products (yogurt, condiments, soups, canned diced tomatoes, other tomato products, and more)</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- For certain products, depending on the characteristics of the ingredients being used in the product, the material is needed to meet quality standards.</li> <li>- Cannot find reliable supplier of ingredients that do not use the material.</li> <li>- Attempts to find organic alternatives are unsuccessful.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Decreased quality of organic products.</li> <li>- Diced tomatoes would not hold their shape during the canning process and would look more like crushed tomatoes.</li> </ul>	4.8
Dairy cultures	5	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Use for acidification, flavor development, and culturing for a variety of dairy products (yogurt, sour cream, cheese, salad dressings, salty snacks, and more)</li> <li>- Essential for transforming fluid milk into cheese and yogurt</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- No information on alternative substance of practices was provided</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Cannot make yogurt or cheese without dairy cultures</li> </ul> <p>Ancillary substances: dextrose, polysorbate, sodium formate, sucrose, maltodextrin</p>	4.8

Enzymes	6	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used frequently in a variety of organic products (yogurt, fruit juices, frozen desserts, bread products, baked goods, snacks, cheese, condiments, syrups, maltodextrins, sugar, and more) for hydrolysis, breaking down lactose (allowing for less added sugar), fruit depectinazation, coagulant and dough conditioner.</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- There is no alternative for certain cheese and dairy products</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Cannot make yogurt or cheese without enzymes</li> </ul> <p>Ancillary substances: glycerol, potassium chloride</p>	4.8
L-Malic acid	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- We do not currently manufacture a confectionary product using L-Malic acid because it is cost prohibitive when compared to Citric Acid. If there were more marketplace demand and the economies of scale were to enable the price to be more competitive, we would love to have this available for formulating.</li> </ul>	3
Magnesium sulfate	0		
Microorganisms	3	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as an acidifier and for flavor development in a variety of organic products (yogurts, teas)</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- No information on alternative substance of practices was provided</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- End of business</li> <li>- Cannot make yogurt</li> </ul> <p>Ancillary substances: dextrose, polysorbate, sodium formiate, sucrose, maltodextrin</p>	4
Perlite	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as a filtering aids for various organic products (fruit juices and spreads)</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Have not conducted a search for organic alternatives</li> <li>- No alternative management practices are sufficient</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Cannot make certain fruit concentrates</li> </ul>	5
Potassium iodide	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as a nutrient in infant formula</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- No information on alternative substance of practices was provided</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Cannot make infant formula in organic form</li> </ul>	4

Yeast	3	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as a leavening agent in a variety of organic baked goods, crackers, bagels</li> <li>- Used for flavor and as a nutritional component in a wide variety of organic</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- There are organic yeast options available, but not always in the appropriate quantity. Even when organic yeast is commercially available, the quality can vary.</li> <li>- Organic yeasts have not met functional requirements regarding flavor.</li> <li>- Organic yeast is successfully being used as a leavening agent in some organic products.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Many baked good would no longer be available in an organic form</li> <li>- Reformulating with organic yeasts to meet specific flavor profiles would be a substantial and costly effort.</li> <li>- Reduced production is reformulations are not successful.</li> </ul>	5
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**§205.605(b) – Synthetic Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).**

Substance	# of responses	Summary of responses	Average rating of Necessity (from 1 to 5, with 5 being “critical – would leave organic without it”)
Alginic acid	0		
Activated charcoal	2	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used for filtering batch water to meet drinking water standards</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Have not conducted a search for organic alternatives</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Would not be able to meet safe drinking water standards</li> <li>- Would shut down operations</li> </ul>	5
Ascorbic acid	5	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as an acidulant, flavor enhancer, antioxidant, vitamin C source in a variety of organic products (frozen desserts, fruit juices, gummy candy, fruit snacks, nutritional supplements)</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Have searched for organic alternatives for Vitamin C sources but potential options (rise hips; acerola) are not commercially available or are otherwise functionally unsuitable (higher usage levels are needed; can add undesirable color and fibrous material)</li> <li>- No alternative management practices are sufficient</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Would not be able to produce fresh pressed juices</li> </ul>	4.5



		<ul style="list-style-type: none"> <li>- Would not be able to fortify with Vitamin C which is typical for some products</li> <li>- Unable to meet consumer demands</li> </ul>	
Calcium citrate	2	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used in fruit fillings to thicken and stabilize the gel structure in various products (yogurt, toaster pastries)</li> <li>- Use to fortify nutritional supplements with calcium</li> <li>- Essential for developing a sugar-acid-pectin gel found in jams, jellies, and other fruit spreads</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- No other known sources available that provide equivalent functionality</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Decline in quality texture and flow characteristics</li> </ul>	3.8
Ferrous sulfate	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as a nutrient in infant formula</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- No information on alternative substance of practices was provided</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Cannot make infant formula in organic form</li> </ul>	3
Hydrogen peroxide	5	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as a sanitizer on manufacturing equipment and other food contact surfaces</li> <li>- Used as a sanitizer of food packaging prior to filling the product (fruit juices, yogurt, other beverages)</li> <li>- Essential for sanitation procedures</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- There are few alternatives and options that are allowed or are appropriate for organic products</li> <li>- Some respondents say there are no alternatives</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- No aseptic packaging of foods</li> <li>- Organic production and handling would be severely limited due to food safety concerns and FSMA requirements</li> <li>- Business would end</li> </ul>	5
Nutrient vitamins and minerals	8	<p><b>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</b></p> <p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Use for nutritional fortification for various organic products (yogurt, milk, fruit juices, cereal, flour, gummy candy, fruit snacks, nutritional supplements)</li> <li>- Essential for meeting nutritional needs</li> <li>- Essential for meeting federal and state regulations for nutrition</li> <li>- Essential for formulating nutritional supplements</li> </ul>	4.9

		<p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Have used a natural vitamin when commercially available</li> <li>- Organic plant extracts are available that can be used for low level fortification, but are less concentrated in the active ingredients so would need to be used at a much higher usage rate impacting flavor and texture</li> <li>- There are not organic options for many nutrients</li> <li>- No alternative management practices are sufficient</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Some products would not be produced in organic form due to poor quality</li> <li>- Unable to comply with state and federal laws</li> </ul> <p>Ancillary substances: acacia gum, corn starch, medium chain triglycerides (from palm oil), tocopherol</p>	
Peracetic acid	8	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used routinely as a sanitizer on manufacturing equipment across multiple processing lines and production facilities</li> <li>- Used as a wash for organic vegetables prone to high bacteria counts</li> <li>- Leaves no residues and has low VOC emissions compared to alternatives</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- There are few alternatives and options that are allowed or are appropriate for organic products</li> <li>- Some respondents say there are no alternatives</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Could not produce organic products</li> <li>- Lowered level of quality and possible safety risks</li> <li>- Organic production and handling would be severely limited due to food safety concerns and FSMA requirements</li> <li>- Business would end</li> </ul>	4.5
Potassium citrate	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as a buffer salt in confectionary products. When combined with citric acid, the pair provides tartness without as significant drop in pH. This is important in preventing the degradation of sucrose in confectionary products and for achieving consistent pH for the gelling on pectin. It offers an advantage over sodium citrate in that it does not add additional sodium to the product.</li> </ul>	3
Potassium phosphate	0		
Sodium acid pyrophosphate	2	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as a leavening agent in various organic products (baked goods, tortillas, snacks, refrigerated baked goods)</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Other allowed leavening agents are not stable enough in a high-moisture dough to allow for refrigerated doughs to rise in the oven when baked at home.</li> </ul>	4.5

Sodium citrate	5	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as an antioxidant, stabilizing salt, and buffer in various organic products (infant formula, yogurt, creamer, cheese, toaster pastries, gummy candy, fruit snacks, nutritional supplements)</li> <li>- Essential in a sugar-acid-pectin gel to help control calcium availability so that the pectin doesn't prematurely gel.</li> <li>- When combined with citric acid, the pair provides tartness without as significant drop in pH. This is important in preventing the degradation of sucrose in confectionary products and for achieving consistent pH for the gelling on pectin.</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Other allowed alternatives do not have proper pH stabilization properties needed in a pectin-based gummy fruit snack</li> <li>- Citric acid is used in conjunction with Sodium Citrate to balance the pH.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Decline in quality</li> </ul>	4.7
Tocopherols	4	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as an antioxidant in various organic products (cereals, snacks, cookies, granola bars)</li> <li>- Essential for preventing rancidity in whole grain products</li> <li>- Used to lessen degradation of flavors due to oxidative rancidity. This extends the shelf life of flavors and of the resulting products made with them. In doing so, the cost of disposing of out of date flavors is reduced and the organoleptic quality of organic products are enhanced.</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Have extensively researched organic rosemary extract as an alternative but has not performed equally to tocopherols.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- No information provided</li> </ul>	4.7

**§205.606 – Non-organically produced agricultural products allowed as an ingredient in or on processed products labeled as “organic” only when the product is not commercially available in organic form.**

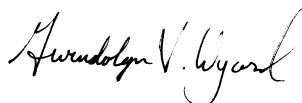
Substance	# of responses	Summary of responses	Average rating of Necessity (from 1 to 5, with 5 being “critical – would leave organic without it”)
Celery powder	4	<p><b>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</b></p> <p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as a nitrate alternative in processed meat products that carry the “uncured” label, as required by USDA-FSIS (hot dogs, meat sticks, landjager, jerky, summer sausage logs, deli ham, deli summer sausage, pepperoni, bacon, and spiral hams).</li> </ul>	4.3

		<ul style="list-style-type: none"> <li>- Essential for providing additional attributes to curing, including maintaining a pink color, flavoring, and lowering acidity of the finished processed meat product.</li> <li>- Essential for blocking the growth of <i>Listeria monocytogenes</i> and <i>Clostridium botulinum</i> in the processed meat product.</li> </ul> <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- No supplier is known to produce organic celery powder at this point.</li> <li>- It is difficult to locate organic celery powder in the sufficient quantity. When organic celery powder is available, the quality of the celery powder is often not a sufficient replacement for non-organic versions.</li> <li>- Not able to identify an organic plant source that could effectively provide the properties of non-organic celery powder</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Organic meat producers, would also no longer be able to produce cured products such as ham, bacon, and hot dogs.</li> <li>- Many certified organic processed meat products would be removed from the market.</li> <li>- Increased food safety risk from <i>Listeria monocytogenes</i> and <i>Clostridium botulinum</i></li> <li>- Decreased quality of food products (color of pepperoni would be a gray-brown, rather than the crimson red typical of pepperoni and other cured meats)</li> </ul>	
Fish oil	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used for Omega 3 supplementation in organic products</li> </ul> <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- No certified organic fish to get it from.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Discontinuation of organic products</li> </ul>	4
Gelatin	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used in the manufacturing of organic gummies</li> </ul> <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- The nature of the gelatin manufacturing process requires a magnitude of scale (sufficient pig and cow hides) in order to be viable. The Organic meat market size has not yet reached this critical mass. We continue to work with our gelatin suppliers in developing a supply chain to support future development of organic gelatin.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Decline in quality of product</li> <li>- Economically devastating</li> </ul>	5
Orange pulp, dried	0		
Seaweed, Pacific kombu	0		

Seaweed, Wakame	0		
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On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Gwendolyn Wyard  
 Vice President of Regulatory and Technical Affairs  
 Organic Trade Association

cc: Laura Batcha  
 Executive Director/CEO  
 Organic Trade Association

## Appendix A – Sample Survey for Handling Inputs

1. Please describe the types of organic products produced or handled on your operation:
2. How many states are your products sold in? Are they exported to other countries?
3. How many years has your operation been certified organic?
4. Which organic products do you use this substance on/in? (e.g., yogurt, fruit juices, baked goods, etc.)
5. What function does the substance provide in your organic products and why is it essential? (e.g., stabilizer, thickener, flavor, sanitizer, etc.)
6. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)

7. Have you conducted a search for the availability of natural (if the substance in question is synthetic) or organic (if the substance in question is natural) alternatives? (e.g. using yeast instead of chemical leavening agents)

- If so, please describe what your search entailed:
- Based on your search, describe the availability of allowed alternatives (organic or natural) in terms of quality, quantity and form:
- If available, have you conducted research (e.g. R & D trials) on the use of allowed natural or organic alternatives in your organic product(s)? Briefly describe the results. Did they meet your specification requirements?

8. Are there any other management practices that would eliminate the need for the substance? (e.g., delayed harvesting instead of using a chemical growth hormone for ripening). If so, please describe the efficacy of the alternative management practices:

9. Describe the impact to your operation should you no longer be allowed to use the substance:

- Organic product effects (effects to the quality of the organic product(s) you are marketing):
- Environmental effects (effects to environment if the substance was no longer allowed; effects to environment from potential alternatives):
- Economic effects (effects to economic health of your operation):

10. On a scale from 1 to 5 stars, rate the overall essentiality of this substance for your organic operation:

Unnecessary (don't need it at all)		Neutral (nice to have but could live without it)		Critical (would leave organic without it)
★	★	★	★	★

11. NOSB collects information about the "ancillary substances" (e.g. carriers, preservatives, stabilizers) that may be used to formulate commercial forms of the substance. Please list any ancillary substances that are identified on the ingredient statement on the specification sheet that accompanies the substance you purchase.





April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Avenue, SW  
Room 2642-So., Ag Stop 0268  
Washington, DC 20250-0268

**Docket:** AMS-NOP-18-0071

**RE: Crops Subcommittee – Strengthening Organic Seed and Planting Stock Guidance (Proposal)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Crops Subcommittee's Proposal on Strengthening the Organic Seed Guidance.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Seed is the fundamental starting point for transforming agriculture through nutritious ecologically grown food, feed and fiber, especially when coupled with the principles behind organic production of building healthy soils, using non-toxic inputs, and stewarding natural resources and the environment. As the foundation for organic farming systems, seed deserves continuous attention, from protecting its genetic resources, to preventing contamination, to building a strong organic seed sector that can supply the needs of a diverse and resilient agriculture.

OTA is committed to the development of the organic seed and planting stock industry, and we are delighted that NOSB passed a recommendation at the fall 2018 meeting to be amend the organic regulations at § 205.204 to require demonstrable improvement of organic seed usage over time. We also agree that NOP's existing Organic Seed, Annual Seedlings and Planting Stock Guidance (NOP 5029) needs to be revised to support this rule change and reflect the current state of the organic seed industry. Increasing support for organic seed lines through a stronger seed requirement is not only fundamental to improving organic farm systems, it is essential to further reducing unintended GMO presence and limiting the extent to which seeds outside of NOP purview are used, and for ensuring the consistent application and enforcement of organic seed requirements.

**The Organic Trade Association largely supports the Subcommittee's proposal and we encourage the full Board to pass it at this meeting.**

With a couple of concerns noted below, we thank the subcommittee for making the following changes from the fall 2018 version:

- The guidance now states that conventional untreated seed must be produced without the use of excluded methods<sup>1</sup>. The Organic Trade Association strongly agrees; it is important that this requirement is explicitly stated in Guidance.
- Seed purity considerations are dealt with in a separate document. This should allow for this proposal to move forward as work on seed purity continues.
- The following language was removed from **4.1.2(c)**: *Horticultural crops, which may have specific flavor profiles, size, color or other characteristics, can also be shown to not have an equivalent organic variety through descriptions provided in seed/planting stock catalogs or websites.* We agree with the removal of this language; however, we remain disappointed about the reference to seed catalogs without a qualifier. The guidance continues to not account for various grower types (small, medium, large and crop type) and how they acquire seed. As we stated in our previous comments, large-scale growers typically do not consult seed catalogs for the characteristics described, especially flavor profiles. In the case of horticultural crops, they have a multitude of sales representatives from seed breeder and distributor companies who service them by putting in trials, taking contracts (either by reserving seed and/or doing contract productions for them), and delivering the seed of the varieties selected from their on-farm trials to them in a timely manner. The data included in seed catalogs will likely not be appropriate because it is generic information that is typically not reflective of subjective traits like ‘flavor.’ Accordingly, it may not be relevant to the exact bioregion, market and slot in which the grower sourcing seed is growing.
- The proposal retains “three” as the minimum number of seed sources that should be contacted instead of our recommended “five.” The Organic Trade Association would have liked to see the number increase to “five.” However, the **exact number** of sources that should be contacted is less important than describing the criteria or conditions that should help determine the number as it relates to the potential number of suppliers offering the desired organic equivalent variety. The search and procurement methods for sourcing organic seed and planting stock provided in 4.2.1((b)(1)(i-vii) are very valuable, and we do not take issue with this final approach.

Additionally, the Organic Trade Association supports:

- **The final language included in 4.1.2(d)**: Documentation of on-farm trials or seed characteristic searches can be provided at the annual inspection. This documentation can

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<sup>1</sup> As defined in 7 CFR 205.2 of USDA’s organic regulations - *Excluded methods*. A variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include cell fusion, microencapsulation and macroencapsulation, and recombinant DNA technology (including gene deletion, gene doubling, introducing a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology). Such methods do not include the use of traditional breeding, conjugation, fermentation, hybridization, in vitro fertilization, or tissue culture.

include which seed characteristics are desired, and be based upon the varietal benefits of the current non-organic seed/planting stock in use. The varietal characteristics discovered during the on-farm trail, of both the non-organic seed/planting stock and the organic seed/planting stock trialed, can be tracked in a simple table or spreadsheet detailing the specific characteristics sought, and whether or not the various varieties grown contained those characteristics.

- **The guidance explaining the role and requirements of seed/planting stock that is sourced or mandated by the buyer of a contracted organic crop (4.2.1(b)(3)).** If seed/planting stock is sourced or mandated by the buyer or handler of a contracted organic crop, the producer must obtain sourcing information and documentation from the contracted buyer/handler. The buyer's attempts to source organic seed/planting stock then becomes part of the producer's Organic System Plan.
- **The guidance on the information certifiers should review to evaluate progress in obtaining organic seeds, planting stock and transplants (4.4.4).** We appreciate the guidance provided on requesting corrective action plans and acting on repeated lack of progress. This of course all needs to be carried out in a sound and sensible manner by certifiers working closely with their certified operators.
- **The use of an organic seed/planting database.** OTA again emphasizes that perhaps the most important tool that can help certified producers, handlers and certifying agents in their efforts to source and evaluate the availability of organic seed and planting stock is a searchable national database of available organic varieties. We continue to support the use the Organic Seed Finder as a primary resource for national organic seed availability data. We are also very interested in the option of having certifiers provide organic seed availability of their certified clients to NOP, in such a way as to include this information in a separate field in the NOP Organic Integrity Database. Operators could then search that field for a specific variety of organic seed, and all certified operations who carry that seed would then be found. If this is feasible, we believe NOP should make such reporting a requirement.
- **Support for Organic Certifier and Inspector Trainings.** Certifiers have the important job of communicating organic seed requirements to organic producers and handlers, granting approval for the use of non-organic seed due to the commercial unavailability of organic seed, issuing non-compliances when adequate searches are not conducted, and reinforcing the need for continuous improvement as appropriate. This job comes with great challenges given the time, resources and complexity involved in verifying a claim that a particular seed variety is "commercially unavailable." Consistent implementation of the organic seed requirements and NOP guidance will significantly be improved through trainings for certifiers and inspectors as well as through best practices. OTA's appreciates NOSB's continued support in this area.

### **Conclusion**

The Organic Trade Association strongly supports the further development of the organic seed and planting stock industry, and we are committed to finding solutions to meet this objective. The goal of our efforts should be to promote the continued growth and improvement in organic seed and planting stock production, and subsequent usage by organic growers without hurting or putting undue burdens on



growers. The intent is not to have non-compliances handed down to farmers trying to comply with the seed and planting stock commercial availability section of the Rule. Instead, the intent is to have an organic regulation that explicitly supports continuous improvement and NOP guidance that will help ensure the consistent application and enforcement of organic seed requirements. This in turn will promote the breeding, development and production of a greater diversity of varieties well suited for organic production systems.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your continuing work in this important area.

Respectfully submitted,

Gwendolyn Wyard  
Vice President, Regulatory and Technical Affairs  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Avenue, SW  
Room 2642-So., Ag Stop 0268  
Washington, DC 20250-0268

**Docket:** AMS-NOP-18-0071

**RE: Crops Subcommittee – Paper (Plant Pots and Other Crop Production Aids) (Discussion)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Crops Subcommittee’s Discussion Document on Paper (Plant Pots and Other Production Aids). The Subcommittee is inviting discussion on a petition for the addition of paper planting pots to the National List for use in organic crop production.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

### **Summary**

- ✓ OTA continues to support the allowance of paper to be planted in the soil when used as a planting aid because paper is already allowed for equivalent uses (e.g., as mulch).
- ✓ OTA supports the decision by NOSB to expand the scope of review to be inclusive of generic products that are paper-based and used as planting or seeding aids.

**We offer the following more detailed comments:**

### **Background**

NOSB received a petition in August 2018 for the addition of paper planting pots to the National List: “§205.601(o) production aids - Plant pot or growing container-hemp or other paper, without glossy or colored inks.” Paper pots are used as a vessel for growing transplants intended to be planted directly in the soil along with the plant material. Nitten paper chain systems, which are the subject of the petition, are used to efficiently transplant closely spaced crops as part of a non-motorized machine transplanting system; the petitioned materials is planted into the soil along with the plant material.

At the last meeting (fall 2018), NOSB presented a discussion document to solicit public comments on the necessity and environmental impact of paper pots and the availability of alternatives. In OTA’s comments at that time, we supported the allowance of paper to be planted in the soil when used as a planting aid

because paper is already allowed for equivalent uses (e.g., as mulch). We also encouraged NOSB to take a broad approach for reviewing paper-based planting aids to be inclusive of generic products that are paper-based and used as planting or seeding aids. We also communicated that organic farmers identify these materials as a necessary part of their operation due to the absence of natural alternative products and management practices that would achieve the equivalent level of efficiency (of time and labor), quality (of crops produced), and waste reduction (of plastic trays, for example).

For the spring 2019 meeting, the Subcommittee has presented a second Discussion Document<sup>1</sup> that continues to explore the petitioned material. NOSB has expanded the scope of its review to include a variety of paper-based production aids including pots, seed tape, collars, and hot caps. The discussion document highlights NOSB's main concern about these materials, which is the use of synthetic fibers. While the NOSB awaits results of a Technical Review on this information, the following discussion questions are presented for stakeholder feedback.

**The Crops Subcommittee has posed the following questions for discussion:**

*1. Are there other paper-based production aids that are not mentioned in this discussion document beyond mulch, compost feedstock, pots, seed tape, hot caps, or collars?*

OTA supports the decision by NOSB to expand the scope of review to be inclusive of generic products that are paper-based and used as planting or seeding aids. The inclusion of hot caps suggests that NOSB intends to broaden the scope to include products that *aren't* intended to degrade in the soil. While OTA doesn't object to this broadened scope, it's worth acknowledging that NOSB's evaluation of these products against the National List criteria may be impacted by whether the product is or is not intended to degrade into the soil.

*2. What synthetic fibers are used in paper-based crop production aids, what is the percentage of synthetic fiber in the paper-based product, and how long, if at all, does it take for the synthetic fiber to completely biodegrade?* No comment.

*3. Are the synthetic fibers used in paper as a crop production aid, also used in newspaper or recycled paper that is currently allowed on the National List?* No comment.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Johanna Mirenda".

Johanna Mirenda  
Farm Policy Director  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

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<sup>1</sup> <https://www.ams.usda.gov/sites/default/files/media/CSPaperPotDDWeb.pdf>





April 4, 2019

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Avenue, SW  
Room 2648-So., Ag Stop 0268  
Washington, DC 20250-0268

**Docket:** AMS-NOP-18-0071

**RE: Crops Subcommittee – 2021 Sunset Reviews**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2021 Sunset Review.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering each crop production material scheduled for review as part of the 2021 Sunset Review cycle. Materials placed on the National List for use in organic crop production should remain on the National List if: 1) they are consistent with organic farming; 2) they are still necessary to the production of the agricultural product because of the unavailability of wholly natural substitute products in organic production; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517] National List). Furthermore, decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at-large. It's critical that NOSB hear from certified farmers on whether these inputs are consistent with and necessary for organic production, or whether there are other effective natural or organic alternatives available.

#### **About OTA Sunset Surveys**

OTA is submitting results to our Sunset Surveys created for each input under review as part of the 2021 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input. See Appendix A for a sample survey. Our surveys do not address information regarding the impacts on human health or the environment.

The surveys are open to any NOP certified organic operation. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) and the Organic Materials Review Institute (OMRI) to distribute the survey to all of their clients as well as to targeted clients they

know are using the inputs under review. OTA also worked through its Farmers Advisory Council<sup>1</sup> to help assist in distribution to NOP certified farmers.

### Results of OTA Sunset Surveys

OTA has received **5** responses on our 2021 Crops Sunset Surveys. Below is a summary of the feedback received via OTA's Sunset Surveys to date.

#### §205.601 – Synthetic substances allowed for use in organic crop production.

Substance	# of responses	Summary of responses	Average rating of Necessity (from 1 to 5, with 1 being "unnecessary" and 5 being "critical /would leave organic without it")
Hydrogen peroxide	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used as a post-harvest sanitizer for citrus as part of a food safety protocol and leaves no residues on the fruit</li> <li>- Used for controlling sweet orange scab and greasy spot in citrus</li> <li>- Used for controlling purple blotch in onions</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Not as effective</li> <li>- Not as safe</li> <li>- Leaves undesirable residues</li> <li>- Undesirable cumulative build up in the soils</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Economic effect on the cost of operation</li> </ul>	5
Ammonium soaps	0		
Horticultural oils	2	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- In organic banana production, it is used to control black sigatoka, a leaf fungus that is the most severe disease in banana production</li> <li>- Use to control many other pests and disease in organic production such as: to control overwintering codling moth, leaf rollers, apple scab, powdery mildew, wooly apple aphid</li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- Natural plant oils are not as effective</li> <li>- Management practices such as leaf surgery that helps reduce the pressure from the disease but must be implemented in conjunction with the use of horticultural oils.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- Reduction in banana yields by over 50% which could eventually leads to abandonment of organic farming activities altogether.</li> <li>- Difficulty controlling most pests and diseases in other crops</li> </ul>	5

<sup>1</sup> OTA's Farmers Advisory Council was established in 2013 to formalize two-way communication between OTA and member producers as well as regional organic producer organizations across the United States. Through dialog and input, FAC gives organic farmers a voice to directly influence OTA's policy and provides an avenue for OTA to share information and advocacy work with this stakeholder group.

Pheromones	0		
Ferric phosphate	0		
Potassium bicarbonate	0		
Magnesium sulfate	0		
Hydrogen chloride	2	<p>The material is necessary because:</p> <ul style="list-style-type: none"> <li>- Used by all U.S. organic cotton farmers for removing the lint from the cotton seed (delinting) in order to be usable in modern mechanical planting equipment. The small fibers have to be removed from the seed so that it will flow through the hopper box in the planter.                             <ul style="list-style-type: none"> <li>o Used only once per year (at planting).</li> <li>o Only planting seed is treated with HCl---no animal feed products are delinted.</li> <li>o The acid is neutralized at the delinting facility with calcium carbonate and thus none of it ever enters the soil on an organic farm.</li> </ul> </li> </ul> <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> <li>- There are no commercially available, effective, natural alternatives for delinting cotton planting seed that work on a consistent basis.</li> <li>- A mechanical delinting process is under development but it has not been perfected and is not in commercial use.</li> <li>- Undelinted seed could be planted by hand. However, that is not an economically viable option in the U.S.</li> </ul> <p>If the material were prohibited:</p> <ul style="list-style-type: none"> <li>- If it is not allowed for delinting purposes, the U.S. organic cotton industry will cease to exist!</li> <li>- There would be no organic cotton grown in the U.S.</li> <li>- Bankruptcy for U.S. organic cotton growers.</li> </ul>	5

**\$205.602 – Nonsynthetic substances prohibited for use in organic crop production.**

Substance	# of responses	Summary of responses
Ash from manure burning	0	
Sodium fluoaluminate	0	

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Johanna Mirenda  
 Farm Policy Director  
 Organic Trade Association

cc: Laura Batcha  
 Executive Director/CEO  
 Organic Trade Association

## Appendix A – Sample Survey for Crop and Livestock Inputs

1. Please describe the types of organic products produced or handled on your operation:
2. How many states are your products sold in? Are they exported to other countries?
3. How many years has your operation been certified organic?
4. Which organic products do you use the substance on/for? (e.g., lettuces, fruit trees, broiler chickens)
5. What function does the substance provide and why is it necessary? (e.g., to control a specific pest or disease, sanitation, etc.)
6. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)
7. Have you tried using any *natural substances* as an alternative to the substance? (e.g., natural oils instead of synthetic pesticides) If so, please describe the availability and efficacy of the alternative substances:
8. Are there any other *management practices* that would eliminate the need for the substance? (e.g., hand weeding instead of using an herbicide; or using a particular harvesting practice to avoid a disease instead of using a fungicide). If so, please describe the efficacy of the alternative management practices:
9. Describe the effects to your operation if you were to no longer be allowed to use this substance in organic production:
  - Agronomic effects (effects to health of crops or livestock):
  - Environmental effects (effects to environment if the substance was no longer allowed; effects to environment from potential alternatives):
  - Economic effects (effects to economic health of your operation):
10. On a scale from 1 to 5 stars, rate the overall necessity of this substance for your organic operation:

Unnecessary (don't need it at all)	Neutral (nice to have but could live without it)	Critical (would leave organic without it)
★	★	★