



October 3, 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-19-0038

Comments to the National Organic Standards Board

October 2019
Pittsburgh, PA

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.

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Crops Subcommittee

- 2021 Sunset Reviews
- Paper (Plant Pots and Other Crop Production Aids) (Petitioned Material Discussion Document)

Materials Subcommittee

- Excluded Methods Terminology (Proposal)
- Genetic Integrity Transparency of Seed Grown on Organic Land (Proposal)
- NOSB Research Priorities (Proposal)
- Marine Materials in Organic Crop Production (Discussion Document)

Policy Development Subcommittee

- Updates to the Policy and Procedures Manual (Proposal)

Livestock Subcommittee

- Use of Excluded Method Vaccines In Organic Livestock Production (Proposal)
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Docket: AMS-NOP-19-0038

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 Council¹ to help assist in distribution to NOP certified farmers.

Results of OTA Sunset Surveys

OTA has received 122 responses on our 2021 Handling Sunset Surveys (34 new responses since the spring meeting). 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 Essentiality (from 1 to 5, with 5 being “critical – would leave organic without it”)
Citric acid	13	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used routinely as a flavor, acidulant, and pH 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, snacks, dressings, refrigerated baked goods, salad dressings, condiments, vegetable oils, fruit concentrates, frozen potatoes, frozen fruits, canned tomatoes, pasta sauce, soup, gummy candy, fruit snacks, nutritional supplement and more). - Essential for shelf-stability of food products. - Essential for food safety - Essential for gel formation: citric acid is used to adjust the pH of pectin products in order for them to form gels - 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. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No other alternatives function in the same manner. - Have searched but not found an organic source that supports meets specification requirements in terms of quantity or quality. - No viable alternatives that meet our need to fully acidify certain ingredients while maintaining the sensory attributes and safety of finished products. - 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 - No management practices have been identified that could eliminate the need for the substance. <p>If the material were prohibited:</p>	4.5

¹ 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"> - Significant negative effects to the quality of the organic products (taste, stability, food safety). - Products do not meet customer expectations - Would not be able to safely produce fruit juices. - Reduced production of organic processed products. - Lack of pH control in products can create a food safety risk. - Products would not be able packaged as shelf-stable 	
Lactic acid	7	<p>The material is essential because:</p> <ul style="list-style-type: none"> - 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, various condiments, salty snacks, confectionaries, and more). - Essential for pH control of certain products. - Essential for maintaining freshness - Provides longer lasting tartness in confectionary products <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There are no organic alternatives that are commercially produced. - No management practices have been identified that could eliminate the need for the substance. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Taste, product stability, and food safety would be negatively affected. - Certain products would be unable to be produced in organic form. 	4.3
Calcium chloride	6	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used routinely as a buffer, firming agent in a variety of organic products (yogurt, condiments, soups, canned diced tomatoes, other tomato products, and more) - Used as coagulant / curd development in dairy and plant-based alternatives <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - For certain products, depending on the characteristics of the ingredients being used in the product, the material is needed to meet quality standards. - Cannot find reliable supplier of ingredients that do not use the material. - Attempts to find organic alternatives are unsuccessful. - No management practices have been identified that could eliminate the need for the substance. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Decreased quality of organic products. - Diced tomatoes would not hold their shape during the canning process and would look more like crushed tomatoes. - Unable to make certain products with a consistent viscosity. 	4.8
Dairy cultures	6	<p>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</p> <p>The material is essential because:</p>	4.8

		<ul style="list-style-type: none"> - Use routinely for acidification, flavor development, and culturing for a variety of dairy products (yogurt, sour cream, cheese, sauces, salad dressings, salty snacks, and more) - Essential for transforming fluid milk into cheese and yogurt <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No information on alternative substance of practices was provided <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make yogurt or cheese without dairy cultures - No management practices have been identified that could eliminate the need for the substance. <p>Ancillary substances: dextrose, polysorbate, sodium formate, sucrose, maltodextrin</p>	
Enzymes	10	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used frequently in a variety of organic products (yogurt, latose-free milk, fruit juices, fruit concentrates, 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. - Helps with fruit pulp - Lactase is used to make lactose-free milk <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There is no alternative for certain cheese and dairy products - Mechanical centrifuge helps but does not eliminate all of the fruit pulp <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make yogurt or cheese without enzymes <p>Ancillary substances: glycerol, potassium chloride</p>	4.8
L-Malic acid	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - 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. 	3
Magnesium sulfate	0		
Microorganisms	4	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as an acidifier and for flavor development in a variety of organic products (yogurts, teas, cocoa products, variety of cultured products) - Essential to ferment cocoa beans <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No information on alternative substance of practices was provided <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - End of business 	4.3

		<ul style="list-style-type: none"> - Cannot make yogurt - Cannot make cocoa products <p>Ancillary substances: dextrose, polysorbate, sodium formate, sucrose, maltodextrin</p>	
Perlite	3	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a filtering aid for various organic products (fruit juices, fruit concentrates, fruit spreads, various oils) <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Have not conducted a search for organic alternatives - No alternative management practices are sufficient - Different fruits do better with specific filtering agents <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make certain fruit concentrates - Oils would not be as clear - Oils would have shorter shelf life - Discontinue production of product 	5
Potassium iodide	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a nutrient in infant formula <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No information on alternative substance of practices was provided <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make infant formula in organic form 	4
Yeast	4	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a leavening agent in a variety of organic baked goods, crackers, bagels - Used for flavor and as a nutritional component in a wide variety of organic <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There are organic yeast options available, but not always in the appropriate quantity. Even when organic yeast is commercially available, the quality can vary. - Organic yeasts have not met functional requirements regarding flavor. - Organic yeast is successfully being used as a leavening agent in some organic products. - Organic yeast is not available in the correct quantities and often does not exhibit the correct properties for consistent application. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Many baked good would no longer be available in an organic form - Reformulating with organic yeasts to meet specific flavor profiles would be a substantial and costly effort. - Reduced production is reformulations are not successful. - Reduced production would lead to reduced purchases of organic ingredients resulting in a loss of business for our organic suppliers and growers. 	5

§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 Essentiality (from 1 to 5, with 5 being “critical – would leave organic without it”)
Alginic acid	0		
Activated charcoal	4	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for filtering batch water used to produce fruit juices - Essential to remove compounds from well water in water purifying system to meet drinking water standards - Used as filtering aid for various oils <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Have not conducted a search for organic alternatives - No alternative practices or substances have been identified <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Would not be able to meet safe drinking water standards - Would shut down operations 	5
Ascorbic acid	7	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as an acidulant, flavor enhancer, stabilizer, antioxidant, vitamin C source in a variety of organic products (frozen desserts, fruit juices, spreads, syrups, gummy candy, fruit snacks, nutritional supplements) - Essential to hold color during processing of fruit - Essential as source of vitamin C and provides tartness <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - 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) - No alternative management practices are sufficient <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Would not be able to produce fresh pressed juices - Would not be able to fortify with Vitamin C which is typical for some products - Unable to meet consumer demands 	4.5
Calcium citrate	2	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used in fruit fillings to thicken and stabilize the gel structure in various products (yogurt, toaster pastries) - Use to fortify nutritional supplements with calcium - Essential for developing a sugar-acid-pectin gel found in jams, jellies, and other fruit spreads <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No other known sources available that provide equivalent functionality <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Decline in quality texture and flow characteristics 	3.8

Ferrous sulfate	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a nutrient in infant formula <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No information on alternative substance of practices was provided <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Cannot make infant formula in organic form 	3
Hydrogen peroxide	8	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a sanitizer on manufacturing equipment and other food contact surfaces - Used as a sanitizer of food packaging prior to filling the product (fruit juices, yogurt, milk, other beverages) - Sterilant for Aseptic Manufacturing and Packaging - Fluid Milk Filler Sanitation - Essential for sanitation procedures <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There are few alternatives and options that are allowed or are appropriate for organic products - No sufficient alternatives have been identified <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - No aseptic packaging of foods - Organic production and handling would be severely limited due to food safety concerns and FSMA requirements - Business would end - People could get sick and die 	5
Nutrient vitamins and minerals	11	<p>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</p> <p>The material is essential because:</p> <ul style="list-style-type: none"> - Use for nutritional fortification for various organic products (yogurt, milk, fruit juices, cereal, flour, gummy candy, fruit snacks, nutritional supplements, various snacks, cereals, and baked goods, as wells as foods for infants and children) - Essential for meeting nutritional needs - Essential for meeting federal and state regulations for nutrition - Essential for formulating nutritional supplements - Standard milk nutrient fortification ingredient: Vitamins A&D, D <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Have used a natural vitamin when commercially available - 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 - There are not organic options for many nutrients - No alternative management practices are sufficient <p>If the material were prohibited:</p>	4.9

		<ul style="list-style-type: none"> - Some products would not be produced in organic form due to poor quality - Unable to comply with state and federal laws - Unable to fortify certain products which are for populations with specific nutritional needs. - Would convert to conventional if not possible to reformulate <p>Ancillary substances: acacia gum, corn starch, medium chain triglycerides (from palm oil), tocopherol</p>	
Peracetic acid	11	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used routinely as a sanitizer on manufacturing equipment across multiple processing lines and production facilities - Used as a wash for organic vegetables prone to high bacteria counts - CIP sanitizer for raw milk tankers - Leaves no residues and has low VOC emissions compared to alternatives - Essential for food safety <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - There are few alternatives and options that are allowed or are appropriate for organic products - No sufficient alternatives have been identified that would make this material unnecessary - No equal alternative for controlling microorganisms as part of our overall food safety program <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Could not produce organic products - Lowered level of quality and possible safety risks - Organic production and handling would be severely limited due to food safety concerns and FSMA requirements - Business would end - Unable to sell fresh fruits and vegetables 	4.5
Potassium citrate	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - 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. 	3
Potassium phosphate	0		
Sodium acid pyrophosphate	3	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a leavening agent in various organic products (baked goods, tortillas, snacks, refrigerated baked goods) <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - 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. <p>If the material were prohibited:</p>	4.5

		- Unable to make certain organic baked goods	
Sodium citrate	6	<p>The material is essential because:</p> <ul style="list-style-type: none"> - 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, various dairy products) - Essential in a sugar-acid-pectin gel to helps control calcium availability so that the pectin doesn't prematurely gel. - 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. - Maintains freshness and pH emulsion <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Other allowed alternatives do not have proper pH stabilization properties needed in a pectin-based gummy fruit snack - Citric acid is used in conjunction with Sodium Citrate to balance the pH. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Decline in quality - Unable to make certain dairy products with a stable and consistent pH 	4.7
Tocopherols	6	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as an antioxidant in various organic products (cereals, snacks, cookies, granola bars, milk products) - Essential for preventing rancidity in whole grain products - Used to lesson 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 in reduced and the organoleptic quality of organic products are enhanced. <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Have extensively researched organic rosemary extract as an alternative but has not performed equally to tocopherols. - Have trialed rosemary oil but it is as effective as tocopherols as an long-lasting antioxidant. It also imparts a distinct flavor that is not desirable in certain products. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Certain products would have significantly shorter shelf-life - May switch to conventional production 	4.7

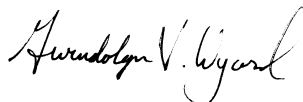
§205.606 – Non-organically produced agricultural products allowed as an ingredient in or on processed products labeled as “organic” only when the product is not commercially available in organic form.

Substance	# of responses	Summary of responses	Average rating of Essentiality (from 1 to 5, with 5 being “critical – would leave organic without it”)
Celery powder	4	<p>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</p> <p>The material is essential because:</p> <ul style="list-style-type: none"> - 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). - Essential for providing additional attributes to curing, including maintaining a pink color, flavoring, and lowering acidity of the finished processed meat product. - Essential for blocking the growth of <i>Listeria monocytogenes</i> and <i>Clostridium botulinum</i> in the processed meat product. <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No supplier is known to produce organic celery powder at this point. - 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. - Not able to identify an organic plant source that could effectively provide the properties of non-organic celery powder <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Organic meat producers, would also no longer be able to produce cured products such as ham, bacon, and hot dogs. - Many certified organic processed meat products would be removed from the market. - Increased food safety risk from <i>Listeria monocytogenes</i> and <i>Clostridium botulinum</i> - 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) 	4.3
Fish oil	2	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for Omega 3 supplementation in organic products <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - No certified organic fish to get it from. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Discontinuation of organic products 	4
Gelatin	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used in the manufacturing of organic gummies <p>Organic alternative are not sufficient because:</p>	5

		<ul style="list-style-type: none"> - 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. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Decline in quality of product - Economically devastating 	
Orange pulp, dried	3	Producers of organic oranges responded to this survey. Year round, these producers generate organic wet orange pulp and peel as a byproduct which is then sold to the food processing industry to be dried or otherwise used.	n/a
Seaweed, Pacific kombu	0		
Seaweed, Wakame	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,



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 essentially 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.



October 3, 2019

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

Docket: AMS-NOP-19-0038

RE: Dairy Cultures (Sunset 2021)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the 2021 Sunset Review of dairy cultures listed on 205.605(a) of the National List (non-agricultural (non-organic), non-synthetics allowed in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))”.

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 dairy cultures on the National List because they are an essential ingredient for organic processing used in a number of different kinds of fermented organic dairy applications such as yogurt, cheese and cultured butter production. Certified organic ‘dairy cultures’ are not commercially available, and we are unaware of any recent or new information demonstrating that they are harmful to the human health or the environment. Please see our 2021 Sunset Survey results for more information on the essentiality of dairy cultures.

We support the retention of dairy cultures as a separate listing on the National List, and do not support folding the allowance into the broader listing of microorganisms.

The Organic Trade Association supports retention of dairy cultures as a separate listing on the National List for the following reasons:

1. Removing dairy cultures from the National List could have a negative impact. Dairy cultures are listed in the ingredient statement of dairy products they are added to, generally as dairy culture, live cultures or microbial cultures. **See exhibit A.** The continued listing of dairy cultures on the National List supports the interests of food manufacturers and shoppers focused on food label literacy and transparency. Organic companies strongly favor a separate listing of dairy cultures on the National List that can be easily cross-referenced with the listing on an ingredient label and visa-versa. The listing of “microorganisms” on the National List does not easily match or translate in lay terms to the appearance of “cultures” on an ingredient label. The Organic Trade Association supports a National List that is user friendly and accessible to shoppers and label readers.

2. The listing of dairy cultures is not redundant. From a technical and phylogenetic perspective, we agree that ‘dairy cultures’ can be viewed as sub-category of microorganisms. However, dairy starter cultures include a unique subset of microorganisms used for certain dairy products to create a desired outcome, most often through their growth and fermentation process. The unique application of dairy cultures, the composition of the starter cultures, and the process to grow the starter cultures, in combination with a distinct listing on the National List, provide an opportunity to create and/or tailor an annotation that could address certain specifications or restrictions such as organic preference or use of ancillary substances. One noteworthy example is the listing of “yeast,” also a microorganism, but maintained as a separate listing with an annotation that supports organic preference. Retaining a separate listing of dairy cultures provides long-term flexibility, potentially saves USDA resources and caters to future innovation.
3. Removing dairy cultures from the National List for the purpose of folding its continued allowance into a separate listing (microorganism) is not an appropriate action during the Sunset Review process. A recommendation to remove a substance from the National List for organizational or “clean-up” purposes should be done through a petition or separate recommendation that follows its own regulatory track, separate from the Sunset process. We believe the background, discussion and proposal will be better tracked and responded to if a stand-alone proposal is presented to the public. We are concerned that a Sunset proposal to remove dairy cultures may get lost in the process and will not be easily searchable or accessible through the listing of microorganisms. We also view the proposed action to be analogous to changing an annotation during the Sunset Review, which is not allowed under the current Sunset process. We strongly urge NOSB to address the organization of the National List outside of the Sunset Review process and focus its review strictly on renewal or removal.

Overall, we believe the potential negative impacts of removing dairy cultures from the National List (as a separate entity) far outweigh any perceived benefits. We urge NOSB to leave the listing as it is. On behalf of our members across the supply chain and the country, the Organic Trade Association thanks NOSB for the opportunity to comment, and for your commitment to furthering organic agriculture.

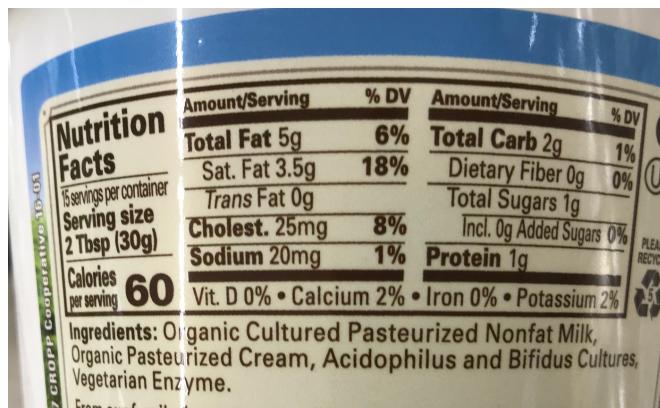
Respectfully submitted,



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

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Exhibit A: Example labels listing dairy cultures / live cultures



INGREDIENTS: Organic Pasteurized Whole Milk, Organic Pasteurized Nonfat Milk, Organic Agave Nectar, Organic Vanilla Extract, Organic Vanilla Flavor, Organic Inulin, Lactase Enzyme, Live Cultures (including 11 probiotic strains: *Bifidobacterium lactis* BB-12®, *L. acidophilus* LA-5®, *L. rhamnosus* LB3, *L. casei* [2 isolated strains], *L. rhamnosus* [2 isolated strains], *L. acidophilus* [2 isolated strains], *Bifidobacterium lactis* [2 isolated strains])

BB-12® and LA-5® are registered trademarks of Chr. Hansen

Ingredients: Organic Cultured Unpasteurized Milk, Sea Salt, Vegetarian Enzyme.
Made with raw milk aged a minimum of 60 days.

INGREDIENTS: Pasteurized organic whole milk, organic nonfat dry milk, LIVE PROBIOTIC CULTURES (*Bifidobacterium lactis* BB-12®, *L. acidophilus* LA-5®, *L. casei*, *L. rhamnosus* LB3), LIVE YOGURT CULTURES (*L. bulgaricus*, *S. thermophilus*).



October 3, 2019

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

Docket: AMS-NOP-19-0038

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.

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 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 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 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 of years, choline¹ 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.

The annotation in the 2012 proposed rule, coupled with nutrients petitioned and passed by 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 is 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

¹ 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.



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



October 3, 2019

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

Docket: AMS-NOP-19-0038

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. We are also pleased to announce that the Organic Trade Association in collaboration with The Organic Center and the University of Wisconsin was just [awarded](#) \$2 million in research funds for the development an organic alternative to conventional celery powder through the Organic Agriculture Research and Extension Initiative (OREI). The announcement was made on October 3, 2019.

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. Significant work and investment to achieve this goal are underway, significant research funding has been secured and measurable progress is being made. Therefore, we request that celery powder remain on the National List until the time that organic celery powder becomes commercially available.

We offer the following more detailed comments:

Non-organic celery powder is essential for the production of ORGANIC processed meats

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 at this time 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 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 for consumers who 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 barriers perhaps are 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 being trialed. **See our comments on research efforts below.**

There is not enough organic celery being produced to support the meat industry

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. In terms of other natural or organic sources that could provide the same function, there are

in fact other vegetables and minerals that contain natural nitrates including beets, Swiss chard, spinach and sea salt. However, each has its benefits and challenges, and 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.

There is a need to develop an organic alternative that is consistent with organic principles

The Organic Trade Association is 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 techniques and trying to mimic those 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.

Significant progress is being 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, again in 2018 and most recently in May 2019. 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 harvested in fall 2016. Unfortunately, the 2017 and 2018 OREI funding proposals were not accepted, slowing research progress down significantly.

Despite the setback, the efforts continue in full force, and **another \$2 million OREI grant was submitted in April 2019 and the announcement that we received the full award was released on October 3rd**. The working group research project, titled “Organic Alternatives to Conventional Celery Powder as a Meat Curing Agent, 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 that 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 to date has put the project behind schedule, we believe significant progress is being made, and the commitment and organization of the Celery Powder Working Group and our research partners have presented a solid model on how to best carry out the process for developing alternatives to a National List material. **See Attachment A & B.**

The Organic Trade Association, in partnership with The Organic Center and the University of Wisconsin, looks forward to continuing our research and sharing updates with NOSB over the next five years.

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.

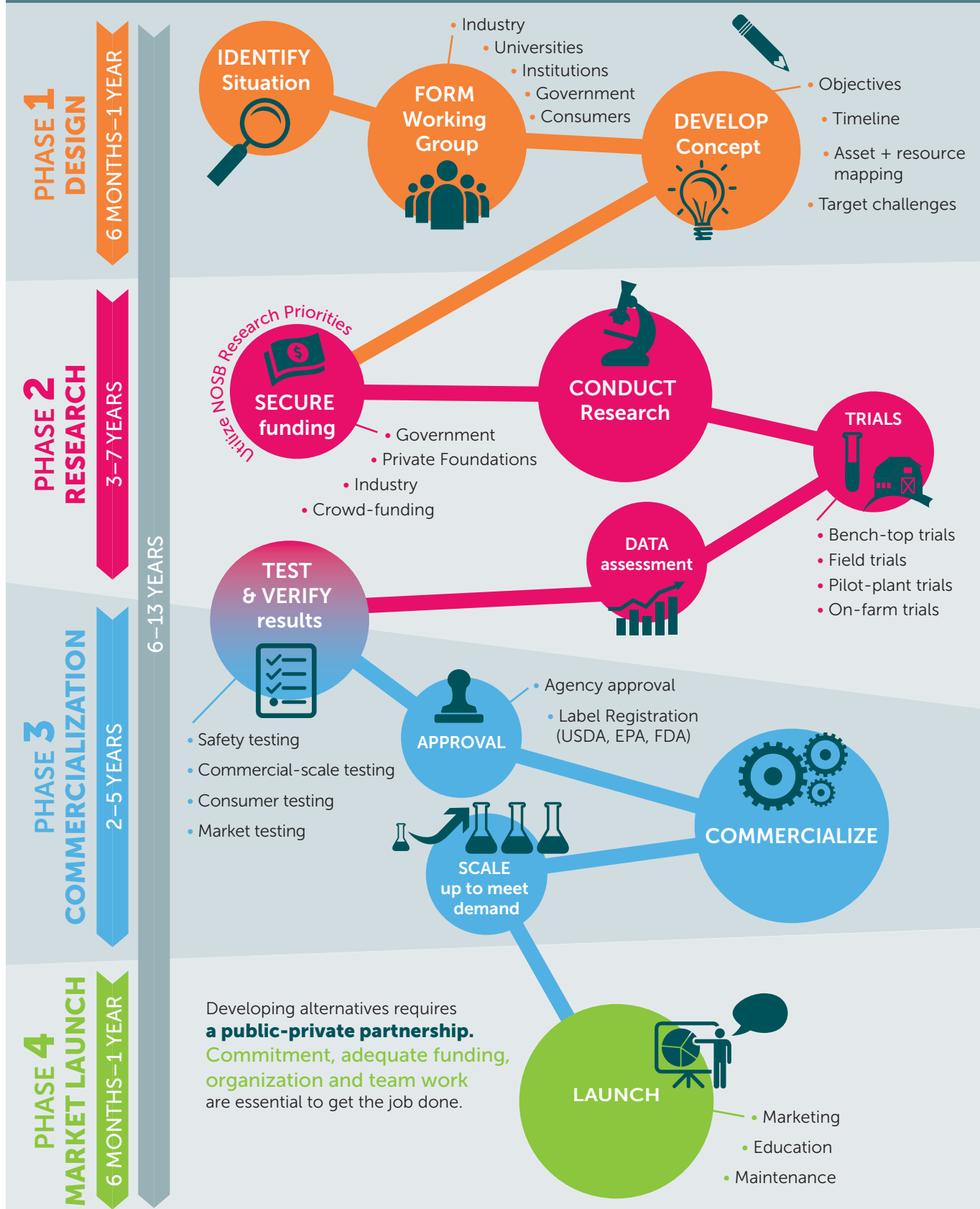
Respectfully submitted,

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: Developing an Organic Alternative to Celery Powder

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



Developing an ORGANIC ALTERNATIVE TO CELERY POWDER

AN ORGANIC TRADE ASSOCIATION WORKING GROUP PROGRESS UPDATE



RESEARCH plan and FUNDING request (OREI)

Working Group REVIEW and SIGN OFF

OREI planning grant AWARD

Update - just announced
on October 3rd -
we received the full \$2
million award!



~~Continue to
apply for the
full OREI
funding request
(\$2 million)~~



Convened National
Stakeholder
Meeting to discuss
research questions





October 3, 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-19-0038

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 Council¹ to help assist in distribution to NOP certified farmers.

Results of OTA Sunset Surveys

OTA has received **8** responses on our 2021 Crops Sunset Surveys (3 are new responses since the spring meeting). 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"> - Used as a post-harvest sanitizer for citrus as part of a food safety protocol and leaves no residues on the fruit - Used for controlling sweet orange scab and greasy spot in citrus - Used for controlling purple blotch in onions <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Not as effective - Not as safe - Leaves undesirable residues - Undesirable cumulative build up in the soils <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Economic effect on the cost of operation 	5
Ammonium soaps	0		
Horticultural oils	2	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - In organic banana production, it is used to control black sigatoka, a leaf fungus that is the most severe disease in banana production - 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 <p>Alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Natural plant oils are not as effective - 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. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Reduction in banana yields by over 50% which could eventually lead to abandonment of organic farming activities altogether. 	5

¹ 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.

		- Difficulty controlling most pests and diseases in other crops	
Pheromones	1	The material is necessary because: <ul style="list-style-type: none"> - Used as fly control in facilities 	5
Ferric phosphate	0		
Potassium bicarbonate	0		
Magnesium sulfate	1	The material is necessary because: <ul style="list-style-type: none"> - Used in liquid fertilizer to provide magnesium as a crop nutrient Alternatives are not sufficient because: <ul style="list-style-type: none"> - Other magnesium sources exhibit production issues and are more challenging to work with If the material were prohibited: <ul style="list-style-type: none"> - Detrimental economic effects. Would have to search for approved alternatives, test them for production issues and efficacy and pull old product from warehouses 	4
Hydrogen chloride	3	The material is necessary because: <ul style="list-style-type: none"> - 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"> o Used only once per year (at planting). o Only planting seed is treated with HCl---no animal feed products are delinted. 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. Alternative are not sufficient because: <ul style="list-style-type: none"> - There are no commercially available, effective, natural alternatives for delinting cotton planting seed that work on a consistent basis. - A mechanical delinting process is under development but it has not been perfected and is not in commercial use. - Undelinted seed could be planted by hand. However, that is not an economically viable option in the U.S. If the material were prohibited: <ul style="list-style-type: none"> - If it is not allowed for delinting purposes, the U.S. organic cotton industry will cease to exist! - There would be no organic cotton grown in the U.S. - Bankruptcy for U.S. organic cotton growers. 	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)



October 3, 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-19-0038

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 Crop 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 continues to support 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.
- ✓ In response to the discussion questions posed by the NOSB Crops Subcommittee, we question if commercially available paper-based production aids would be compliant.

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 material is planted into the soil along with the plant material.

At the fall 2018 meeting, NOSB presented a discussion document to solicit public comments on the necessity and environmental impact of the material and the availability of alternatives. At the spring 2019 meeting, NOSB presented a second discussion document that continued to explore the petitioned material, and expanded the scope of its review to include a variety of paper-based production aids including pots, seed tape, collars, and hot caps. Out of concern for the use of synthetic fibers in paper-based planting aids, NOSB requested a technical report to evaluate the types of synthetic fibers and the biodegradability of the synthetic fibers used in these types of products. The technical report is now available¹. At this meeting (fall 2019), NOSB presents a third discussion document² that summarizes the Crops Subcommittee's evaluation of these paper production aids against the National List criteria using the information from the technical report.

Scope of Review

Consistent with our previous comments, we encourage NOSB's scope of review to be inclusive of generic products that are paper-based and used as planting or seeding aids that are left to degrade in the soil. This broadened approach will make efficient use of NOSB's efforts to review the existing variety of paper-based planting aids that share these key common characteristics (as underlined above). If the listing on the National List for these products were limited only to paper "pots" or "containers," it may exclude other paper-based planting aids made of the same material (paper) and used in the same manner (planted in ground), but are designed in slightly different customized design for whatever particular planting method is used.

At the spring 2019 meeting, NOSB indicated its plans to include seed tape, collars, and hot caps. At that time, we questioned NOSB's intent to broaden the scope to include products that *aren't* intended to degrade in the soil. At that time, we did not object to this broadened scope, but acknowledged 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.

Now that NOSB is considering a potential future annotation that specifies biodegradability parameters, we feel it important to revisit the question of scope. OTA suggests that the appropriate scope of review is generic products that are paper-based and used as planting or seeding aids that are left to degrade in the soil. Other production aids that are not intended to degrade in the soil (which is a very large category of very diverse products) should be outside the scope of review. Rather, we suggest a practical scope of review that is *broad enough* to capture the petitioned material as well as similar inputs that are paper-based and used as planting or seeding aids that are left to degrade in the soil (e.g. pots, chains, seed tape), but *narrow enough* to provide clear boundaries around the types of inputs intended to be included under the listing.

To address this scope of generic materials on the National List, the listing could read "Planting Aids" or "Seeding and Transplanting Aids," for example. The annotation for such listing would establish

¹ <https://www.ams.usda.gov/sites/default/files/media/PaperTRFinal7262019.pdf>

² <https://www.ams.usda.gov/sites/default/files/media/CSPaperPotsDDFall2019.pdf>

requirements common to all such products (e.g. “made from virgin or recycled paper; without glossy or colored inks”) and any other limitations as identified by NOSB regarding additives or other issues.

Discussion Questions

The NOSB Crops Subcommittee has requested feedback on the following discussion questions.

1. *Please comment on the following options under consideration by the subcommittee for listing at §205.601(o) as production aids:*
 - a. *“Virgin or recycled paper, without colored or glossy inks,” or*
 - b. *“Virgin or recycled paper, without colored or glossy inks; any synthetic polymer fibers included must not exceed 15% of the paper and must be 100% bio-based with content determined using ASTM D6866 (incorporated by reference; see 205.3), and demonstrates at least 90% biodegradation absolute or relative to microcrystalline cellulose in less than two years, in soil, according to one of the following test methods: ISO 17556 or ASTM D5988 (both incorporated by reference; see §205.3)”*

No comment regarding Option A.

Regarding Option B, we have questions about whether NOSB has confirmed that commercially available forms of generic paper-based production aids (that are intended to be allowed under this listing) will actually comply with the restrictive annotation. A clear understanding of the scope of allowable products under this annotation is critical, especially if the Board intends to expand the scope of the review to include seed tape and other planting aids intended to degrade in the soil.

2. *Synthetic polymer content—*
 - a. *Should a maximum synthetic polymer content be stated explicitly? If so, what is the appropriate level?*
 - b. *What is the amount (or range) of synthetic polymer content in products currently available?*
 - c. *How would synthetic content be measured? How would a certifier or Material Review Organization verify content? For example, if a product included recycled paper as an ingredient, how would the synthetic polymer content be determined?*
 - d. *Is it possible to manufacture paper production aids that use only natural fiber sources and that meet the product specifications for their intended use?*

No additional comments.

3. *Biodegradability—*
 - a. *Should a biodegradability standard be included for these products? If so, is this the appropriate biodegradability standard?*
 - b. *Does maximum synthetic polymer content need to be stated if there is a biodegradability requirement?*
 - c. *As the products biodegrade, what is the impact on the soil? Also, can fragments be consumed by wildlife or livestock before they are completely degraded?*

No additional comments.

4. *Bio-based content—*

- a. *Should a minimum bio-based content standard be included for these products?*
- b. *Is 100% bio-based content achievable for these products? If not, what should be the minimum bio-based content requirement?*

No additional comments.

5. *Is genetic engineering involved in the production of these products?*

No additional comments.

6. *Does the annotation need to specify that added fungicides, insecticides, or other synthetic materials not typically found in paper would not be allowed, or is that already understood?*

No additional comments.

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



October 3, 2019

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

Docket: AMS-NOP-19-0038

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 the excluded method status of “induced mutagenesis” and “embryo transfer (embryo rescue)” in animals.

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 organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers’ associations, distributors, importers, exporters, consultants, retailers and others. OTA’s Board of Directors is democratically elected by its members. 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 recognizes that the definition of “excluded methods¹” was based on the efforts of NOSB in 1995, and several new technologies have emerged since that time. As a result, it is extremely helpful for organic producers and handlers as well as Accredited Certifying Agencies (ACAs) and USDA’s National Organic Program (NOP) to have guidance including clear and up-to-date terminology to make consistent and concrete determinations regarding compliance with the prohibition of excluded methods. For this reason, we continue to be supportive of NOSB’s work on a terminology chart that complements and provides additional detail to the existing regulatory definition of “excluded methods.”

The Organic Trade Association supports the recommendations that have been made to date and this includes the clarification provided in the 2016 Recommendation that gene editing techniques, such as CRISPR, are currently prohibited under the National Organic Program regulations per the existing definition of “excluded methods.” The the term ‘bioengineering,’ as defined by USDA, does not and

¹ *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.



should not affect the definition of “excluded methods” or any other definition under USDA’s National Organic Program. We maintain that gene editing and the other methods that are listed as ‘excluded methods’ in the terminology chart are inconsistent with our existing definition and are therefore prohibited.

As we continue to work on a terminology chart, it is important that we do not lose sight of the existing strength of our definition of ‘excluded methods’ and the first sentence that needs to be maintained and held central to these discussions:

“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.”

Although the definition was written pre-2000, this first sentence provides a key foundation that should be applied to all new emerging technology. The Guidance is extremely helpful because it provides additional examples beyond the ones that are included (but not limited to) in the regulatory definition of ‘excluded methods.’

With respect to the recommendation for this fall 2019 meeting, we support a full board recommendation to add the following to the NOP excluded methods guidance as proposed by the subcommittee:

Induced mutagenesis – Developed via use of in vitro nucleic acid techniques

- Add as an **“excluded method”** – “YES” in the chart

Embryo transfer, embryo rescue, in animals

- Add as **NOT an excluded method** – “NO” in the chart

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
Vice President of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



October 3, 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-19-0038

RE: Materials Subcommittee Proposal – 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 Proposal on Genetic Integrity Transparency of Seed Grown on Organic Land. The subcommittee is putting forth a proposal for NOP to issue "Instruction to Certifiers" to encourage their certified organic producers to obtain information from their seed or planting stock suppliers about any GE contamination found in the seed/planting stock they are purchasing. The proposal addresses all seed or planting stock that has a GE equivalent in the marketplace. There is no specific requirement, other than for certifiers to instruct their clients about the option to request GE contamination test results from their seed and planting stock providers.

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, and that placing a control point at the beginning of the process will help set the 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 one of the fundamental practices that encourages prevention of GMO contamination throughout the supply chain.

In summary:

1. The Organic Trade Association generally supports the intent behind the subcommittee's proposal. The following sections of the proposal, however, are problematic and in need of revision or further clarification:

- The proposal in 1A encourages producers to contact their suppliers “**to obtain GE contamination test results.**” In order to encourage a more realistic outcome consistent with what we believe seed suppliers will be willing to provide, we suggest the sentence be revised to read: “...**to obtain information regarding the levels of GE contamination.**”
 - We are unclear if the instruction applies to both organic *and* non-organic seed / planting stock. It is important to note that positive GE contamination data for organic seed obtained by the certifier could trigger an investigation on the seed itself (see NOP Policy Memo 11-13). GE contamination data for non-organic seed, however, would not trigger an investigation for the seed itself. This could potentially impose undue burden on organic seed growers and suppliers. Furthermore, in addition to the organic production requirements for organic seed, there is also an already an established process for certifiers to follow when GE contamination is discovered in an organic crop.
2. The Organic Trade Association supports NOSB’s continued request for a NOP funded task force to systematically collect data on GE contamination to better inform the extent of the problem and to help inform an appropriate solution.
 3. The Organic Trade Association recommends that NOSB 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. The proposal for the fall 2019 meeting presents a significant departure from the original discussion in 2013 (to develop a seed purity standard), but it continues to reflect the overriding goal of keeping GE contamination out of organic food, feed and fiber.

The Organic Trade Association emphasizes that all reputable organic seed companies are testing, and that organic 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 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. As such, we support a recommendation that encourages and supports this continued practice. We do not support a proposal that would discourage this practice or create an undue or unfair burden on organic seed growers and suppliers. In fact, we are most supportive of a proposal that encourages organic certification and use of organic seed and discourages use of non-organic seed when organic seed is available. We also place strong emphasis on the support of a process-based standard and robust implementation of GE contamination prevention measures vs. handing down penalty to organic seed producers for inadvertent

GE contamination.

To help meet our goals, strengthen the proposal and support future work in this area, we respectfully ask NOSB to consider the following suggestions:

The proposal is in need of minor revisions and/or clarification

1. The proposal in 1A encourages producers to contact their suppliers to obtain GE contamination test results. From our understanding based on the results of Organic Seed Alliance survey and in consultation with our member organic seed suppliers, the reference to “test results” sets up an unrealistic expectation of what seed suppliers would be willing to share.

We recommend that the language in the proposal be revised to say “can contact their suppliers.....to obtain information *regarding the levels of GE contamination* that may be present.” If requested, we do not believe seed suppliers will be willing to provide actual test results. However, we do believe they will be willing to share information on contamination levels.

2. In the proposal, the Subcommittee explains:

“To meet the current certification standard, farmers are required to provide documentation that the seed they plant was not produced using excluded methods. This standard is met in one of two ways. 1) Certified organic seed breeding companies must verify excluded methods were not used in the production of certified organic seed. 2) For non-organic seed, a non-GE affidavit is required if the crop has a genetically engineered equivalent in the marketplace. Affidavits typically state “to the best of the seed supplier’s knowledge, the seed was not produced using excluded methods”; however, the affidavit does not address the issue of possible contamination of the seed lot with seed produced using excluded methods. The *intentional* use of seed produced by an excluded method is prohibited. Non-GE affidavits have been accepted as proof by organic certifiers that the seed is acceptable in organic systems.

It is unclear if the proposed instruction to collect GE contamination is intended to apply to both organic and non-organic seed / planting stock. It is important to note that positive GE contamination data obtained by the certifier could trigger an investigation and require GE prevention improvements on the organic seed (see NOP Policy Memo 11-13). However, it would not trigger an investigation of non-organic seed, if the investigation is for the seed/planting stock itself vs. a “finished organic crop” as is suggested in the proposal. This could potentially impose undue burden on organic seed growers and suppliers.

The Organic Trade Association recommends that the instruction to collect GE contamination information be directed at the purchase and use of **non-organic seed**. The organic certificate should provide adequate compliance documentation to producers for the purchase of organic seed. Furthermore, the regulations and associated NOP policy already require certifiers to investigate unintended GE contamination in organic crops and product. Certifying agents are already responsible for working with organic producers to identify the source of the inadvertent GMOs

and to implement improvements to avoid contact with GMOs in the future. Therefore, we recommend that the instruction be directed at the collection of GE contamination data for non-organic seed that is used when organic seed is not available.

Meaningful data collection is needed to inform an appropriate solution

The proposal on the table for this meeting would bring about instruction from NOP to certifiers to be proactive in encouraging their farmers who grow organic crops to obtain information from their seed or planting stock suppliers about any GE contamination found in the seed. The intent of the proposal is not to set any specific seed purity requirement but rather facilitate a conversation between certifiers and their certified farmer clients that would aid producers in collection of testing data to help inform choice and ultimately support a goal of low-to-no detection of GE contamination of their organic crops. The proposal is not recommending that the testing data be used to inform a seed purity standard.

The Organic Trade Association has consistently emphasized that any seed data collection efforts to inform the feasibility of a seed purity standard need 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 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 for the sake of informing a seed purity standard should happen outside of the certification and compliance system. Therefore, we support NOSB's continued efforts towards a NOP funded task force:

"The NOSB continues to request that the NOP fund a task force that would collect information on the genetic integrity of seed planted on organic land so the organic community - from farmers to consumers - would have statistical information detailing GE contamination issues. This task force would be empowered to collect data for multiple years, since growing conditions and crop production issues change from year to year, and in order to collect useful information, numerous years and regions must be tracked. We know there are issues with some crops in some regions, but there has not been a comprehensive review of data to provide a clear picture of the problems. Without this information, the organic community cannot develop solutions."

The Organic Trade Association envisions that the primary function of a seed task force would be to design a feasibility study based on testing (data collection) that would be administered and carried out by USDA. A data collection effort that yields statistically significant and meaningful results needs to be designed systematically according to established sampling protocols and testing specifications. This panel of experts would not only design the framework for the data collection the organic community continues to call for, but it would also act as an expert panel to interpret the data being collected. This, in turn, would help shape a NOSB recommendation to NOP on appropriate crop-specific testing thresholds for seed if that is a direction we want to continue to pursue. We can expect that any established threshold is going to need to be acceptable to consumers and realistic for seed growers. It would also need to be established on a crop-by-crop basis.

OTA continues to request a proposal for 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 is void of procedures and criteria specific to GE testing. We continue to hear that certifiers would be more likely to increase GE testing if there were testing guidelines and protocols to follow. An update to NOP’s existing residue testing guidance and inclusion of guidance on GE testing should therefore 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 will also be very important. Certifiers are 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.

As a next agenda item, 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 is 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 continued effort towards a USDA funded systematic approach for 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. Furthermore, a list of tests and testing laboratories along with approved methods of sampling and testing methods could in turn be used by the seed task force in the design of a feasibility study on GE contamination.

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 order to improve the proposal to NOP, we recommend the following:

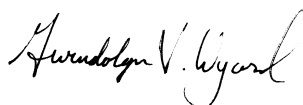
1. Revise 1A to read “Producers who are growing...can contract their suppliers to obtain ~~GE contamination test results~~ information regarding the levels of GE contamination.”
2. Revise the instruction so that the suggested collection of GE contamination information is specific to the purchase and use of non-organic seed. The organic certificate and existing investigative requirements should provide adequate compliance documentation to producers for the purchase of organic seed.

We also request: 1) NOSB continue its efforts towards a NOP funded task force; and 2) NOSB focus next on a recommendation to NOP requesting guidance on GMO testing for certifying agencies and industry.

Finally, although we do not have an exact solution at this time, we feel it is important to note that some of the excluded methods of concern are currently not testable and would not be addressed by this proposal. To this point, we continue to place emphasis on the outcomes of a process-based standard vs. the test results of a product. Testing, in fact, is an important tool to help determine compliance, but it should never become the be-all and end-all.

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



October 1, 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-19-0038

RE: Materials Subcommittee - Research Priorities 2019 (Proposal)

Dear Ms. Arsenault:

Thank you very much for this opportunity to provide comments on the Materials Subcommittee proposal on Research Priorities for 2019.

The Organic Center is a non-profit organization with the mission of convening credible, evidence-based science on the environmental and health benefits of organic food and farming and communicating findings to the public. We are a leading voice in the area of scientific research about organic food and farming, and cover up-to-date studies on sustainable agriculture and health while collaborating with academic and governmental institutions to fill knowledge gaps.

The Organic Center thanks the Materials Subcommittee for its recommendation on Research Priorities. We appreciate the creation of the Research Priority Framework and the efforts made by each Subcommittee to bring forth its research priorities for 2019.

Summary:

- ✓ The Organic Center supports the subcommittee's proposed 2019 Research Priorities. The proposed priorities are in line with the needs of the organic industry, and will serve as an important resource to guide The Center's research priorities and project development.
- ✓ Based on feedback we've received during our own outreach efforts, we would also like to suggest that the areas of **soil health**, **climate change**, and **pathogen protection** be considered for inclusion in the 2019 Research Priorities.



We offer the following more detailed comments:

Current Research Needs

We have reviewed the list of topics included for 2019 priorities, and we're particularly pleased to see the inclusion of "Organic no-till practices for diverse climates, crops, and soil types," "Development of systems-based plant disease management," "Strategies for the prevention, management, and control of invasive insects," and "Production of celery for celery powder yielding nitrates sufficient for cured meat." The Organic Center is actively involved in conducting and communicating research on these issues, and we expect the prioritization of these topics by NOSB may help us secure further funding.

Organic No-Till Practices

The Organic Center is collaborating with Dr. Kate Tully's lab at the University of Maryland to examine practices improving soil health on organic farms. One of the areas that we included was the comparison of no- and low-till in organic production versus standard tillage in organic production. Overall, our results suggest that surface-level soil organic carbon levels are higher in low/no-till organic plots compared to standard organic tillage plots. However, we also found that no/low-tillage in organic was associated with significant reductions in yield. These findings suggest that while organic farmers could improve carbon sequestration through no/low-tillage, there needs to be further research to support farmers wishing to make this conversion to ensure that it is a viable and economically feasible option for a wider variety of crops. We are thankful that NOSB included this priority in its 2019 Research Priorities, as it will help encourage research on this critical issue, and provide much-needed tools to help organic farmers realize the benefits of reduced tillage without the threat of reduced yields.

Plant Disease Management

The Organic Center has been working on several aspects of plant disease management directly called out in NOSB 2019 Research Priorities. For example, we have an active project on citrus greening, caused by the bacterium *Candidatus liberibacter*. Our research to find organic solutions to control citrus greening disease is an ongoing project in collaboration with the University of Florida, the University of California, Davis, USDA-ARS, citrus growers, and other non-profits. We recently published a scientific paper and accompanying farmer guide consolidating existing literature on allowable methods for combating citrus greening in organic groves. It details science-based best practices for organic citrus growers. We leveraged this paper to apply for an OREI planning grant to develop a proposal that takes a systems-based approach to combat both the bacterium that causes citrus greening disease and its insect vector, the Asian citrus psyllid, in organic systems.

Invasive Insects

In addition to our work on the Asian citrus psyllid, The Organic Center is also completing research to develop Integrated Pest Management strategies for organic rice production in the Southern United States. This project is being conducted in collaboration with Texas A&M



University's AgriLife Research & Extension Center, Texas A&M Department of Soil and Crop Sciences, USDA's ARS Dale Bumpers National Rice Research Center, University of Arkansas Rice Research and Extension Center, and University of Arkansas at Pine Bluff Department of Agriculture. Flooded rice production systems used by organic farmers result in increased pressure from the diseases, weeds, and insect pests not commonly found in dryland cropping systems. This is especially problematic in the South because of the region's warm, humid environments and long growing season. This project focuses on developing cover crop-based production systems in combination with cultivar choice and seed treatment to enhance disease, weed, insect pest, and nutrient management, allowing producers to grow organic rice more sustainably and profitably in the South.

Celery Powder

In collaboration with the Organic Trade Association's National List Innovation Working Group and the University of Wisconsin, Madison, we are investigating the potential for developing organically grown celery or other vegetables used in the curing of organic meat products. This OREI-funded research will help 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 to achieve target nitrate levels in the curing crop to produce the required shelf life and prevent bacteria in the cured meat, and to produce the desired flavor, color and texture in food.

Additional Research Needs

The Organic Center is continually collecting information on research needs from multiple sectors of the organic community. We conduct industry roundtables, work with the Organic Trade Association's Farmers Advisory Council, meet with professors on our Science Advisory Board and hold one-on-one meetings with individual companies, farmers, professors, and consumers. We feel that the NOSB Materials Subcommittee's proposed 2019 Research Priorities are in line with the needs of the organic industry, and appreciate the release of this report as an important resource to guide The Center's own research priorities and project development. Based on feedback we've received during our own outreach efforts, we would also like to suggest that the areas of soil health, climate change, and pathogen protection be considered for inclusion in the 2019 Research Priorities.

Soil Health

The U.S Department of Agriculture's Natural Resource Conservation Service (USDA NRCS) defines soil health as "the continued capacity of the soil to function as a vital living ecosystem that sustains plants, animals and humans." While many other definitions of soil health exist, the majority of modern definitions exemplify the ecological attributes of soils, recognizing that their importance extends far beyond simple crop production.

A growing body of scientific literature evaluates the relative contribution of different management practices for improving soil health. However, significant variation in characteristics

assessed and the methods used to gauge those means that oftentimes results across different studies are not comparable. Even when scientific studies do use comparable measures of soil health, they may come to contradictory conclusions. Management decisions that lead to an improvement in soil quality in one study may be less effective in another, suggesting that some protocols must be carefully considered based on localized conditions to achieve best results. As such, reaching solid conclusions on best-management practices for achieving optimal soil health and fertility can be difficult, particularly for organic farmers who cannot rely on formulaic recommendations for fertilizer application.

To address this, The Organic Center is collaborating with researchers from the University of Maryland–College Park to conduct a comprehensive review of the most current science that evaluates organic compliant methods for optimizing soil health to develop best practices for organic farmers. Specifically, this project seeks to (1) review the literature comparing soil health on organic and conventional farms and discussing practices that differ between them that could be contributing to this difference; (2) understand variance in characterization of soil health and indicators used to assess it within the scientific literature; (3) identify science-supported best practices for maintaining and building soil health in organic systems; (4) identify practices that lead to variable results based on geography, climate, soil type, or commodity grown and therefore must be optimized based on local variables, and (5) identify areas where more research is needed.

Climate Change

Climate change is having serious consequences on our environment and public health. More extreme weather events, sea level rises, ocean acidification, increased frequency and intensity of wildfires highlight just a few areas that have been impacted recently. Food systems are especially vulnerable to climate change, and they are in an interesting predicament—they are a significant contributor to one of their own biggest threats. However, a growing body of research demonstrates that organic farming is poised to be part of the climate change solution, and some strategies employed by organic farming can also help with resilience to current climate issues such as drought and flooding.

The Organic Center recently held its annual Organic Confluences Conference, co-hosted this year by USDA, FiBL, The Climate Collaborative, and ISOFAR. The 2019 focus of the conference was on mitigating and adapting to climate change. It brought together scientific experts, farmers, policymakers, and organic stakeholders to address the current impacts of climate change and best practices within the organic sector for mitigation and adaptation, while examining methods for encouraging the adoption of strategies for fighting climate change. We are currently working on a white paper detailing the outcomes of the event, but it is clear that additional research is needed to address this issue; the long-term security of our food system depends on it.



The Organic Center is already engaged in climate research. For example, we are working on a project in collaboration with researchers at the University of Maryland to pinpoint specific strategies organic farmers can take to increase carbon sequestration in the soil. We are also working with Harvard University's Department of Public Health examining the specific aspects of organic agriculture that can contribute the greatest benefits to climate stability. These net benefits include carbon sequestration in the soil and reduced energy usage by avoiding synthetic nitrogen fertilizer.

However, additional research is needed to pinpoint specific strategies that organic farmers can take to reduce greenhouse gas emissions and respond to current climate challenges threatening the future of our food security.

Pathogen Prevention

Organic agriculture is one of the most strictly regulated agricultural systems. Instead of relying on synthetic fertilizers, the National Organic Program regulations require organic crop producers to manage crop nutrients and soil fertility through crop rotations, cover crops, and the application of plant and animal materials such as manure and compost. Simultaneously, the NOP regulations require organic farmers to maintain and support biodiversity on their farms. Unfortunately, some third-party food safety auditors believe that some biodiversity-maintenance strategies employed by organic farmers may increase the risk for introduction of human pathogens on the field. While some research has been conducted disproving this myth, more research, extension, and education are needed to fully understand the relationship between on-farm biodiversity and food safety – and this research must be communicated to third-party food safety auditors and incorporated into their audits.

Organic regulations also require that raw manure is applied with 90- or 120-day pre-harvest intervals to reduce the possibility of pathogen presence. However, in 2015, the U.S. Food and Drug Administration (FDA) published the final version of the FSMA Produce Safety Rule after a public comment period on the proposed rule requirements.

Of the revisions between the proposed rule and the final rule, most notable to the organic sector were changes made relating to the use of manure and the required application interval between applying untreated manure and harvesting crops covered by the FSMA Produce Safety Rule. FDA deferred from its earlier proposed nine-month minimum interval requirement to give the agency time to conduct research into determining an appropriate science-based application interval. The Organic Center has been collaborating with the University of California, Davis, among other organizations, to address the need for additional information on raw manure intervals to provide critical information for guidelines on risk mitigation of foodborne pathogens for organic and sustainable agriculture.

Please do not hesitate to contact us for information on the data that we have been collecting or with questions you would like us to pose the research community.



Again, on behalf of The Organic Center, I would like to extend my thanks to the Materials Subcommittee for your commitment to furthering organic agriculture.

Respectfully submitted,

Jessica Shade
Director of Science Programs
The Organic Center



October 3, 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-19-0038

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 maintains supportive of efforts to move towards the allowance of only aquatic plants produced and harvested in a sustainable manner.
- ✓ We still have questions about the extent of the problem that needs to be solved, and have identified gaps in the record where technical information is needed regarding the effect seaweed harvesting has on the environment as documented by scientific evidence, and the existing legal framework for seaweed harvesting in countries where most seaweed is sourced.
- ✓ We identify additional activities that NOSB can do to support continuous improvement in sustainable sourcing of inputs used in organic agriculture.

We offer the following more detailed comments:

I. Background

Marine materials (i.e., aquatic plants such as seaweeds and 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 marine ecosystems. The 2015 Sunset Review of the §205.601(j) listing of aquatic plant extracts prompted NOSB to take a closer look at the potential for environmental harm caused by the harvest of marine materials for use in crop input materials. At the time, NOSB was also looking closely at the need for clear taxonomic nomenclature of marine materials across the National List.

At the spring 2019 meeting, the NOSB Materials Subcommittee presented a discussion document¹ that explores options of addressing the environmental impact of harvesting seaweed for use in organic crop production. The primary approach identified by the subcommittee is through existing organic certification tools, by requiring that aquatic plants be certified organic. The discussion document also summarizes a number of alternative approaches including: limiting or prohibiting harvest of certain marine algae; exploring other existing third-party standards for sustainable harvesting; or adding annotations to material listings on the National List to require sustainable harvesting.

OTA supports efforts to move towards the allowance of only aquatic plants produced and harvested in a sustainable manner. As described in our comments² at the spring 2019 meeting, OTA was not able to take a position of support on any of the suggested approaches because there is a lack of information about the extent of the problem that needs to be solved, whether organic certification can achieve the intended sustainability goals for marine algae, and whether industry can build up sufficient supply of certified organic marine algae to meet needs of organic producers. To further explore these issues and attempt to respond to the questions raised in NOSB's discussion document, OTA established a member task force. We thank NOSB for keeping the discussion document³ open for comments through to the fall 2019 meeting to allow our member task force to more deeply engage with these issues.

II. Understanding the extent of the problem that needs to be solved

To identify an appropriate solution among the approaches put forward by the subcommittee, we must have a strong understanding of the problem needing to be solved. Comprehensive technical information is a foundation to effective policy development. Ideally, conclusions about the environmental harm from seaweed harvesting should be informed by data representative of the areas where seaweeds are harvested around the globe, as well as being relevant to seaweed harvested specifically for use in fertilizers. Furthermore, an accurate understanding of the status quo should be informed by the oversight and enforcement mechanisms outside of the NOP regulatory framework throughout the countries where seaweeds are harvested that may influence environmental impact. This information is essential to understanding the current situation and potential net positive outcome of an NOSB recommendation specific only to crop inputs on organic farms.

After further review of the NOSB discussion record on this subject, we identified a lack of technical information in the following key areas:

- **The effect seaweed harvesting has on the environment as documented by scientific evidence**
- **Existing legal framework for seaweed harvesting in countries where most seaweed is harvested.**

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

² https://ota.com/sites/default/files/indexed_files/OTA_MarineMaterials_NOSBSpring2019_AMS-NOP-18-0071_final.pdf

³ <https://www.ams.usda.gov/sites/default/files/media/MSMarineMaterialsDDFall2019.pdf>

To support NOSB's evaluation of these issues, we encourage subject-matter experts to share technical information to the Board through the public comment process.

The following questions are posed to the scientific community:

1. How much seaweed biomass exists globally? How much of the existing biomass is being harvested? Should there be substantial concern about these harvests?
2. What harm, if any, is being caused by seaweed harvesting? Is evidence of environmental harm being documented by researchers, government bodies, or other third parties?
3. Is there a depletion of natural resources due to harvesting seaweeds from wild native ecosystems?
4. Are there changes in species diversity resulting from harvesting of selective species, and do these changes have negative impacts?
5. Are there negative impacts from cultivation of seaweeds (versus wild communities)?
6. Are there specific changes that need to be made to make seaweed harvesting more sustainable?

The following questions are posed to seaweed harvesters and seaweed-based input suppliers:

1. What are the legal regulations in the country/state(s) where your seaweed supply is harvested (i.e. permits or licenses)? Describe the extent to which environmental impacts are evaluated by the legal system.
2. Describe the harvesting practices for your seaweed supply. Provide any data or references to document the extent of environmental harm caused by seaweed harvesting. Describe any negative or positive impacts to the environment from your harvesting practices.
3. Are there specific changes that need to be made to make seaweed harvesting more sustainable?
4. Of all seaweed harvested, how much volume is used in the production of organic ingredients (used in farming) and organic products (consumer facing products)? What is the economic value of this volume?

III. Continuous improvement in sustainable sourcing of inputs for use in organic production

This is a complex topic with many intersecting issues at play. We want to see continuous improvement in sustainable sourcing of inputs, but we must approach the issue carefully, using science-based information and thoughtful consideration of the global industry impacts of any new regulatory requirements, so that organic farmers continue to have reliable access to essential tools for production.

We identify the following areas where NOSB activities can support continuous improvement in sourcing inputs for used in organic production:

1. Continue seeking technical information to fill information gaps identified above. Consider including this as an NOSB Research Priority.

2. Consider redefining the scope of this work agenda item to give the Board more options to address environmental concerns specific to individual species, regions, or harvest methods. The fall 2019 Discussion Document states that *“numerous commenters have suggested that there may be some species, regions, and/or harvest methods for which a limited or prohibited harvest should be recommended. While this could inform future NOSB work, that is not within the capacity of this current discussion document and proposal effort.”*
3. Continue the work of developing clear and accurate terms and definitions for marine materials in the NOP regulations. Develop recommendations to clarify the taxonomic nomenclature of marine materials on the National List across crops, livestock, processing scopes.
4. Explore options to address in a consistent manner the environmental impact of inputs sourced from natural substances such as mineral, plant, or animal matter. What does it look like to ensure “not harmful to environment” of non-synthetic inputs not on the National List? Could there be a uniform approach to all non-synthetic inputs, such as a preference for less harmful or certified organic substances based on commercial availability? Could there be special annotations carved out for high risk substances, such as those sourced directly from native wild ecosystems?
5. Explore opportunities for NOP certification to be better positioned as a tool for ensuring sustainable agriculture in marine environments. Continuous improvement of the regulations and guidance are needed to accommodate the unique conditions of marine agriculture. Additional guidance on the certification of marine plants under crop and wild crop standards would assist the organic community in ensuring that NOP certification can provide certain outcomes for sustainability.
6. Work with NOP to confirm the legal authority under OFPA to require organic certification of a crop input material.

IV. Conclusion

OTA supports efforts to move towards the allowance of only aquatic plants produced and harvested in a sustainable manner. Obtaining a comprehensive understanding of the global environmental impact of seaweed harvesting is a challenging task, as is the task of identifying appropriate solutions to address the real world impacts on marine environments that may be caused by sourcing inputs for use in organic agriculture. We encourage NOSB to continue seeking technical information to better understand the effect seaweed harvesting has on the environment as documented by scientific evidence, and the existing legal framework for seaweed harvesting in countries where most seaweed is sourced. We also identify other activities that NOSB can do to support continuous improvement in sustainable sourcing of inputs. We recognize and appreciate NOSB’s efforts in this area, and we plan to remain engaged in ongoing discussions on this complex and important topic.



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,

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



October 3, 2019

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

Docket: AMS-NOP-19-0038

RE: Policy Development Subcommittee – Policy and Procedures Manual Revision (Proposal)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Policy Development Subcommittee's Proposal on revising its Policy and Procedures Manual. The Subcommittee is proposing a list of minor revisions and suggested changes as summarized in the table below. The Organic Trade Association supports all of the proposed changes.

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 organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

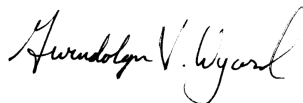
Section / Page	Proposed Change	OTA support?
III. D Page 8	Added to the NOSB Secretary's duties: To monitor and notify Subcommittee Chairs periodically of public comments posted in the open docket between the period when the meeting notice is posted in the Federal Register and when the proposals are posted (pg 8).	Yes
IV. F. 1 Page 20	Clarified language about when the new NOSB Chair takes office to match the language that is in VIII. F.	Yes
IV. G. 2 Page 22	Another type of discussion document: Petition material discussion document	Yes
IV. H. Page 23	Clarified the steps in the material review process for a new petition	Yes

IV. H. Page 24 Steps 2 & 3	Added clarifying language about how a Subcommittee determines sufficiency of a petition	Yes
IV. H. Pages 25 - 26, Steps 4 & 7	Added a process for a Subcommittee to develop a discussion document based on a petition	Yes
VIII. E. Page 34	Added an additional bullet point under the section about the policy for public communication between NOSB meetings for posting discussion documents and proposals between public meetings for review and public comment	Yes

The proposed changes to the NOSB Policy and Procedures Manual are easily understood and consistent with our understanding of existing practice or practices intended to be carried out. We have no concerns or questions.

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



October 3, 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-19-0038

RE: Livestock Subcommittee – Use of Excluded Method Vaccines in Organic Livestock Production

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Proposal on the Use of Excluded Method Vaccines in Organic Livestock Production. The subcommittee is proposing a regulatory amendment regarding the use of excluded methods vaccines in organic livestock 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.

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 support the NOSB fall 2019 proposal in principle, based on several key principles that align with OTA's Position on GMO Vaccines. We believe the NOSB's fall 2019 proposal on Vaccines from Excluded Methods is effective to meet these key principles. However, if NOSB passes this proposal, there are several outstanding issues that need to be addressed so that our identified key principles are upheld during rulemaking.

We offer the following more detailed comments:

I. OTA Position GMO Vaccines (“Vaccines made with excluded methods”)

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 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.

II. 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 position¹ (supported by the legal opinion of USDA's Office of General Counsel) is that GMO vaccines are allowed only if they are 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 Review² on vaccines made with excluded methods that 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 Report³ to the NOSB Livestock Subcommittee (February 5, 2013).
- Presented a comprehensive overview and recommendation⁴ 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 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 has stated that 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. At the spring 2019

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

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

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

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

meeting, the subcommittee presented a discussion document⁵ with three options of clarifying the allowance of excluded methods vaccines in the regulations:

- 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.
- 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.

For the fall 2019 meeting, the subcommittee presents a proposal⁶ that vaccines from excluded methods may be used when an equivalent vaccine not produced through excluded methods is not commercially available. This proposal would implement Option #3 as described in the last meeting’s discussion document. The subcommittee’s proposal includes information about how to determine commercial availability of a vaccine not produced through excluded method terminology.

III. Key principles regarding the restricted use of vaccines

The Organic Trade Association supports 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. The NOSB Fall 2019 proposal is to amend §205.105(e) to allow vaccines from excluded methods ***only when*** an equivalent vaccine not produced through excluded methods is not commercially available.

OTA identifies several key principles that should underlie any future recommendation for vaccines used in organic livestock production in order to align with OTA’s Position on GMO Vaccines. We believe the NOSB’s fall 2019 proposal on Vaccines from Excluded Methods is effective to meet each of these principles, as described below. Based on these principles, we support the spirit and direction of the proposal because of the underlying principles that it represents.

1. GMO vaccines are more narrowly restricted than what is being done under status quo.

Generally speaking, GMO vaccines have been allowed without further scrutiny or restriction. However, more specific scrutiny of GMO vaccines is needed than what is currently being done under the status quo. Blanket or carte blanche approvals of GMO vaccines are not aligned with historical and legal interpretations of the regulations, which required NOSB to give consideration of vaccines under the National List criteria under §205.600(a). The NOSB fall 2019 proposal is

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

⁶ <https://www.ams.usda.gov/sites/default/files/media/LSVaccinesExcludedMethodsProposalFall2019.pdf>

effective in adding further scrutiny/restriction on vaccines from excluded methods than what is being done under current practices.

2. Preference is given to non-GMO equivalent alternatives.

Although there has always been one narrow exception in the regulations for the use of excluded methods in vaccines, the overarching and clear tenant of regulations is to prohibit GMOs in the production and handling of organic production. In cases where a non-GMO alternative is commercially available, such an exception is not needed, and the non-GMO alternative should be encouraged. The NOSB fall 2019 proposal is effective in adding a requirement that non-GMO versions are used when commercially available.

3. Organic producers have access to safe and effective vaccines to promote animal welfare.

Vaccines are an integral part of a preventive livestock health care plan and are essential for promoting animal welfare. Even though some vaccines are only available using excluded method technology, organic producers should be at a disadvantage when it comes to providing adequate health care to their livestock. The NOSB fall 2019 proposal is effective in ensuring that organic producers have timely access to vaccines that are necessary to prevent that specific animal disease or health problem.

4. Certification agencies reach consistent determination about which vaccines are allowed.

Consistent enforcement of the regulations is critical for ensuring a level playing for organic operations. Currently, there are inconsistencies between certifiers about which vaccines are allowed. The NOSB fall 2019 proposal is effective in clarifying consistent requirements for verifying the restricted allowance of vaccines from excluded methods.

IV. Further work by NOP to uphold key principles

If NOSB passes this proposal, there are several issues that still need to be addressed by NOP so that these principles are upheld during rulemaking. These issues address administrative and enforcement aspects of implementing the NOSB fall 2019 proposal. Although these items are necessary to be addressed, we do not feel that these are barriers to our support of the underlying principles of NOSB's fall 2019 proposal. As stated by the Board in the NOSB spring 2012 Livestock Subcommittee review of GMO Vaccines: *"The NOSB should recommend policy based on what is consistent with an organic system of production rather than administrative and enforcement exigencies. A key factor regarding GMO vaccines is: are we making the decision based on the proper considerations? NOSB is a policy body, not an administrative or enforcement body. NOP is responsible for administering and enforcing policy related to GMO vaccine use."*

Therefore, we direct these outstanding items to NOP:

1. **Confirm that NOSB has completed its review of GMO vaccines under the provisions of §205.600(a) to ensure compliance with the legal opinion of USDA’s Office of General Counsel.** Such review was requested by NOP in its 2010 Memo⁷ and must be verified as complete prior to proceeding with any regulatory amendments. This is extremely important given that the NOSB fall 2019 proposal would *remove* the language from the regulations that currently requires GMO vaccines to be reviewed under the provisions of §205.600(a).
2. **Ensure that the GMO vaccines are included in the Sunset Review of the listing of vaccines on the National List.** Under the NOSB fall 2019 proposal, the restricted allowance of GMO vaccines would appear in §205.105(e), which is separate from the existing listing of “Biologics – vaccines” on the National List at §205.604(a). When the listing of “Biologics – vaccines” at §205.604(a) undergoes its scheduled Sunset Review, the restricted allowance of GMO forms should be incorporated into that review. This way, NOSB can collect information on whether/which GMO vaccines are being allowed, and evaluate whether the restricted allowance of GMO complies with the criteria for the National List.
3. **Protect organic producers from being mandated to use a GMO vaccine when a non-GMO version is commercially available.** Future situations could occur when a state or federal mandate requires the use of a GMO vaccine to control a certain disease outbreak (e.g. as part of a Federal or State emergency pest or disease treatment program.) In these cases, we do not want to see organic producers pressured or required to use vaccines that would otherwise be prohibited by the organic regulations. If an equivalent non-GMO alternative is commercially available to control the specific disease, organic producers should be allowed to use such non-GMO vaccine. NOP should work with USDA, FDA, EPA and other relevant agencies and/or State Departments of Agriculture to ensure that these policies are aligned and organic producers are protected.
4. **Support certification agencies and certified operators with guidance on identifying vaccines from excluded methods and enforcing the commercial ability restriction.** The NOSB fall 2019 proposal identifies resources to determine if a vaccine had or had not been produced through excluded methods, and other helpful information for how to apply the definition of commercial availability to vaccines (with specific consideration of vaccine efficacy and delivery method). Incorporating such information into guidance, instruction, and/or training materials will support accurate and consistent implementation of the restriction, and ensure that certifiers can provide efficient review and approval of Organic Systems Plans that include usage of restricted materials such as GMO vaccines. Additionally, NOP should formalize NOSB Recommendations on Excluded Methods Terminology into 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. NOP should also continue to support NOSB work agenda items on excluded method terminologies related to vaccines. For example, some forms of transposons (used in animal vaccines) are still listed as “to be determined” in the NOSB Excluded Methodology Chart.

⁷<https://www.ams.usda.gov/sites/default/files/media/NOSB%20Memo%20Response%20to%20Rec%20from%20April%202010%20Meeting.pdf>

V. Conclusion

The Organic Trade Associations continues to 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 support the NOSB fall 2019 proposal in principle, based on several key principles that align with OTA's Position on GMO Vaccines. We believe NOSB's fall 2019 proposal on Vaccines from Excluded Methods is effective to meet these key principles. However, if NOSB passes this proposal, there are several outstanding issues that need to be addressed so that our identified key principles are upheld during rulemaking.

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



October 3, 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-19-0038

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 Council¹ to help assist in distribution to NOP certified farmers.

Results of OTA Sunset Surveys

OTA has received 17 responses on our 2021 Livestock Sunset Surveys (15 new responses since the spring meeting). 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	1	The material is necessary because: <ul style="list-style-type: none"> - Used as needed for dairy livestock as an antidote for organophosphate insecticide (and other cholinesterase inhibitor) toxicosis and some gastrointestinal applications (excessive salivation, diarrhea). 	5
Hydrogen Peroxide	2	The material is necessary because: <ul style="list-style-type: none"> - Used to disinfect/sanitize hoof infections - Used to disinfect/sanitize medical equipment for Displaced Abomasum Surgery or other emergency procedures - Used as a pre and post teat dip in dairy livestock as a disinfectant to protect teat from bacterial infection between cows. - A general disinfectant (active against cryptosporidia, an important pathogen of calves, for example). If the material were prohibited: <ul style="list-style-type: none"> - Negative agronomic effects: mastitis, hoof rot - Unsafe working conditions for workers 	5
Iodine	2	The material is necessary because: <ul style="list-style-type: none"> - Used routinely as a teat dip, calf naval dip, and disinfectant for hoof treatment - Used as a general disinfectant 	5
Magnesium sulfate	1	The material is necessary because: <ul style="list-style-type: none"> - Used orally as needed in dairy livestock as a laxative and as a treatment for hypomagnesemic tetany (a life-threatening electrolyte disturbance of grazing cattle). 	5
Fenbendazole	2	The material is necessary because: <ul style="list-style-type: none"> - Needed as a tool for emergencies for dairy animals as a dewormer when preventative measures are not effective. 	4

¹ 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"> - Effective as a parasiticide useful in treating both young and adult cattle. Has the benefit of a label for milking cows, and is thus useful for lungworm infestations, which can be problematic in grazing cows. 	
Moxidectin	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used as needed for dairy cattle as an effective parasiticide that does not harm beneficial dung beetles 	5
Peracetic acid	2	<p>The material is necessary because</p> <ul style="list-style-type: none"> - Used daily/routinely as a food contact surface sanitizer in CIP process per FDA limitations to sanitize raw milk tankers - Surface disinfectant 	5
Xylazine	0		
Methionine	4	<p>Note: In addition to survey responses summarized here, please also see the separate comment submitted by the Organic Trade Association on this material.</p> <p>The material is necessary because:</p> <ul style="list-style-type: none"> - Used to provide an essential amino acid to organic poultry - Used to ensure proper growth and production of organic poultry <p>Alternatives are not sufficient because:</p> <ul style="list-style-type: none"> - No alternatives are commercially available to synthetic methionine - Outdoor access can provide some of the methionine need. Other respondent(s) say that pasture producers almost zero methionine. All respondents report challenge in climates where insects are not naturally occurring year round, when it is not possible get enough methionine into the diet without supplementation. - Cannot get close to a balanced ration without methionine. - Over-feeding protein can lead to too much nitrogen in the manure which contribute to nitrogen runoff challenges - Much higher amounts of protein would need to be fed which in turn would create higher nitrogen loads to hen housing and environment on outdoor grounds <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Reduced egg production - Decreased broiler growth - Severe deficiencies especially during the growing stages of replacement pullets - Bird health would suffer; Unhealthy/dead chickens - Would leave organic production 	5
Trace minerals	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Essential nutrients included in dairy livestock rations needed for metabolic functions such as growth/development, immunity and reproduction. 	5
Vitamins	1	<p>The material is necessary because:</p> <ul style="list-style-type: none"> - Essential nutrients included in dairy livestock rations needed for proper animal function such as growth/development, immunity and reproduction. 	5

		Alternatives are not sufficient because: - Bioavailability in feedstuffs is highly variable	
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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,



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)
★	★	★



October 3, 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-19-0038

RE: Livestock Subcommittee – Methionine (2021 Sunset Review)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Sunset Review of Methionine used in Organic Livestock 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.

The Organic Trade Association supports the continued listing of methionine on the National List under its restrictive annotation. Although research and development of natural alternatives is progressing, the need for synthetic methionine remains necessary for organic poultry production, thereby satisfying the National List criteria. We agree with the Livestock Subcommittee's assessment that this material should not be removed from the National List. It is essential that viable alternatives be researched and trialed on commercial-scale flocks before prohibiting the use of this essential amino acid.

OTA poultry members report that methionine is necessary for providing essential amino acids to organic poultry to ensure proper growth, and that alternative production practices or natural alternatives are not sufficient to provide the necessary amounts of the essential amino acid to promote flock health. Access to pasture has not proven to provide sufficient methionine intake, and alternative feed ingredients that are high in methionine are not available in natural or organic forms. As evidenced by the responses to our Sunset Surveys, methionine scores a "5" on scale from 1 to 5, with 1 being "unnecessary" and 5 being "critical /would leave organic without it". Please see the separate comment submitted by the Organic Trade Association for full results of our Sunset Surveys created for each input under review as part of the 2021 Sunset Review cycle.

We fully support efforts to research and develop natural alternatives that would reduce the need for synthetic methionine supplementation. We support NOSB's resolution from 2015 for aggressive industry and independent research on natural alternative sources of methionine, breeding poultry that perform well on less methionine, and management practices for improved poultry animal welfare. We also support this



area of reach as a top NOSB Research Priority. We appreciate and applaud the Methionine Task Force for its regular updates to NOSB on progress in finding alternatives.

This year the new annotation for methionine came into effect. Under the new annotation, methionine is restricted at the following maximum rates as averaged per ton of feed over the life of the flock: laying chickens—2 pounds; broiler chickens – 2.5 pounds; turkeys and all other poultry—3 pounds. By calculating the methionine limits as a lifetime average (instead of as a maximum level as fed, as it was previously), producers can adjust methionine supplementation based on the changing nutritional needs of the birds at specific stages of production. The industry will be adapting to this new restriction on methionine usage over the coming years. NOSB can continue to monitor the implementation and outcomes of the new annotation at subsequent Sunset Reviews.

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,

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association



October 3, 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-19-0038

RE: Livestock Subcommittee – Fenbendazole (Petitioned Material Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the Livestock Subcommittee's Petitioned Material Discussion Document on Fenbendazole. The subcommittee is inviting discussion on a petition requesting a revision to the annotation for fenbendazole to expand the use to poultry.

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.

NOSB is considering a petition requesting a revision to the annotation for fenbendazole at §205.603(a)(23)(i) to include an allowance for use in laying hens and replacement chickens intended to become laying hens. The petition does not request changes to the current restrictions on fenbendazole, which limit its use only for emergency treatment when organic system plan-approved preventive management does not prevent infestation.

Fenbendazole is currently allowed in the NOP regulations under the following restrictive conditions at §205.238(b) and §205.603(a)(23)(i) for use in breeder stock, dairy animals, and fiberbearing animals.

§205.238(b) When preventive practices and veterinary biologics are inadequate to prevent sickness, a producer may administer synthetic medications: Provided, That such medications are allowed under §205.603.

Parasiticides allowed under §205.603 may be used on:

- (1) Breeder stock, when used prior to the last third of gestation but not during lactation for progeny that are to be sold, labeled, or represented as organically produced; and
- (2) Dairy animals, as allowed under §205.603.
- (3) Fiber-bearing animals, as allowed under §205.603.

§205.603(a)(23) Parasiticides—prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-

approved preventive management does not prevent infestation. In breeder stock, treatment cannot occur during the last third of gestation if the progeny will be sold as organic and must not be used during the lactation period for breeding stock. Allowed for fiber-bearing animals when used a minimum of 36 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.

(i) Fenbendazole (CAS #43210-67-9)—milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days following treatment of cattle; 36 days following treatment of goats, sheep, and other dairy species.

At this point, OTA does not have concerns with the petitioned allowance of fenbendazole for these reasons:

- Fenbendazole is already permitted under restricted conditions for other livestock species, hence it has already satisfied criteria for the National List in terms of not being harmful to the environment or human health, and being compatible with organic farming principles. In terms of essentiality for production of organic laying hens, we will continue to conduct member outreach and encourage organic egg producers to submit comments regarding the need for this input.
- The petitioned use would still be subject to the existing restrictions for fenbendazole, which limit its use only for emergency treatment when organic system plan-approved preventive management does not prevent infestation. Under these highly restricted conditions, poultry operation would still be required to establish preventive health care conditions as required by the NOP regulations and fundamental to organic production principles. Fenbendazole would be a new tool for emergency situations to control internal parasites. Organic livestock producers need adequate tools in their restricted toolbox to control infestations, and ensure animal safety and wellbeing.

Discussion Questions

The NOSB Livestock Subcommittee has requested feedback on the following discussion questions.

1. Is this material needed by organic poultry producers? If so, why?

OTA members in the organic egg sector have expressed a need for this material. Organic poultry producers identify a need for additional effective internal parasite treatment tools to address emergency situations when preventive practices have failed. Roundworm is a specific internal parasite for which organic poultry producers need better treatment tools, particularly for flocks exposed to outdoor access.

2. Do currently allowed alternatives work to control internal parasites? And at what level of effectiveness?

Alternative substances such as diatomaceous earth, essential oils, and apple cider vinegar have limited efficacy for preventing parasites or decreasing worm levels. There are no allowed alternative tools that have been identified that are effective in treating and eliminating parasites once they have infected flocks.

3. What are some of the “emergency” events that would trigger use of this product? And how would producers determine those events?

Poultry producers regularly monitor flock health and could establish an action threshold based on health deterioration, mortality, decreased egg production, lethargy, stool analysis, measurement of confirmed parasite presence, or other factors that could be described in an operation’s Organic System Plan.

For guidance on determining whether an event qualifies as an “emergency,” producers and certifiers can refer to the Spring 2018 NOSB Recommendation that includes the following definition of emergency treatment for parasite control in organic livestock, “An urgent, non-routine situation in which the organic system plan’s preventive measures and veterinary biologics are proven, by laboratory analysis or visual inspection, to be inadequate to prevent life-threatening illness or to alleviate pain and suffering.”

Furthermore, as OTA commented in fall 2017 and spring 2018, we see value in developing guidance on “routine use of parasiticide” which is currently defined in §205.2 as “the regular, planned, or periodic use of parasiticides,” so that certifiers can consistently identify and take corrective actions against noncompliant routine uses of parasiticides. Tying the justification for use of a synthetic parasiticide to actions taken by producers (i.e. routine use of parasiticides) rather than an occurrence (i.e. an emergency) better matches how organic system plans are reviewed and verified, and would give certifiers better ability to ensure that synthetic parasiticides are not misused. Records and inspections can be used to justify a conclusion that parasiticides were “routinely used” much more easily than they were used in the absence of a legitimate “emergency.” Guidance that addresses both how producers can justify the “emergency” use of parasiticides as well as how certifiers can consistently identify “routine use of parasiticide” will ensure a level playing field for organic producers.

4. Is there a concern with the 2.4 ppm residue of fenbendazole in eggs? Please submit information that supports this concern, or lack of concern.

At this point, we have not received indications of concern from our members.

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, reading "Johanna Mirenda".

Johanna Mirenda
Farm Policy Director
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association