



March 19, 2018

Robert Pooler
National Organic Program, Standards Division
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-14-0079

RE: Proposed Rule; Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Handling)

Dear Mr. Pooler:

Thank you for this opportunity to provide comment on the amendments to the National List of Allowed and Prohibited Substances (National List) as recommended to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB).

- **National List AMENDMENTS:** This rule proposes to change the use restrictions for seventeen substances allowed for organic production or handling on the National List: micronutrients; chlorhexidine; parasiticides; fenbendazole; moxidectin; xylazine; lidocaine; procaine; methionine; excipients; alginate; flavors; carnauba wax; chlorine; cellulose; colors; and, glycerin.
- **National List ADDITIONS:** This rule also proposes to add sixteen new substances on the National List to be allowed in organic production or handling: hypochlorous acid; magnesium oxide; squid byproducts; activated charcoal; calcium borogluconate; calcium propionate; injectable vitamins, minerals, and electrolytes; kaolin pectin; mineral oil; propylene glycol; acidified sodium chlorite; zinc sulfate; potassium lactate; and, sodium lactate. In addition, this proposed rule would list the botanical pesticide, rotenone, as a prohibited substance in organic crop production. Finally, this proposed rule would remove ivermectin as an allowed parasiticide for use 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.

Summary

The Organic Trade Association supports the judicious use of materials that have been added to the National List due to their necessity in a certain organic production system or due to their essential function in an organic processed product or organic handling system. We also strongly support the critical role of NOSB and its responsibility to ensure that materials added to or removed from the National List meet the criteria of the Organic Foods Production Act (OFPA) and USDA's organic regulations (7 CFR 205). Specifically, materials should be added or remain on the National List if: 1) they are necessary 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 for adding or removing a material from the National List must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at large.

Except for our requested adjustment to the annotation for Natural Flavors, the Organic Trade Association supports the NOSB recommendations that informed this proposed rule. In all instances where this proposed rule will change the use restriction for materials on the National List, we request that a 12-month implementation period be provided from the date the final rule is published. Regardless of the extensive review and comment period provided prior to and during the NOSB meetings, OTA remains realistic about our ability to reach every single organic certificate holder. Many certified operators may be unaware of the NOSB recommendations and this proposed rule, and they will not become aware of the changes until a final rule is released and they are notified of the change by their certifier.

OTA requests the following changes be made and reflected in the final rule:

- **The requirement to use organic flavors when commercially available applies only to products labeled as “ORGANIC”:** The Organic Trade Association strongly supports applying commercial availability to natural flavors on § 205.605 of the National List. However, the proposed change to require the use of organic flavors when commercial available should only apply to products labeled as “organic.” The Organic Trade Association’s petition to require the use of organic flavors when they are commercially available was explicitly intended to apply to products labeled as “organic” only, since commercial availability does not apply to the “made with organic” label category (See **Appendix A & B**). The proposed rule erroneously applies this change to both “organic” and “made with” products.
- **12-month implementation period:** To allow industry adequate time to comply with the proposed changes, we respectfully request a 12-month implementation period be provided from the date the final rule is published to accommodate the changes proposed under this rule.

OTA also requests that NOP issue guidance on Commercial Availability Criteria:

- Given the proposed amendments for natural flavors, glycerin, and carnauba wax that will require the use of organic forms when they are *commercially available*, OTA urges NOP to act on the recommendation that NOSB passed in November 2007 titled “Further Guidance on the

Establishment of Commercial Availability Criteria” (see **Appendix C**). The recommendation provided broader clarifications to the terms of commercial availability for use by certifying agents and the organic industry at large. To date, NOP has not acted on this important recommendation. In the fall of 2005, NOSB passed a recommendation for guidance on commercial availability of seed. NOP did, in fact, act on this recommendation, and final guidance became effective on March 4, 2013. To improve the clarity, quality and consistency of the process for determining and verifying commercial availability in organic processed products, OTA requests that NOP prioritize action on the 2007 recommendation, and release proposed guidance for public review and comment.

We offer the more detailed comments on each proposed National List input:

CROPS (§ 205.601 & § 205.602)

Substance	Proposed Rule Action	NOSB Recommendation
Micronutrients AMEND LISTING	Revise the annotation for this listing at §205.601(j) to read: “Not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. <u>Soil deficiency must be documented by testing. Micronutrient deficiency must be documented by soil or tissue testing, advice from certified crop advisors or professional agronomists, agricultural extension information, or other methods approved by the certifying agent.</u> ”	Fall 2015 (1 member absent) NOSB initiated the change in response to Sunset review. Vote: Yes: 12 No: 1 Abstain: 1
OTA comments: Consistent with our comments to NOSB, the Organic Trade Association supports amending the listing for micronutrients to allow for additional flexibility on ways for farmers to justify their use of these substances. OTA supports the additional language that USDA has proposed, as it reflects the potential sources of information that farmers could use to justify the use of micronutrients, and ensures a more consistent application of the standards between certifiers and across varying regions and cropping systems.		

Substance	Proposed Rule Action	NOSB Recommendation
Hypochlorous Acid (Crops, Livestock, and Processing) ADD TO THE LIST	Add to §205.601(a), §205.603(a), and §205.605(b) as a chlorine material for use as a disinfectant and sanitizer with the annotation, “Generated from electrolyzed water.”	Spring 2016 Result of a Petition Vote: Yes: 15 No: 0 Abstain: 0
OTA comments: The Organic Trade Association supports the listing of electrolyzed water on the National List. We agree with NOSB’s assessment that electrolyzed water offers a better alternative chlorine material to the options currently available to organic producers and handlers. Furthermore, NOP Policy Memo 15-4 clearly communicates that the current chlorine listings allow the use of electrolyzed water in organic production and handling. This rule change will achieve consistency between the organic regulations and NOP guidance as well as current industry practice.		

Magnesium Oxide (Crops) ADD TO THE LIST	Add to §205.601(j) for use as a plant or soil amendment with the annotation, “For use only to control the viscosity of a clay suspension agent for humates.”	Spring 2014 Result of a Petition Vote: Yes: 13 No: 2
OTA comments: The Organic Trade Association did not take a position on NOSB’s recommendation to add Magnesium oxide. However, we do not take exception to its addition to the National List.		

Squid byproducts (Crops) ADD TO THE LIST	Add to §205.601(j) for use as a plant or soil amendment with the annotation, “From food waste processing only. Can be pH adjusted with sulfuric, citric, or phosphoric acid. The amount of acid used shall not exceed the minimum needed to lower the pH to 3.5.”	Spring 2016 Result of a Petition Vote: Yes: 15 No: 0 Abstain: 0
OTA comments: Consistent with our comments to NOSB, the Organic Trade Association supports the addition of squid byproducts to the National List with the proposed annotation.		

Substance	Proposed Rule Action	NOSB Recommendation
Rotenone ADD TO THE PROHIBITED LIST	Add to §205.602 as <i>prohibited</i> for use in organic crop production.	Initially in Fall 1994 Revisited in August 2012 Vote: Yes: 15 No: 0
OTA comments: The Organic Trade Association supports the prohibition of rotenone in organic production. We recognize that rotenone is no longer allowed in U.S.-based agriculture following EPA’s action on the substance’s tolerance. However, it does remain in use in foreign countries on organic products, namely bananas. It is critical that organic producers have alternative tools available to them before removing ones that have proven effective, and we understand that alternative products are now registered for use on bananas in all of the major countries that supply organic bananas to the U.S. market. While organic is certainly not an input-substitution standard, it is important to consider the availability of alternatives when taking action to eliminate tools from the farmer’s toolbox. We agree with USDA that the time has come to act on NOSB’s recommendation and prohibit rotenone from use in all organic production, both domestic and foreign.		

LIVESTOCK (§ 205.603)

Substance	Proposed Rule Action	NOSB Recommendation
Chlorhexidine (Livestock) AMEND LISTING	Revise the annotation for this listing at §205.603(a) to read: “Allowed for surgical <u>medical</u> procedures conducted by <u>under the supervision of a licensed</u> veterinarian. Allowed for use as a teat dip when alternative germicidal agents and/or physical barriers have lost their effectiveness.”	2009 Recommendation to amend, Added to the NL in 2002 (1999 recommendation) NOSB initiated in response to comments

		Vote: Yes: 13 No: 0 Abstain: 0 Absent: 2
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OTA comments: The Organic Trade Association did not submit comments to NOSB on their recommendation to amend this listing, and we do not take exception to the proposed amendment.

Parasiticides (Livestock) AMEND LISTING	<p>Revise the annotation for this listing at §205.603(a) to read: “Prohibited in slaughter stock, allowed in emergency treatment for dairy and breeder stock when organic system plan-approved preventive management does not prevent infestation. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for 90 days following treatment. 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. <u>Allowed for fiber-bearing animals when used a minimum of 90 days prior to harvesting of fleece or wool that is to be sold, labeled, or represented as organic.</u>” NOP is also proposing to revise section 205.238(b) of the NOP regulations to replace the 90-day withholding time for milk and milk products with a cross-reference to withholding times specified at 205.603 (see below for proposed revisions to withholding times), replace the term “stock” with “animal,” and add an allowance for parasiticides to be used in fiber-bearing animals.</p>	April 2016 Recommendations in response to public request/comments Vote: Yes: 15 No: 0 Abstain: 0 Absent: 0
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OTA comments: Consistent with the Organic Trade Association’s comments to NOSB, we support the proposed amendment to the allowance for synthetic parasiticides in organic livestock production. We see this change as a step forward to create more consistent and common-sense standards and which allows for the removal of ivermectin (a change we also support). We are particularly pleased to see the inclusion of fiber-bearing animals in the allowance to come into alignment with foreign organic standards, and to help foster the development of a domestic organic wool industry to support growing consumer demand for organic fiber products. However, we would like to acknowledge that the proposed 90 day withholding time for fleeces harvested from treated animals is not based on doubling of FDA recommended withholding times as is the proposed restriction for parasiticides used on dairy animals. It appears to be an arbitrary time period, and one that Organic Trade Association member sheep producers indicate could be problematic for production cycles. These members have supported aligning the withholding time for fleeces with the proposed withholding times for dairy, and we would support such a change in the final rule. We also support the continued prohibition of the use of synthetic parasiticides on organic meat animals, as well as the continued restrictions on their use on breeder stock.

Fenbendazole (Livestock) AMEND LISTING	<p>Revise the annotation for this listing at §205.603(a) to read: “Only for use by or on the lawful written order of a licensed veterinarian. Milk or milk products from a treated animal cannot be labeled as provided for in subpart D of this part for: 2 days</p>	April 2016 Recommendations in response to public request/comments
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	following treatment of cattle; 36 days following treatment of goats, sheet and other dairy species.”	Vote: Yes: 15 No: 0 Abstain: 0 Absent: 0
OTA comments: Consistent with The Organic Trade Association’s comments to NOSB, we support the proposed amendment to Fenbendazole. We believe this change will ensure consistency in how withdrawal periods are established for livestock drugs used by organic producers, and it will ensure organic producers have effective and available alternatives following the removal of ivermectin (a change we also support).		
Moxidectin (Livestock) AMEND LISTING	Revise the annotation for this listing at §205.603(a) to read: “ For control of internal parasites only. <u>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, sheet and other dairy species.</u> ”	April 2016 Recommendations in response to public request/comments Vote: Yes: 15 No: 0 Abstain: 0 Absent: 0
OTA comments: Consistent with The Organic Trade Association’s comments to NOSB, we support the proposed amendment to Moxidectin. We believe this change will ensure consistency in how withdrawal periods are established for livestock drugs used by organic producers, and it will ensure organic producers have effective and available alternatives following the removal of ivermectin (a change we also support).		
Xylazine (Livestock) AMEND LISTING	Revise the annotation for this listing at §205.603(a) to read: “Federal law restricts this drug to use by or on the lawful written or oral order of a licensed veterinarian, in full compliance with the AMDUCA and 21 CFR part 530 of the Food and Drug Administration regulations. Also, for use under 7 CFR part 205, the NOP requires: (i) Use by or on the lawful written order of a licensed veterinarian; (ii) The existence of an emergency; and (iii) A meat withdrawal period of at least 8 days after administering to livestock intended for slaughter; and a milk discard period of at least 4 days after administering to dairy animals.”	Fall 2009 Recommendation in response to comments that it is used more frequently as sedative for non-emergencies. Vote: Yes: 13 No: 0 Abstain: 0 Absent: 2
OTA comments: The Organic Trade Association did not submit comments to NOSB on its recommendation to amend this listing. We do not take exception to the proposed amendment, and we believe this amendment will ensure consistency in how withdrawal periods are established for livestock drugs used by organic producers.		
Lidocaine & Procaine (Livestock) AMEND LISTING	Revise the annotation for both listings at §205.603(b) to read: “As a local anesthetic, use requires a withdrawal period of 90 <u>8</u> days after administering to livestock intended for slaughter and 7 <u>6</u> days after administering to dairy animals.”	Spring 2016 NOSB On the list since 2002. Recommendation based on comments received during 2015 Sunset review. Vote: Yes: 15 No: 0 Abstain: 0

OTA comments: Consistent with The Organic Trade Association’s comments to NOSB, we support the proposed amendment to Lidocaine and Procaine. We believe this change will ensure consistency in how withdrawal periods are established for livestock drugs used by organic producers.

<p>Methionine (Livestock) AMEND LISTING</p>	<p>Revise the annotation for this listing at §205.603(d) to read: “DL-Methionine, DL-Methionine-hydroxy analog, and DL-Methionine-hydroxy analog calcium (CAS #'s 59-51-8, 583-91-5, 4857-44-7, and 922-50-9)—for use only in organic poultry production at the following maximum levels <u>pounds</u> of synthetic <u>100 percent</u> methionine per ton of feed <u>in the diet, averaged over the life of the flock</u>: Laying and broiler chickens—2 pounds; <u>Broiler chickens – 2.5 pounds</u>; Turkeys and all other poultry—3 pounds.”</p>	<p>Spring 2015 Recommendation in response to a 2011 petition amend the max rates specified in the 2010 recommendation for the rate allowance after October 2012. It revises the maximum rates of synthetic methionine as averages per ton of feed over the life of the bird, rather than as a maximum quantity (pounds) per ton of feed. Vote: Yes: 10 No: 4 Absent: 1</p> <p>NOSB is committed to the phase-out of synthetic methionine for organic poultry production and encourages aggressive research for alternatives. Yes: 15 No: 0</p>
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OTA comments: Consistent with The Organic Trade Association’s comments to NOSB in 2012, 2014, and 2015, we support the proposed amendment to the annotation for methionine. NOSB’s proposal and this proposed rule change ensure that the 50% step down proposed by NOSB in 2010 is equally administered across all classes of organic poultry (i.e. Broilers were subject to a steeper decline in maximum allowable methionine in diets than any other class of poultry). It also reflects the intent of the Methionine Task Force’s original petition from 2009 requesting that methionine limits be calculated over the life of the flock, which recognizes that methionine requirements change throughout the birds’ stage of life. Organic Trade Association egg and broiler producer members indicate that this change will ensure they can better meet their flocks’ changing nutritional requirements and reduce the over-feeding of crude protein in poultry diets, to meet minimum methionine levels for proper bird nutrition, which has resulted in increased flock stress, increased mortality, increased volatile ammonia levels in houses, and an increase in foot problems. Until viable natural alternatives to synthetic methionine are developed and adopted, we believe this amendment to the National List will better balance various interests including: (i) providing the basic maintenance requirements of organic poultry; (ii) satisfying consumer preference to reduce the use of synthetic methionine in organic poultry production; and (iii) motivating the organic poultry industry to continue the

pursuit of commercially sufficient sources of allowable natural sources of methionine. We wholeheartedly support NOSB’s resolution for aggressive research into alternatives to synthetic methionine, and we applaud the Methionine Task Force for its regular updates to NOSB on progress in finding alternatives. It is essential that viable alternatives be researched and trialed on commercial-scale flocks before prohibiting the use of this essential amino acid.

Excipients (Livestock) AMEND LISTING	Revise the annotation for this listing at §205.603(f) to read: “Excipients, only for use in the manufacture of drugs and biologics used to treat organic livestock when the excipient is: Identified by the FDA as Generally Recognized As Safe; Approved by the FDA as a food additive; or Included in the FDA review and approval of a New Animal Drug Application or New Drug Application or; Approved by APHIS for use in veterinary biologics.”	2009 Recommendation to amend current listing (added in 2007) to minimize the variation in certifying agents’ interpretation of excipients and ensure consistent enforcement. Vote: Yes: 13 No: 0 Abstain: 0 Absent: 2
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OTA comments: The Organic Trade Association did not submit comments to NOSB on its recommendation to amend this listing. We do not take exception to the proposed amendment, and we believe this amendment will ensure more consistent application of the organic standards when reviewing and approving livestock drugs and biologics.

Substance	Proposed Rule Action	NOSB Recommendation
Hypochlorous Acid (Crops, Livestock, and Processing) ADD TO THE LIST	Add to §205.601(a), §205.603(a), and §205.605(b) as a chlorine material for use as a disinfectant and sanitizer with the annotation, “Generated from electrolyzed water.”	Spring 2016 Result of a Petition Vote: Yes: 15 No: 0 Abstain: 0 Absent: 0

OTA comments: The Organic Trade Association supports the listing of electrolyzed water on the National List. We agree with NOSB’s assessment that electrolyzed water offers a better alternative chlorine material to the options currently available to organic producers and handlers. Furthermore, NOP Policy Memo 15-4 clearly communicates that the current chlorine listings allow for the use of electrolyzed water in organic production and handling. This rule change will achieve consistency between the organic regulations and NOP guidance as well as current industry practice.

Activated Charcoal (Livestock) ADD TO THE LIST	Add to §205.603(a) for use as a livestock medical treatment with the annotation, “Must be from vegetative sources.”	2002 Recommendation Result of a petition Vote: Yes: 12 No: 0 Abstain: 0 Absent: 2
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OTA comments: The Organic Trade Association did not take a position on NOSB’s recommendation to add Activated Charcoal. However, we do

not take exception to its addition to the National List.

Calcium Borogluconate (Livestock) ADD TO THE LIST	Add to §205.603(a) for use as livestock medical treatment, with the annotation, “For treatment of milk fever only.”	2000 Recommendation NOSB initiated as part of early meetings Vote: Yes: 14 No: 0 Abstain: 0 Absent: 0
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OTA comments: The Organic Trade Association did not take a position on NOSB’s recommendation to add Calcium Borogluconate. However, we do not take exception to its addition to the National List.

Calcium Propionate (Livestock) ADD TO THE LIST	Add to §205.603(a) for use as livestock medical treatment, with the annotation, “For treatment of milk fever only.”	Fall 2002 Recommendation Result of a petition Vote: Yes: 10 No: 0 Abstain: 0 Absent: 2 (This is what meeting minutes indicate, but accuracy of vote count is in question)
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OTA comments: The Organic Trade Association did not take a position on NOSB’s recommendation to add Calcium Propionate. However, we do not take exception to its addition to the National List.

Kaolin Pectin (Livestock) ADD TO THE LIST	Add to §205.603(a) for use as livestock medical treatment, with the annotation, “For use as an adsorbent, antidiarrheal, and gut protectant.”	Fall 2002 Recommendation FR does not indicate petition or history otherwise Vote: Yes: 12 No: 0 Abstain: 1 Absent: 1
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OTA comments: The Organic Trade Association did not take a position on NOSB’s recommendation to add Kaolin Pectin. However, we do not take exception to its addition to the National List.

Mineral Oil (Livestock) ADD TO THE LIST	Add to §205.603(a) for use as livestock medical treatment, with the annotation, “For relief of intestinal impaction, prohibited for use as a dust suppressant.”	Fall 2002 Recommendation FR does not indicate petition or history otherwise Vote: Yes: 12 No: 0 Abstain 0 Absent: 2
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OTA comments: The Organic Trade Association did not take a position on NOSB’s recommendation to add Mineral Oil. However, we do not

take exception to its addition to the National List.

Injectable Vitamins, Minerals, and Electrolytes ADD TO THE LIST	Add to §205.603(a) for use as livestock medical treatment, with the annotation, “Formulated injectable supplements of trace minerals per §205.603(d)(2), vitamins per §205.603(d)(3), and electrolytes per §205.603(a)(8), with excipients per §205.603(f), in accordance with FDA and restricted to use by or on the order of a licensed veterinarian.”	2009 Recommendation in response to public comments. Update to original listing of vitamins, minerals & electrolytes to add “injectable” forms. Vote: Yes: 14 No: 0 Abstain: 0 Absent: 1
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OTA comments: The Organic Trade Association did not take a position on NOSB’s recommendation to add injectable forms of vitamins, minerals, and electrolytes, and we support this addition. We believe that the addition of injectable forms of these necessary livestock production tools to the National List will ensure a more consistent application of the organic regulations.

Propylene glycol (Livestock) ADD TO THE LIST	Add to §205.603(a) for use as a livestock medical treatment, with the annotation, “Only for treatment of ketosis in ruminants.”	Fall 2002 Recommendation in response to a petition Vote: Yes: 13 No: 0 Abstain: 0 Absent: 1
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OTA comments: The Organic Trade Association did not take a position on NOSB’s recommendation to add Propylene glycol. However, we do not take exception to its addition to the National List.

Acidified Sodium Chlorite (Livestock) ADD TO THE LIST	Add to §205.603(a) and §205.603(b) for use in livestock production with the annotation, “Allowed for use on organic livestock as a teat dip treatment.”	Spring 2015 Recommendation in response to a petition, supportive comments from livestock producers Vote: Yes: 14 No: 0 Absent: 1
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OTA comments: Consistent with our comments to NOSB, the Organic Trade Association supports addition of Acidified Sodium Chlorite to the National List with the proposed annotation.

Zinc Sulfate (Livestock) ADD TO THE LIST	Add to §205.603(a) for use in livestock production, with the annotation. “For use in hoof and foot treatments only.”	Spring 2015 Recommendation Vote: Yes: 12 No: 2 Absent: 1
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OTA comments: Consistent with our comments to NOSB, the Organic Trade Association supports addition of Zinc Sulfate to the National List with the proposed annotation.

Substance	Proposed Rule Action	NOSB Recommendation
Ivermectin REMOVE FROM THE LIST	Remove § 205.603(a)(17) (ii) Ivermectin (CAS #70288-86-7)	Fall 2016 Recommendations - would leave organic livestock producers with two synthetic parasiticides for emergency treatment, fenbendazole and moxidectin. Vote: Yes: 14 No: 0 Abstain: 0 Absent: 1
OTA comments: Consistent with our comments to NOSB, the Organic Trade Association supports removal of Ivermectin from the National List.		

HANDLING/PROCESSING (§ 205.605 AND § 205.606)

Substance	Proposed Rule Action	NOSB Recommendation
Alginic Acid (Processing) AMEND LISTING	Remove the listing from §205.605(a) and add it to §205.605(b); this proposed action would result in this substance being classified as <i>synthetic</i> and being permitted in synthetic form.	2015 Recommendation made in response to public comment re: guidance document NOP 5033, Classification of Materials & the definition of “synthetic” Vote: Yes: 13 No: 0 Abstain: 1
OTA comments: Consistent with our comments to NOSB, the Organic Trade Association supports this change. Based on the information provided in the Technical Review and NOP’s Guidance on Classification of Materials (NOP Guidance 5033), OTA concurs with NOSB’s recommendation and the NOP’s proposed rule action.		

Flavors (Processing) AMEND LISTING	Revise the annotation for this listing at §205.605(a) to read: “ <u>Non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.</u> ”	Fall 2015 Recommendation in response to OTA’s 2014 petition. Vote: Unanimous, Yes: 14 No: 0 Abstain: 0
OTA comments: The Organic Trade Association has long advocated for the use and further development of organic flavors. Currently, there is no requirement to use organic flavors; all use is voluntary. In response to the growing number of organic flavors available in the marketplace, we submitted a petition in 2014 to revise the current listing of Flavors on the National List to require organic flavors to be used in products labeled as		

“organic” when they are commercially available in the necessary quality, quantity or form. We continue to believe this regulatory change is consistent with the intent of the law, and therefore strongly we support NOP’s proposal to revise the annotation for the listing of natural flavors at §205.605 of the National List.

As an important point of clarification, the Organic Trade Association did not intend for the annotation change to apply to products labeled as “made with organic specified ingredients or food group(s).” As clearly articulated in our petition and in our comments to NOSB (**Appendix A and B**), natural flavors used in the 30% of a “made with” product should continue to be allowed provided they are non-synthetic, non-GMO and made without the use of synthetic solvents, carriers and artificial preservatives. The annotation we suggested in our petition submitted on November 6, 2014 and further articulated during the NOSB deliberations, is as follows:

Flavors – Non-synthetic flavors may be used in products labeled as “organic” when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

As explained to us at the time NOSB drafted its recommendation, the Handling Subcommittee removed the phrase “in products labeled as organic” because it would appear that natural flavors, in general, are only *allowed* in “organic” products. We believe NOSB’s revision to our suggested language resulted in the following explanation in this proposed rule, that could unfortunately be read as a requirement to use organic flavors in “made with” products when commercially available:

Pg. 63 (Proposed Rule AMS-NOP-14-0079): “In addition, the NOSB recommended a revision to convey that the listing for flavors applies to products in the “organic” and “made with organic (specified ingredients or food group(s))” categories.”

The Organic Trade Association respectfully requests that the intent of our petition be clearly conveyed in the final rule. This clarification would maintain the regulatory status quo for all non-agricultural and agricultural ingredients allowed in the “made with” label category. With this one important correction in mind, the Organic Trade Association continues to express our strong belief that the organic flavor supply has grown to a size where it is no longer appropriate to allow the use of non-organic natural flavors when organic forms may be commercially available. At the same time, the number of available certified organic flavors is not sufficient to completely meet the current needs of the marketplace, given the numerous and different types and forms used by the organic sector. Natural Flavors must remain on the National List, but additional requirements to source organic are warranted. As proposed in this rule, the insertion of a commercial availability clause into the annotation on natural flavors not only strikes the right balance and moves the organic sector a positive direction, it supports the vision of the early NOSB that originally recommended the allowance of natural flavors in organic products provided organic forms were not available.

Since the first recommendation by NOSB to include the use of natural flavors in organic foods in 1995, there has been the expectation that over time, manufacturers would begin to produce certified organic flavors, and efforts would be made to support the use and development of organic

flavors. In 2007, NOP recognized that Accredited Certifying Agents (ACAs) were certifying flavors and that over time there would be more sources. Below are the results of a survey conducted by ACAs in 2011:

3. Indicate the number of natural flavors you certify under the following categories:								
Natural Flavor 11 responses	Extracts 11 responses	Essential Oils 11 responses	Distillates 9 responses	Oleoresin 7 responses	Essence 9 responses	Powders 9 responses	Emulsions 8 responses	Other 7 responses
TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
1,978	964	1,341	125	33	112	177	12	26

The 2011 survey also reported that 157 companies were being certified at the time. A similar survey was conducted in September 2014 with the following results:

3. Indicate the number of natural flavors you certify under the following categories:									
Natural Flavor (Compounded flavor) 5 responses	Natural Flavor (WONF) 7 responses	Extracts 6 responses	Essential Oils 5 responses	Distillates 4 responses	Oleoresin 5 responses	Essence 4 responses	Powders 5 responses	Emulsions 4 responses	Other 2 responses
TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
2,146	405	272	1,645	4	18	33	254	19	0

This survey reported that 189 companies are being certified at this time. However, since there were fewer responses submitted than in the 2011 survey, this number may be significantly higher.

When flavors were initially included on the National List, the number of flavor compounds comprising natural flavors was estimated number up to 100 or more. There were no known companies making organic flavors at that time. The data from the ACA surveys demonstrate that these numbers have grown substantially, not only for natural flavors in general, but certainly for certified organic flavors.

During the NOSB 2012 Sunset Review, in response to public comments, NOSB acknowledged the evolution of the organic flavor industry and the investment in further developing organic alternatives. At that time, NOSB stated on record that it could envision a time when flavors would not need to be listed. NOSB also communicated its belief in the final Sunset recommendation that *“the full category should not be relisted in five years when next reviewed for sunset.”*

Although we are not at a point where complete removal of natural flavors from the National List is appropriate, a requirement to use organic flavors when they are commercially available will require companies currently using non-organic flavors to start sourcing organic flavors to find out if they are available and if they meet the requirements of their products in the quantity, quality and form needed. This research and sourcing process married with a requirement to use organic flavors when they are commercially available will further stimulate the development of organic flavors, which, in turn, will increase the supply. Flavor manufacturers will be able to enter into the organic arena with confidence that their organic flavors must be used if they meet the necessary quality, quantity and form of the end-user product.

Revising the annotation on natural flavors to require organic forms when commercially available meets the intent of the law. It is time that the organic sector supports continuous improvement by requiring the use of organic flavors in products labeled “organic” when commercially available. As with any change that places additional requirements on certified operators, we acknowledge the inherent challenges and resources that will be involved. We recognize that certified companies, including certified flavor manufacturers, will need to increase the time and resources spent on sourcing organic flavors. We also recognize that certifying agents will need to spend more time and resources verifying the commercial availability claims made by operators unable to find organic flavors. Given the existing and growing supply of organic flavors, the Organic Trade Association does not believe the organic sector can afford to continue its business without including some requirement to use organic flavors. We agree there will be work involved, but we also believe that the organic sector must embrace the supply of organic flavors and determine if they are available in sufficient quantity, quality and form.

The Organic Trade Association is not requesting that natural flavors be removed from the National List. We recognize that organic flavors are not available in sufficient quantity, quality and form to satisfy the current demand for all applications. Therefore, the allowance to use natural flavors when organic alternatives do not exist must continue. The Organic Trade Association’s requested change, as proposed by this rule, will provide organic food producers and flavor manufacturers with the flexibility and time to source and research the existing supply of organic flavors, and decide whether they meet the quantity and functionality needed to meet customer and consumer expectation.

Formal guidance from NOP is needed on commercial availability practices

OTA recognizes the need to improve the quality and consistency of the verification process for determining commercial availability. The ultimate success of this rule change will partly rely on the success of the certification process and certifier due diligence in verifying commercial availability claims. It will also rely on certified operators developing and following a clear plan for sourcing and determining the commercial availability of organic flavors (as submitted and agreed upon in the Organic Systems Plan) and certifiers making sound and sensible decisions accordingly. OTA believes that certifiers and certified operations are doing a good job on this front, but there is significant room for improvement and consistency. There is a need for guidance and training that would bring about a better understanding of commercial availability criteria (quantity, quality and form) and the documentation needed to support commercial availability claims. This would result in greater consistency in practice between one certifier to the next and throughout the organic industry as a whole.

In November of 2007, NOSB passed a titled “Further Guidance on the Establishment of Commercial Availability Criteria.” The recommendation provided broader clarifications to the terms of commercial availability for use by certifying agents and the organic industry at large. To date, NOP has not acted on this important recommendation. In the fall of 2005, NOSB passed a recommendation for guidance on commercial availability of seed. NOP did, in fact, act on this recommendation and final guidance became effective on March 4, 2013. To improve the clarity, quality and consistency of the process for determining and verifying commercial availability in organic processed products, OTA requests that NOP prioritize action on the 2007 recommendation and release proposed guidance for public review and comment as soon as possible.

Carnauba Wax (Processing) AMEND LISTING	Remove the listing from §205.605(a) and add it to §205.606; this proposed action would result in this substance being classified as <i>agricultural</i> and being permitted only if organic forms are not commercially available.	Fall 2015 Recommendation in response to 2017 Sunset review and classification of materials guidance 5033. Vote: Yes: 12 No: 1 Abstain: 1
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OTA comments: Consistent with our comments to NOSB, the Organic Trade Association supports this change. Based on the information provided in the Technical Review and NOP’s Guidance on Classification of Materials (NOP Guidance 5033), OTA concurs with NOSB’s recommendation and the NOP’s proposed rule action.

Cellulose (Processing) AMEND LISTING	Revise the annotation for this listing at §205.605(b) to read: “For use in regenerative casings, <u>powdered cellulose</u> as an anti-caking agent (non-chlorine bleached) and filtering aid. <u>Microcrystalline cellulose is prohibited.</u> ”	Spring 2012 Recommendation in response to the 2013 Sunset Review & public comment request. AMS specifically seeks comments on the need for this additional language concerning microcrystalline cellulose. Vote: Yes: 14 No: 1 Abstain: 0
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OTA comments: The Organic Trade Association supports the continued allowance of cellulose for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. NOP is asking if additional language that would prohibit microcrystalline cellulose is necessary. We have received feedback from some companies making NOP certified dietary supplements that microcrystalline cellulose is the preferred anti-caking agent for making supplements in tablet form. It appears that organic alternatives may be available but further research is needed. Given the fact that NOSB considered microcrystalline cellulose in its initial review, it may be prudent for NOSB to reconsider this form of cellulose at the next Sunset Review and ensure that the Technical Review includes microcrystalline cellulose. NOSB received comments from organic food processors in 2013, but we believe the NOP certified dietary supplements companies may have been unaware of the proposed changes.

<p>Chlorine (Processing) AMEND LISTING</p>	<p>Revise the annotation for this listing at §205.605(b) to read: “For disinfecting and sanitizing food contact surfaces, <u>equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact are permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below</u> Except, That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit <u>for chlorine material</u> under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).</p>	<p>Fall 2011 Recommendation in response to 2010 NOP Guidance on Chlorine in order to achieve consistency between the two. Vote: Yes: 13, No: 1, Abstain: 0, Absent: 0</p>
<p>OTA comments: Consistent with our comments to NOSB, the Organic Trade Association supports this change. The revision as proposed will achieve consistency between the USDA organic regulations and NOP Guidance on “The Use of Chlorine Materials in Organic Production and Handling (NOP 5026).” It will also support current industry practice in accordance with FDA and EPA approvals, and allow operators to continue to adequately achieve food safety requirements.</p>		
<p>Glycerin (Processing) AMEND LISTING</p>	<p>Remove the listing from §205.605(b) and add it to §205.606 with the annotation, “produced from agricultural source materials and processed using biological or mechanical/physical methods as described under §205.270(a); this proposed action would result in this substance being classified as <i>agricultural</i> and being permitted only if organic forms are not commercially available.</p>	<p>Spring 2015 Recommendation in response to a 2012 petition to remove glycerin completely from the National List due to availability of organic. This change is a compromise that allows for agricultural forms and encourages development and use of organic forms. Vote: Yes: 14 No: 0 Absent: 1</p>
<p>OTA comments: Consistent with our comments to NOSB, the Organic Trade Association supports the proposal to remove synthetic glycerin from 205.605(b) of the National List. Based on the availability of alternatives, OTA agrees that glycerin produced by hydrolysis of fats and oils using an alkali process (and any other synthetic form) should be removed from the National List in favor of natural and organic alternatives. We also support the proposal to add “Glycerin” to § 205.606 of the National List and allow agricultural forms processed using biological or mechanical/physical methods as described under §205.270(a). This approach will align with NOP’s Classification of Materials Guidance (NOP 5033), require use of organic glycerin in organic products when it is commercially available, and allow for non-organic agricultural forms of glycerin in products when organic is not required. This is a step in the right direction as we continue to build the supply of organic glycerin.</p>		
<p>Colors (Processing) AMEND LISTING</p>	<p>Revise the listings for colors at §205.606(c) to replace CAS#s with the binomial name of the agricultural source of the color.</p>	<p>AMS-NOP action in response to a request made by NOSB resulting from the 2012 Sunset Review & public comments. AMS review determined that</p>

		CAS numbers are not assigned to the fruit and vegetable raw materials used to make colors. Consequently, CAS numbers may not be appropriate.
<p>OTA comments: The Organic Trade Association supports the change to replace Chemical Abstract Services numbers with the binomial name of the agricultural source. This makes both practical and technical sense for colors derived from agricultural products. The CAS numbers have been reportedly problematic for many years, and we are glad to see this correction.</p>		

Substance	Proposed Rule Action	NOSB Recommendation
<p>Hypochlorous Acid (Crops, Livestock, and Processing) ADD TO THE LIST</p>	<p>Add to §205.601(a), §205.603(a), and §205.605(b) as a chlorine material for use as a disinfectant and sanitizer with the annotation, “Generated from electrolyzed water.”</p>	<p>Spring 2016 Recommendation Result of a Petition Vote: Yes: 15 No: 0 Abstain: 0 Absent: 0</p>
<p>OTA comments: The Organic Trade Association supports the listing of electrolyzed water on the National List. We agree with NOSB’s assessment that electrolyzed water offers a better alternative chlorine material to the options currently available to organic producers and handlers. Furthermore, NOP Policy Memo 15-4 clearly communicates that the current chlorine listings allow for the use of electrolyzed water in organic production and handling. This rule change will achieve consistency between the organic regulations and NOP guidance as well as current industry practice.</p>		

<p>Potassium Lactate & Sodium Lactate (Processing) ADD TO THE LIST</p>	<p>Add to §205.605(b) for use in organic processing, with the annotation, “for use as an antimicrobial agent and pH regulator only.”</p>	<p>Spring 2016 Recommendation in response to request by NOP. Originally petitioned in 2005, but NOP clarified that a petition was not necessary due to components making up the material being on the NL. Vote: Yes: 12 No: 1 Abstain: 2</p>
<p>OTA comments: As explained in the proposal, both sodium lactate and potassium lactate have been allowed for use in organic handling since their approval by NOP on January 22, 2004. This decision (to not require a petition for sodium and potassium lactate for inclusion to the National List) was originally based on the fact that all three of the materials used to produce sodium lactate and potassium lactate (lactic acid, sodium hydroxide and potassium hydroxide) were already approved and on the National List. OTA agrees that NOP’s decision was not consistent with previous NOSB recommendations on classification of materials, and we support the action taken by NOSB and NOP to take these two materials through the appropriate petition process to see whether or not they meet OFPA and National List criteria. As we communicated during the time of the NOSB review, member outreach was inconclusive as to whether these two materials are needed. In our review, however, we believe any allowance should</p>		

be limited to microbial use for meat and poultry processing. In terms of usage, it appears that sodium lactate is more commonly used. One member reported the use of high pressure processing as an effective alternative. However, we expect that this technology is very expensive and is out of reach for many small and regional operations, particularly artisan and specialty meat processors. We also note that sodium lactate is allowed under the European Union (EU) organic regulations as an approved food additive for use in processing foodstuffs of animal origin only, and is listed as follows: “Milk-based and meat products.” Potassium lactate, however, is not allowed in the EU.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Program 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

Appendices

Appendix A: Organic Trade Association’s 2014 Cover Letter: “Petition to amend the annotation to Natural Flavors on 205.605(a)”

Appendix B: Organic Trade Association’s 2015 comment to NOSB Handling Subcommittee on petition to revise the annotation for Natural Flavors

Appendix C: National Organic Standards Board, Handling Committee - Recommendation for the Establishment of Commercial Availability Criteria

November 6, 2014

National List Manager
USDA/AMS/NOP, Standards Division
1400 Independence Ave. SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

Re: Petition to amend the annotation to Flavors on the National List as a non-agricultural (non-organic) substance allowed in or on processed products labeled as “organic or “made with organic (specified ingredient),” at §205.605(a).

Dear National List Manager:

Please accept the attached petition to revise the current listing of Flavors on the National List to require organic flavors to be used in products labeled as “organic” when they are commercially available in the necessary quality, quantity or form. The proposed change is as follows (changes in red):

Flavors – Non-synthetic flavors may be used in products labeled as “organic” when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Natural flavors appear on the National List as a broad category listing, therefore many different natural forms are allowed. Examples include extracts, oleoresins, essential oils, compounded flavors, and distillates. OTA believes that the number of certified organic flavors currently in the marketplace is substantial. However the number of available certified organic flavors is not sufficient to meet the current needs of the marketplace, given the numerous and different types and forms used by the organic sector. Currently, there is no requirement to use organic flavors; all use is voluntary at this time.

In order to further the use and development of organic flavors, OTA is submitting this petition to revise the current listing of Flavors to require organic flavors in products labeled “organic” when they are commercially available in the necessary quality, quantity or form.

Historically, commercial availability only applied to § 205.606. However, moving Flavors from §205.605 to § 205.606 would cause a significant disruption to the industry. The complexity of such a broad category and the significant number of distinctly different natural flavor makes it impractical to individually list flavors on the National List. This was acknowledged by the NOSB at both Sunset Reviews.

Furthermore, the NOSB on October 28, 2010 applied the concept of commercial availability to yeast, listed on § 205.605(a), when used as a food or fermentation agent in products labeled as “organic.” And on February 11, 2010, a petition was submitted to NOSB to remove silicon dioxide from §205.605(b) because rice hulls can serve as an alternative. The final decision by the board on December 2, 2011 was to add an annotation for Silicon dioxide stating “Permitted as a defoamer. Allowed for other uses when organic rice hulls are not

commercially available.” In both these cases, the NOSB recognized that organic alternatives had been developed and were available for use although not sufficiently available. Through the decisions to extend the concept of commercial availability to non-agricultural nonsynthetic, as well as agricultural, materials, the NOSB has encouraged the organic sector to continuously increase its use of organic ingredients and to invest in the development of organic alternatives to other substances or ingredients used in organic handling operations.

OTA is requesting that the NOSB again encourage and support continuous improvement by mandating the use of organic flavors when commercially available.

Thank you for your assistance in putting this petition before the NOSB. If you need any additional information, please contact me via email or telephone: gwyard@ota.com or (503) 798-3294.

Respectfully submitted,



Gwendolyn Wyard
Regulatory Director of Organic Standards and Food Safety
Organic Trade Association (OTA)

CC: Laura Batcha, Executive Director / CEO, OTA



October 7, 2015

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-15-0037

RE: Handling Subcommittee –Petition to revise the annotation for Natural Flavors on 205.605(a)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on the petition to require the use of organic flavors when they are commercially available.

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 the growth of organic trade to benefit the environment, farmers, the public and the economy.

Summary

OTA has long advocated for the use and development of organic flavors. In the current listing for "Flavors" on §205.605(a) as a broad category allowance, commercial availability¹ does not apply, and there is no requirement that organic alternatives be used when available. All use of organic flavors is voluntary. We believe the organic flavor supply has grown to a size where it is no longer appropriate to simply allow the use of non-organic natural flavors when organic forms may be commercially available. At the same time, the number of available certified organic flavors is not sufficient to completely meet the current needs of the marketplace, given the numerous and different types and forms used by the organic sector.

In order to further the use and development of organic flavors, OTA submitted a petition to revise the listing of natural flavors on § 205.605 of the National List to require the use of organic flavors in products labeled "organic" when the flavors are commercially available in the necessary quality, quantity or form. We are not requesting that commercial availability be applied to natural flavors used in "made with organic X" products. Natural flavors used in the 30% of a "made with" product would continue to be allowed provided they are non-synthetic, non-GMO and made without the use of synthetic solvents, carriers and artificial preservatives.

¹ *Commercially available.* The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

Since the first recommendation by NOSB to include the use of Natural Flavors in organic foods in 1995, there has been the expectation that over time, manufacturers would begin to produce certified organic flavors, and efforts would be made to support the use and development of organic flavors. In 2007, the National Organic Program (NOP) recognized that Accredited Certifying Agents (ACAs) were certifying flavors and that over time there would be more sources. During the NOSB 2012 Sunset Review, in response to public comments, NOSB acknowledged the evolution of the organic flavor industry and the investment in further developing organic alternatives. At that time, NOSB stated on record that it could envision a time when flavors would not need to be listed. NOSB also communicated its belief in the final Sunset recommendation that *“the full category should not be relisted in five years when next reviewed for sunset.”*

OTA, through the work of its Flavor Task Force formed in 2010 by the request of NOSB, has conducted extensive outreach to organic stakeholders including flavor manufacturers (organic and natural), certifying agents, organic manufacturers using flavors (organic and natural), and suppliers of minor ingredients used in natural and organic flavors. We received widespread support for the submission of our petition, and we continue to receive positive feedback for moving forward.

As with any change that places additional organic requirements on certified operators, we acknowledge the inherent challenges and additional resources that will be involved. We recognize that certified companies, including certified flavor manufacturers will need to increase the time and resources spent on sourcing organic flavors. We also recognize that certifying agents will need to spend more time and resources verifying the commercial availability claims made by operators unable to find organic flavors. Given the growing supply of organic flavors and the roughly **180 certified flavor** companies in business at this time, OTA does not believe the organic sector can afford to continue its business without including some requirement to use organic flavors. We believe that that the organic sector must embrace the growth challenges we’ve mentioned and move forward.

Revising the annotation on natural flavors is the right thing to do. OTA is requesting that NOSB and the organic sector at-large encourage and support continuous improvement by mandating the use of organic flavors in products labeled “organic” when commercially available.

We offer our more detailed comments:

The Supply of Organic Flavors

Natural flavors appear on the National List as a broad category listing. Therefore, many different natural forms are allowed. Examples include extracts, oleoresins, essential oils, compounded flavors, and distillates. The types of flavors allowed must be consistent with the FDA definition of “natural flavors” codified in 21 CFR 101.22².

² **21 CFR 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.**

The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional.

Even though organic certification of natural flavors is not required, many operators have voluntarily chosen certification because of the great demand by consumers. Below are the results of a survey of ACAs by The Accredited Certifiers Association Inc. in 2011. (See **Appendix A** for an explanation of the following categories.)

3. Indicate the number of natural flavors you certify under the following categories:								
Natural Flavor 11 responses	Extracts 11 responses	Essential Oils 11 responses	Distillates 9 responses	Oleoresin 7 responses	Essence 9 responses	Powders 9 responses	Emulsions 8 responses	Other 7 responses
TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
1,978	964	1,341	125	33	112	177	12	26

This survey also reported that 157 companies were being certified at the time. The actual number may be even higher. A similar survey was sent in September 2014 with the following results:

3. Indicate the number of natural flavors you certify under the following categories:									
Natural Flavor (Compounded flavor) 5 responses	Natural Flavor (WONF) 7 responses	Extracts 6 responses	Essential Oils 5 responses	Distillates 4 responses	Oleoresin 5 responses	Essence 4 responses	Powders 5 responses	Emulsions 4 responses	Other 2 responses
TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
2,146	405	272	1,645	4	18	33	254	19	0

This survey reported that 189 companies are being certified at this time. However, since there were fewer responses submitted than in the 2011 survey, this number may be significantly higher.

When flavors were initially included on the National List, the number of flavor compounds comprising natural flavors was estimated number up to 100 or more. There were no known companies making organic flavors at that time. The data from the ACA surveys demonstrate that these numbers have grown substantially, not only for natural flavors in general, but certainly for certified organic flavors.

Commercial Availability of Organic Flavors

Applying commercial availability to flavors is largely consistent with the original 1995 NOSB Recommendation (see **Appendix B**) to make efforts toward the ultimate production of an organic natural flavor, and it will satisfy NOSB’s 2012 Sunset Review statement that *“the full category should not be relisted in five years when next reviewed for sunset.”*

A review of the ACA survey results as well as a quick run down the aisles at an organic foods grocery store reveals that the number of certified organic flavors currently in the marketplace is substantial. Applying commercial availability to natural flavors would be a **significant step in the right direction** and it would lay the critical foundation to build upon for the next Sunset Review. A requirement to use organic flavors when they are available will require companies currently using non-organic flavors to start sourcing organic flavors to find out if they meet the requirements of their products in the quantity, quality and form needed. This research and sourcing process married with a requirement to use organic flavors when they are commercially available will further stimulate the development of organic flavors, which, in

turn, will increase the supply. Flavor manufacturers will be able to enter into the organic arena with confidence that their organic flavors must be used if they meet the necessary quality, quantity and form of the end-user product.

Take for example peppermint extract. Currently, a certified operator can use **non-organic** peppermint extract without any requirement to explore an organic form let alone use it. Organic peppermint extract is made using organic alcohol and organic peppermint. The product is not complex and organic forms are readily available. The commercial search and documentation process between a certified operator and its certifier in this case would be fairly straight-forward. A complex flavor on the other hand, such as a compounded natural strawberry flavor, would be much more difficult to source, and the documentation process for demonstrating its commercial availability status would be much more involved. None-the-less, organic natural strawberry flavor does exist and it could conceivably work in many different types of products. However, at this time, manufactures of certified organic products are not required to investigate its potential.

OTA is aware of the inherent problems associated with the commercial availability clause in the organic regulations, namely that it is a good effort process operating in a capitalistic supply and demand economy. It is understood, or at least expected, that if there is demand, the supply will come. But, if operators are not mandated to use an organic ingredient and can instead demonstrate that a flavor, for example, does not meet the quality or form they are looking for, then they can use the non-organic form rather than demanding an organic version. Commercial availability doesn't always work as well as it was intended! OTA recognizes the need to improve the rigor of the verification process for determining commercial availability, and we accept that a revision to the annotation won't create a perfect result. However, we strongly believe that it will move us in the right direction along the continuous improvement spectrum, and create enough change to help swing the pendulum more permanently in favor of organic flavors.

Retention of Flavors on 205.605 (a) with a requirement to use organic when available

OTA believes that it is appropriate to retain flavors on § 205.605 of the National List (listing for allowed non-agricultural substances) and apply commercial availability to the entire broad category listing. Certified operators will then work with their certifiers to determine the types of organic flavors available in the required quantity, quality and form. The process of parsing out and sourcing organic flavors is going to be a process best facilitated by ACAs.

Removing individual types of flavors such as simple flavor extracts or attempting to move some or all flavors from §205.605 to §205.606 would cause a significant disruption to the industry, and require resources NOP and NOSB simply do not have. First, the complexity of such a broad category listing makes it impractical to individually list flavors on the National List. This was acknowledged by NOSB at both previous Sunset Reviews. Second, if flavors as a broad category were moved to §205.606, then non-agricultural flavors would no longer be allowed according to the requirements for inclusion on §205.606: Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Flavors are both agricultural and non-agricultural, and it would be extremely difficult to separate out the **literally thousands of flavors** into agricultural and non-agricultural categories. The OTA Flavor Task Force explored this option extensively and concluded that it was not a reasonable or practical approach. Also, some non-agricultural flavors can be produced organically because they are derived from or

produced using agricultural source material. Flavors produced via fermentation are a great example, and are analogous to yeast, which is used as a flavor as well and classified as non-agricultural. Several products of fermentation are classified as non-agricultural, yet they can be produced organically provided the agricultural source material is certified organic and all other ingredients and processing aids meet the NOP product composition requirements for labeling a product “organic.” Additionally, some flavors are derived from agricultural material but the isolated flavor component is classified as non-agricultural according to the current NOP definition of non-agricultural³. Again, similar to yeast, the “non-agricultural” distinction does not preclude the ability for the flavor to be certified organic due to the agricultural source material.

To consider to sunset some flavors but not others, or to move some to § 205.606 would be an arbitrary exercise that would take resources we do not have. NOSB as well as accredited certification agents would have to make thousands of determinations about which flavors were agricultural and allowed. This would be a time-consuming and costly endeavor that, at this time, would be done without final guidance from NOP on how to make agricultural and non-agricultural determinations. At the end of the day, certifiers and certified operators need only search for organic flavors and make determinations between organic and non-organic flavors.

Finally, precedent has been set for applying commercial availability to certain substances on 205.605. NOSB on October 28, 2010, applied the concept of commercial availability to yeast, listed on §205.605a, when used as a food or fermentation agent in products labeled as “organic.” And on February 11, 2010, a petition was submitted to NOSB to remove silicon dioxide from §205.605(b) because rice hulls can serve as an alternative. The final decision by NOSB on December 2, 2011, was to add an annotation for silicon dioxide stating, “Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.” In both these cases, NOSB recognized that organic alternatives had been developed and were available for use although not sufficiently available. Through the decisions to extend the concept of commercial availability to non-agricultural non-synthetic (205.605(a), NOSB has encouraged the organic sector to continuously increase its use of organic ingredients and to invest in the development of organic alternatives to other substances or ingredients used in organic handling operations.

OTA is requesting that NOSB recognize the complexity of flavors and apply the precedent set with yeast and silicon dioxide, and again encourage and support continuous improvement by mandating the use of organic flavors when commercially available while retaining the broad category listing of flavors on §205.605a.

Formal guidance from NOP is needed on commercial availability practices

As mentioned earlier, OTA recognizes the need to improve the rigor of the verification process for determining commercial availability. If our petition is adopted and a rule change is made to require organic flavors when they are commercially available, the ultimate success of the rule change will partly

³ *Non-agricultural substance.* A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a non-agricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

rely on the success of the certification process and certifier's due diligence in verifying commercial availability claims. OTA believes that many certifiers are doing an excellent job on this front, but there is room for improvement along with greater consistency in practice between one certifier to the next.

In May 2006, NOSB passed a "Recommendation for establishment of Commercial Availability Criteria" when making commercial availability decisions regarding the use of materials on 205.606. To date, NOP has not acted on this recommendation. In the fall of 2005, NOSB passed a recommendation for guidance on commercial availability of seed. NOP did, in fact, act on this recommendation and final guidance became effective on March 4, 2013. In favor of making the commercial availability clause function as it was intended in certified organic products, OTA requests that NOSB urge NOP to prioritize action on the 2006 recommendation and release proposed guidance for public review and comment.

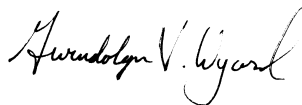
Standardized questionnaire to verify compliance

During the spring 2015 NOSB comment period, NOSB asked the public if a standardized questionnaire on natural flavors would be helpful. OTA responded by saying that there **is** a Natural Flavor Questionnaire (Affidavit/Declaration) in use by several accredited certifiers. This questionnaire was developed by a group of certifiers with technical assistance from flavor manufactures and flavor chemists. It appears to be one of the most thorough affidavits in circulation. However, it may not be in use by all ACAs. **See Appendix C.** Although the use of this questionnaire is outside the scope of our petition, we believe its use is important for verifying the compliance of natural flavors used in organic products. It could also be revised to include questions about the commercial availability of organic flavors. Therefore, OTA requests that NOSB make a recommendation to NOP requesting that the flavor questionnaire be formally recognized and offered to ACAs in guidance as the standardized questionnaire to use.

In closing, we thank the Board for its time and commitment and for considering this timely and very important petition.

Again, on behalf of our members across the supply chain and country, OTA thanks NOSB for the opportunity to comment and for your commitment to furthering organic agriculture.

Respectfully submitted,



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

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendix A: Flavor Nomenclature – "Types of Flavors"

Appendix B

NATIONAL ORGANIC STANDARDS BOARD - FINAL RECOMMENDATION ADDENDUM NUMBER 14 THE USE OF NATURAL FLAVORS IN ORGANIC FOODS - Date adopted: October 31, 1995

Additionally, manufacturers shall provide written documentation in their Organic Handling Plan showing efforts made toward the ultimate production of an organic natural flavor as listed in the stepwise progression below:

Natural flavor constituents and non-synthetic carrier base and preservative agents (ex. grain ethanol, non-synthetic glycerin and non-synthetic acetic acid.).

Organic flavor constituents, organic carrier base, and organic preservative agents.

Organic flavor constituents extracted using organically produced solvents, organic carrier base, and organic preservative agents.

Appendix C: Natural Flavor Questionnaire

Note: Appendices are not attached

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: November 30, 2007

Subject: Further Guidance on the Establishment of Commercial Availability Criteria

Chair: Andrea Caroe

(sign)

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement: XXXXXX

Other: _____

Statement of the Recommendation (including Recount of Vote):

The recommendation, as amended, proposes further standardized criteria to be used by NOSB, ACA's, and the organic industry when making commercial availability determinations for agricultural ingredients.

NOSB Vote:

Motion: Bea James

Second: Julie Weisman

Board Vote: Yes – 15

No – 0

Abstain – 0

Absent - 0

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

§ 205.2 Commercial availability [defined] – the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling as determined by the certifying agent in the course of reviewing the organic plan.

§ 205.201(a) (2) “The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food groups (s))” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

* * * *

(2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of **commercial availability**, as applicable.”

Statutory Background

7 U.S.C. 6518:

Sec. 2119. **NATIONAL ORGANIC STANDARD BOARD.**

(k) Responsibilities of the Board.

(2) National List. The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 2118.

Response by the NOP:

In general agreement

**National Organic Standards Board
Certification and Accreditation Committee
Further Guidance on the Establishment of Commercial Availability Criteria**

November 30th, 2007

Introduction

In light of the June 9, 2005 court final order and judgment arising from *Harvey v. Johanns*, the NOSB was asked to review petition procedures for adding materials to § 205.606 of the National List. On September 12, 2006 the Handling Committee submitted a recommendation to the NOP for the establishment of commercial availability criteria. Although the recommendation establishes the process for establishing commercial availability in the petitioning process, the NOSB is proposing broader clarifications to the terms of commercial availability for use by certifying agents, and the organic industry at large.

Background

The ability for any person to petition to amend the National List is authorized by the OFPA (7 U.S.C. 6518(n)) and the NOP regulations, in § 205.607 *Amending the National List*. This authorization provides that any person may petition the NOSB for the purpose of handling a substance evaluated by the NOSB recommendation to the Secretary for inclusion on, or removal from, the National List. The NOSB is authorized to review petitions under specified evaluation criteria in OFPA (7U.S.C. 6518(m)), and forward recommendations for amending the National List to the Secretary. Since the NOP regulation became effective in October 2002, several petitions to include synthetic or non-synthetic substances in their respective sections of the National List have been reviewed by the NOSB.

§ 205.606 states “*Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.*”

However, some producers, handlers, and certifiers may have misinterpreted § 205.606 to mean that any non-organic agricultural product which was determined by an accredited certifying agent to be not commercially available in organic form could be used in organic products, without being individually listed pursuant to the National List procedures.

In January 2005, the First Circuit decision in *Harvey v. Johanns* held that such a misinterpretation is contrary to the plain meaning of the OFPA and ordered that 7 CFR § 205.606 shall not be interpreted to create a blanket exemption to the National List requirements specified in §§6517 and 6518 of the OFPA (7 U.S.C. 6517-6518).

Consistent with the district court’s final judgment and order, dated June 9, 2005, on July 1, 2005, the NOP published a notice regarding §205.606 (70 FR 38090), and on June 7, 2006, the NOP published a Final Rule revising § 205.606 to clarify that the section shall be interpreted to permit the use of a non-organically produced agricultural product only when the product has been listed in § 205.606 pursuant to National List procedures, and when an accredited certifying agent has determined that the organic form of the agricultural product is not commercially available (71 FR 32803).

USDA was ordered to notice the content of this Declaratory Judgment and Order within 30 days in the published Federal Register and on the NOP web site, and remove all conflicting references and notify its certifying agents of the same. USDA-NOP complied with a Federal Register notice published on July 1, 2005 and on its web site.

On January 18, 2007 the NOP released 7 CFR Part 205 (Docket No. AMS-TM-06-0223; TM-06-12) *Notice of Guidelines on Procedures for Submitting National List Petitions*. This Federal Register Notice provides guidance on who may submit petitions, what substances may be petitioned and the information that is required to be included within a submitted petition. Additionally, this notice establishes some new commercial availability evaluation criteria that will be applied

during the petition review of non-organic agricultural substances for inclusion onto or removal from § 205.606 of the National List.

The Federal Register Notice was developed in collaboration with the NOP and based on the October 2006 NOSB recommendation on commercial availability which modified the information to be included in a petition to provide for the review of non-organic agricultural substances to be included onto § 205.606. Although the notice helped to clarify the information to be included for all types of petitions submitted to amend the National List, additional clarification on commercial availability is recommended for use by ACA's for the review of ingredients in specific organic system plans.

Regulatory Citations Background

§ 205.2 Commercial availability [defined] – the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling as determined by the certifying agent in the course of reviewing the organic plan.

§ 205.201(a) (2) “The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food groups (s))” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

* * * *

(2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of **commercial availability**, as applicable.”

Statutory Background

7 U.S.C. 6518:

Sec. 2119. **NATIONAL ORGANIC STANDARD BOARD.**

(k) Responsibilities of the Board.

(2) **National List.** The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 2118.

Discussion

The current petition procedures as required under § 205.606 and § 205.607 (b) for placing nonorganic agricultural substances or materials on the National List specifically as it relates to commercial availability are not adequate. As noted in the background portion of this document on January 18, 2007 the NOP released 7 CFR Part 205 (Docket No. AMS-TM-06-0223; TM-06-12) *Notice of Guidelines on Procedures for Submitting National List Petitions*. Although the Federal Register Notice gives further clarification on submitting information in a petition, further clarification is still needed for the industry at large. Evidence of this was revealed in the March 2007 NOSB meeting in which many petitions submitted for inclusion onto the National List were received by the NOP, but not all of these petitions were eligible for consideration. There were various reasons why many of the petitions did not contain sufficient information; including insufficient documentation of commercial availability.

The NOSB is recommending that the following additional guidance on commercial availability for use by the NOP to educate about and enforce the 606 review requirements of accredited certifying agents.

Additional consideration specifically on commercial availability of organic seed was considered in this guidance document. On March 21, 2001 the NOSB submitted response to questions on commercial availability of organic seed,

then on August 17, 2005 the NOSB submitted a formal recommendation to the NOP on commercial availability of organic seed, and finally during the October 2006 NOSB meeting the Crops Committee submitted a formal response to the public comment concerning the recommendation from the August 2005 commercial availability recommendation of organic seed. Public commenters have submitted serious concerns about the inconsistent efforts to source and organic seed by certified organic farmers and that the verification efforts of accredited certifying agents are inconsistently applied. One commenter reported that only 10% of the seed used on certified organic farms is organic. Organic seed has poses a particular issue regarding the determination of commercial availability primarily because petition procedure for 606 are for agricultural ingredients used in handling and not for petitioning for the use of non-organic seed. There is no requirement that farmers petition the NOSB to review and recommend the listing of varieties of seeds as commercially unavailable as organic. Therefore, the NOSB recommends evaluation of the above listed documents in order to improve the ability to enforce 205.204 as well as collaboration between the certification and accreditation, crops and livestock committees to review the above documents on seed and determine the process for enforcement of commercial availability of organic seed with a goal to present a recommendation at the spring 2008 NOSB meeting

The following recommendation below proposes further standardized criteria to be used by NOSB, ACA's, and the organic industry when making commercial availability determinations for agricultural ingredients..

Recommendation

A. NOSB and NOP role in review of commercial availability

In support of an ACA's role for determining commercial availability of a material the NOSB recommends that the NOP:

Implement training procedures and process to ACA's for protocol on determining commercial availability. Training should include a review of NOP's current and any new courses of action for determining commercial availability, as well as review of procedures for proactive steps that the applicant or certified operator takes to generate the organic form of commercially unavailable organic ingredients and materials.

B. ACA's role in determining commercial availability.

The ACA, in determining that an agricultural ingredient or material listed on § 205.606 is not commercially available in organic form, shall:

1. Evaluate the applicant or certified operator's documented claim that no organic substitutes of the ingredients or materials are commercially available in the form, quality, or quantity needed by the operation to fulfill the required function as appropriate to the operation. Documented claims should be accompanied by supporting evidence demonstrating that the organic forms of the ingredients or materials do not meet the functional requirements for the form, quality, quantity or equivalent variety necessary to the operation. Examples of such evidence include but are not limited to test data, market reports, third party research, reports on local growing season, and letters from suppliers. [Note: The global market is the universe of supply for agricultural ingredients – local market conditions are not sufficient criteria – aside from as described above.]
2. Validate that the applicant or operator has credible documentation that the ingredient or material is not commercially available in an organic form by reviewing available information that includes a list of all known sources of organic ingredients or materials. Documentation could include various detailed results (commensurate with known supply) of the applicants' efforts to contact credible sources of ingredients or materials and should also show the applicants effort to do such research with proper lead time. Examples of documentation would include dated letters stating ingredient or material, needed and the form, quantity and quality specifications required to fulfill availability, as well as follow up documentation from the addressee explaining the response to the request.

3. ACA's will maintain and keep accessible sources of information which list available organic ingredients or materials if the certifying agent finds that such sources exist..
4. ACA's will keep an up-to-date listing of certified organic 205.606 ingredients. This list will be maintained and submitted to the NOP annually by the ACA for the NOP to collate into a master list of materials and ingredients that are available in organic form. It is recommended that the data base of all organic materials and ingredients will be maintained by the NOP, or other NOP appointed organization.
5. Require certified operators to update commercial availability information in each organic system plan update. The NOSB would like to recommend that the NOP consider requiring a plan to include detailed documentation of proactive steps that the applicant or certified operator is taking to generate the organic form of commercially unavailable organic ingredients or materials. Examples of proactive steps could be, but are not limited to, the following: documentation of research, funding of research, funding or sourcing of development, promotion to develop the organic source of material, incentive or bonus to crops in transition to organic status, hiring of consultants to help promote and source organic material, or grower contracting.

All documentation of the above will be incorporated as part of the ACA's annual audit process of the certified parties to validate authentic and established processes for commercial availability determinations as part of the Organic System Plan.

Conclusion

The NOSB recommends the above additional adaptations be adopted to establish acceptable criteria and procedures to determine commercial availability.

CAC vote:

Moved: *Bea James* ***Second:*** *Joe Smillie*

Yes: 6 *No-* 0 *Abstain:* 0 *Absent:* 0