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MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

FROM: Miles V. McEvoy
Deputy Administrator
National Organic Program (NOP)

A handwritten signature in blue ink, appearing to read "Miles V. McEvoy", with a large, stylized flourish at the end.

SUBJECT: Response to National Organic Standards Board Recommendations (October 2015)

Background

The National Organic Standards Board (NOSB) is a 15-member Federal Advisory Committee comprised of organic community and stakeholder representatives. The Board was established by the Organic Foods Production Act of 1990 and charged with the following:

- Providing advice to the USDA about whether substances should be allowed or prohibited in organic production and/or handling
- Assisting with the development of standards for organic production, and
- Advising the Secretary on other aspects of the implementation of the Organic Foods Production Act.

The NOSB advises USDA on which substances should be allowed or prohibited in organic farming and processing, based on criteria under the Organic Foods Production Act. The NOSB must also review each substance on the [National List](#) every five years to determine whether it continues to meet all required criteria; this is referred to as the “sunset” review.

This memorandum responds to National Organic Standards Board (NOSB) recommendations as a result of the oral comments given via webinar on October 13th and 20th, 2015, as well as at the October 26-29, 2015 meeting of the NOSB in Stowe, Vermont. The NOSB provided a series of recommendations to USDA at the meeting. All motions by the NOSB require a 2/3 majority to pass.

Summary of Recommendations from Fall 2015 NOSB Meeting

1. Petitioned Substances. The NOSB recommended one amendment to the National List of Allowed and Prohibited Substances (National List). This section of the USDA organic regulations includes synthetic substances allowed in crop and livestock production, nonsynthetic substances prohibited in crop and livestock production, and all substances allowed in the handling of organic products.

Substance	Section	Action Considered by NOSB and the NOSB Recommendation
Flavors	§205.605(a)	The motion to amend the annotation passed

2. 2017 Sunset Review: The NOSB completed the 2017 sunset review for 198 substances. The NOSB considered motions to remove each of these substances from the National List. Please see Appendix 1 for a complete list of all substances reviewed and those recommended for removal.

Upon completing the Sunset 2017 review, the NOSB recommended 11 substances for removal: lignin sulfonate, furosemide, magnesium carbonate, chia (*Salvia hispanica L.*), dillweed oil, galangal, inulin-oligofructose enriched, lemongrass, peppers (Chipotle chile), Turkish bay leaves, and whey protein concentrate.

Substance	Section	Action Considered by NOSB NOSB Recommendation
Lignin sulfonate	§205.601(1)(1)	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review and also acknowledged and supported the petition that requested its removal.
Furosemide	§205.603(a)	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Magnesium carbonate	§205.605(b)	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Chia (<i>Salvia hispanica</i> L.)	§205.606	The motion to remove the following substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Dillweed oil	§205.606	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Galangal	§205.606	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Inulin-oligofructose enriched	§205.606	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.

Lemongrass	§205.606	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Peppers (Chipotle chile)	§205.606	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Turkish bay leaves	§205.606	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.
Whey protein concentrate	§205.606	The motion to remove this substance from the National List passed. The NOSB recommended removal from the National List as a result of its sunset review.

3. Other Recommendations

EPA List 4 Inert ingredients

The NOSB passed a recommendation to revise the annotation for inerts at 205.601(m) and 205.603(e).

Micronutrients for Crop Production, 205.601(j)

The NOSB passed a recommendation to revise the annotation for micronutrients at 205.601(j)(6).

Reclassification of Alginic acid

The NOSB passed a recommendation to reclassify alginic acid, which is currently listed on 206.605(a), as synthetic and move it to section 205.605(b).

Reclassification of Carnauba wax

The NOSB passed a recommendation to reclassify carnauba wax, which is currently listed on 206.605(a), as agricultural and move it to section 205.606.

NOP Discussion and Response

The NOP reviewed the NOSB's recommendations and will be pursuing the following intended actions.

1. Petitioned Substances

Flavors

At the October 2015 meeting, the NOSB recommended to revise the flavors annotation at §205.605(a) to read: *Non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.*

Flavors are currently listed at §205.605(a) with the annotation "*Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.*"

The 2017 Sunset review was also considered at the fall 2015 meeting concurrently with the petition to revise the flavor annotation. Flavors are comprised of several types of products, e.g., distillates, extracts, isolates, oleoresins, essential oils, compounded flavors, reaction flavors. Natural flavors can be produced from plants, animals and microorganisms.

NOP Response:

The NOP has reviewed the NOSB's recommendation and plans to move forward with a proposed rule for public comment.

2. 2017 Sunset Review

The NOSB completed the sunset review for 198 substances as a part of the Sunset 2017 review and recommended the removal of 11 substances: lignin sulfonate, furosemide, magnesium carbonate, chai (*Salvia hispanica L.*), dillweed oil, galangal, inulin-oligofructose, lemongrass, peppers (Chipotle chile), Turkish bay leaves, and whey protein concentrate. Please see the end of this document for a complete list of all substances reviewed and those recommended for removal.

- Lignin sulfonate: The NOSB determined that its use in organic crop production, specifically as a floatation agent in post-harvest handling, is no longer essential. The NOSB therefore recommended its removal from the National List.
- Furosemide: Comments were provided from the public on the use of furosemide. Those in support of relisting stated that furosemide is an important diuretic-saluretic for the humane treatment of organic animals. Comments in opposition stated that its use is limited and there are other natural alternatives. The NOSB recommended removing

furosemide from the National List based on it not being necessary for organic livestock production.

- Magnesium carbonate: The NOSB determined that this material, which is currently only allowed in “made with organic” products, is not essential to organic handling and that alternatives exist. The NOSB recommended removing magnesium carbonate from the National List.
- Chia (*Salvia hispanica L.*): The NOSB requested information from the public related to commercial demand, commercial availability, alternatives, and necessity and use. Several comments from a cross-section of the organic community were received in support of the delisting of chia, noting its wide commercial availability in organic form. The NOSB determined that based on the commercial availability of organic chia, it should be removed from the National List.
- Dillweed oil: The NOSB requested information from the public related to commercial demand, commercial availability, alternatives, and necessity and use. No comments were received that supported the relisting of dillweed oil. According to the NOSB Handling Subcommittee proposal, dillweed oil also meets the definition of flavors, non-synthetic, and dillweed and dillweed oil appear to be commercially available in organic form. The NOSB therefore recommended removing it from the National List.
- Galangal: The NOSB requested information from the public related to commercial demand, commercial availability, alternatives, and necessity and use. No comments were received that supported the relisting of galangal. According to the NOSB Handling Subcommittee proposal, galangal appears to be commercially available in organic form. The NOSB therefore recommended removing it from the National List.
- Inulin-oligofructose: The NOSB requested information from the public on commercial availability, ancillary substances, current use and demand for inulin-oligofructose, and alternatives. Given the comments received concerning the availability of organic inulin, the separate listing of fructooligosaccharides, information from certifiers of operations switching to organic inulin, and the absence of information on continued commercial unavailability of the organic inulin, the NOSB recommended removing it from the National List.
- Lemongrass: The NOSB requested information from the public related to commercial demand, commercial availability, alternatives, and necessity and use. Comments were received from a cross-section of the organic community in support of delisting frozen lemongrass noting it is commercially available in organic form. No specific comments received supported relisting or addressed commercial unavailability of frozen organic lemongrass. The NOSB therefore recommended lemongrass-frozen be removed from the National List.

- Peppers (Chipotle chile): The NOSB requested information from the public related to commercial demand, commercial availability, alternatives, and necessity and use. Several comments from a cross-section of the organic community were received in support of delisting chipotle peppers noting its commercial availability in organic form. No specific comments received supported relisting or addressed commercial unavailability of organic chipotle peppers. The NOSB therefore recommended peppers (Chipotle chile) be removed from the National List.
- Turkish bay leaves: The NOSB requested information from the public related to commercial demand, commercial availability, alternatives, and necessity and use. According to the NOSB, searches of publically available organic sourcing sites found organic sources of Turkish bay leaves. The NOSB therefore recommended Turkish bay leaves be removed from the National List.
- Whey protein concentrate: The NOSB requested information from the public related to ancillary ingredients, commercial demand, commercial availability, alternatives, and necessity and use. Information received from the original petitioner stated that they had secured a supply of organic whey protein for several years. There was no detailed information on whether organic supplies were insufficient. The NOSB therefore recommended the removal of whey protein concentrate from the National List on the basis that organic whey protein concentrate is available.

This action completes the NOSB's responsibility to review substances scheduled for the 2017 sunset review, according to the Organic Foods Production Act (OFPA) sunset provision (7 U.S.C. 6517(e)).

NOP Response:

The NOP accepts the NOSB's completed 2017 Sunset review. The NOP is reviewing these recommendations and plans to move forward with a proposed rule for public comment. AMS also intends to publish a notice to renew the other 187 substances, as listed in the relevant tables at the end of this document, on the National List for another five years.

3. Other Recommendations

EPA List 4 Inert ingredients

The NOSB passed a recommendation to revise the annotation for inerts at sections 205.601(m) and 205.603(e) of the National List.

The purpose for the annotation change is to remove reference in the regulation to the EPA List 4, since it is no longer maintained by the Environmental Protection Agency. In order to thoroughly evaluate inerts for compatibility with organic materials, the NOSB plans to work with the EPA Safer Choice Program. This recommendation acknowledges the current nomenclature in use by the EPA regarding FIFRA 25(b) and 40 CFR 180.1122, while laying a framework for some inerts to be reviewed individually. The recommended annotation is as follows:

205.601(m) and 205.603(e) – *As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.*

- (i) *Substances permitted for use as inerts in minimal risk products exempt from pesticide registration under FIFRA section 25(b).¹*
- (ii) *Substances included on the EPA's Safer Chemical Ingredient List.*
- (iii) *Inert ingredients that are exempt from the requirement of a tolerance under 40 CFR 180.1122 – for use only in passive pheromone dispensers.*

NOP Response:

The NOP has reviewed the NOSB's recommendation and plans to collaborate further with EPA's Safer Choice Program to develop a program for inert ingredient review, and to initiate notice and comment rulemaking to revise the annotations for inert ingredients at 205.601(m) and 205.603(e).

Micronutrients on Section 205.601(j)

The NOSB passed a recommendation to revise the annotation for micronutrients for organic crop production at 205.601(j)(6). The current listing reads as follows:

205.601 (j) - As a plant or soil amendment.

(6) Micronutrients - not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Soil Deficiency must be documented by testing.

to:

205.601 (j) - As a plant or soil amendment.

(6) Micronutrients - not to be used as a defoliant, herbicide, or desiccant. Those made from nitrates or chlorides are not allowed. Deficiency must be documented.

The NOSB recommended that the annotation be changed because they determined there are a number of ways to determine soil and crop deficiencies, including tissue testing, professional opinions from agronomists and crop advisors, extension publications, and regional knowledge.

NOP Response:

The NOP has reviewed the NOSB's recommendation and plans to initiate rulemaking for public comment to revise the annotation for micronutrients at section 205.601(j)(6).

¹ http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf. EPA has published a proposed rule at [FR 77:76979](https://www.federalregister.gov/d/2015-07-27) to codify the list of actives and inerts eligible for minimal risk products, when finalized the NOP reference will cite this.

Reclassification of Alginic Acid

The NOSB passed a recommendation to reclassify alginic acid, which is currently listed as a nonsynthetic substance on 206.605(a), as synthetic and move to section 205.605(b).

Alginic acid exists naturally in both brown seaweeds and two bacterial genera. However, the NOSB determined that the manufacturing process for industrial alginic acid could be considered a synthetic process when assessed against Draft Guidance on Classification of Materials (NOP Guidance 5033) document and the information presented in the 2015 technical report.

The NOSB recommended that alginic acid remain on the National List but that the listing is changed from section 205.605(a) to section 205.605(b) due to the determination that alginic acid would be classified as synthetic under the Draft Classification of Materials document.

NOP Response:

The NOP has reviewed the NOSB's recommendation and plans to initiate rulemaking for public comment to revise the listing for alginic acid. If finalized, alginic acid, which is currently listed on section 205.605(a), will be classified as synthetic and moved to section 205.605(b).

Reclassification of Carnauba Wax as Agricultural

The NOSB passed a recommendation to reclassify carnauba, which is currently listed on 205.605(a), as agricultural and move it to section 205.606.

Carnauba wax is extracted from palm trees. It is used to coat fruits and vegetables, candies and as a base for chewing gum. The NOSB assessed the manufacturing process of carnauba wax against the Draft Guidance on Classification of Materials (NOP Guidance 5033) document and determined it to be agricultural, based on the definition of "agricultural product" at § 205.2 of the USDA organic regulations. According to the NOSB, there is also some organically grown carnauba on the market.

NOP Response:

The NOP has reviewed the NOSB's recommendation and plans to initiate rulemaking for public comment to revise the listing for carnauba wax. If finalized, carnauba wax, which is currently listed on 205.605(a), will be classified as agricultural and moved to section 205.606.

4. Summary

The NOP acknowledges and sincerely appreciates the hundreds of hours NOSB members provided in developing the NOSB October 2015 recommendations, particularly the substantial amount of work required due to the large number of 2017 sunset reviews needed. In addition, the NOP supports the NOSB's vital role in representing the diversity of the organic community to enhance organic regulatory implementation and ensure organic product integrity.

Appendix 1 – 2017 Sunset Review

Sunset 2017 Review			
Action Considered: Motion to Remove Outcome: Passed			
Final NOSB Recommendation: See Below			
Use Area	Substance	Section	NOSB Final Recommendation
Crops	Lignin sulfonate	205.601(l)(1)	Remove from National List as a floating agent in postharvest handling
Livestock	Furosemide	205.603(a)	Remove from National List
Handling	Magnesium carbonate	205.605(b)	Remove from National List
Handling	Chia (Salvia hispanica L.)	205.606	Remove from National List
Handling	Dillweed oil	205.606	Remove from National List
Handling	Galangal	205.606	Remove from National List
Handling	Inulin-oligofructose enriched	205.606	Remove from National List
Handling	Lemongrass	205.606	Remove from National List
Handling	Peppers (Chipotle chile)	205.606	Remove from National List
Handling	Turkish bay leaves	205.606	Remove from National List
Handling	Whey protein concentrate	205.606	Remove from National List

Sunset 2017 Review – Crop Production			
Action Considered: Motion to Remove Outcome: Failed			
Status: Sunset Review Completed			
Substance	Section	Substance	Section
Alcohols: Ethanol	205.601(a)	Hydrated lime	205.601(i)
Alcohols: Isopropanol	205.601(a)	Potassium bicarbonate	205.601(i)
Chlorine Materials: Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite	205.601(a)	Aquatic plant extracts	205.601(j)
Soap-based algicide/demossers	205.601(a)	Humic acids	205.601(j)
Hydrogen peroxide	205.601(a), (i)	Lignin sulfonate (chelating agent)	205.601(j)
Herbicides, soap-based	205.601(b)	Magnesium sulfate	205.601(j)
Newspaper or other recycled paper	205.601(b), (c)	Micronutrients: Soluble Boron Products, Sulfates, carbonates, oxides, or silicates of zinc, copper,	205.601(j)

		iron, manganese, molybdenum, selenium, and cobalt	
Plastic mulch and covers (petroleum-based other than polyvinylchloride (PVC))	205.601(b)	Liquid fish products	205.601(j)
Soaps, ammonium	205.601(d)	Vitamin B1, C, E	205.601(j)
Ammonium carbonate	205.601(e)	Ethylene	205.601(k)
Boric acid	205.601(e)	Sodium silicate	205.601(l)
Elemental sulfur	205.601(e), (i), (j)	EPA List 4 - Inerts of Minimal Concern	205.601(m)
Lime sulfur	205.601(e), (i)	Microcrystalline cheesewax	205.601(o)
Oils, horticultural	205.601(e), (i)	Ash from manure burning	205.602(a)
Soaps, insecticidal	205.601(e)	Arsenic	205.602(b)
Sticky traps/barriers	205.601(e)	Lead salts	205.602(d)
Sucrose octanoate esters	205.601(e)	Potassium chloride	205.602(e)
Pheromones	205.601(f)	Sodium fluoaluminate (mined)	205.602(f)
Vitamin D3	205.601(g)	Strychnine	205.602(h)
Coppers, fixed	205.601(i)	Tobacco dust (nicotine sulfate)	205.602(i)
Copper sulfate	205.601(i)		

Sunset Review - Handling

Action Considered: Motion to Remove | Outcome: Failed

Status: Sunset Review Completed

Substance	Section	Substance	Section
Acid, Alginic	205.605(a)	Potassium acid tartrate	205.605(b)
Acid, Citric & lactic	205.605(a)	Potassium carbonate	205.605(b)
Attapulgate	205.605(a)	Potassium citrate	205.605(b)
Bentonite	205.605(a)	Potassium phosphate	205.605(b)
Diatomaceous earth	205.605(a)	Sodium citrate	205.605(b)
Kaolin	205.605(a)	Sodium hydroxide	205.605(b)
Perlite	205.605(a)	Sodium phosphates	205.605(b)
Calcium carbonate	205.605(a)	Sulfur dioxide	205.605(b)
Calcium chloride	205.605(a)	Tocopherols	205.605(b)
Dairy cultures	205.605(a)	Xanthan gum	205.605(b)
Enzymes	205.605(a)	Casings	205.606
Flavors	205.605(a)	Celery powder	205.606
Magnesium sulfate	205.605(a)	Colors: Beet juice extract color	205.606
Nitrogen	205.605(a)	Colors: Black currant juice color	205.606
Oxygen	205.605(a)	Colors: Pumpkin juice color	205.606
Potassium chloride	205.605(a)	Colors: Red cabbage extract color	205.606

Potassium iodide	205.605(a)	Colors: Black/Purple carrot juice color	205.606
Sodium bicarbonate	205.605(a)	Colors: Blueberry juice color	205.606
Sodium carbonate	205.605(a)	Colors: Carrot juice color	205.606
Waxes: Carnuba Wax	205.605(a)	Colors: Cherry juice color	205.606
Waxes: Wood rosin	205.605(a)	Colors: Chokeberry—Aronia juice color	205.606
Yeast	205.605(a)	Colors: Elderberry juice color	205.606
Acidified sodium chlorite	205.605(b)	Colors: Grape juice color	205.606
Alginates	205.605(b)	Colors: Grape skin extract color	205.606
Ammonium bicarbonate	205.605(b)	Colors: Paprika color	205.606
Ammonium carbonate	205.605(b)	Colors: Purple potato juice	205.606
Ascorbic acid	205.605(b)	Colors: Red radish extract color	205.606
Calcium citrate	205.605(b)	Colors: Saffron extract color	205.606
Calcium hydroxide	205.605(b)	Colors: Turmeric extract color	205.606
Calcium phosphates: monobasic, dibasic, tribasic	205.605(b)	Fish oil	205.606
Carbon dioxide	205.605(b)	Fructooligosaccharides	205.606
Chlorine Materials: Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite	205.605(b)	Gelatin	205.606
Ethylene	205.605(b)	Gums: Arabic, Carob bean, Guar, Locust bean	205.606
Ferrous sulfate	205.605(b)	Kelp	205.606
Glycerides, mono and di	205.605(b)	Konjac flour	205.606
Glycerin	205.605(b)	Lecithin—de-oiled	205.606
Hydrogen peroxide	205.605(b)	Orange pulp, dried	205.606
Magnesium chloride	205.605(b)	Orange Shellac - unbleached	205.606
Magnesium stearate	205.605(b)	Pectin (non-amidated forms only)	205.606
Nutrient vitamins and minerals	205.605(b)	Seaweed, Pacific kombu	205.606
Ozone	205.605(b)	Starches, Cornstarch (native), Sweet potato	205.606
Phosphoric acid	205.605(b)	Wakame seaweed (Undaria pinnatifida)	205.606

Sunset Review - Livestock Production

Action Considered: Motion to Remove | Outcome: Failed

Status: Sunset Review Completed

Substance	Section	Substance	Section
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Alcohols: Ethanol, Isopropanol	205.603(a)	Parasitocides: Moxidectin	205.603(a)
Aspirin	205.603(a)	Peroxyacetic/Peracetic acid	205.603(a)
Atropine	205.603(a)	Phosphoric acid	205.603(a)
Biologics, Vaccines	205.603(a)	Poloxalene	205.603(a)
Butorphanol	205.603(a)	Tolazoline	205.603(a)
Chlorhexidine	205.603(a)	Xylazine	205.603(a)
Chlorine Materials: Calcium hypochlorite, Chlorine dioxide, Sodium hypochlorite	205.603(a)	Copper sulfate	205.603(b)
Electrolytes	205.603(a)	Formic Acid	205.603(b)
Flunixin	205.603(a)	Lidocaine	205.603(b)
Glucose	205.603(a)	Lime, hydrated	205.603(b)
Glycerin	205.603(a)	Mineral oil	205.603(b)
Hydrogen peroxide	205.603(a)	Procaine	205.603(b)
Iodine	205.603(a), 205.603(b),	Sucrose octanoate esters	205.603(b)
Magnesium hydroxide	205.603(a)	Methionine	205.603(d)
Magnesium sulfate	205.603(a)	Trace minerals	205.603(d)
Oxytocin	205.603(a)	Vitamins	205.603(d)
Parasitocides: Fenbendazole	205.603(a)	Excipients	205.603(f)
Parasitocides: Ivermectin	205.603(a)	Strychnine	205.604(a)