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Washington, D.C. 20250-0268

December 17, 2010

MEMORANDUM FOR THE CHAIRPERSON OF THE NATIONAL ORGANIC STANDARDS BOARD

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

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

SUBJECT: National Organic Standards Board Recommendations (October 2010)

This memorandum responds to recommendations made at the October 2010 business meeting of the National Organic Standards Board (NOSB). The NOSB addressed the following: 1) the renewal and rejection of materials on the National List used in crop production, livestock production and handling; 2) changes in the existing listings for hops, yeast, pectins and colors; 3) the addition of formic acid to § 205.603(b) of the National List for use as a pesticide solely within honeybee hives; 4) regulations for organic apiculture production; 5) regulations to more specifically allow the use of preventatives and pain relief medications in the absence of illness under § 205.238 of the livestock health practice standard; and 6) clarifying the types of handlers that can be excluded from certification under § 205.101(b).

The NOSB made recommendations on their procedures to: 1) allow for the creation of ad-hoc committees on the NOSB to address special topics; 2) affirm the need for communications between the NOP and the NOSB to be in writing and posted for public review; and 3) allow for limited changes to national list annotations during the sunset review process. The NOSB also issued updates on their New Member Guide. Finally, the NOSB recommended the formation of a Task Force on Flavors, and an immediate prohibition on the use of Nanotechnology along with hosting a symposium on Nanotechnology.

NOP DISCUSSION AND RESPONSE:

1. Sunset 2012

The NOSB is congressionally mandated to review all substances listed on the National List and determine if their exemptions or prohibitions should be renewed for another five years; this is referred to as Sunset. After technical information, public comments, and details regarding alternative products were reviewed, the NOSB voted to renew 56 substances and reaffirm their prior votes on 148 substances which would have otherwise expired in 2012. The NOP accepts the NOSB's recommendations to relist the following Sunset 2012 substances:



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Table 1: Sunset 2012 Material Listings Voted to be Relisted by the NOSB

Section	Material	Sunset Date
§ 205.601 Synthetic substances allowed for use in organic crop production.	Hydrogen peroxide	October 21, 2012
	Soap-based algicide/demossers	October 21, 2012
	Herbicides, soap-based	October 21, 2012
	Soaps, ammonium	October 21, 2012
	Ammonium carbonate	October 21, 2012
	Boric acid	October 21, 2012
	Elemental sulfur	October 21, 2012
	Lime sulfur	October 21, 2012
	Oils, horticultural-narrow range oils as dormant, suffocating, and summer oils	October 21, 2012
	Soaps, insecticidal	October 21, 2012
	Sticky traps/barriers	October 21, 2012
	Sucrose octanoate esters (CAS #s—42922–74–7; 58064–47–4)	December 11, 2012
	Hydrated lime	October 21, 2012
	Hydrogen peroxide	October 21, 2012
	Lime sulfur	October 21, 2012
	Oils, horticultural-narrow range oils as dormant, suffocating, and summer oils	October 21, 2012
	Potassium bicarbonate	October 21, 2012
	Elemental sulfur	October 21, 2012
	Aquatic plant extracts (other than hydrolyzed)	October 21, 2012
	Elemental sulfur	October 21, 2012
	Humic acids	October 21, 2012
	Soluble boron products	October 21, 2012
	Sulfates of zinc	October 21, 2012
	Sulfates of copper	October 21, 2012
	Sulfates of iron	October 21, 2012
	Sulfates of manganese	October 21, 2012
	Sulfates of molybdenum	October 21, 2012
	Sulfates of selenium	October 21, 2012
	Sulfates of cobalt	October 21, 2012
	Carbonates of zinc	October 21, 2012
	Carbonates of copper	October 21, 2012
	Carbonates of iron	October 21, 2012
	Carbonates of manganese	October 21, 2012
	Carbonates of molybdenum	October 21, 2012
	Carbonates of selenium	October 21, 2012
	Carbonates of cobalt	October 21, 2012
	Oxides of zinc	October 21, 2012
	Oxides of copper	October 21, 2012
	Oxides of iron	October 21, 2012
	Oxides of manganese	October 21, 2012
	Oxides of molybdenum	October 21, 2012



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§ 205.601 Synthetic substances allowed for use in organic crop production (continued).	Oxides of selenium	October 21, 2012
	Oxides of cobalt	October 21, 2012
	Silicates of zinc	October 21, 2012
	Silicates of copper	October 21, 2012
	Silicates of iron	October 21, 2012
	Silicates of manganese	October 21, 2012
	Silicates of molybdenum	October 21, 2012
	Silicates of selenium	October 21, 2012
	Silicates of cobalt	October 21, 2012
	Liquid fish products	October 21, 2012
	Vitamin B ₁	October 21, 2012
	Vitamin C	October 21, 2012
	Vitamin E	October 21, 2012
	EPA List 4-Inerts of Minimal Concern	October 21, 2012
§ 205.602 Nonsynthetic substances prohibited for use in organic crop production.	Ash from manure burning	October 21, 2012
	Arsenic	October 21, 2012
	Lead salts	October 21, 2012
	Potassium chloride	October 21, 2012
	Sodium fluoaluminat (mined)	October 21, 2012
	Strychnine	October 21, 2012
	Tobacco dust (nicotine sulfate)	October 21, 2012
§ 205.603 Synthetic substances allowed for use in organic livestock production.	Atropine (CAS #–51–55–8)	December 13, 2012
	Vaccines	October 21, 2012
	Butorphanol (CAS #–42408–82–2)	December 13, 2012
	Chlorhexidine	October 21, 2012
	Electrolytes—without antibiotics	October 21, 2012
	Flunixin (CAS #–38677–85–9)	December 13, 2012
	Hydrogen peroxide	October 21, 2012
	Iodine	October 21, 2012
	Magnesium hydroxide	December 13, 2012
	Oxytocin—use in postparturition therapeutic	October 21, 2012
	Ivermectin	October 21, 2012
	Peroxyacetic/peracetic acid (CAS #–79–21–0)	December 13, 2012
	Phosphoric acid	October 21, 2012
	Poloxalene (CAS #–9003–11–6)	December 13, 2012
	Tolazoline (CAS #–59–98–3)	December 13, 2012
	Xylazine (CAS #–7361–61–7)	December 13, 2012
	Iodine	October 21, 2012
	Lidocaine	October 21, 2012
	Lime, hydrated	October 21, 2012
	Mineral oil	October 21, 2012
	Procaine	October 21, 2012
	Sucrose octanoate esters	December 11, 2012
	Trace minerals	October 21, 2012
	Vitamins	October 21, 2012
	Excipients	December 13, 2012
	Ethanol	October 21, 2012
	Isopropanol	October 21, 2012
	Aspirin	October 21, 2012



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§ 205.603 Synthetic substances allowed for use in organic livestock production (continued).	Calcium hypochlorite	October 21, 2012
	Chlorine dioxide	October 21, 2012
	Sodium hypochlorite	October 21, 2012
	Furosemide	December 13, 2012
	Glucose	October 21, 2012
	Glycerine	October 21, 2012
	Magnesium sulfate	October 21, 2012
	Copper sulfate	October 21, 2012
	EPA List 4-Inerts of Minimal Concern	October 21, 2012
§ 205.604 Nonsynthetic substances prohibited for use in organic livestock production	Strychnine	October 21, 2012
§ 205.605(a) Nonsynthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic”	Calcium hypochlorite	October 21, 2012
	Alginic acid	October 21, 2012
	Citric acid	October 21, 2012
	Lactic acid	October 21, 2012
	Bentonite	October 21, 2012
	Calcium carbonate	October 21, 2012
	Calcium chloride	October 21, 2012
	Dairy cultures	October 21, 2012
	Diatomaceous earth	October 21, 2012
	Kaolin	October 21, 2012
	Nitrogen – oil free grades	October 21, 2012
	Oxygen – oil free grades	October 21, 2012
	Perlite	October 21, 2012
	Potassium chloride	October 21, 2012
	Sodium bicarbonate	October 21, 2012
	Sodium carbonate	October 21, 2012
	Carnauba wax—nonsynthetic	October 21, 2012
	Flavors	October 21, 2012
	Magnesium sulfate	October 21, 2012
	Autolysate	October 21, 2012
	Bakers yeast	October 21, 2012
	Brewers yeast	October 21, 2012
	Nutritional yeast	October 21, 2012
	Smoked yeast	October 21, 2012
§ 205.605(b) Synthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic.”	Alginates	October 21, 2012
	Ammonium bicarbonate	October 21, 2012
	Ammonium carbonate	October 21, 2012
	Ascorbic Acid	October 21, 2012
	Calcium citrate	October 21, 2012
	Calcium hydroxide	October 21, 2012
	Calcium phosphates monobasic	October 21, 2012
	Calcium phosphates dibasic	October 21, 2012
	Calcium phosphates tribasic	October 21, 2012
	Carbon dioxide	October 21, 2012



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§ 205.605(b) Synthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (continued).	Ethylene	October 21, 2012
	Monoglycerides	October 21, 2012
	Diglycerides	October 21, 2012
	Glycerin	October 21, 2012
	Hydrogen peroxide	October 21, 2012
	Magnesium carbonate	October 21, 2012
	Magnesium chloride	October 21, 2012
	Magnesium stearate	October 21, 2012
	Ozone	October 21, 2012
	Potassium acid tartrate	October 21, 2012
	Potassium carbonate	October 21, 2012
	Potassium citrate	October 21, 2012
	Potassium hydroxide	October 21, 2012
	Potassium phosphate	October 21, 2012
	Xanthan gum	October 21, 2012
	Calcium hypochlorite	October 21, 2012
	Chlorine dioxide	October 21, 2012
	Sodium hypochlorite	October 21, 2012
	Ferrous sulfate	October 21, 2012
	Pectin (low-methoxy)	October 21, 2012
	Phosphoric acid	October 21, 2012
	Silicon dioxide	October 21, 2012
	Sodium citrate	October 21, 2012
	Sodium hydroxide	October 21, 2012
	Sodium phosphates	October 21, 2012
	Sulfur dioxide	October 21, 2012
§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."	Casings, from processed intestines	June 27, 2012
	Celery powder	June 27, 2012
	Chia (Salvia hispanica L.)	June 27, 2012
	Dillweed oil (CAS # 8006-75-5)	June 27, 2012
	Fish oil (fatty acid CAS #'s 10417-94-4 and 25167-62-)	June 27, 2012
	Galangal, frozen	June 27, 2012
	Gelatin (CAS # 9000-70-8)	June 27, 2012
	Arabic gum	October 21, 2012
	Guar gum	October 21, 2012
	Locust bean gum	October 21, 2012
	Carob bean gum	October 21, 2012
	Kelp	October 21, 2012
	Konjac flour (CAS # 37220-17-0)	June 27, 2012
	Lemongrass, frozen	June 27, 2012
	Orange shellac – unbleached (CAS # 9000-59-3)	June 27, 2012
	Peppers (chipotle chile)	June 27, 2012
	Sweet potato starch, for bean thread production only	June 27, 2012
	Turkish bay leaves	June 27, 2012
	Wakame seaweed (Undaria pinnatifida).	June 27, 2012
	Annatto extract color (pigment CAS # 1393-63-1) –	June 27, 2012
	Beet juice extract color (pigment CAS # 7659-95-2)	June 27, 2012



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§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" (continued).	Beta-carotene extract color from carrots (CAS # 1393-63-1)	June 27, 2012
	Black currant juice color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Black/purple carrot juice color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Carrot juice color (pigment CAS # 1393-63-1)	June 27, 2012
	Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Chokeberry – Aronia juice color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Elderberry juice color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Grape juice color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Grape skin extract color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Paprika color - dried powder and vegetable oil extract	June 27, 2012
	Pumpkin juice color (pigment CAS # 127-40-2)	June 27, 2012
	Purple potato juice color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Red cabbage extract color (pigment CAS #'s: 528-58-5, 528-53-5)	June 27, 2012
	Red radish extract color (pigment CAS #'s 528-58-5, 528-53-5)	June 27, 2012
	Saffron extract color (pigment CAS # 1393-63-1)	June 27, 2012
	Turmeric extract color (CAS # 458-37-7)	June 27, 2012
	Fructo-oligosaccharides (CAS#308066-66-2)	June 27, 2012
	Hops (humulus lupulus)	June 27, 2012
	Inulin, oligofructose enriched	June 27, 2012
	Pectin (high-methoxy)	October 21, 2012
	Cornstarch (native)	October 21, 2012
	Whey protein	June 27, 2012

The Livestock Committee has completed their Sunset 2012 review. The NOP recognizes that the NOSB Crops and Handling Committees have requested additional technical review for the following substances. They will defer issuing recommendations for the following substances until the April 2011 NOSB meeting:

Table 2: Sunset 2012 Material Listings Deferred Until the Spring 2011 NOSB Meeting

Section	Material	Sunset Date
§ 205.601 Synthetic substances allowed for use in organic crop production.	Calcium hypochlorite	October 21, 2012
	Chlorine dioxide	October 21, 2012
	Sodium hypochlorite	October 21, 2012
	Ethanol	October 21, 2012
	Isopropanol	October 21, 2012
	Copper hydroxide	October 21, 2012
	Copper oxide	October 21, 2012
	Copper oxychloride	October 21, 2012
	Copper sulfate	October 21, 2012
	Newspapers or other recycled paper, without glossy or colored inks (2 listings)	October 21, 2012
	Plastic mulch and covers	October 21, 2012
	Pheromones	October 21, 2012
	Sulfur dioxide	October 21, 2012



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§ 205.601 Synthetic substances allowed for use in organic crop production.	Vitamin D ₃	October 21, 2012
	Streptomycin	October 21, 2012
	Lignin sulfonate (2 listings)	October 21, 2012
	Magnesium sulfate	October 21, 2012
	Ethylene gas	October 21, 2012
	Sodium silicate	October 21, 2012
§ 205.602 Nonsynthetic substances prohibited for use in organic crop production	Sodium nitrate	October 21, 2012
§ 205.605(a) Nonsynthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic for use in crop production.	Enzymes	October 21, 2012
	Potassium iodide	October 21, 2012
§ 205.605(b) Synthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic for use in organic crop production.	Nutrient vitamins	October 21, 2012
	Nutrient minerals	October 21, 2012
	Potassium iodide	October 21, 2012
	Tocopherols	October 21, 2012

2. Rejection of Ethylene Glycol, Tall Oils, and Tetra-methyl-decyne-diol Petitioned for Use in Crops

At the October 2010 NOSB meeting, the NOSB rejected three substances—ethylene glycol, tall oils, and tetra-methyl-decyne-diol—that were petitioned to add to the National List of Allowed Substances. These materials were petitioned for use as synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in § 205.601, or as an active pesticide ingredient in accordance with any limitations on the use of such substances. The Crops committee also accepted the withdrawal of Ethylene DDS from consideration as requested by the petitioner. Additionally, the NOSB requested that the industry refrain from submitting additional petitions for inert ingredients used in pesticides until the issues regarding the review of EPA’s listings of inert ingredients are resolved.

As reported at the October 2010 NOSB meeting, the NOP has presented a draft Memorandum of Understanding (MOU) for EPA to consider how the NOP and EPA can work together with the NOSB to effectively review the large number of inert ingredients for their compliance with the National Organic Standards. The NOP continues to work on the next steps which include: 1) determine the optimal configuration of a working group of EPA programs and NOP staff, along with some selected NOSB members; 2) evaluating the current EPA classification of inert ingredients, and 3) develop the criteria and process for the evaluation of the inert ingredients.



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3. Recommendations to Remove the Allowance of Non-organic Hops from Use and to Change the Listings of Yeast, Pectins and Colors Allowed for Use in Handling, and the Proposed Formation of a Task Force on Flavors.

Hops – Hops – The NOSB considered a petition to remove hops from § 205.606 and made a recommendation that hops be removed from § 205.606 effective January 1, 2013. The NOP accepts the recommendation.

Yeast – The NOSB considered a petition to remove yeast from § 205.605(a) and add it to § 205.606. The NOSB recommended that yeast should remain on § 205.605(a) as a nonsynthetic, nonagricultural ingredient but added an annotation to require yeast to be organic if its end use is for human consumption. The annotation also allows nonorganic yeast to be used when equivalent organic yeast is not commercially available. The NOP accepts the NOSB's recommendation.

Pectins – The NOSB recommended to remove pectin as an allowed synthetic ingredient from § 205.605(b) and to modify the annotation of pectin on §205.606 to allow non-amidated forms only. The NOP accepts the recommendations.

Colors –The NOSB recommended adding an annotation to § 205.606(d) that states that colors must not be produced using synthetic solvents and carrier systems or any artificially preservatives. The NOP accepts the NOSB's recommendation.

Flavors Task Force – The NOP concurs with the need for a more extensive review of the category of flavors currently listed on § 205.605(a) to determine if there are flavors that should be considered agricultural and required to be organically produced. The NOP does not believe there is a need for an NOP sponsored task force on flavors at this time. The NOP believes the formation of an informal industry group to develop a flavor recommendation for the NOSB to consider would accomplish the same goal more effectively.

4. Addition of Formic Acid for Use in Honeybee Hives

After receiving public comment that mite infestations were decimating organic apiaries in Hawaii, the NOSB accepted a petition to allow formic acid as a miticide. The NOSB recommended adding formic acid to § 205.603(b) with the annotation: "for use solely as a pesticide in honeybee hives." The NOP accepts the NOSB's recommendation.

5. Regulations Proposed for Organic Apiculture

The NOP concurs with the need for standards for organic apiculture and appreciates the NOSB's extensive work on this important topic. It is a priority for the NOP to have proposed regulations for apiculture developed for publication in the federal register by the end of the 2011 calendar year. The NOP accepts the NOSB's recommendation.

6. Regulation Change on Livestock Health Care Practice Standard (§ 205.238(c)(2))

Over the past couple of years, the NOSB has been working to better define and strengthen the animal welfare practices in the National Organic Standards. As a part of this process, the NOSB is seeking to



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incorporate the growing body of knowledge regarding the products and practices that prevent disease. The NOSB has recommended amending § 205.238(c)(2) to clarify that preventative and pain relief medications are allowed. The overall intent of § 205.238, the livestock health care practice standard, is to establish and maintain preventive livestock health care practices. Under § 205.603(a) and (b), medical treatments are allowed for preventative purposes and pain relief (e.g. aspirin, glycerine, mineral oil). The NOP appreciates and concurs with the NOSB's concern for animal welfare, but believes that additional rulemaking is unnecessary and that preventatives and pain relief medications are currently allowed.

7. NOSB Procedural Recommendations

The NOP understands that the NOSB issued four recommendations on their internal policies and materials:

Establishment of Ad-Hoc Committees – The NOSB voted to implement a new policy allowing the establishment of ad-hoc committees to accommodate specialized topics to be addressed by the NOSB.

NOP/NOSB Collaboration – The NOSB voted to adopt a policy emphasizing the need for official requests, responses, and outcomes of collaborative efforts between the NOP and the NOSB to be in writing. The NOP will also post these written communications to our website for review and public comment at NOSB business meetings. The priorities of the NOSB and the NOP need on-going consideration in the context of the overall workplan of both. The monthly calls of the Executive Committee provide a good forum to establish and clarify current and emerging priorities, along with expectations and outcomes of audits and evaluations.

Sunset Review – The NOSB voted to allow removing, adding, or amending an annotation, as long as it results in the restriction or clarification of the use of a material. The NOP will work to make sure NOSB's recommendations on the National List are reflected in the regulations.

New Member Guide – The NOSB issued updates to its New Member Guide, intended to assist new NOSB members acclimate to regulatory processes and their unique role as a board member.

8. Recommendation Providing Guidance to Limit the Types of Handlers Excluded from Certification under § 205.101(b).

The NOP accepts NOSB's conclusion that the language in § 205.101(b) does not exclude handlers of organic unpackaged bulk agricultural commodities (i.e. grain, soybeans, hay, fresh vegetables, etc. or animals) from certification. The NOP will develop instructions to remind certifying agents and handlers of unpackaged bulk agricultural products of the regulatory requirements. The instructions will include responsibilities and provide examples of best practices for documenting the chain of custody for products.

9. Nanotechnology

The NOP understands that the NOSB considers nanomaterials to be synthetic and prohibited under the National Organic Program regulations. The NOP appreciates the time and consideration that NOSB



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has given to this issue. There are significant questions remaining regarding the definition and regulation of nanotechnology and nanomaterials.

At present, the lack of a legal definition is one of the biggest obstacles to regulating nanomaterials. In the absence of scientific or legal agreement on the definition of nanomaterials across regulatory agencies, it would be difficult for organic producers and handlers, certifying agents, and the NOP to identify the presence of nanomaterials and verify their absence in organic products. Due to the lack of scientific or legal consensus with nanotechnology and nanomaterials, the proposed working definition provided by the NOSB recommendation will help guide NOP questions and inquiries. The NOP accepts the NOSB recommendation and intends to gather additional information about how nanomaterials are regulated and used in agricultural production and handling. Rather than holding a symposium at this time, the NOP will gather information from other agencies that are reviewing their regulatory oversight of nanomaterials and report back to the NOSB.

10. Summary

The NOP sincerely appreciates the NOSB's time and efforts in crafting these recommendations. We look forward to continuing to facilitate your important work in a collaborative manner to advance the organic food industry and protect organic integrity.

Finally, we would like to sincerely thank the outgoing NOSB members—Kevin Engelbert, Dan Giacomini, Jennifer Hall, Jeff Moyer, and Joe Smillie—for their exemplary service. Over the past five years, they have generously donated a considerable amount of time and energy to the NOSB during a very important period of growth within the organic industry. The NOP is very appreciative of their guidance and support and hopes to have the opportunity to work with them in the future.