



United States
Department of
Agriculture

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Room 2646-S, Ag Stop 0268
Washington, D.C. 20250-0268

September 30, 2010

MEMORANDUM FOR THE CHAIRMAN OF THE NATIONAL ORGANIC STANDARDS BOARD

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

SUBJECT: National Organic Standards Board Recommendations (April 2010 & November 2009)

The National Organic Standards Board (NOSB) made recommendations in April 2010 that addressed the following: renewal and rejection of materials on the National List used in crop production, livestock production and handling; annotation changes for the use of methionine in organic poultry production; a clarification on a livestock health practice standard under 205.238; inerts in pesticides allowed for use in organic production; regulations for terrestrial plants in containers and enclosures (greenhouses); regulations on the use of inert atmospheric gases in products labeled and sold as 100% organic; a two-tiered voting approach for materials petitioned to the National List; and the classification of materials. The NOSB also made a recommendation on vaccines in November 2009 for which NOP was to provide additional information to the Board.

DISCUSSION:

1. Sunset 2011 - §205.601: Synthetic substances allowed for use in organic crop production.

The NOSB reviewed the following material on the National List for use in organic crop production, due to sunset in 2011, and recommended continued listing until review of the petition to remove is completed for this material. The NOP concurs with the April 2010 NOSB recommendation to renew the following listing for crop production substances, and any restrictive annotations, that are due to sunset in 2011:

§205.601

As slug or snail bait. Ferric phosphate (CAS # 10045-86-0).

2. Sunset 2012 – §205.601: Synthetic substances allowed for use in organic crop production.

The NOSB reviewed the following materials on the National List for use in organic crop production, due to sunset in 2012, and recommended to continue listing on the basis that no new information was presented to support removal. The NOP concurs with the April 2010 NOSB recommendation to renew the following forty-four listings for crop production substances, and any restrictive annotations:



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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	
Oxides of selenium	October 21, 2012	



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Section	Material	Sunset Date
	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

The NOP also recognizes that the NOSB will present a recommendation on one material listing for §205.601 at the October 2010 Meeting.

Section	Material	Sunset Date
§ 205.601 Synthetic substances allowed for use in organic crop production	EPA List 4-Inerts of Minimal Concern	October 21, 2012

The NOP also recognizes that the NOSB has requested additional technical review for nineteen material listings, and will defer issuing recommendations for these materials 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
	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



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3. Sunset 2012 – §205.602: Nonsynthetic substances allowed for use in organic crop production.

The NOSB reviewed the following materials on the National List for use in organic crop production, due to sunset in 2012, and recommended to continue listing on the basis that no new information was presented to support removal. The NOP concurs with the April 2010 NOSB recommendation to renew the following seven listings for crop production substances, and any restrictive annotations:

Section	Material	Sunset Date
§ 205.602 Nonsynthetic substances allowed 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

The NOP recognizes that the NOSB has requested additional technical review for the listing for Sodium nitrate, due to sunset in October 2012, and will defer issuing a recommendation for this material until the spring 2011 NOSB meeting.

4. Sunset 2012 – §205.603: Synthetic substances allowed for use in organic livestock production.

The NOSB reviewed the following materials on the National List for use in organic livestock production, due to sunset in 2012, and recommended to continue listing on the basis that no new information was presented to support removal. The NOP concurs with the April 2010 NOSB recommendation to renew the following twenty-five listings for livestock production substances, and any restrictive annotations:

Section	Material	Sunset Date
§ 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 applications	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



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Section	Material	Sunset Date
	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

The NOP recognizes that the NOSB will present recommendations on twelve material listings for §205.603 at the October 2010 Meeting.

Section	Material	Sunset Date
§ 205.603 Synthetic substances allowed for use in organic livestock production	Ethanol	October 21, 2012
	Isopropanol	October 21, 2012
	Aspirin	October 21, 2012
	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

5. Sunset 2012 – §205.604: Nonsynthetic substances prohibited for use in organic livestock.

The NOSB reviewed the following materials on the National List for use in organic livestock production, due to sunset in October 2012, and recommended to continue listing on the basis that no new information was presented to support removal. The NOP concurs with the April 2010 NOSB recommendation to renew the listing for strychnine for livestock production substances, and any restrictive annotations.

6. Sunset 2012 – §205.605(a): Nonsynthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The NOSB reviewed the following materials on the National List for use in organic handling, due to sunset in 2012, and recommended to continue listing on the basis that no new information was presented to support removal. The NOP concurs with the April 2010 NOSB recommendation to renew the following seventeen listings for handling substances, and any restrictive annotations:

Section	Material	Sunset Date
§ 205.605(a) Nonsynthetic substances allowed as ingredients in or on processed products labeled	Calcium hypochlorite	October 21, 2012
	Alginic acid	October 21, 2012
	Citric acid	October 21, 2012
	Lactic acid	October 21, 2012



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Section	Material	Sunset Date
as "organic" or "made with organic"	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

The NOP recognizes that the NOSB will present recommendations on seven material listings for §205.605(a) at the October 2010 Meeting.

Section	Material	Sunset Date
§ 205.605(a) Nonsynthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic"	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

The NOP also recognizes that the NOSB has requested additional technical review for two material listings, and will defer issuing recommendations for these materials until the spring 2011 NOSB meeting.

Section	Material	Sunset Date
§ 205.605(a) Nonsynthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic for use in organic crop production.	Enzymes	October 21, 2012
	Potassium iodide	October 21, 2012

7. Sunset 2012 – §205.605(b): Synthetic substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))."

The NOSB reviewed the following materials on the National List for use in organic handling, due to sunset in 2012, and recommended to continue listing on the basis that no new information was presented to support



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removal. The NOP concurs with the April 2010 NOSB recommendation to renew the following twenty-five listings for handling substances, and any restrictive annotations:

Section	Material	Sunset Date
§ 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
	Ethylene	October 21, 2012
	Monoglycerides* <i>To be reconsidered at Fall 2010 meeting</i>	October 21, 2012
	Diglycerides* <i>To be reconsidered at Fall 2010 meeting due</i>	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	

The NOP recognizes that the NOSB will present recommendations on eleven material listings for §205.605(a) at the October 2010 Meeting.

Section	Material	Sunset Date
§ 205.605(b) Synthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic	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



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The NOP also recognizes that the NOSB has requested additional technical review for four material listings, and will defer issuing recommendations for these materials until the spring 2011 NOSB meeting.

Section	Material	Sunset Date
§ 205.605(a) Nonsynthetic 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

8. Sunset 2012 – §205.606: Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

The NOSB reviewed the following materials on the National List for use in organic production and handling, due to sunset in 2012, and recommended to continue listing on the basis that no new information was presented to support removal. The NOP concurs with the April 2010 NOSB recommendation to renew the following nineteen listings for organic production and handling substances, and any restrictive annotations:

Section	Material	Sunset Date
§ 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 (<i>Salvia hispanica L.</i>)	June 27, 2012
	Dillweed oil (CAS # 8006-75-5)	June 27, 2012
	Fish oil (fatty acid CAS #'s 10417-94-4 and 25167-62-8)	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 (<i>Undaria pinnatifida</i>).	June 27, 2012

The NOP recognizes that the NOSB will present recommendations on twenty-five material listings for §205.606 at the October 2010 Meeting.



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Section	Material	Sunset Date
§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."	Annatto extract color (pigment CAS # 1393-63-1) – water	June 27, 2012
	Beet juice extract color (pigment CAS # 7659-95-2)	June 27, 2012
	Beta-carotene extract color from carrots (CAS # 1393-63-1)	June 27, 2012
	Black currant juice color (pigment CAS #'s: 528-58-5,	June 27, 2012
	Black/purple carrot juice color (pigment CAS #'s: 528-58-	June 27, 2012
	Blueberry juice color (pigment CAS #'s: 528-58-5, 528-53-	June 27, 2012
	Carrot juice color (pigment CAS # 1393-63-1)	June 27, 2012
	Cherry juice color (pigment CAS #'s: 528-58-5, 528-53-0,	June 27, 2012
	Chokeberry – Aronia juice color (pigment CAS #'s: 528-	June 27, 2012
	Elderberry juice color (pigment CAS #'s: 528-58-5, 528-	June 27, 2012
	53-0, 643-84-5, 134-01-0, 1429-30-7, and 134-04-3)	
	Grape juice color (pigment CAS #'s: 528-58-5, 528-53-0,	June 27, 2012
	Grape skin extract color (pigment CAS #'s: 528-58-5, 528-	June 27, 2012
	Paprika color - dried powder and vegetable oil extract (CAS	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-	June 27, 2012
	Red cabbage extract color (pigment CAS #'s: 528-58-5,	June 27, 2012
	Red radish extract color (pigment CAS #'s 528-58-5, 528-	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 (<i>humulus lupulus</i>)	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	

9. Methionine

The NOSB issued a two-part recommendation on the use of synthetic methionine in organic poultry production in April 2010. The first part of the recommendation extended the allowance for methionine in organic poultry production until October 1, 2012, at the following maximum allowable limits of methionine per ton of feed: 4 pounds for layers, 5 pounds for broilers, and 6 pounds for turkeys and all other poultry.

The NOP responded to this recommendation by issuing an interim rule on August 24, 2010 that extends the use of methionine at the levels specified above. The interim rule will become effective Oct. 1, 2010, and is currently available for comments until October 25, 2010. The NOP will issue a final rule for this amendment to the National List no later than March 2011.

The second part of the recommendation is for a step down in the maximum allowable limits of methionine per ton of feed after October 1, 2012 to the following: 2 pounds for layers and broilers and 3 pounds for turkeys and all other poultry. The NOSB recommendation indicates that this step down will be feasible in conjunction with stocking rates for poultry specified in the NOSB's November 2009 animal welfare recommendation.



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The NOP is concerned that there is limited scientific or economic justification for the step down in the maximum allowable limits of methionine. It will be challenging for the NOP to complete the rulemaking process on the step down rates without additional justification. The NOP may not be able to complete a proposed and final rule before October 1, 2012 without additional justification. If the NOP is unsuccessful in completing rule making prior to October 1, 2012, then methionine will not be allowed in organic poultry production after October 1, 2012.

The NOP is requesting that the NOSB provide additional justification on the methionine step down rates of 2 pounds of methionine per ton of feed for layers and broilers and 3 pounds of methionine per ton of feed for turkeys and all other poultry. The NOP is requesting that the board provide scientific and economic justification as well as the likelihood that natural alternatives to synthetic methionine will be available by October 1, 2012. The NOP would also suggest the Board revisit the National Research Council (NRC) requirements for poultry feed to determine whether the step down levels are appropriate.

Furthermore, the NOP believes that it is unlikely for a rule change on stocking rates to be completed prior to October 2012. The Board may want to consider whether the time horizon for a stocking rate rule has any implications for the second part of their recommendation on the use of synthetic methionine.

10. Clarification on Livestock Health Care Practice Standard (205.238(c)(1))

In November 2009 the NOSB approved an animal welfare recommendation. In April 2010 the NOSB reconsidered a portion of the November 2009 recommendation and voted to delete the last sentence of §205.238(c)(1) from their November recommendation. The intent of this deletion is to permit milk from a cow treated with an allowed synthetic substance under §205.603 to be fed to young organic livestock during the withholding period. The NOSB's animal welfare recommendation affirms the intent of the regulations that milk produced after the treatment but during the withholding period may be fed to young organically managed livestock. The NOP concurs with the NOSB's clarification and will consider this sentence removed from the NOSB's November 2009 animal welfare recommendation.

11. Inerts in Pesticides

In April 2010, the NOSB issued a formal recommendation to the National Organic Program (NOP) regarding the use of inerts in pesticides allowed for use in organic production. The NOSB proposed six steps to accomplish the changes in regulation needed to amend the current listing for inert ingredients on the National List. These steps include NOSB review of synthetic inert materials currently on the obsolete EPA List 4, inerts of minimal concern; and EPA List 3, inerts of unknown toxicity.

The NOSB requested that the NOP create and enter into a Memorandum of Understanding (MOU) with the EPA to assist in the evaluation of the materials previously known as EPA List 4 and EPA List 3. The MOU will involve collaboration between EPA, NOSB, and NOP to determine how best to evaluate these materials for listing, maintain the list, and continue to evaluate new inert materials for inclusion on the List.

In response to the Board's recommendation, the NOP has written a draft MOU for EPA to consider how the NOP and EPA can work together in conjunction with the NOSB to resolve issues surrounding inert ingredients used in pesticides allowed in organic production. The NOP understands that the evaluation of inert pesticide



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ingredients for organic agriculture production will be challenging work for the NOSB. The NOP is concerned about the feasibility of the NOSB's proposal to have the NOSB individually review all synthetic inert ingredients currently used in NOP compliant pesticide formulations. Neither the NOSB nor the NOP has access to necessary information or expertise to successfully and efficiently complete the task. The NOP is requesting support from EPA in identifying and evaluating suitable inert pesticide ingredients to be considered for use in organic agriculture production.

As the collaboration between NOSB, EPA, and NOP continues, the NOP would also like the NOSB to consider how inert ingredients are regulated under other organic standards. At this time, the National Organic Standards have one of the most prescriptive requirements for inert ingredients among organic standards worldwide. Outside of the United States most organic standards generally specify allowed active ingredients but leave it to the respective governmental environmental agencies to evaluate the safety of inert ingredients.

The NOP recognizes that amending the current listing for inert ingredients will take time. In the interim, the approval of new inert ingredients must continue to follow the process outlined in the NOP policy statement issued on September 6, 2007. Petitions for new inert ingredients may be submitted to the NOSB using the National List petition procedures. Petitioned substances must be recommended by the NOSB and added to the National List through notice and comment rulemaking before use in organic agriculture.

12. Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses)

The NOP thanks the NOSB for their completion of work on greenhouse standards through their April 2010 recommendation. The NOP will develop a proposed rule based on the NOSB final recommendations.

13. The Use of Inert Atmospheric Gases in Products Labeled and Sold as 100% Organic

The April 2010 NOSB recommendation on the use of inert atmospheric gases in packaging states that such gases should not be considered ingredients or processing aids, but rather as "packaging aids" that do not need consideration in determination of a 100% organic label claim.

The NOP is considering this proposal in context of additional guidance under development regarding clarification of the 100% organic labeling category. The NOP regulations do not provide for another category of food additives, aside from ingredients and processing aids. The NOP regulation provides an allowance for most packaging materials, provided they do not contain synthetic fungicides, preservatives or fumigants.

Gases used in packaging are regulated by FDA as direct food substance, at 21 CFR, Part 184—Direct Food Substances Affirmed As Generally Recognized As Safe (GRAS). Nitrogen gas is regulated by FDA at 21 CFR 184.1540, which states;

“The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:
(1) The ingredient is used as a propellant, aerating agent, and gas as defined in §170.3(o)(25) of this chapter.”



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Carbon dioxide is similarly characterized by FDA as an ingredient at the GRAS listing of 21 CFR 184.1240, with permitted uses as leavening agent, processing aid, and as a propellant and gas.

Argon gas is not listed by FDA as GRAS; however, FDA did issue a notice in 2000 stating that they did not have questions about a manufacturer's claim that the substance is GRAS for the use as a replacement for air in containers of wines, and fruit and vegetable juices. Argon is not listed in the FDA Inventory of Effective Food Contact Substance Notifications.

The NOSB describes a new category of substances as "packaging aids" and believes that these should not be considered ingredients or processing aids. However, no definition of "packaging aid" or "inert atmospheric gases" is provided in their recommendation.

NOP does not see a basis for exempting a category of ingredients as "packaging aids" from regulations governing composition or labeling of products, since they are not considered packaging. Packaging aids as a class of materials may include substances that are designed to react with foods and should not be exempted from review by the NOSB.

Inert atmospheric gases include nitrogen (N₂ - approximately 80% by volume of dry air) and argon (approximately 1% by volume of dry air). Nitrogen and carbon dioxide (which is atmospheric though not an inert gas) are currently listed as allowed ingredients on 205.605(b). However, argon is not listed. It is not permitted in organic food products.

NOP will take the recommendation under advisement for future guidance on clarification of the 100% label category.

14. Two-tiered Voting Approach for Materials Petitioned to the National List

The NOP recognizes the amendments to the NOSB Policy Manual. The changes to the manual will be incorporated into the official NOSB Policy Manual.

15. Classification of Materials

The NOP appreciates the extensive work completed by NOSB on this important subject. The classification of materials is a key function of the NOSB and the foundation for decisions made by certifying agents, materials review programs, and the NOP. The distinction between synthetic and nonsynthetic materials is a fundamental premise of the OFPA in determining what is permitted or not in organic production. The classification of some substances as agricultural is also important as this determines whether they must be sourced from organic sources for use in handling or livestock feed. Substances classified as agricultural may be used in "made with organic (specified ingredient(s))" products without appearing on the National List.

The November 2009 and April 2010 NOSB recommendations on materials classification proposed a number of new definitions to help clarify the Board's decision making process. The NOP agrees that some additional definitions are useful, but would like further clarification from the Board of how these definitions will be used in



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the classification process. Such clarification is necessary for NOP to determine whether guidance or a regulatory change is more appropriate to address this issue.

The NOP urges the NOSB to continue to formulate procedures (such as the draft worksheet decision trees) for classification of materials. However, the NOP recommends that the NOSB work on classification of materials according to their use. For instance, crop materials and inputs for livestock health care should be evaluated to determine whether they are synthetic or nonsynthetic, as this is the fundamental question in regards to the National List. Materials used in food handling and livestock feed should be reviewed first to determine whether they are agricultural or non-agricultural as this is the fundamental question in how they are considered under the NOP regulations. The NOP does not believe it is necessary or appropriate to have one single classification system for classes of substances that have different criteria for end use. The National List includes substances that are allowed in one category but are not allowed in other categories (e.g. phosphoric acid is a prohibited synthetic in crop production but allowed as a processing aid).

The NOP is responding to the NOSB proposal (shown in italics) on classification of materials by section as detailed below:

1. *Guiding Principles*

- *The classification of a material is determined by both the source of the inputs and the process used to make the material.*
- *The same material can be agricultural, non-synthetic or synthetic depending on source and process.*

The NOP supports the first statement, but finds the second point redundant. As a material is reviewed by the NOSB, it should be classified accurately based on the review of information available at the time. If multiple forms of the same substance are possible, the NOSB should annotate the listing to indicate which forms are allowed.

- *If a material is processed such that it is classified as synthetic then the material is classified as synthetic regardless of source. A material of this type would most correctly be referred to as an "agriculturally sourced material which has been processed in such a way as to classify the material synthetic." Materials that are manufactured in full compliance with the final rule are outside the scope of this principle; their status with regards to use in organic is not affected by this recommendation*

The NOP agrees that an agricultural material can be processed in a manner that renders it synthetic.

2. *NOSB Practices*

- *Voting on the classification of a petitioned material before voting on whether a petitioned material should be listed on the National List.*
- *Increase, where appropriate, the NOSB's use of annotations to properly list source or process where either are a determining factor for how a material is classified and placed on the National List.*
- *Refocus on fully understanding the technical aspects of a petitioned material and all the variations of source and process available in the marketplace to manufacture the material.*

The NOP supports these practices and would like to clarify the response given to the Board in April regarding voting process. The NOP supports the NOSB taking two votes on each material: the first to classify the



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substance, and the second to decide whether to list the substance. As noted above, the process for classification should be tailored to the category of use. Crop and livestock materials need only to be considered as synthetic or nonsynthetic, whereas materials used in handling or in livestock feed require a determination of agricultural status.

3. NOSB Proposed Definitions

- a. Chemical Change *An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of “substance”) Processing, as defined in §205.2, of agricultural products using materials allowed on the applicable section of the National List (i.e., §205.601 for crops, §205.603 for livestock and §205.605 / §205.606 for handling), does not result in chemical change as it applies to classification of materials.*

The NOP does not support the above definition. The additional underlined sentence, as adopted in the May NOSB recommendation, adds a meaning to the term “chemical change” that is contrary to common understanding of a widely used term. It is a tenet of good regulatory drafting that definitions adopted should not contradict commonly understood definitions or include a substantive rule within a definition. The proposal to exempt certain processing methods and synthetic materials from causing the effect of chemical change is a substantial regulatory provision, which conflicts with the common understanding of chemical change, and could cause unintended consequences. Substances derived from agriculture used in food processing can be classed as agricultural despite common chemical changes achieved through baking, cooking, roasting etc. This criterion can be added to the evaluation worksheet for determination of agricultural status, and should not be in the larger definition of chemical change.

The NOP prefers the definition and discussion regarding chemical change provided in the NOP April 2006 “Recommended Framework to Further Clarify the Definition of Synthetic”.

<http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5070270&acct=nosb>

- b. Extract - *To separate, withdraw, or obtain one or more essential constituents of an organism, substance or mixture by use of solvents, mechanical or physical methods.*

The NOSB discussion of this point states:

“For our recommendation, extraction with a synthetic not on the National List would not result in a material being classified as synthetic unless either the extraction resulted in chemical change or the synthetic remained in the final material at a significant level. Also, extraction is broadly defined to also include mechanical and physical separation in addition to solvent extraction. This is consistent with current classification practices.”

The NOP believes this is an important definition, but feels that it needs further clarification. The NOSB only mentions solvent extraction, but does not clarify if other synthetic materials may be used in the extraction process. More elaboration is needed to describe what constitutes change when a substance is extracted from a natural source (as referenced in the April 2006 framework).

- c. Formulate: *To combine different materials according to a recipe or formula to prepare the product being evaluated.*



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- d. *Manufacture: To make a crop, livestock or handling input from raw materials.*

The NOP does not object to the definitions for “formulate” and “manufacture” but questions the need for them. It is not clear how these definitions will be used.

- e. *Nonagricultural Substance: A product, such as a mineral or atmospheric gas, that does not originate from agriculture. For the purposes of this part agricultural refers to the production or handling of crops or livestock.*

The NOP does not object to the above definition, but proposes that some ambiguity remains. For example, does the removal of the example of “bacterial culture” mean that microorganisms, dairy cultures, and their products are considered agricultural? The NOSB has indicated they will be determining this on a case by case basis. If so, it would be useful to develop criteria for this review of microorganisms and their products. The NOP acknowledges that the current definition, which includes pectins and gums as nonagricultural conflicts with the present listings at 205.606.

- f. *Naturally Occurring Biological Process: Chemical changes that occur in living cells or due to the action of products of living organisms, such as enzymes.*

NOP supports the above definition.

- g. *Substance: An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering System (INS) number, or FDA or other agency standard of identity).*

The NOP believes that the definition of “substance” is important for clarifying the meaning of chemical change. However, this needs careful consideration as to the impact this definition may have since the word “substance” is used extensively throughout the current rule. It is part of the definitions of agricultural inputs, fertilizer, and ingredient. One must petition a “substance” to the National List following procedures referenced at 205.607. Some “substances” now on the National List are more accurately described as combinations or classes of substances, such as mulches, soaps, vaccines, natural flavors, microbial cultures, etc.

The NOP appreciates the work the NOSB has done to provide clarification on this challenging area. The NOP looks forward to collaboration in development of worksheets used for decision making for classification of crops, livestock, and processing materials. It may be worth considering the revision of committee recommendation forms for materials into specific versions according to their petitioned end use. The revised versions could retain the current OFPA and rule criteria questions that are currently in the checklist format and incorporate a new section that spells out the relevant end-use specific classification questions supported by the decision-making criteria essential to those classifications.

16. Vaccines

On November 5, 2009, the NOSB made a recommendation to clarify that vaccines produced through excluded methods (genetically modified organisms or GMOs) are allowed under 205.603 and do not need to be individually petitioned for allowance on the National List. Further, the NOSB recommended that vaccines produced from non-excluded methods be located and used before those produced by excluded methods.



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The preamble to the National Organic Program final rule (FR Vol. 65, No. 246, page 80554) states:

The Act allows use of animal vaccines in organic livestock production. Given the general prohibition on the use of excluded methods, however, we believe that animal vaccines produced using excluded methods should not be allowed without an explicit consideration of such materials by the NOSB and without an affirmative determination from the NOSB that they meet the criteria for inclusion on the National List. It is for that reason that we have not granted this request of commenters but, rather, provided an opportunity for review of this narrow range of materials produced using excluded methods through the National List process.

The NOP's understanding is that excluded methods are prohibited under Section 205.105(e) *except for* vaccines. Further, this exception applies to vaccines that are produced through excluded methods only if those GMO vaccines are approved according to 205.600(a). Vaccines are listed under 205.603(a)(4) under "Biologics-Vaccines". The NOSB has not reviewed vaccines in accordance with 205.600(a). The listing under 205.603(a)(4) of Biologics-Vaccines does not include the allowance of GMO vaccines. The NOP requested a legal review from USDA's Office of General Counsel (OGC) to determine whether vaccines produced through excluded methods are currently allowed under 205.603(a)(4). The OGC opinion supports the position that GMO vaccines are allowed only if they are approved according to 205.600(a).

The NOP recommends that the NOSB review GMO vaccines under the provisions of 205.600(a). The NOP suggests that the Board request a technical review for biologics-vaccines, including the status of genetically modified vaccines and an assessment of the economic impact of using commercial availability criteria for non-genetically modified vaccines. After the Board completes the evaluation according to the OFPA criteria, it may submit a recommendation to the NOP to add GMO vaccines to the National List of Allowed and Prohibited Substances.



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Attachment to Memorandum: References pertinent to Classification of Materials

The Organic Food Production Act of 1990, (7U.S.C. 6501 et. seq.)

7 USC 6502 Definitions

Agricultural Products- the term “agricultural product” means any agricultural commodity or product, whether raw or processed, including any commodity of product derived from livestock that is marketed in the United States for human or livestock consumption.

Organically Produced - the term “organically produced” **means** an agricultural product that is produced and handled in accordance with this title.

Synthetic – The term “synthetic” means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from a naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Processing – The term “processing” means cooking, baking, heating, drying, mixing, grinding, churning, separating, extraction, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, or otherwise manufacturing, and included the packaging, canning, jarring, or otherwise enclosing food in a container.

NOP regulation, 7CFR Part 205

§205.2 Terms defined

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or bacterial culture that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural 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.

Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term used in the Act”

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