



United States
Department of
Agriculture

Agricultural
Marketing
Service

1400 Independence Avenue, S.W.
Room 2646-S, Mail Stop 0268
Washington, D.C. 20250-0268

August 11, 2011

MEMORANDUM FOR THE CHAIRPERSON OF THE NATIONAL ORGANIC STANDARDS BOARD

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

SUBJECT: National Organic Standards Board Recommendations (April 2011)

This memorandum responds to recommendations made at the April 2011 business meeting of the National Organic Standards Board (NOSB). The NOSB recommended the following: 1) renewing, removing, or amending the final 28 material listings on the National List of Allowed and Prohibited Substances scheduled to expire during 2012; 2) amending the existing listing for tetracycline; 3) adding attapulgite, used to clarify plant and animal oils, to § 205.605(a); and 4) amending the definition of chemical change.

The NOSB made recommendations to make the following changes to their Policy and Procedures Manual: 1) harmonize the Vice Chair and Policy Development Committee job descriptions; 2) amend their procedures for completing committee recommendations.

NOP DISCUSSION AND RESPONSE:

1. Sunset 2012

The NOSB is mandated by the Organic Foods Production Act (OFPA) of 1990 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. During their Sunset review, the NOSB evaluated the available technical information, public comments, and alternative products for the final 28 material listings scheduled to expire in 2012. The NOSB then voted to renew twenty material listings, amend six material listings, and remove two material listings.

The NOP accepts the NOSB's recommendations on these 28 Sunset 2012 material listings as summarized in Table 1 and Table 2, with additional information on three groups of substances:

Chlorine materials

The NOP accepts, with a slight modification, the NOSB's recommendation to relist chlorine materials with an amended annotation. The NOSB's recommendation is consistent with the NOP's final guidance on the use of chlorine materials. This guidance described the proper use of chlorine to disinfect tools and equipment.¹ The annotation only applies to the use of chlorine in direct contact with crops or

¹ Guidance - NOP 5026: The Use of Chlorine Materials on Organic Production and Handling. Issued May 9, 2011.



United States
Department of
Agriculture

Agricultural
Marketing
Service

1400 Independence Avenue, S.W.
Room 2646-S, Mail Stop 0268
Washington, D.C. 20250-0268

irrigation water. Therefore, the NOP finds it unnecessary to include “disinfecting tools or equipment” in the annotation.

The NOP plans to incorporate the NOSB recommendation to allow levels of chlorine in edible sprout production in accordance with Environmental Protection Agency (EPA) labeling. However, chlorine use for edible sprout production and alternatives were not addressed by commenters or the committee in detail at the April 2011 public meeting. Therefore, the NOP will seek further public comment on this issue during rulemaking.

Sodium nitrate

The NOSB recommended removing the annotation on sodium nitrate, which currently allows restricted use of sodium nitrate for up to 20% of the crop’s total nitrogen requirement. The recommended removal of this annotation will completely prohibit the use of sodium nitrate in organic crop production. The NOP intends to propose removing the annotation with an effective date of October 21, 2012. If the annotation was removed in the final rule, sodium nitrate could not be used as a fertilizer, an ingredient in a fertilizer, or a soil amendment in organic crop production as of October 21, 2012.

Nutrient vitamins and minerals

In an April 2010 memo to the NOSB, the NOP stated that its previous interpretation of the nutrient vitamins and minerals annotation was incorrect. The memo described that the NOP had consulted with the Food and Drug Administration (FDA) to review the existing annotation, which references 21 CFR 104.20. The FDA and NOP identified certain substances that had been allowed under the previous (incorrect) interpretation of 21 CFR 104.20 that are not allowed under the current annotation. In the April 2010 memo, the NOP requested that the NOSB review the current annotation along with the 1995 NOSB recommendation and make a recommendation regarding possible amendments to the nutrient vitamins and minerals listing. The NOP also stated that it would issue guidance on nutrient vitamins and minerals to clarify which substances were allowed in accordance with 21 CFR 104.20. The guidance would also provide a transition period for businesses to reformulate products in order to comply with National List requirements.

The NOSB Handling Committee took on the task of reviewing the nutrient vitamin and minerals listing. At the October 2010 NOSB meeting in Madison, Wisconsin, the NOSB Handling Committee presented a discussion document and received public comments. In March 2011, the NOSB Handling Committee proposed an annotation change to the nutrient vitamins and minerals listing and requested public comments. The NOSB received approximately two thousand public comments on nutrient vitamins and minerals. Based on the public comments and discussion at the April 2011 board meeting, the NOSB recommended renewing the nutrient vitamins and minerals listing with no annotation change.

The NOP believes that certifiers, consumers and the organic trade need a clear list of allowed nutrient vitamins and minerals. We believe that the prolonged state of uncertainty regarding which nutrient vitamins and minerals are allowed has presented an untenable situation for certified operations and the organic trade. Therefore, given the public support at the April 2011 NOSB meeting to resolve this issue, the NOP plans to publish a proposed rule for the Sunset 2012 listing for nutrients vitamins and minerals that will amend the current annotation. We believe that making this change will correct the drafting error, provide a clear list of allowed nutrient vitamins and minerals, and provide greater regulatory certainty than program guidance. This rule would propose to amend the current annotation to read, “Vitamins and minerals. For food—vitamins and minerals identified as essential in 21 CFR § 101.9. For infant formula—vitamins and minerals as required by 21 CFR § 107.100 or § 107.10.”



United States
Department of
Agriculture

Agricultural
Marketing
Service

1400 Independence Avenue, S.W.
Room 2646-S, Mail Stop 0268
Washington, D.C. 20250-0268

This proposed rule with the annotation change would not include docosahexaenoic acid (DHA), arachidonic acid (ARA), taurine, lutein, choline, and inositol. These substances are not allowed under the current annotation and would not be allowed under the proposed annotation change. Petitions to add these substances to the National List have been received and will be considered at upcoming NOSB meetings. The compliance date of the proposed rule with the nutrient vitamin and mineral annotation change would be implemented with adequate time to allow the NOSB to review the petitions. Additionally, if the NOSB recommended adding these substances to the National List, the compliance date would provide the NOP with enough time to complete rulemaking. This implementation period would also provide adequate time for the organic trade to adjust their product formulations if needed.

Table 1: Sunset 2012 Material Listings Recommended for Renewal at April 2011 Meeting

§ 205.601 Synthetic substances allowed for use in organic crop production			
Section	Material	Sunset Date	Recommended Annotation Change
§ 205.601(a)(1)(i)	Ethanol	October 21, 2012	None.
§ 205.601(a)(1)(ii)	Isopropanol	October 21, 2012	None.
§ 205.601(a)(2)(i)	Calcium hypochlorite	October 21, 2012	For pre-harvest use, residual chlorine levels in the water in direct crop contact or as water from cleaning irrigation systems applied to soil must not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act. For disinfecting or sanitizing equipment or tools or in edible sprout production, chlorine products may be used up to maximum labeled rates.
§ 205.601(a)(2)(ii)	Chlorine dioxide		
§ 205.601(a)(2)(iii)	Sodium hypochlorite*		
§ 205.601(b)(2)(i)	Newspapers or other recycled paper, without glossy or colored inks	October 21, 2012	None.
§ 205.601(b)(2)(ii)	Plastic mulch & covers	October 21, 2012	None.
§ 205.601(c)	Newspapers or other recycled paper, without glossy or colored inks	October 21, 2012	None.
§ 205.601(f)	Pheromones	October 21, 2012	None.
§ 205.601(g)(2)	Vitamin D ₃	October 21, 2012	None.
§ 205.601(i)(2)	Copper hydroxide	October 21, 2012	None.
§ 205.601(i)(2)	Copper oxide	October 21, 2012	None.
§ 205.601(i)(2)	Copper oxychloride	October 21, 2012	None.
§ 205.601(i)(3)	Copper sulfate	October 21, 2012	None.
§ 205.601(i)(11)	Streptomycin	October 21, 2012	For fire blight control in apples and pears, only until October 21, 2014.
§ 205.601(j)(4)	Lignin sulfonate (listings)	October 21, 2012	As chelating agent or dust suppressant.
§ 205.601(j)(5)	Magnesium sulfate	October 21, 2012	None.
§ 205.601(k)	Ethylene gas	October 21, 2012	None.
§ 205.601(l)(2)	Sodium silicate	October 21, 2012	None.
§ 205.601(l)(1)	Lignin sulfonate	October 21, 2012	None.



United States
Department of
Agriculture

Agricultural
Marketing
Service

1400 Independence Avenue, S.W.
Room 2646-S, Mail Stop 0268
Washington, D.C. 20250-0268

§ 205.602 Nonsynthetic substances prohibited for use in organic crop production

Section	Material	Sunset Date	Recommended Annotation Change
§ 205.602(g)	Sodium nitrate*	October 21, 2012	Remove annotation.

§ 205.605(a) Nonsynthetic substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic”

Section	Material	Sunset Date	Recommended Annotation Change
§ 205.605(a)	Enzymes	October 21, 2012	None.
	Potassium iodide	October 21, 2012	None.

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

Section	Material	Sunset Date	Recommended Annotation Change
§ 205.605(b)	Nutrient vitamins*	October 21, 2012	None.
	Nutrient minerals*	October 21, 2012	None.
	Tocopherols	October 21, 2012	None.

*See description above.

Table 2: Sunset 2012 Material Listings Not Recommended for Renewal at April 2011 Meeting

§ 205.601 Synthetic substances allowed for use in organic crop production

Section	Material	Sunset Date
§ 205.601(g)(1)	Sulfur dioxide	October 21, 2012

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

Section	Material	Sunset Date
§ 205.605(b)	Potassium iodide	October 21, 2012

2. Sunset Process for Annotation Changes

The NOP recognizes that the NOSB’s Sunset policy offers the opportunity to amend existing annotations to clarify the use of substances on the National List. In addition, the NOSB may further restrict the use of substances during the Sunset process by proposing annotation changes.

The NOP encourages the NOSB to ensure that proposals for annotation changes through this Sunset policy are fully vetted during the process and supported by information provided in public comment and/or technical reports. In the absence of information to support a change, the NOP suggests that the NOSB avoid making changes to an annotation during the Sunset process. Annotation changes that may occur during deliberations at a NOSB meeting may not have the full benefit of public comment, and the NOP must ensure that changes to the regulations are clear and consistent. Additionally, when substances are listed in multiple sections of the National List, the NOP encourages the appropriate



United States
Department of
Agriculture

Agricultural
Marketing
Service

1400 Independence Avenue, S.W.
Room 2646-S, Mail Stop 0268
Washington, D.C. 20250-0268

NOSB Committees to work towards harmonized annotations when possible.

3. Rejection of Nickel, Petitioned for Use in Crops

At the April 2011 meeting, the NOSB rejected nickel, which was petitioned to be added to the group of micronutrients currently listed at § 205.601 of the National List. The NOSB cited environmental and human health concerns with a range of uses for nickel as the basis for their rejection. We accept the NOSB's recommendation not to list this material. In future reviews of substances that have a broad spectrum of utility (such as nickel), the NOP recommends that, to the extent possible, the NOSB review materials with a lens limited to the manner and amount that the substance would be used in organic production and handling.

4. Rejection of Calcium Acid Pyrophosphate, and Expanded Use of Sodium Acid Pyrophosphate, Petitioned for Use in Handling

At the April 2011 meeting, the NOSB rejected two substances petitioned for use in handling: calcium acid pyrophosphate (CAPP), a leavening agent, and sodium acid pyrophosphate (SAPP), petitioned for expanded use as a sequestrant on cooked and uncooked produce. CAPP was petitioned for addition to § 205.605(b) of the National List. SAPP was petitioned to expand its use on § 205.605(b), since it is currently permitted only as a leavening agent. Also, the NOSB did not recommend adding CAPP to the National List since they determined that the petition did not demonstrate that the material is essential for organic handling, and because SAPP is currently listed for the same purpose as a leavening agent. The NOSB also did not recommend expanding the use of SAPP as a sequestrant on cooked and uncooked produce, as the NOSB did not find evidence that SAPP was necessary or essential for this purpose in organic handling. We accept the NOSB's recommendations on these substances.

5. Extension of the Tetracycline Expiration Date

The NOSB considered a petition to remove the expiration date for tetracycline, which is only allowed through October 21, 2012 for control of fire blight in tree fruit. The NOSB is concerned that the continued use of antibiotics in organic—even when limited to apples and pears—creates antibiotic resistance and allows producers to continue to grow varieties that are highly susceptible to fire blight instead of selecting naturally resistant ones. However, the NOSB received many public comments stating that alternative treatments for fire blight are not effective, that all pear and apple varieties are susceptible to fire blight to some extent, and that less susceptible varieties are not palatable to consumers. Therefore, to avoid negatively impacting the organic tree fruit industry, the NOSB recommended extending the expiration date to October 21, 2014. During this time, the NOSB expects that the industry will create a task force to coordinate efforts to identify, test, and implement non-antibiotic fire blight treatments. In response to the requests by the NOSB and the industry for additional resources to support research on alternatives to fire blight, the NOP issued letters to the USDA National Institute for Food and Agriculture (NIFA) and the USDA Agricultural Research Service (ARS) to request their assistance in prioritizing research on such alternatives.² The NOP accepts the NOSB's recommendation on this material.

² May 2011 Letters submitted by NOP to USDA ARS and NIFA on fire blight research. Available at the NOP website at: <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5091325>



United States
Department of
Agriculture

Agricultural
Marketing
Service

1400 Independence Avenue, S.W.
Room 2646-S, Mail Stop 0268
Washington, D.C. 20250-0268

6. Addition of Attapulgit for Clarifying Plant and Animal Oils

The NOSB accepted a petition to allow attapulgit, a natural substance used to clarify plant and animal oils in organic products. The NOSB recommended adding attapulgit to § 205.605(a) with the annotation: allowed as a processing aid in the handling of plant and animal oils. The NOP accepts the NOSB's recommendation on this material.

7. No Decisive Vote to Classify Corn Steep Liquor

Corn Steep Liquor (CSL), a byproduct of the corn wet milling process and other corn processing techniques, has been considered a non-synthetic input for liquid fertilizer formulations for organic crop production. The NOSB was asked to classify CSL using the classification of materials parameters that they voted to accept at the November 2009 meeting. At the April 2011 meeting, the NOSB motion to classify CSL failed, not reaching the necessary two-thirds majority for a decisive vote. The NOP appreciates the NOSB's extensive deliberation on the classification of this substance and will consider additional means to address this issue. The NOP notes that CSL continues to be allowed in organic crop production.

8. Continued Work on Animal Welfare

At the April 2011 meeting, the NOSB continued work on animal welfare recommendations, including specific stocking densities for each species. Additionally, the NOSB Livestock Committee introduced a proposal to address animal welfare during animal handling, transit, and slaughter. Based on public comment, the NOSB Livestock Committee withdrew their proposals, opting to continue their work on these proposals in concert with the development of guidance documents and outcome-based scorecards for each species. The NOP appreciates the NOSB's efforts to enhance animal welfare in organic livestock production and looks forward to your future work in this area.

9. Amendment to Definition of Chemical Change

At the April 2011 meeting, the NOSB recommended amending their recommendation concerning the definition of chemical change. The NOP accepts the NOSB's recommendation.

10. Classification of Materials

The NOP appreciates the NOSB's multi-year effort to clarify the classification of materials and recognizes that this is a highly complex and challenging area. The NOP plans to develop draft guidance on this topic based upon the November 2009 NOSB Recommendation for Classification of Materials. The NOP will collaborate with the NOSB Materials Committee throughout this process and, upon publication of draft guidance, will solicit additional public comments on this issue. The NOP looks forward to collaborating with the NOSB as this project progresses.

11. Amendments to the Policy and Procedures Manual

The NOP understands that the NOSB issued recommendations to change two of their internal policies:

Vice Chair and Policy Development Committee Job Descriptions – The NOSB voted to implement changes to the Vice Chair and Policy Development Committee job descriptions (Sections II and IV



United States
Department of
Agriculture

Agricultural
Marketing
Service

1400 Independence Avenue, S.W.
Room 2646-S, Mail Stop 0268
Washington, D.C. 20250-0268

respectively) to remove duplication and clarify these roles.

Completing Committee Proposals – The NOSB also voted to amend the procedures for completing committee proposals in Section V of the Policy and Procedures Manual so that, at any point in the process prior to the Board’s vote, the presenting committee may convene and vote to withdraw its proposal.

12. Summary

The NOP sincerely appreciates the NOSB’s time and efforts in crafting these recommendations. We would also like to congratulate our new members—Colehour Bondera, Nick Maravell, Mac Stone, Jennifer Taylor, and Calvin Walker—for successfully completing their first NOSB meeting.

We look forward to continuing to facilitate your important work in a collaborative manner to protect organic integrity from farm to table.