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March 21, 2012

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

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

SUBJECT: National Organic Standards Board Recommendations (December 2011)

This memorandum responds to recommendations made at the November 29 to December 2, 2011 business meeting of the National Organic Standards Board (NOSB) in Savannah, Georgia. The NOSB recommended that the NOP:

- 1) Renew eight and remove one material listing on the National List of Allowed and Prohibited Substances (National List) scheduled to expire during 2013.
- 2) Remove annatto extract color from § 205.606.
- 3) Add arachidonic (ARA) single-cell oil and docosahexaenoic (DHA) algal oil, both nutrient supplements, to § 205.605(a) with restrictions.
- 4) Amend the listing for beta-carotene color on § 205.606.
- 5) Amend the listing for potassium hydroxide on § 205.605(b).
- 6) Amend the listing for silicon dioxide on § 205.605(b).
- 7) Amend the listing for chlorine materials on § 205.605(b).
- 8) Strengthen animal welfare requirements in organic livestock production.
- 9) Evaluate material review organizations against specific parameters.
- 10) Develop baseline qualification criteria for organic inspectors.
- 11) Publish guidance on unannounced inspections of certified organic operations.

The NOSB also voted to make the following changes to their Policy and Procedures Manual:

1. Add a description of the Administrative Team.
2. Amend job description of Executive Director to allow for more regular updates with the public.
3. Clarify transition procedures for officers, committee chairs, and new members.

NOP DISCUSSION AND RESPONSE:

1. Sunset 2013

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



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available technical information, public comments, and alternatives to nine material listings scheduled to expire in 2013. The NOSB then voted to renew eight material listings and remove one material listing. The NOP accepts the NOSB's recommendations on the Sunset 2013 material listings as summarized in Table 1 and will develop proposed rules for public comments once the NOSB has completed review of all Sunset 2013 substances. Regarding the listings for peracetic acid at § 205.601, the NOP acknowledges that the NOSB issued a previous recommendation in November 2009 to amend the annotations for peracetic acid. The NOP plans to issue a proposed rule that would align the NOSB's Sunset 2013 recommendation with the November 2009 recommended annotation for peracetic acid.

Table 1: Recommended Sunset 2013 Material Listings at December 2011 Meeting

Substance	Section	Sunset Date	NOSB Recommendation	Notes
Copper sulfate	§ 205.601(a)	November 3, 2013	Relist	None.
Copper sulfate	§ 205.601(e)	November 3, 2013	Relist	None.
Ozone	§ 205.601(a)	November 3, 2013	Relist	None.
Peracetic acid	§ 205.601(a)	November 3, 2013	Relist	See NOP Response.
Peracetic acid	§ 205.601(i)	November 3, 2013	Relist	See NOP Response.
Calcium chloride	§ 205.602	November 3, 2013	Relist	None.
Animal enzymes	§ 205.605(a)	November 3, 2013	Relist	None.
Tartaric acid	§ 205.605(a)	November 3, 2013	Relist	None.
Tartaric acid	§ 205.605(b)	November 3, 2013	Remove from list	None.

2. Annatto Extract Color - § 205.606

In response to a petition, the NOSB recommended removing annatto extract color from § 205.606. Based on market surveillance and public comments, the NOSB determined that both liquid and powder forms of organic annatto extract color were commercially available in sufficient quantities. This recommended action, if published in a Final Rule, would require that all annatto extract color present in organic products be organic. The NOP plans to move forward with proposed rules for public comment.

3. Arachidonic acid (ARA) Single-Cell Oil and Docosahexaenoic acid (DHA) Algal Oil - § 205.605(a)

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 NOP's consultation with the Food and Drug Administration (FDA) to review the existing annotation in the NOP regulations, which references FDA guidelines at 21 CFR 104.20. The FDA and NOP identified certain substances, including ARA and DHA, which had been allowed under the previous (incorrect) interpretation of 21 CFR 104.20, but are not allowed under the current annotation in the NOP regulations.



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The NOSB Handling Committee reviewed petitions to add DHA and ARA as separate listings on § 205.605(a). The NOSB weighed information from the petitions and technical reports, in addition to thousands of public comments representing a wide spectrum of perspectives. Ultimately, the NOSB voted ten in favor of and four against listing both of these nutrients on the National List with the following annotations:

- ARA.** Arachidonic acid fungal oil (ARA), not hexane extracted; other ingredients that are agricultural must be organic.
- DHA.** Docosahexaenoic acid (DHA) from Algal Oil, not hexane extracted; other ingredients that are agricultural must be organic.

Many commenters expressed concern that DHA and ARA may come from genetically engineered sources. It is important to note that the use of genetically engineered ingredients (genetically modified organisms) is prohibited in 100 percent organic, organic, and “made with” organic products. Under the USDA organic regulations, 7 CFR §205.105(e), to be sold as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of excluded methods (e.g. genetically modified organisms).

The NOP plans to move forward with proposed rules for public comment once the NOSB has completed review of all nutrient petitions currently under consideration.

4. Beta-Carotene Color - § 205.606

In response to a petition, the NOSB recommended changing the annotation on the beta-carotene listing on § 205.606 to read: “Beta-carotene extract color, derived from carrots or algae (CAS#7235-40-7).” If published in a Final Rule, this change would add algae as a beta-carotene source and correct the Chemical Abstracts Service (CAS) number. The NOP plans to move forward with proposed rules for public comment.

5. Potassium Hydroxide - § 205.605(b)

In response to a petition, the NOSB recommended changing the annotation on the potassium hydroxide listing on § 205.605(b) to read: “Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.” This substance is currently only allowed for peeling peaches during the Individually Quick Frozen (IQF) production process. If published in a Final Rule, this change would allow potassium hydroxide to be used during alternative peach peeling processes. The NOP plans to move forward with proposed rules for public comment.

6. Silicon Dioxide - § 205.605(b)

In response to a petition, the NOSB recommended changing the annotation on the silicon dioxide listing on § 205.605(b) to read: “Silicon dioxide – for use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available.” The use of this substance is currently allowed without restriction. If published in a Final Rule, the change proposed by the NOSB would limit



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the use of silicon dioxide as noted above.

The NOP will need to evaluate the economic impact and recordkeeping burden of the NOSB silicon dioxide recommendation before any proposed rules can be developed for public comment. Due to the limited resources that the NOP has available for standards development, it is unlikely that the NOP will move this recommendation forward in the near future.

7. Chlorine Materials - § 205.605(b)

As part of their Sunset 2012 review, the NOSB reviewed the listing of chlorine materials on §§ 205.601, 205.603, and 205.605(b). During the span of the NOSB's review, the NOP published guidance on the use of chlorine materials in organic production and handling¹. To align the § 205.605(b) listing with this guidance, the NOSB recommended amending its annotation to read: "Chlorine materials (calcium hypochlorite, chlorine dioxide, and sodium hypochlorite) for disinfecting and sanitizing food contact surfaces, equipment and facilities may be used up to maximum labeled rates. Chlorine materials in water used in direct crop or food contact is permitted at levels approved by the FDA or EPA for such purpose, provided the use is followed by a rinse with potable water at or below the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act. Chlorine in water used as an ingredient in organic food handling must not exceed the maximum residual disinfectant limit for the chlorine material under the Safe Drinking Water Act." The NOP plans to move forward with proposed rules for public comment.

8. Animal Welfare

On November 5, 2009, the NOSB approved a recommendation to create more explicit rules for the care and handling of organic livestock. The 2009 recommendation called for revised regulatory language for sections § 205.238 (Livestock health care practice standard) and § 205.239 (Livestock living conditions). On December 2, 2011, the NOSB approved additional animal welfare recommendations. The 2011 NOSB recommendation included proposed new regulations on physical alterations and livestock living conditions for mammals and birds. The NOSB also recommended new language to cover animal handling and transit to slaughter. Additionally, the 2011 NOSB animal welfare recommendation included a range of indoor and outdoor stocking rates for chickens (laying hens and breeders, pullets, and broilers).

The NOP is evaluating the 2009 and 2011 recommendations to determine how best to proceed. The recommendations include additional requirements that would impose economic costs and record keeping burdens on organic livestock producers. We will be gathering additional information about the economic impact of any proposed rulemaking in this area. We also need to determine how these animal welfare requirements would be monitored and enforced by certifying agents. At future NOSB meetings, the NOP will report on our progress evaluating these recommendations. The NOP appreciates the NOSB's work on this issue.

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



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9. Material Review Organizations

To facilitate consistent and uniform material review decisions, the NOSB recommended that the NOP actively regulate material review organizations. The NOSB recommended that material review organizations:

- Obtain accreditation from the NOP to review materials for compliance with the USDA organic regulations.
- Use the NOP's material classification guidance (under development) when making synthetic versus non-synthetic determinations.
- Be accredited to ISO Guide 65 standards, which require the implementation of a quality management system with detailed review protocols and policies.
- Use the NOP's guidance for permitted generic substances (under development).
- Be at least partially financed by manufacturers of products seeking review.
- Adopt the appeals process utilized by certifying agents and be subject to compliance and enforcement actions by the NOP.

The NOP will report back to the NOSB at your upcoming meetings on how we plan to proceed with these recommendations.

10. Inspector Qualifications

The NOSB recommended that the NOP develop guidance on baseline qualification criteria for organic inspectors to cover specific metrics in three areas:

- Baseline pre-requisite expertise for initial "organic inspector" status.
- Continuing education requirements for inspectors.
- Accreditation criteria for certifying agents to ensure adequate monitoring and oversight.

The NOP has commissioned additional work in this area, under contract with the International Organic Inspectors Association (IOIA). The NOP intends to utilize this recommendation to develop baseline qualification criteria for organic inspectors.

11. Unannounced Inspections of Certified Organic Operations.

To uphold organic integrity, the NOSB recommended that the NOP develop guidance on unannounced inspections to address the following:

- Required unannounced inspections for at least five percent of their certified operations per year.
- Unannounced inspections may be random, risk-based, or the result of a complaint or investigation.
- Unannounced inspections may be limited in scope, depth, and breadth; samples may be collected. If a full inspection is conducted, it may be used as the annual on-site inspection.



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The NOP will explore ways to implement unannounced inspection requirements to enhance organic integrity.

12. Amendments to the NOSB Policy and Procedures Manual

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

Committee transparency (Section I). The NOSB amended the role of the NOSB Special Assistant to include more regular updates with the public. This will include the posting of committee meeting minutes and other resources. The NOP is committed to providing this information to the public in a regular, accessible manner that does not cause undue strain on its resources. The NOP proposes the following procedure to fulfill this request:

1. The minutes from each committee meeting will be prepared by the NOSB Special Assistant and approved by the committee on an ongoing basis.
2. At the end of each month, the NOSB Special Assistant will combine the approved minutes for each committee into a single PDF.
3. The minutes will be posted on the NOSB Committee page:
<http://www.ams.usda.gov/NOSBCommittees>

Administrative Team (Section IV). The NOSB voted to add a description of the Administrative Team, which is comprised of the NOSB Chair, Vice Chair, Secretary, and Special Assistant.

NOSB member and leadership transition (Section V). The NOSB clarified transition procedures for officers, committee chairs, and new members.

13. Summary

The NOP recognizes and sincerely appreciates the number of hours each NOSB member volunteers each month during their five-year term. We look forward to continuing to facilitate your important work in a collaborative manner to protect organic integrity from farm to table.

Additionally, Savannah was the last meeting for four NOSB members:

Steve DeMuri, Handling Committee Chair
Tina Ellor, Prior Crops Committee Chair

Katrina Heinze, Materials Committee Chair
Tracy Miedema, NOSB Chair

The NOP thanks Steve DeMuri, Tina Ellor, Katrina Heinze, and Tracy Miedema for their five years of dedicated service to the organic community. We recognize the outstanding work they have done and look forward to future opportunities to collaborate.