



United States
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Room 2646-S, Mail Stop 0268
Washington, D.C. 20250-0268

September 27, 2012

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

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

SUBJECT: National Organic Standards Board Recommendations (May 2012)

This memorandum responds to recommendations made at the May 22 to 25, 2012 business meeting of the National Organic Standards Board (NOSB) in Albuquerque, New Mexico. The NOSB recommended that the NOP:

- 1) Renew six material listings, three with recommended annotation changes, on the National List of Allowed and Prohibited Substances (National List) scheduled to expire November 3, 2013.
- 2) Add choline and inositol to § 205.605(b) with restrictions.
- 3) Add citrus hystrix and curry leaf to § 205.606.
- 4) Develop guidance materials to material review organizations.
- 5) Transmit a letter to Secretary Vilsack regarding the establishment of a Genetically Modified Organism (GMO) ad-hoc NOSB sub-committee.
- 6) Encourage USDA research agencies to prioritize funding for emerging organic research needs as recommended by NOSB on an annual basis.
- 7) Provide additional information to the NOSB on GMO vaccines.

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 available technical information, public comments, and alternatives to six material listings scheduled to expire on November 3, 2013. The NOSB recommended renewing the existing listing for three of the six substances with no annotation changes. The NOSB recommended amending annotations for three of the six substances (summarized in Table 1). For each of these three substances, the NOSB also recommended to renew the existing listing. The NOSB recommendations to renew the listings are provided to the NOP to allow for a continuation of the current use of a substance if it is not possible to amend the annotation during the sunset rulemaking. The NOP plans to evaluate each of the Sunset 2013 recommendations and issue a proposed rule for public comment to address these material listings.



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Table 1: Recommended Sunset 2013 Material Listings at May 2012 Meeting

Substance	Section	NOSB Recommendation
EPA List 3 Inerts	§ 205.601(m)	<ol style="list-style-type: none"> 1. Relist with the following annotation: Inert ingredients exempt from the requirement of a tolerance under 40 CFR 180.1122 that were formerly on EPA List 3 in passive polymeric dispenser products may be used until October 21, 2017. The NOSB also recommended the addition of a definition for the term “passive polymeric dispenser products” and modification of the introductory text of § 205.601(m) as part of their recommendation. 2. Renew existing listing.
Agar-Agar	§ 205.605(a)	Renew existing listing.
Calcium Sulfate	§ 205.605(a)	Renew existing listing.
Carrageenan	§ 205.605(a)	<ol style="list-style-type: none"> 1. Relist with the following annotation: CAS # 9000-07-1 (general), 9062-07-1 (iota), 11114-20-8 (kappa), and 9064-57-7 (lambda). Carrageenan would not be allowed for use in infant formulas. 2. Renew existing listing.
Glucono Delta-Lactone	§ 205.605(a)	Renew existing listing.
Cellulose	§ 205.605(b)	<ol style="list-style-type: none"> 1. Relist with the following annotation: For use in regenerative casing, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. 2. Renew existing listing.

In August 2011, the NOP commented on the Sunset process for annotation changes as part of our response to the NOSB’s April 2011 recommendations. In our response, the NOP stated that the NOSB should ensure that proposals for annotation changes through the NOSB’s Sunset policy are fully vetted during the process and supported by information provided in public comment and/or technical reports.



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In the absence of information to support a change, the NOP suggested that the NOSB avoid making changes to an annotation during the Sunset process. The NOP communicated our concern that 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.

The NOP is making reference to these comments as part of this response as they are also applicable to the process followed for the NOSB's review of Sunset 2013 materials. The NOP requests that the NOSB consider these issues regarding annotation changes for materials in their future Sunset reviews.

2. Choline and Inositol - § 205.605(b)

In an April 2010 memo to the NOSB, the NOP stated that its previous interpretation of the nutrient vitamins and minerals annotation at § 205.605(b) was incorrect. The memo described NOP's consultation with the Food and Drug Administration (FDA) to review the existing annotation in the USDA organic regulations, which references FDA guidelines at 21 CFR 104.20. The FDA and NOP identified certain substances, including choline and inositol, which were allowed under the previous (incorrect) interpretation of 21 CFR 104.20.

The NOSB Handling Committee reviewed petitions to add choline and inositol as separate listings on § 205.605(b). The NOSB weighed information from the petitions and technical reports, in addition to public comments representing a wide spectrum of perspectives. The NOSB voted to list both of these nutrients on the National List with the following annotations:

Choline. Choline chloride (CAS # 67-48-1) and Choline bitartrate (CAS # 87-67-2) for use in infant formula and medical nutritional enteral products.

Inositol. CAS # 87-89-8 (myo-inositol) and 6917-35-7 (non-specific isomer) for use in infant formula and medical nutritional enteral products.

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.

3. Citrus Hystrix and Curry Leaf - § 205.606

In response to petitions, the NOSB recommending adding two substances to § 205.606: citrus hystrix (kaffir lime) and curry leaf. The NOP intends to initiate rulemaking for public comment to add these substances to the National List. If finalized, non-organic citrus hystrix or curry leaf could only be added to processed organic products if organic forms were not commercially available.

4. Material Review Organizations

In December 2011, the NOSB recommended that all material review organizations be accredited or formally recognized in a new material review scope. At the May 2012 meeting, the NOSB



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recommended that the NOP develop guidance materials to material review organizations to promote consistency and uniformity in the short term. The recommendation outlined a range of criteria and processes that these groups should use when reviewing substances.

The NOP recognizes the need for additional guidance in this important area. The NOP is currently developing guidance for the classification of materials and permitted substances for crop production. Based on recommendations by the NOSB, the classification of materials guidance will help material review organizations consistently determine if a given substance is synthetic or nonsynthetic, and agricultural or nonagricultural. The permitted substances list will help organic farmers and certifying agents determine which synthetic and nonsynthetic substances are allowed in organic crop production. The NOP looks forward to receiving public comments on both of these important resources.

5. Letter to Secretary Vilsack

The NOSB voted to send a letter to the Secretary of Agriculture regarding their establishment of a GMO ad-hoc sub-committee. The letter outlined some of the issues this sub-committee intends to address. The NOP transmitted this letter to Secretary Vilsack on May 25, 2012.

6. Organic Research Priorities

The NOSB recommended a set of criteria for identifying research needs and a process for the NOSB to develop and publish a yearly recommendation on emerging research needs. When the NOP receives such a recommendation it will then, as it has before, formally request that USDA research agencies, such as the Agricultural Research Service and the National Institute of Food and Agriculture, respond to those recommendations with specific actions to pursue the identified priorities.

7. GMO Vaccines

The NOSB requested additional information from the NOP before it makes additional recommendations to address the status of GMO vaccines in organic livestock production. To address this important issue, the NOP has established a working group consisting of two NOP staff, two NOSB members, and a staff member from the Animal and Plant Health Inspection Service. The working group plans to present an update at the fall 2012 NOSB meeting.

8. Summary

The NOP recognizes and sincerely appreciates the number of hours each NOSB member volunteers each month during their five-year term.



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This was also the first meeting for five members who joined the NOSB on January 24, 2012:

Carmela Beck, Producer
Andrea (Zea) Sonnabend, Scientist
Tracy Favre, Environmentalist

Harold V. Austin, IV, Handler
Jean Richardson, Ph.D., Consumer / Public Interest

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