



National List of Allowed & Prohibited Substances

Materials Update

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Materials Committee – NOSB

NOSB Public Meeting – October 2010

Topics

- National List of Allowed and Prohibited Substances
 - Petitioned and Sunset Review Items
 - Material Review Process
 - National List Criteria
 - Sunset Review Criteria
 - Final Notes
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National List of Allowed and Prohibited Substances

National List of Allowed and Prohibited Substances

| Crop | Livestock | Handling |
|--|---|--|
| § 205.601 <u>Synthetic</u> substances <u>allowed</u> for use in organic crop production | § 205.603 <u>Synthetic</u> substances <u>allowed</u> for use in organic livestock production | “[Listed] nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic”, only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.” |
| § 205.602 <u>Nonsynthetic</u> substances <u>prohibited</u> for use in organic crop production | § 205.604 <u>Nonsynthetic</u> substances <u>prohibited</u> for use in organic livestock production | § 205.606 <u>Nonorganically</u> produced <u>agricultural</u> products <u>allowed</u> as ingredients in or on processed products labeled as “organic” |

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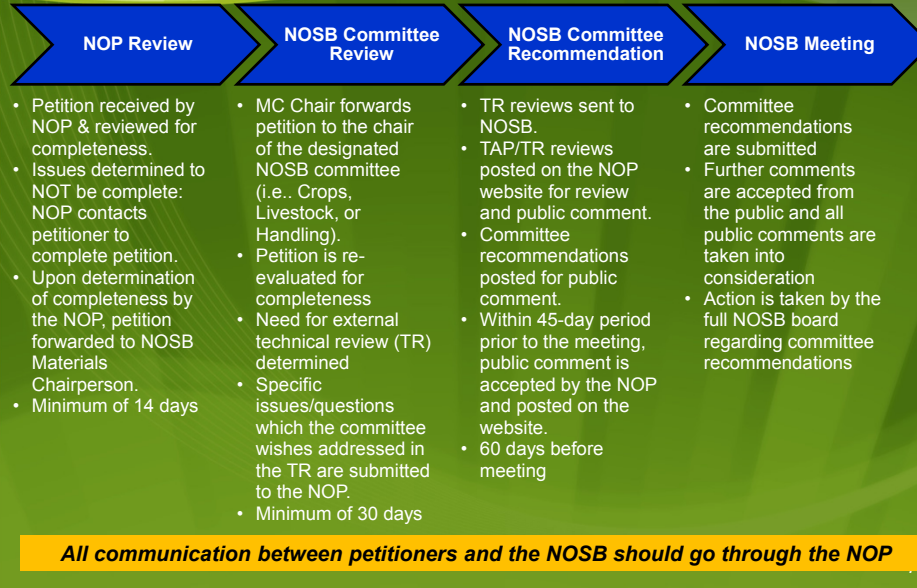
Material Review Process

- **Material Petitions** – Use to:
 - Add a new listing to the National List
 - Change the annotation for an existing listing on the National List
 - Remove a material currently on the National List
- Guidelines are available:
 - Federal Register Notice, 72 FR 2167, January 18, 2007

Material Review Process

- The minimum timeframe for National List Material Review is 145 days.
 - Absolute minimum timeframe
 - Does not include time for Rulemaking
- **Timeframe is dependent on:**
 - Completeness of petition on initial submission
 - Manpower within the specific reviewing committee and board overall
 - Timeframe relative to NOSB public meetings
 - Completion and review of Technical Reviews

Material Review Process



Material Review Process

National List Criteria

- Organic Foods Production Act 1990 – as amended (7 U.S.C. 6518(m))
- NOP Regulations (§ 205.600)

National List Criteria -- **GENERAL**

1. The potential of such substance for detrimental chemical interactions with other materials used in organic farming systems;
2. The toxicity and mode of action of the substance and of its breakdown products of any contaminants, and their persistence and areas of concentration in the environment;
3. The probability of environmental contamination during manufacture, use, misuse, or disposal of such substance;
4. The effect of the substance on human health;
5. The effect of the substance on biological and chemical interactions in the agroecosystem, including the physiological effects of the substance on soil organisms (including the salt index and solubility of the soil), crops and livestock;
6. The alternatives to using the substance in terms of practices or other available materials; and
7. Its compatibility with a system of sustainable agriculture.

.....--Federal Register [Docket Nos. AMS-TM-06-0223; TM-06-12]

National List Criteria: **PROCESSING AID OR ADJUVANT**

1. The synthetic substance cannot be produced from a natural source and there is no organic substitute;
2. The substance's manufacture, use and disposal do not have adverse effects on the environment and are done in a manner compatible with organic handling;
3. The nutritional quality of the food is maintained when the substance is used, and the substance itself, or its breakdown products do not have an adverse effect on human health as defined by applicable Federal regulations;
4. The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;
5. The substance is listed as generally recognized as safe (GRAS) by Food and Drug Administration (FDA) when used in accordance with FDA's good manufacturing practices (GMP) and contains no residues of heavy metals or other contaminants in excess of tolerances set by FDA; and
6. The substance is essential for the handling of organically produced agricultural product

.....-- § 205.600 (b)

National List Criteria: § 205.606 – AGRICULTURAL AND POTENTIALLY COMMERCIALY UNAVAILABLE

The NOSB will consider:

- A. Why the substance should be permitted in the production or handling of an organic product;
 - B. The current industry information regarding availability of and history of unavailability of an organic form in the appropriate form, quality, or quantity of the substance. Industry information includes, but is not limited to the following:
 1. Regions of production, including factors such as climate and number of regions;
 2. Number of suppliers and amount produced;
 3. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;
 4. Trade related issues such as evidence of hoarding, war, trade barriers or civil unrest that may temporarily restrict supplies; and
 5. Other issues which may present a challenge to a consistent supply.
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Material Review Process

Sunset Review Criteria

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Sunset Review Criteria

Sunset Provision -- No exemption or prohibition contained in the National List shall be valid unless the National Organic Standards Board has reviewed such exemption or prohibition as provided in this section within 5 yrs of such exemption or prohibition being adopted or reviewed and the Secretary has renewed such exemption or prohibition.

-OFPA § 2118(e)

Exemptions (NL listings) were accepted because the evidence available showed that the:

- Material was found not harmful to human health or the environment,
 - Material was necessary because of the unavailability of wholly nonsynthetic alternatives, and
 - Use of the material was consistent and compatible with organic practices
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Sunset Review Criteria

Sunset is the opportunity to revisit the continued need for the exemption.

- Sunset review is to determine if conditions relevant to acceptance of exemption (listing) have changed
- If a review finds that the initial conditions still exist, the listing is renewed for an additional period of time

The sunset review process is NOT:

- to add new substances to the NL
 - to change an existing annotation
 - the time to reinterpret unchanged information and conditions
- *These issues are dealt with in the Petition Process*
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Materials Update

Update – Petitioned Material Status Crops Committee

This meeting:

- Sunset 2012 (EPA List 4)
- Ethylene glycol
- Ethylene DDS
- Tall oils
- Tetramethyl-decyne-diol

Petitions to Remove:

- Ferric Phosphate

Petitions to Add a Substance:

- Ammonium nonanoate
- Indole-3-butyric acid
- Nickel
- Propane

Inert Ingredient Petitions

- 1,1-Difluoroethane
- Propylene glycol monolaurate
- Polycaprolactone
- Manganese sulfate monohydrate
- Methyl laurate

Petitions and technical reports are available to the public on the NOP website

Update – Petitioned Material Status Livestock Committee

This Meeting:

- Sunset 2012 (12 materials)
- Formic acid

No other petitions for livestock materials are outstanding

Petitions and technical reports are available to the public on the NOP website

Update – Petitioned Material Status Handling Committee

This Meeting:

- Sunset 2012 (43 materials)
- Yeast
- Pectin
- Glucosamine
- Hops

Petitions and technical reports are available to the public on the NOP website

Update – Petitioned Material Status Handling Committee (cont.)

Petitions to Remove:

- Annatto extract color
- Silicon dioxide

Annotation Change:

- Beta carotene
- Sodium acid pyrophosphate
- Sulfur dioxide (wine)

Petitions to Add a Substance:

- ARA single-cell oil
- Attapulgate
- Barley betafiber
- Calcium acid pyrophosphate
- Caramunch malt
- Dextrin
- DHA algal oil
- Gibberellic acid
- Sugar beet fiber
- Sulfuric acid
- Taurine (pet food)

Petitions and technical reports are available to the public on the NOP website

Update – Sunset Review Status

| Committee | Sunset 2012 (at this meeting) | Sunset 2012 (Spring 2011 NOSB meeting) | Sunset 2013 | Sunset 2014 | Sunset 2015* |
|-----------|----------------------------------|--|----------------|----------------|-----------------|
| Crops | 1 | 22 | 5 | None | 1 |
| Livestock | 12 | None | None | None | None to date |
| Handling | 43 | 6 | 7 | None | None to date |

** Sunset 2015 includes any materials added to the National List through rulemaking by December 31, 2010*

Final Notes

NOSB Reviewer Role – *Overview for Public*

- Our practice is for committee chair to assign a petitioned or sunset material to a committee member to lead the review
 - Often chosen due to their area of expertise
- Role of this lead person is to:
 - Find relevant information on material
 - Develop initial perspective for recommendation
 - Provide all perspectives to rest of committee
 - Lead committee debate
 - Write committee recommendation with input from rest of committee
 - Present committee recommendation at NOSB meeting
 - Write final NOSB recommendation

NOSB Reviewer represents the committee

May or may not represent their own personal perspective

Website Listings

- NOP: www.ams.usda.gov/nop/
- NOSB: www.ams.usda.gov/nosb/
- Public Comment: www.regulations.gov



THANK YOU

