



National List of Allowed & Prohibited Substances

Materials Update

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Materials Committee – NOSB

NOSB Public Meeting – April 2011

Topics

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



National List of Allowed and Prohibited Substances

National List of Allowed and Prohibited Substances

Crop	Livestock	Handling <i>(Ingredients listed on product ingredient listing)</i>
<p>§ 205.601 <u>Synthetic</u> substances <u>allowed</u> for use in organic crop production</p>	<p>§ 205.603 <u>Synthetic</u> substances <u>allowed</u> for use in organic livestock production</p>	<p>“[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.”</p>
<p>§ 205.602 <u>Nonsynthetic</u> substances <u>prohibited</u> for use in organic crop production</p>	<p>§ 205.604 <u>Nonsynthetic</u> substances <u>prohibited</u> for use in organic livestock production</p>	<p>§ 205.606 <u>Nonorganically</u> produced <u>agricultural</u> products <u>allowed</u> as ingredients in or on processed products labeled as “organic”</p>

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

NOP Review

- Petition received by NOP & reviewed for completeness.
- Issues determined to NOT be complete: NOP contacts petitioner to complete petition.
- Upon determination of completeness by the NOP, petition forwarded to NOSB Materials Chairperson.
- Minimum of 14 days

NOSB Committee Review

- MC Chair forwards petition to the chair of the designated NOSB committee (i.e.. Crops, Livestock, or Handling).
- Petition is re-evaluated for completeness
- Need for external technical review (TR) determined
- Specific issues/questions which the committee wishes addressed in the TR are submitted to the NOP.
- Minimum of 30 days

NOSB Committee Recommendation

- TR reviews sent to NOSB.
- TAP/TR reviews posted on the NOP website for review and public comment.
- Committee recommendations posted for public comment.
- Within 45-day period prior to the meeting, public comment is accepted by the NOP and posted on the website.
- 60 days before meeting

NOSB Meeting

- Committee recommendations are submitted
- Further comments are accepted from the public and all public comments are taken into consideration
- Action is taken by the full NOSB board regarding committee recommendations

All communication between petitioners and the NOSB should go through the NOP

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]

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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

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 or 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



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
- the time to reinterpret unchanged information and conditions
- *These issues are dealt with in the Petition Process*

Resources:

- November 2010 Sunset Process to include annotations recommendation -- <http://www.ams.usda.gov/AMSV1.0/getfile?dDocName=STELPRDC5088004&acct=nosb>
 - June 2005 ANPR on Sunset
 - March 2005 NOSB Sunset Process
 - October 2004 Sunset Recommendation from Materials
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Sunset Review Criteria – Changing Annotations

New for this Meeting (based on Oct. '10 NOSB Recommendation)

Annotation changes during sunset review of materials

Process Highlights – *“The committee and subsequently the Board will first take up the annotation amendment and then vote on the material’s renewal.”*

- The committee may request a third party technical review in anticipation of scientific evidence and claims likely to be made during public comment to the ANPR.
- The appropriate NOSB committee begins review of the material with the intent of providing a recommendation to the entire Board for the material’s removal, renewal, or renewal with the addition of an annotation. The review is conducted based on “Force of Evidence” as presented by Board members, public comments, and scientific data from other sources.
- The reviewing NOSB committee provides its recommendation to the full Board and the public no less than 60 days prior to the Board Meeting which would include the following:
 - (i). Simple motion to remove, add, or amend an annotation, resulting in the restriction or clarification of the use of a material (if applicable).
 - (ii). Simple motion to renew the existing listing.....

Materials – Status Update



Update – Petitioned Material Status Crops Committee

This meeting:

- Tetracycline
- Nickel
- Sunset 2012 (22 listings)

Petitions to Remove:

- Ferric Phosphate

Withdrawn

- Methyl laurate (inert)
- Polycaprolactone (inert)

Petitions to Add a Substance:

- Ammonium nonanoate ‡
- Indole-3-butyric acid ‡
- Propane ‡
- Propylene glycol monolaurate

Petitions for Inert Ingredients

- 1,1-Difluoroethane
- Manganese sulfate monohydrate

‡ Waiting for technical report

Update – Petitioned Material Status Livestock Committee

This Meeting

- None

Petition to Amend Annotation

- Methionine

Technical Reports in Development

- GMO Livestock Vaccines

Update – Petitioned Material Status Handling Committee

This Meeting:

- Attapulgate
- Calcium acid pyrophosphate
- Sodium acid pyrophosphate
- Sunset 2012 (6 listings)

Petitions to Remove:

- Silicon dioxide

Annotation Change:

- Potassium hydroxide
- Sulfur dioxide (wine)

‡ Waiting for Technical Report

Petitions to Add a Substance:

- ARA single-cell oil
- Bergamot bitter orange powder
- Dextrin
- DHA algal oil
- Gibberellic acid
- Sodium gluconate
- Sugar beet fiber
- Sulfuric acid ‡
- Taurine ‡

Waiting on Petitioner Response:

- Annatto extract color
- Barley betafiber
- Beta carotene ‡
- Caramunch malt

Update – Sunset Review Status

Committee	Sunset 2012 (Spring 2011 NOSB meeting)	Sunset 2013	Sunset 2014	Sunset 2015	Sunset 2016*
Crops	22	5	None	4	2
Livestock	None	None	None	None	TBD
Handling	6	7	None	4	10

** Sunset 2016 will also include any materials added to the National List through rulemaking by December 31, 2011*

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

Motions from Committees

Our practice is for recommendations on materials to be made in the affirmative from committee

Affirmative Motion

- Motion is to list Google Rocks on the NL section § 205.602 Non-synthetic substances prohibited for use in crop production
- Motion fails in the crops committee with 1 yes, 5 no votes
- CC brings motion to full board with a motion to list
- NOSB then can vote to list or motion can fail

Non-affirmative Motion

- Motion is not to list Google Rocks on the NL
- Motion passes in the CC with 5 yes, 1 no vote
- CC brings motion to full board with motion to not list
- NOSB Vote
 - Motion passes then Google Rocks not listed
 - Motion fails then Google Rocks are in limbo and get sent back to CC to come back at next NOSB meeting

Not our Practice

Website Listings

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





THANK YOU

