



National List of Allowed & Prohibited Substances

Materials Update

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***NOSB Public Meeting
November 2011***

Topics

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



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 – Changing Annotations

(added November 2010 to NOSB Policy)

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.

**Two
Vote
Process**

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Sunset Review – Changing Annotations

(added November 2010 to NOSB Policy)

Considerations on Process

- Use of materials on the NL is allowed in context of the entirety of Final Rule and the process of being certified. For example,
 - OSP's require that cultural, mechanical, physical and other management practices be used prior to use of NL allowed synthetic (§ 205.206)
 - Certifiers verify compliance of non-organic ingredients with § 205.105 (produced without use of excluded methods, ionizing radiation and sewage sludge)
- Our recommendation says that annotation changes during sunset are the result of the Force of Evidence
 - Must be supported by technical reviews and /or public comment
 - Sunset review is not the time to reinterpret unchanged information and conditions. We must have evidence that the information was not originally considered by NOSB.
 - Materials coming off the NL during the sunset process are a tool being removed from producers/handlers
 - Are the alternatives viable or experimental? Is there scientific data supporting the efficacy of the alternative?
- Sunset is NOT the only time NOSB can initiate annotation changes

Material Review Process Notes

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

Technical Reviews – NOP request for consideration

- Capacity and resources for TR's is not unlimited
- Volume of petitions under review is high -- There are 27 petitions under consideration by the NOSB, not including those on the Fall agenda.
- Plan TR requests and workplans
 - What TR's are already available?
 - What new information do we believe is available?
 - Does every material need a new TR every time?



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

Materials – Status Update



Update – Petitioned Material Status Crops Committee

This meeting

- Ammonium nonanoate
- Indole-3-butyric acid
- Propane
- Sunset 2013 (5 listings)

Petitions to Remove

- Ferric Phosphate

Petitions to Add a Substance

- Oxidized lignite
- Propylene glycol monolaurate

Technical Reports Requested

- Propylene glycol monolaurate

Petitions for Inert Ingredients

- 1,1-Difluoroethane
- Manganese sulfate monohydrate

Update – Petitioned Material Status Livestock Committee

This Meeting

- None

Petition to Amend Annotation

- Methionine

Petitions to Add a Substance

- Nonanoic acid (pelargonic acid)

Technical Reports requested

- Vaccines from GMOs
- Methionine
- Nonanoic acid

Update – Petitioned Material Status Handling Committee

This Meeting

- Annatto extract color
- ARA single-cell oil
- Beta-carotene color
- DHA algal oil
- Potassium hydroxide
- Silicon dioxide
- Sulfur dioxide
- Sunset 2013 (3 listings)

Petitions to Remove

- Tartaric acid (synthetic)

Waiting for Petitioner Response

- Caramunch malt

Update – Petitioned Material Status Handling Committee

Petitions to Add a Substance to § 205.605 (Non-Agricultural)

- Ascorbyl palmitate
- Beta-carotene (nutrient)
- Choline (two petitions)
- Dextrin
- Gibberellic acid
- Inositol
- L-Methionine
- Lycopene
- Nucleotides
- Sodium gluconate
- Sulfuric acid
- Taurine

Petitions to Add a Substance to § 205.606 (Agricultural)

- Barley betafiber
- Bergamot bitter orange powder
- Curry leaf
- Kaffir lime leaves and fruit
- Lutein
- Sugar beet fiber

Explanation that the NOSB will be prioritizing nutrient petitions for Spring 2012 due to anticipated annotation change for nutrient vitamins and minerals

Update – Sunset Review Status

Committee	Sunset 2013 (Fall 2011 NOSB meeting)	Sunset 2013 (Spring 2012 meeting)	Sunset 2014	Sunset 2015	Sunset 2016*
Crops	6	1	None	4	2
Livestock	None	None	None	None	TBD
Handling	3	5	None	4	10

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



THANK YOU

