



**National Organic Program:
National List Basics &
Navigating EPA Changes
To Allowed Ingredients (Inerts) in
Pest Management Materials**

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Agricultural Marketing Service
United States Department of Agriculture**

EPA/CPDA Symposium on Inert Ingredients

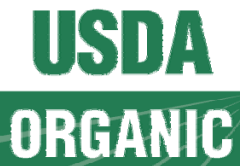
Arlington, VA

February 4, 2010



USDA National Organic Program History

-  **1990** **Organic Foods Production Act (OFPA)**
-  **1993** **USDA names first National Organic Standards Board (NOSB)**
-  **1997** **USDA publishes first proposal**
-  **03/00** **USDA publishes second proposal**
-  **12/00** **USDA publishes final regulation**
-  **04/02** **Accreditations and certifications begin**
-  **10/02** **Full implementation**



USDA National Organic Program Overview





USDA National Organic Program Overview

- **Accreditation:** Accredit Certifying agents, Approve State Organic Programs (SOP), & International Agreements
- **Compliance and Enforcement:** Complaint Processing
- **Standards Development & Interpretation:** Promulgate, Amend, and Implement Regulations & Provide Guidance
- **National Organic Standards Board**
15-member federal advisory committee appointed by the Secretary that serve 5 year rotating terms

Board Composition

- Producers (4)
- Handlers/processors (2)
- Retailers (1)
- Scientists (1)
- Consumers (3)
- Environmentalists (3)
- Accredited Certifying Agent (1)



National List Basics: OFPA & The Rule

- The Organic Foods Production Action (OFPA) of 1990
 - **100% Organic** – 100% of Agricultural Ingredients are certified organic
 - **Organic** – 95% of Agricultural Ingredients are certified organic
 - All synthetic substances are prohibited for organic production and handling unless excepted by the NOSB as allowed;
 - Nonsynthetic substances are allowed for organic production and unless excepted by the NOSB as prohibited;
- The National Organic Standards – October 2002

Title 7: Agriculture § 205.1 – 205.699
The e-CFR site contains the most current version of the National Organic Standards. [Electronic Code of Federal Regulations \(e-CFR\) website](#)
- The National List in the Rule: § 205.600 – 205.607
See Handout # 1



National List Basics: § 205.600 – 205.607

Organic Crop Production

§ 205.601 Synthetic substances allowed for use in organic crop production.

- a. Algaecides, disinfectants, and sanitizers
- b. Herbicides, weed barriers
- c. Compost feedstocks
- d. Animal repellents
- e. Insecticides
- f. Insect management. Pheromones.
- g. Rodenticides
- h. Slug or snail bait. Ferric phosphate
- i. Plant disease control.
- j. Plant or soil amendments
- k. Plant growth regulators. Ethylene gas...
- l. Floating agents in postharvest handling.



National List Basics: § 205.600 – 205.607

Organic Crop Production

§ 205.601 Synthetic substances allowed for use in organic crop production.

- m. As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances. ***Revisit this in later slide***
 - 1) EPA List 4—Inerts of Minimal Concern.
 - 2) EPA List 3—Inerts of Unknown Toxicity allowed:
Inerts used in passive pheromone dispensers.
- n. Seed preparations. Hydrogen chloride - for delinting cotton seed for planting.
- o. to z. [Reserved]



National List Basics: § 205.600 – 205.607

Organic Crop Production

§ 205.602 Non-Synthetic substances prohibited for use in organic crop production.

- *Also includes non-synthetics restricted by annotation for use in organic crop production.*
- **Prohibited non-synthetics:** Ash from manure burning; Arsenic; Lead salts; Sodium fluoaluminate (mined); Strychnine; Tobacco dust (nicotine sulfate).
- **Restricted non-synthetics:** Calcium chloride (brine process); Potassium chloride; Sodium nitrate.



National List Basics: § 205.600 – 205.607

Organic Livestock Production

§205.603 Synthetic substances allowed for use in organic livestock production.

- b. As topical treatment, external parasiticides, or local anesthetic as applicable.
- (1) Copper sulfate.
 - (4) Lime, hydrated—as an external pest control, not permitted to cauterize physical alterations or deodorize animal wastes.
 - (5) Mineral oil—for topical use and as a lubricant.
.....
 - (7) Sucrose octanoate esters—in accordance with approved labeling



National List Basics: § 205.600 – 205.607

Organic Livestock Production

§205.603 Synthetic substances allowed for use in organic livestock production.

..... e. As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

(1) EPA List 4—Inerts of Minimal Concern

§205.604 Non-Synthetic substances prohibited for use in organic livestock production.



National List Basics: § 205.600 – 205.607

Organic Handling Production (The 5%)

§205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

(a) Non-synthetics allowed:

(b) Synthetics allowed:

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Only the following 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.



Navigating EPA Changes To Allowed Ingredients (Inerts) in Pest Management Materials

Organic Crop Production

§ 205.601 Synthetic substances allowed for use in organic crop production.

- m. As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.
 - 1) EPA List 4—Inerts of Minimal Concern.
 - 2) EPA List 3—Inerts of Unknown Toxicity allowed:
Inerts used in passive pheromone dispensers.



EPA Slide 1: The Origins of the List System

- **The Food Quality Protection Act (FQPA)**
1996
 - New standard of review for pesticides.
 - List created to prioritize Reassessment.
- USDA and EPA consult on 2000 NOP Rule.
 - A good choice – restrictive and expedient.
 - But...List was temporal and ad hoc.
- Agreement that issue would need to be addressed in future.

EPA Slide 2: Limitations of the List

- The List is a characterization of an ingredient pre-Reassessment. (Data change things.)
- The List was not statutory. (40 CFR is boss.)
- The List had imprecise defining criteria.
 - Numerical limits and 4B.
 - Outliers - 4B issues.
 - Where's the eco?
- The List did not account for NOP values – persistence, ecotoxicity, character of synthetic production, etc...
- Reassessment made the List irrelevant.



EPA Slide 3: What List?

- 2006: Reassessment starts wrapping up.
- 2007: EPA pulls the List. Everything is List 4 now. The meaninglessness of equivalency statements.
- 2006-2007: EPA and USDA AMS NOP confer. USDA freezes List pre-Reassessment.
- 2008-2009: NOSB begins discussion on developing new NOP-specific inerts criteria. Discussions are ongoing.
- Don't ask. We don't know yet. It's too early.
- No cause for anxiety.



Navigating EPA Changes To Allowed Ingredients (Inerts) in Pest Management Materials

- September 2007 - NOP Policy 5008:
- Reassessed Inert Ingredients - Handout # 2
 1. Will Need to Amend NOP regulations
 2. EPA Inerts List 4, August 2004; except the List 4 inert ingredients that have been revoked for use in pesticide formulations and are now also prohibited under NOP :
 - Acetylated lanolin alcohol - Revoked in 70 FR 31401, June 1, 2005.
 - Acrylic acid methyl ester, polymer with acrylonitrile and 1,3-butadiene; Revoked in 71 FR 14411, March 22, 2006; the tolerance exemption is called “Nitrile rubber modified acrylonitrile methylacrylate conforming to 21 CFR 177.1480.
 - Coumarone – indene resin; Revoked in 71 FR 14411, March 22, 2006.
 - Manganous oxide; Revoked in 71 FR 45415, August 9, 2006.
 - Pentaerythritol monostearate; Revoked in 71 FR 14411, March 22, 2006.
 - Pentaerythritol tetrastearate; Revoked in 71 FR 14411, March 22, 2006.
 - Polyglyceryl phthalate ester of coconut oil fatty acid; Revoked in 71 FR 45415, August 9, 2006.
 - Sodium fluoride; Revoked in 70 FR 31401, June 1, 2005.



Navigating EPA Changes To Allowed Ingredients (Inerts) in Pest Management Materials

Public Business Meeting of the NOSB, November 2009
Crops Committee Discussion Document (on website)
Reassessed Inert Ingredients - Handout # 3

The NOSB needs to review all inert ingredient components used in current NOP compliant pesticide formulations for consideration for inclusion on the National List of Allowed Materials on 205.601.

Proposed Guidance to the NOP (This was not up for Vote)

- 1) The NOP shall notify all manufacturers of pesticides allowed for use in organic production that any materials which are inert ingredient components used in any of their current NOP compliant formulations be brought forward for review by the NOSB.
- 2) Any material not introduced for review during an initial grace period will not be considered for inclusion on the National List of Allowed Materials and will Not Be Allowed for use in pesticide formulations in organic production.
- 3) Following the initial review of this materials list, any and all materials to be listed under the category of inerts will need to be petitioned to the NOSB through the normal materials petition process.

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Navigating EPA Changes To Allowed Ingredients (Inerts) in Pest Management Materials

Proposed Guidance to the NOP (This was not up for Vote)

From the date of public notice of the approval of this recommendation:

4) Manufacturers of pesticides allowed for use in organic agriculture will have 6 months to submit materials which are inert ingredient components for review.

5) Materials not submitted for review will have a 1 year grace period, after which they will no longer be allowed.

6) Submitted materials rejected during NOSB review will be prohibited after a 1 year grace period, unless health and environmental risks dictate an expedited termination of use.

7) Delete 1) and 2) under 205.601

(m) As synthetic inert ingredients as classified by the Environmental Protection Agency (EPA), for use with nonsynthetic substances or synthetic substances listed in this section and used as an active pesticide ingredient in accordance with any limitations on the use of such substances.

~~(1) EPA List 4—Inerts of Minimal Concern.~~

~~(2) EPA List 3—Inerts of Unknown Toxicity allowed:~~

8) List the specific inert ingredient components recommended for inclusion on 205.601 (m) by the NOSB

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Amending the National List: § 205.607

- **Petition Process:** Any Person May Petition
- **Petition Procedures:** 72 FR 2167 - See Handout # 4

Information to Be Submitted in a Petition

- **Petition receipt and NOP review:**
Completeness - 30 working days
Incomplete – more information from petitioner
- **Complete:** NOSB ED & NOSB Materials Chair, assigned to committee (crops); technical review questions developed and requested; petition posted on the NOP website



Amending the National List: § 205.607

NOSB Committee Petitioned Material Review Process

1. Technical Review is complete and received by committee
2. Committee Discussion with Evaluation Criteria Checklist
(next slide & Handout #5)
3. Committee (Crops) recommendation (motion) to NOSB:
Posted to Website to NOSB Meeting Agenda 45 days before public
4. Public comments to Meeting Notice to [regulations.gov](https://www.regulations.gov) and oral comment at meeting
5. NOSB takes action on material recommendation at meeting
6. Final NOSB Recommendation to Secretary for Rulemaking:
Recommendations and transcripts of each NOSB meeting are posted to website following meeting



Evaluating Materials for the National List: § 205.600

Material Evaluation Criteria Summary

See Handout # 5 – Evaluation Criteria Checklist (ECC)

- Potential for detrimental chemical interactions.
- Environmental toxicity.
- Environmental contamination.
- Effect on human health.
- Effect on ecosystem, particularly soil biology.
- Alternatives.
- Compatibility with sustainable agriculture.



Evaluating Materials for the National List: § 205.600

- **Evaluation Criteria Checklist (Handout #5)**
Reviewing committee fills this out; not the petitioner

- **Evaluation Criteria Satisfied?**

Documentation attached

1. Impact on Humans and Environment

Yes No N/A

2. Essential & Availability Criteria

Yes No N/A

3. Compatibility & Consistency

Yes No N/A



NOP Rulemaking for Materials : 18 – 24 months

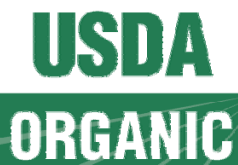
➤ **Final NOSB Recommendation to Secretary for Rulemaking**

➤ **Proposed Rule**

- **Proposed Rule: proposed standards, mandatory analysis**
- **Mandatory Agency reviews: Internal & External**
- **Request for public comments**

➤ **Final Rule**

- **Analyze proposed rule public comments**
 1. **Review of comments**
 2. **Issues raised by comments: responses**
- **Final rule drafting and Agency reviews**
- **Publication of Final Rule**
- **NOP Regulations: not amended until FR effective date**



Sunset Review: Every 5 Years – List 4 Inerts


- The Sunset Review of National List Materials every 5 years is provided for in OFPA and further described in ANPR for Sunset 2007, June 2005. *See Handout # 6*
 - List 4 Inerts is up for 2nd Sunset Review: Complete 2012
- During the sunset review process the NOSB may:
 - Consider old Technical Advisory Panels (TAPs), Technical Reviews (TR), and new information submitted in public comment or that they obtain through their own expertise.
 - Request a new TAP or TR.
 - Remove an exempted material from the National List due to a **lack of public comment** substantiating the importance of a continued listing.
- In summary, it is the responsibility of:
 - The public to provide the evidence regarding the importance of the renewal or removal of a material on the National List.
 - The NOSB to thoughtfully review and weigh the evidence regarding the renewal or removal of a material on the National List.



Sunset Review: Every 5 Years – List 4 Inerts

- Public comments in support of renewing the substance or that request removal of the substance from the National List should provide clear reasons and documentation.
- In order to support the renewal of a substance on the National List the comments should demonstrate that the material is:
 - Not harmful to human health or the environment;
 - Necessary because alternative materials or practices are not available;
 - Consistent and compatible with organic practices.
- In order to support the removal of a substance on the National List the comments should demonstrate that the material is:
 - Harmful to human health or the environment;
 - No longer necessary because alternative materials or practices are available;
 - No longer consistent and compatible with organic practices.

Spring 2010 NOSB Meeting: April 26-29, 2010; Davis, CA

The logo for the USDA Organic program, featuring the text "USDA" in a bold, green, sans-serif font above the word "ORGANIC" in a similar font, all contained within a circular emblem with a green and white background and a brown border.

USDA
ORGANIC

- Crops Committee is deliberating their recommendation on Inerts for deliberation and vote at the Spring 2010 meeting.
- March 12: Federal Register Notice for Meeting, Meeting Agenda, and all committee recommendations will be published, and public comment will open.
- March 12- April 12: Written public comments submitted to www.regulations.gov.
- March 12 - April 12: Requests for 5 minute oral public comment should be sent to: valerie.frances@ams.usda.gov.
- Current intention is to have: 1) Full 9 hour day of public comment on Tuesday, April 27th from 8 am to 5 pm; NOSB deliberations on recommendations on Wednesday, April 28th ; and further discussion and votes on Thursday, April 29th.
- Written comments can also be submitted at the meeting



NOP Contacts: Further Information

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National Organic Program
Agricultural Marketing Service
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www.ams.usda.gov/nop