



National Organic Program
U.S. Department of Agriculture

Materials Update and Process Overview

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National Organic Standards Board Meeting

April 29, 2014

San Antonio, Texas



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Outstanding Petitions - Crops

- This meeting:
 - Laminarin
 - Magnesium oxide
 - Streptomycin
 - Vinasse

Petitions are posted on the NOP website



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Outstanding Petitions - Crops

- Under Subcommittee review:
 - Exhaust gas (carbon monoxide)*
 - Allyl isothiocyanate*
 - Aluminum sulfate
 - Propylene carbonate (inert)

* Technical report in development

Petitions are posted on the NOP website



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Outstanding Petitions - Livestock

- This meeting:
 - Methionine
 - Acidified sodium chlorite
 - Aquaculture petitions



Aquaculture petitions – this meeting

- Chlorine
- Tocopherols
- Minerals
- Vitamins
- Biologics: Vaccines
- Micronutrients (plants)
- Carbon dioxide (plants)
- Chlorine (plants)
- Lignin sulfonate (plants)
- Vitamins B1, B12, H (plants)



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Outstanding Petitions - Livestock

- Under Subcommittee review:
 - Aluminum sulfate
- Withdrawn:
 - Lignin sulfonate (aquatic animals)

Petitions are posted on the NOP website



Outstanding Petitions - Handling

- This meeting:
 - Ammonium hydroxide
 - Glycerin
 - Polyalkylene Glycol Monobutyl Ether (PGME)



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Outstanding Petitions - Handling

- Under Subcommittee review:
 - Gibberellic acid
 - Triethyl citrate
 - Whole algal flour

Petitions are posted on the NOP website



Sunset 2015 Materials - Crops

- Three sunset substances
 - Aqueous potassium silicate (2 listings)
 - Sodium carbonate peroxyhydrate
 - Sulfurous acid
- Updated technical reports available for all three substances



Sunset 2015 Materials - Handling

- Four sunset substances:
 - Gellan gum
 - Marsala wine
 - Sherry wine
 - Tragacanth gum
- No new technical reports



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Petition Process Overview

- Petition Submission
- NOP Review
- Subcommittee Review
- Technical Report
- Subcommittee Proposal
- Public Comment
- NOSB recommendation



Petition Process

The Organic Foods Production Act:

Sec. 2119. [7 U.S.C. 6518] National Organic Standards Board.

(n) Petitions.—The Board shall establish procedures under which persons may petition the Board for the purpose of evaluating substances for inclusion on the National List.



Petition Process

USDA Organic Regulations, 7 CFR Part 205

§205.607 Amending the National List.

- (a) Any person may petition the National Organic Standards Board for the purpose of having a substance evaluated by the Board for recommendation to the Secretary for inclusion on or deletion from the National List in accordance with the Act.
- (b) A person petitioning for amendment of the National List should request a copy of the petition procedures from the USDA at the address in §205.607(c).



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Petition Guidelines

- Most recent version of petition guidelines were published in the Federal Register on January 18, 2007 [72 FR 2167]
- Guidelines explain what information must be included in a petition
- No specific template or form is required
- No fee or cost to petition
- Petitions may contain confidential business information (CBI). CBI is not available to NOSB or public.



NOP's Process

- NOP confirms receipt of petition
- NOP reviews incoming petition for eligibility and sufficiency (generally within 30 days of submission)
- NOP is the primary point of contact for any correspondence between NOSB and petitioner



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NOP's Review

- Ensures that petitions are eligible and complete when they are distributed to the Subcommittee
- Checklists are completed by NOP staff to verify that petitions meet the eligibility criteria and petition guidelines



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NOP's Review

- Acceptance of a petition by NOP for NOSB review is an administrative matter and does not reflect a decision by NOP on the substantive merits of the petition.



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NOSB Subcommittee Process

Petitions are posted on the NOP website at the time they are sent to the NOSB for review

Initial Subcommittee review should be completed within 60 days of receipt of petition

At this stage, the Subcommittee may request:

- a) Additional information from petitioner
- b) Technical report



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Updated Petitions

- Petition updates include
 - Responses to Subcommittee requests
 - Updated (unsolicited) information after petition has been sent to NOSB
- Updates are posted alongside petition on NOP website



Technical report content

- Technical reports are completed by third-party contractors
- Technical report evaluation questions align with OFPA criteria. Content does not include:
 - Proprietary information
 - Economic impact information
- NOP accepts quality, accuracy and completeness of technical reports



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Technical reports, cont.

- NOP reviews all TRs before they are distributed to the Subcommittee to ensure they meet the requirements of the contract
- NOP ensures that TRs are sufficient and complete when they are distributed to the Subcommittee
- Date listed on technical report reflects the date the report was submitted to NOP



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Technical reports, cont.

- Occasionally, NOP will request that a subject matter expert from the Agricultural Research Service review a draft copy of the report. When this occurs, it will be noted when NOP distributes the report to the Subcommittee



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Evaluation Criteria for Materials

- Criteria are provided for in the Organic Foods Production Act of 1990 (OFPA)
- Technical report questions and NOSB checklists align with OFPA criteria
- Different criteria for production uses vs. handling
- Additional criteria for synthetic processing aids and adjuvants at § 205.600(b)



NOSB Process - Checklists

- The NOSB checklists are a tool to facilitate and document evaluation of the petitioned substance against the OFPA criteria
- OFPA does not require checklists, but requires that Board shall consider seven different criteria



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NOSB Review Checklists:

- Checklists document NOSB's review against various OFPA criteria
- In general, narrative responses address uses that are within the scope of the petition (although there may be exceptions, such as effects from misuse)



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Substantive Changes to Proposals

- Subcommittee may make changes to proposals based on written or in-person public comment
- If there are substantive changes to a proposal based on public comment, the proposal should be taken back to Subcommittee for revision
- This allows for another public comment opportunity on the revised proposal



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Voting Procedures

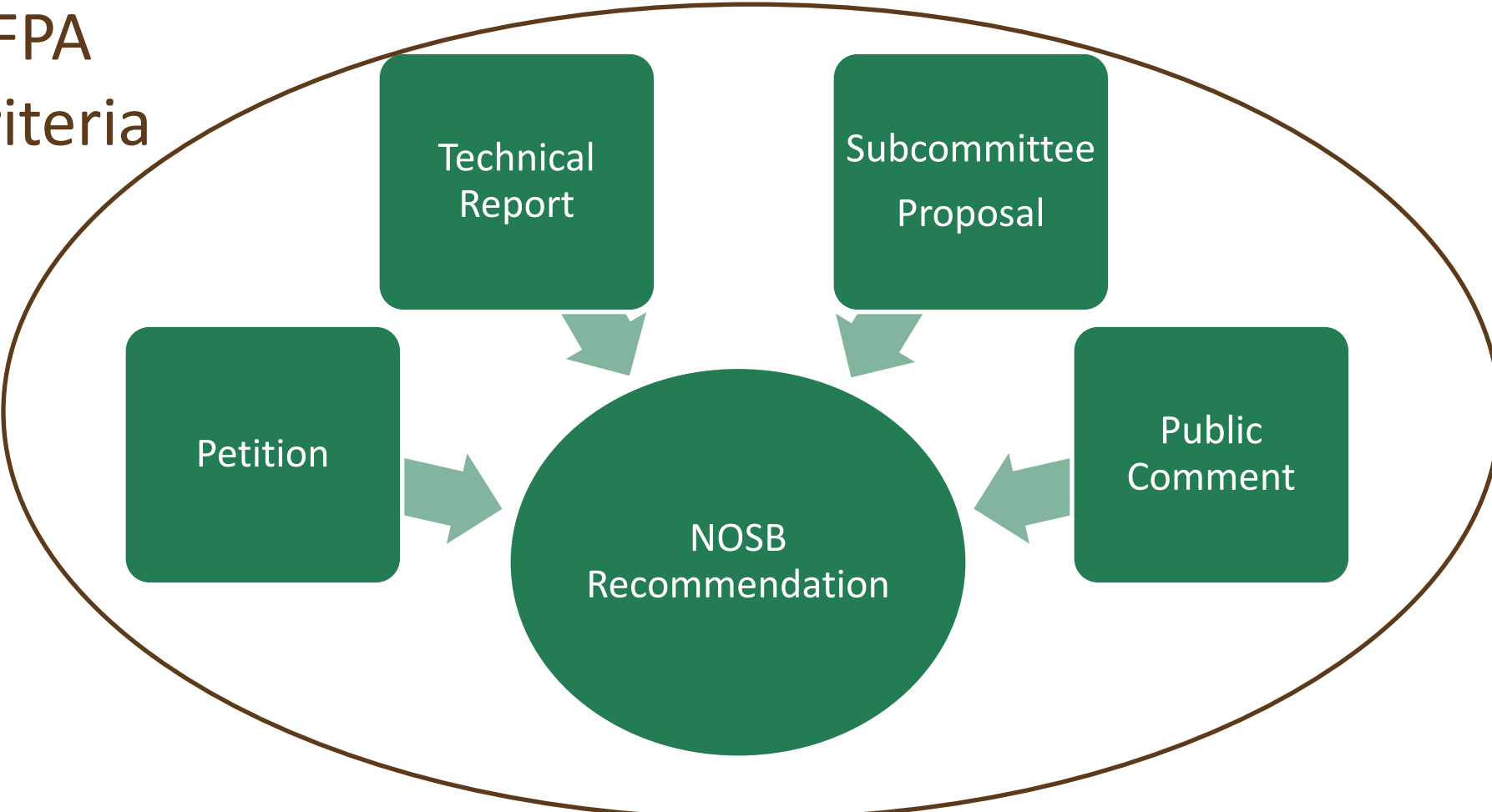
- For petitioned substances, NOSB votes on two motions:
 - 1st motion: Classification (if not previously classified)
 - Synthetic / Nonsynthetic
 - Agricultural / Nonagricultural
 - 2nd motion: To list/remove/amend
- 2/3 majority needed for decisive vote (10 votes / 15 members)



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OFPA Criteria





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Update NOSB-NOP-EPA Working Group on Inert Ingredients

National Organic Standards Board Meeting

April 28, 2014

San Antonio, Texas



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Working Group on Inert Ingredients

- **NOSB:** Jay Feldman, Zea Sonnabend
- **NOP:** Emily Brown Rosen, Lisa M. Brines
- **EPA:** Chris Pfeifer (BPPD), Kerry Leifer
(Registration Division, Inerts)



Background

- The Organic Foods Production Act of 1990 indicates that the National List may provide for the use of inerts in pesticides that are not classified by EPA as “inerts of toxicological concern”
- NOP definition of “inert ingredient” follows from FIFRA definitions (i.e., not necessarily chemically/biologically “inert”)



NOP Rule - National List

- List 4 – Inerts of Minimal Concern
 - Synthetic inert ingredients classified as List 4A and 4B by EPA are allowed in pesticides for organic use (§ 205.601(m) and § 205.603(e))
- List 3 inerts are allowed in passive pheromone dispensers only (§ 205.601(m)(2))
- Both are subject to sunset review, List 4 must be renewed or changed by October, 2017



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Issue

- EPA put inerts into lists according to toxicology and use pattern
- EPA revised system of assessment in 2006 and no longer uses or maintains Lists 1-4
- NOP is operating with obsolete list of inerts, last updated August 2004
- Manufacturers are petitioning for use of inerts that do not appear on the old lists



Timeline of actions

- April 2010 initial NOSB recommendation
 - Proposed to work with EPA for review of inerts
 - Various options for review and listing
- Oct 2010 - NOSB renewed List 4 inerts due to sunset in 2012
- Dec 2010, IWG established



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Timeline of actions

- October 2012, NOSB recommendation
 - proposed policy to review all known inerts by groups, with individual inclusion on National List
- Oct 2012 - May 2013
 - IWG developed lists of known inerts, grouping for review
 - IWG developed plan for public notification and comment



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Timeline of actions

- May 2013-April 2014
 - NOP met with EPA staff, Design for the Environment
 - A voluntary label program for safer chemical products
 - Publishes a Safer Chemical Ingredient List
 - Detailed criteria also published

<http://www.epa.gov/dfe>
 - IWG reviewed aspects of the program, developed questions
 - DfE responded
 - compared list of known inerts in organic to those reviewed by DfE



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Current status

- NOP is consulting with OGC
 - Options for collaboration with EPA
- IWG continues to meet and plan
- If DfE option is viable, next steps will be further consultation with NOSB
 - Public notification and comment



Look for the label!



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Questions?

