



Standards Update & Materials Review

January 31, 2017

USDA Agricultural Marketing Service
National Organic Program



Agenda



- National List
- Rulemaking
- NOSB
- Clarifications
- Status Updates

Updated National List Petition Process



- Changes to the National List may be requested using petitions
- Used for generic materials, not brand-name products
- Any person may submit a petition
- Process updated on March 11, 2016
- New Program Handbook document, NOP 3011
- Implemented two NOSB recommendations

Updated National List Petition Process



- Eliminates provision for submission of Confidential Business Information (CBI)
- Clarified procedures for certain types of petitions, such as annotation (restrictions)
- Answers common questions about the petition process to clarify the role of the NOP, the role of the NOSB, and the criteria used to evaluate petitions

Petition Example



- Petitioned Material: **Sulfur**
- Petitioner: Georgia Gulf Sulfur Corporation
- Petitioned Use: **Livestock use** as a pesticide (repellent for mites, fleas, and ticks)
- Status: Under review by National Organic Standards Board (NOSB)



Sunset 2016:

Renewal published February 22, 2016:

- Crops - Renewed ferric phosphate and hydrogen chloride
- Handling – L-malic acid, microorganisms, activated charcoal, peracetic/peroxyacetic acid; sodium acid pyrophosphate

Renewal effective September 12, 2016

National List – Sunset 2016



Final Rule published August 3, 2016 – removed 5 handling substances from the National List:

- Egg white lysozyme
- Cyclohexylamine
- Diethylaminoethanol
- Octadecylamine
- Tetrasodium pyrophosphate

Removal effective **September 12, 2016**

Organic products manufactured on or after September 12, 2016, need to comply with the new requirements.

National List – Sunset 2017



Proposed rule: Published January 17, 2017

Substances proposed for removal:

205.601

- Lignin sulfonate
(205.601) - floating
agent use only

205.605

- Magnesium carbonate

205.603

- Furosemide (205.603)

National List – Sunset 2017



Proposed rule: Published January 17, 2017

Substances proposed for removal:

205.606

- Chia
- Dillweed oil
- Galangal
- Inulin-oligofructose enriched
- Lemongrass
- Chipotle chili pepper
- Turkish bay leaves
- Whey protein concentrate

Comments on proposed rule are due **March 20, 2017**

National List – Sunset 2017



Renewal notice under development

NOSB Completed review of 187 Substances:

- Crops, 52 listings
- Livestock, 41 listings
- Handling, 94 listings

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Administrative Procedures Act

- Fosters transparency and public participation in the rulemaking process.

Basic requirements:

- Publish a proposed rule in the Federal Register.
- Invite and consider public comments.
- Issue final rule at least 30 days before effective date.

Rulemaking oversight



- Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB)
 - Operates as an “information aggregator” across government
 - Facilitates interagency coordination & communication
 - Considers costs and benefits of regulations
 - Ensures public engagement in process
 - Ensures compliance with relevant statutes
- [Reginfo.gov dashboard](https://www.reginfo.gov)

How does NOP initiate a rulemaking?



- Submit a regulatory workplan
 - Summarizes objectives, possible alternatives, and effects of action to policy officials (non-technical)
 - Provides information needed for “designation” of significance
- Priority rulemaking actions appear on the Unified Agenda
 - Communicates to OMB and public about agencies regulatory plan

Significance designation



- **OMB reviews rules that may:**
 - **Have an annual effect on the economy of over \$100 million or more, or adversely affect the economy, a sector of the economy, jobs, or competition;**
 - **Create serious inconsistency or interferes with an action of another agency;**
 - **Materially alter the budgetary impact of existing programs; or**
 - **Raise novel legal or policy issues.**

Public Comments



- The notice-and-comment process enables anyone to submit a comment on any part of a proposed rule.
- An agency is not permitted to base its final rule on the number of comments in support of the rule over those in opposition to it.
- The agency must base its reasoning and conclusions on the rulemaking record, consisting of the comments, scientific data, expert opinions, and facts accumulated during the pre-rule and proposed rule stages.
- If the rulemaking record contains persuasive new data or sound policy arguments, the agency may decide to terminate the rulemaking.
- Or, the agency may decide to continue the rulemaking but change aspects of the rule to reflect these new issues.

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National Organic Standards Board (NOSB)



- The NOSB is a Federal Advisory Committee which advises USDA. It has:
 - a **charter** with established mission and duties
 - a Designated Federal Official (DFO)
 - Subcommittees and Chair
 - Opportunity for public participation
- Fifteen members appointed by the Secretary of Agriculture to five-year terms
- Five new appointees began service in January 2017
- Next meeting is April 19-21, 2017 in Denver, CO
- Webinar option for public comments

NOSB Recommendations 1994-2016



- Practice Standards
 - 179 recommendations
 - 152 addressed including
 - Animal Welfare Standards
 - Classification of Materials Final Guidance
 - Calculation of Ingredients Draft Guidance
 - 22 in process
 - Aquaculture (3)
 - Pet food
 - Apiculture
 - Pesticide Drift, fumigation (2)
 - Mushrooms
 - 5 Outstanding

NOSB Recommendations 1994-2016



- National List
 - 287 recommendations
 - 254 addressed
 - 33 outstanding or in process
- Sunset
 - 133 reviews completed
 - Outstanding sodium nitrate

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Material Review Interim Instruction



- Published on August 30, 2016
- NOP 3012 replaces Policy Memo 11-4, Verification of Materials
- 60 day comment period closed October 31, 2016
- Final instruction will be issued after assessing comments

Material Review Interim Instruction



The interim instruction is enforceable but is subject to change after assessment of public comments. The interim instruction:

- Specifies the **criteria** and **process** that certifiers must follow when reviewing and approving substances for use in organic production and handling
- Describes the USDA organic regulations as they relate to materials reviews
- Defines the terms “Material Review Organization (MRO)” and “materials”

Material Review Interim Instruction



Outlines **certifier requirements**:

- Required documentation
- Classification determinations (synthetic vs. nonsynthetic or agricultural vs. nonagricultural)
- Appropriate education, training, and experience levels for personnel conducting material reviews
- Requirement for clear written protocols and procedures related to materials reviews

Material Review Interim Instruction



- Outlines the process that occurs when different certifying agents and MROs reach different conclusions on whether a product complies with the USDA organic regulations

Material Discrepancy



- Issue: review of a synthetic inert ingredient in a formulated product
 - Product intended to be used for pest control (microbial inoculant and nematode control)
 - Product was not labeled as a pesticide (labeled as soil amendment)
- Is synthetic List 4 inert ingredient permitted under section 205.601(m)?

Material Discrepancy



National List, 205.601(m):

§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.

Material Discrepancy



Definitions, 205.2:

Inert ingredient. Any substance (or group of substances with similar chemical structures if designated by the Environmental Protection Agency) other than an active ingredient **which is intentionally included in any pesticide** product (40 CFR 152.3(m)).

Pesticide. Any substance which alone, in chemical combination, or in any formulation with one or more substances is defined as a pesticide in section 2(u) of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136(u) *et seq*).

Material Discrepancy



- Determination:
 - Synthetic inert ingredients can only be used in labeled pesticide products
- Notification & Resolution:
 - NOP sent letters to certifiers involved
 - General letter to certifiers being drafted

Classification of Materials



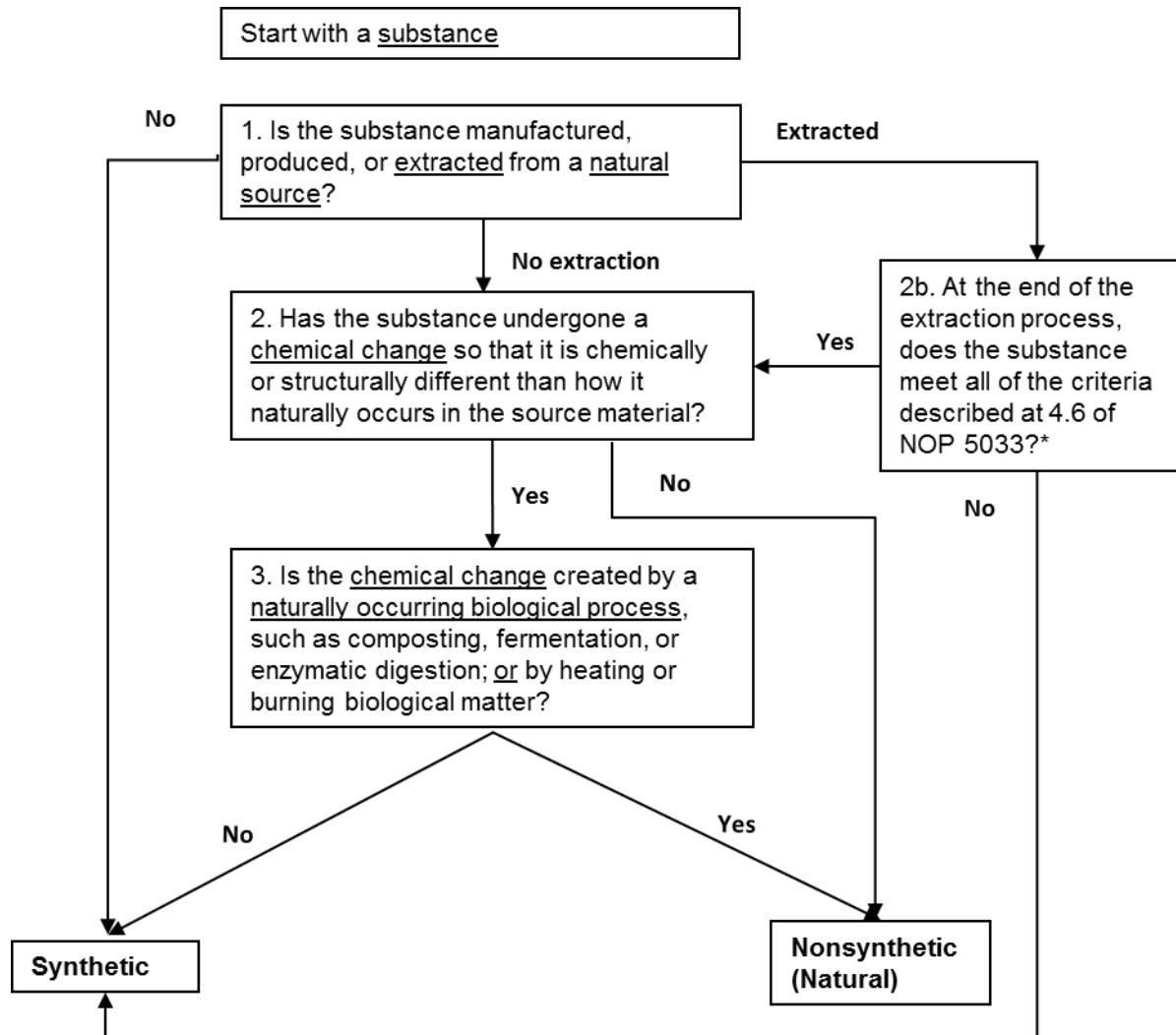
- Final guidance published December 5, 2016
- Implements several NOSB recommendations on classification of materials
- Describes the procedure used to classify materials as synthetic or nonsynthetic, and as agricultural or nonagricultural, under the USDA organic regulations

Classification of Materials

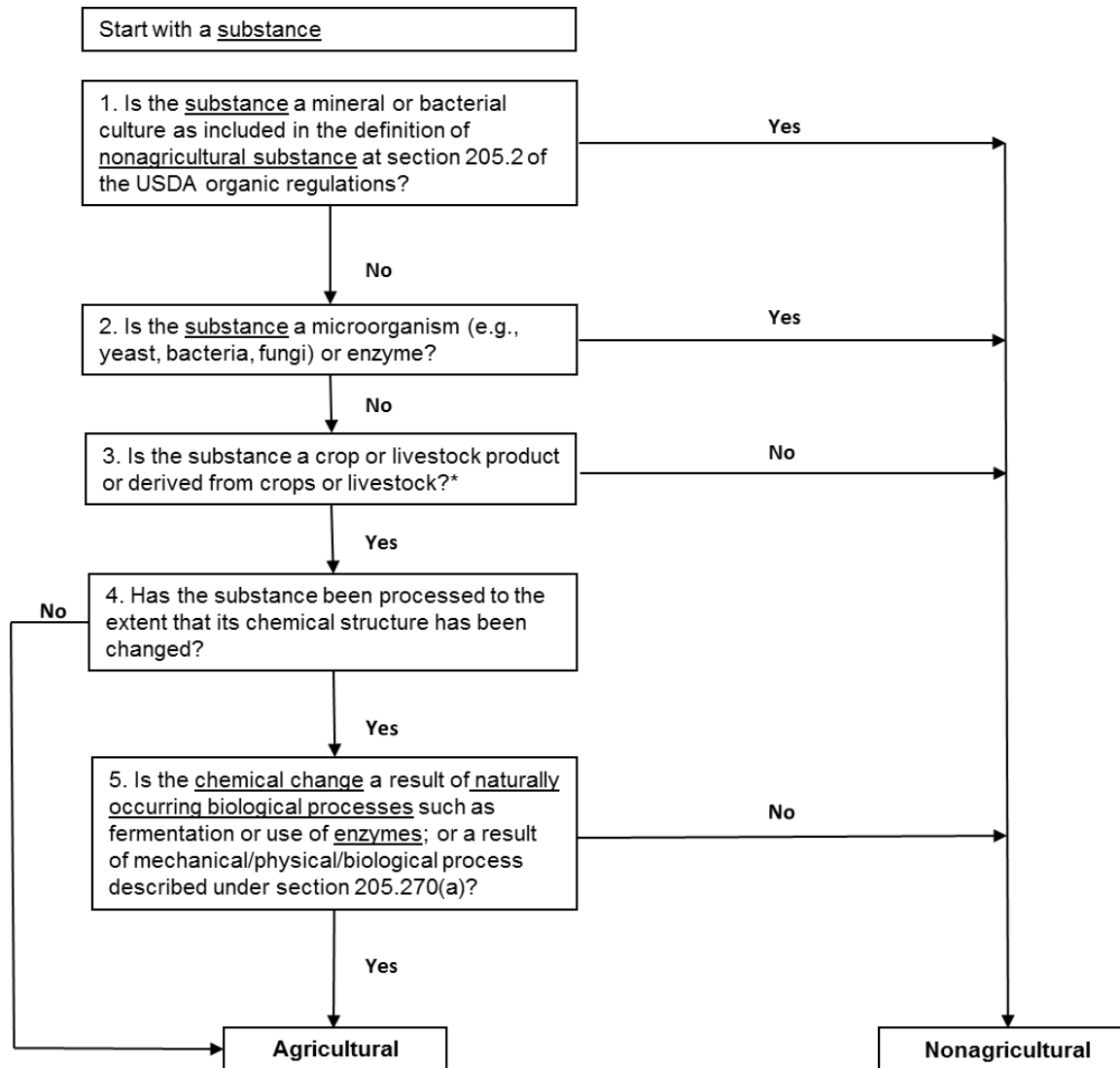


- Four related documents:
 - NOP 5033 – Provides overview and instructions
 - Decision Trees
 - NOP 5033-1
 - NOP 5033-2
 - NOP 5033-3 – Response to comments

Synthetic / Nonsynthetic Decision Tree



Agricultural / Non-Ag Decision Tree



Example: Citric Acid & Sodium Citrate



- Manufactured, produced, or extracted from natural source? **Yes (both)**
- Undergone a chemical change so that it is chemically or structurally different than it is in the source material? **No & Yes**
- Is chemical change a result of naturally occurring biological processes...or a result of physical/mechanical process? **No**

Example: Citric Acid & Sodium Citrate



- Classification Tree Results:
 - Citric acid → Nonsynthetic
 - Sodium citrate → Synthetic
- Consistent with National List placement:
 - Citric acid → 205.605(**a**)
 - Sodium citrate → 205.605(**b**)

Materials for Organic Crop Production



- Final guidance published December 5, 2016
- A tool for organic producers to understand the input materials that NOP has reviewed
- Illustrative list of allowed natural and synthetic materials (NOP 5034-1)
- Limited appendix of prohibited materials (NOP 5034-2)
- Phase-in (implementation) period of **1 year** from date of publication

Materials for Organic Crop Production



- Will be updated periodically to reflect changes to National List
- Send comments on current entries and emerging issues to NOP.Guidance@ams.usda.gov

Draft Guidance in Development



- Materials for Organic *Livestock* Production

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Treated Lumber—Draft Guidance



Published August 30, 2016 to clarify requirement:

The producer must not use lumber treated with arsenate or other prohibited materials for new installations or replacement purposes in contact with soil or livestock.



**§ 205.206—Crop pest, weed, and disease
management practice standard**



Policy and Procedures:

- 36-month transition is not relevant for treated lumber; pesticide in wood is not an “application”
- As transition is not relevant, cannot correct noncompliance with a 36-month transition alone





Policy and Procedures:

- Treated lumber on operations prior to certification does not necessitate any action, **unless treated lumber is in contact with crops**
- Treated lumber on added parcels (added to certified operations) is also permitted **unless treated lumber is in contact with crops**



Policy and Procedures:

Installation *after certification* and in contact with crops, soil or livestock in the organic production area:

- Not in compliance
- Noncompliance must be corrected to continue certification
- Once corrected, additional 36-month transition is not required

Treated Lumber—Draft Guidance



Comments received on draft included:

- Lumber installed prior to certification that does not contact the edible portion of the plant should be allowed
- Contact with any part of a plant, including roots, is not the same as contact with the edible portion of plant
- Currently certified operations would be impacted (i.e. required to remove lumber that is in contact with roots or plants, even if that is not edible crop)



Next Steps

- NOP is reviewing comments for prior to issuing final guidance

Calculating Percent Organic Ingredients



- Draft guidance published December 5, 2016
- Provides guidelines on how to calculate the organic ingredient percentage in multi-ingredient products
- Comments due by **February 6, 2017***

Draft Guidance: Request for Comments



- Comments needed on
 - certifier policies related to calculation of multi-ingredient ingredients, and how the industry is currently calculating organic content in complex processed products
 - How the guidance will impact certified operations and products
 - Sound and sensible approaches currently employed.

Questions?

