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Classification: Update on the Development of Draft Guidance

*Organic Integrity from Farm to Table,
Consumers Trust the Organic Label*

National Organic Standards Board Meeting

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Background

- NOSB has issued a number of formal recommendations for classification (April 2011, May 2010, November 2009, August 2005)
- In a memo to the NOSB on August 11, 2011, the NOP indicated its plans to develop draft guidance on classification based upon the November 2009 NOSB Recommendation for Classification of Materials
- NOP has not yet published draft guidance; this presentation provides an overview of the program's current thinking on these issues



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Why is classification guidance needed?

- To ensure consistent determination of synthetic / nonsynthetic for inputs
- To ensure consistent determination of agricultural / nonagricultural status
- To determine proper placement of materials on National List
- To implement outstanding NOSB Recommendations



Purpose of Classification Guidance

- To describe NOP policies related to classification of materials
- To describe procedures used to classify substances as synthetic or nonsynthetic, or as agricultural or nonagricultural
- For the classification guidance to be used in conjunction with a Permitted Substance List (NOP 5034, in development) for crop inputs



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Format for Classification Guidance

Three related documents:

NOP 5033 – Guidance: Classification of Materials

NOP 5033-1 – Synthetic / Nonsynthetic Decision Tree

NOP 5033-2 – Agricultural / Nonagricultural Decision Tree



Definitions

- New definitions were included in the NOSB Recommendation of April 10, 2011
- Definitions will not be added to regulations; definitions provided and used within the guidance document
- Some definitions to be updated or amended for clarity
- NOP does not intend to amend the definition for “nonagricultural” under § 205.2 at this time, but could consider under a rulemaking action



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Definition: Chemical Change

NOSB Recommended Definition:

Chemical Change. An occurrence whereby the identity of a substance is modified, such that the resulting substance possesses a different distinct identity (see related definition of “substance”)

NOP Proposed Clarification:

Chemical change. A process (i.e., chemical reaction) whereby a substance is transformed into one or more other distinct substances.



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Definition: Extract

NOSB Recommended Definition:

Extract. To separate, withdraw, or obtain one or more essential constituents of an organism, substance or mixture by use of solvents, mechanical or physical methods.

NOP Proposed Clarification:

Extract. To separate, withdraw, or obtain one or more constituents of an organism, substance, or mixture by use of solvents (dissolution), acid-base extraction, or mechanical or physical methods.



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Definition: Substance

The term “substance” is used extensively in the NOP regulations, but is not defined under § 205.2

NOSB Recommended Definition:

Substance. An element, molecular species, or chemical compound that possesses a distinct identity (For example, a distinct identity may be demonstrated through the material having a separate Chemical Abstract Service (CAS) number (in some cases the same material may have multiple CAS numbers), Codex International Numbering system (INS) number, or FDA or other agency standard of identity).



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Definition: Substance

NOP Proposed Clarification:

Substance. A generic type of material, such as an element, molecular species, or chemical compound that possesses a distinct identity (e.g., having a separate Chemical Abstracts Service (CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard of identity).



Crop Inputs: Synthetic / Nonsynthetic

- Classification is needed to determine whether substance is allowed, prohibited, or needs to be on the National List
- § 205.601 – Allowed synthetic inputs
- § 205.602 – Prohibited natural inputs
- Other natural substances are allowed



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Crop Inputs: Synthetic / Nonsynthetic

- Classification is to be made according to the decision tree, NOP 5033-1
- NOP is developing draft guidance for permitted crop inputs, NOP 5034, which lists allowed nonsynthetic and synthetic inputs
- Substances not classified on the permitted substances list, NOP 5034 (in development) will need a review process
- NOP will review requests for adding nonsynthetic substances to NOP 5034 based on classification guidance



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Crop Inputs: Synthetic / Nonsynthetic (cont.)

- Substances classified as nonsynthetic on section 205.605(a) of the National List are permitted as nonsynthetic crop inputs, unless listed on section 205.602 of the National List
- Substances classified as synthetic on section 205.605(b) of the National List are prohibited as crop inputs, unless the substance is also listed on section 205.601 of the National List
- Substances classified as agricultural on section 205.606 of the National List are permitted as crop inputs, unless listed on section 205.602 of the National List



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Livestock Inputs

- Classification is needed to determine whether substance is allowed or needs to be on the National List
- Classification is needed for livestock feed ingredients to determine whether ingredient must be certified organic
- § 205.603 – Allowed synthetic inputs
- § 205.604 – Prohibited natural inputs
- Other natural substances are generally allowed
- Agricultural substances used for livestock feed must be certified organic



Livestock Inputs

- Classification as synthetic / nonsynthetic is to be made according to the decision tree, NOP 5033-1
- Substances not previously classified by the NOSB at a public meeting may need a review process



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Livestock Inputs (cont.)

- Substances classified as nonsynthetic on section 205.605(a) of the National List are permitted as nonsynthetic livestock inputs, unless listed on section 205.604 of the National List
- Substances classified as nonsynthetic in the Permitted Substances List (in development) are permitted as nonsynthetic livestock inputs, unless listed on section 205.604 of the National List
- Substances classified as synthetic on section 205.605(b) of the National List are prohibited as livestock inputs, unless the substance is also listed on section 205.603 of the National List
- Substances classified as agricultural on section 205.606 of the National List would be permitted as nonsynthetic; livestock feed ingredients must be certified organic.



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Handling Inputs

- Classification is needed to determine placement of non-organic substances on the National List
- Classification is important for determining allowance of non-organic agricultural ingredients in the “made with organic” category
- § 205.605(a) – Allowed nonsynthetic
- § 205.605(b) – Allowed synthetic
- § 205.606 – Allowed non-organic, agricultural ingredients (subject to commercial availability)



Handling Inputs: Classification Order

- Classification as **agricultural** or **nonagricultural** to be made first
- Classification as agricultural or nonagricultural to be made according to the decision tree, NOP 5033-2
- For substances which are **nonagricultural**, further classification as synthetic or nonsynthetic according to decision tree NOP 5033-1



Special Issues

- Separation methods
- Solvents in handling
- Eligibility for organic certification
- Timeline and next steps



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Separation Methods

- Some substances are isolated from mixtures using separation techniques
- Separation methods include, but are not limited to distillation, solvent extraction, acid-base extraction, and physical or mechanical methods (e.g. filtration, crushing, centrifugation, gravity separation, etc.)
- The isolated substance may be certified organic, nonsynthetic, synthetic, agricultural or nonagricultural, depending on the starting material and process used



Certified Organic Substances

- Materials used as ingredients, extractants, or other processing aids must be organic or comply with the National List
- Examples of substances used to extract organic ingredients:
 - Organic ethanol
 - Citric acid
 - Water
 - Supercritical carbon dioxide
 - Sodium hydroxide
- Under § 205.270, use of volatile synthetic solvents or other synthetic processing aids are prohibited, unless listed at § 205.605



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Solvents in handling – what this means

- No synthetic solvents or other synthetic processing aids in or on organic products, or in or on organic ingredients, unless listed on § 205.605
- Solvents may be considered as part of manufacturing process for substances on § 205.605, that are reviewed by NOSB and not further restricted. Examples include: lecithin, pectin, shellac
- Nonorganic agricultural ingredients in “made with” products may have been produced with synthetic processing aids and solvents.
- Non organic ingredients listed on § 205.606, for use in organic products, may have been produced using synthetic solvents or processing aids, unless specifically annotated otherwise.



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Solvents in handling

§ 205.270(c) The handler of an organic handling operation **must not** use in or on ***agricultural products intended to be sold, labeled, or represented as “100 percent organic,” “organic,” or “made with organic ...,”*** or in or on any ***ingredients labeled as organic:***

(2) A volatile synthetic solvent or other synthetic processing aid not allowed under §205.605: *Except, That, nonorganic ingredients in products labeled “made with organic (specified ingredients or food group(s))”* are not subject to this requirement



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Solvents for Non-Organic Substances

- Solvents may be used in various ways in the manufacture of a substance, e.g., as reaction media, as an extractant, for purification or crystallization, concentration standardization, etc.
- NOSB may consider the use of any synthetic substance, including solvents, as part of its review of petitioned materials
- Volatile synthetic solvents are prohibited for handling **organic** products under 205.270, unless listed on 205.605.
- According to the draft guidance, the use of a synthetic solvent in the process does not necessarily result in a substance being classified as synthetic



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Nonorganic Substances – What separation techniques can result in the substance being classified as “nonsynthetic”?

Nonsynthetic substances meet the following criteria:

1. At the end of the extraction process, the substance has not been transformed into a different substance via chemical change.

Example:

Citric Acid – produced by microbial fermentation of a carbohydrate substance, isolated and purified through various techniques, but is not transformed into a different substance, classified as nonsynthetic on § 205.605(a)



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Nonorganic Substances – What separation techniques can result in the substance being classified as “nonsynthetic”?

2. The substance has not been isolated in a form that does not occur in nature

Examples:

Citric acid – Natural when produced by microbial fermentation of carbohydrate substances, classified as nonsynthetic on § 205.605(a)

Potassium Citrate – A potassium salt of nonsynthetic citric acid, classified as synthetic on § 205.605(b)



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Nonorganic Substances – What separation techniques can result in the substance being classified as “nonsynthetic”?

3. Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product

Example:

Pyrethrins used as crop input for pest control

Extracted from flowers with a synthetic solvent, solvent is removed prior to ingredient formulation (nonsynthetic)



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Nonorganic Substances – What separation techniques can result in the substance being classified as “nonsynthetic”? (cont.)

4. When used in crop or livestock production, substances used for formulation are nonsynthetic or included on the appropriate section of the National List; or

Example:

Natural botanical pesticides – Inerts must be natural or on National List, § 205.601(m)



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Nonorganic Substances Used in Handling – Classification as Nonsynthetic

5. When used for handling or processing, nonorganic substances used for formulation are provided for in the NOSB's review of the substance or are included in the substance's annotation on the National List.

NOP has requested for NOSB to clarify “other ingredients” allowed in handling inputs, which is on the workplan for the Handling Subcommittee.



Eligibility for Organic Certification

- NOSB had previously recommended other definitions of chemical change, to prevent processed agricultural products methods from being classified as “synthetic” (May 24, 2010 NOSB Recommendation)
- If a substance contains or is made up of agricultural ingredients, and can meet the USDA NOP organic production, handling, processing and labeling standards, it may be eligible to be certified under the NOP regulations
- The classification guidance is not intended to determine the eligibility of a substance for organic certification



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NOP 5033-1 Synthetic / Nonsynthetic Decision Tree

- Is the substance manufactured, produced, or extracted from a natural source?
- Does the substance undergo a chemical change?
- Is the substance created by a natural occurring biological process, such as composting, fermentation, or enzymatic digestion; or by heating or burning biological matter?



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NOP 5033-1 Synthetic / Nonsynthetic Decision Tree

- Is the substance created by a natural occurring biological process, such as composting, fermentation, or enzymatic processes; or by heating or burning biological matter?
- Is the substance combined with other materials to produce a commercial product?
- Are all of the components present in the generic substance nonsynthetic?



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Table of Example Classifications with Explanations

Substance	Classification	Explanation
Ash (burned wood)	Nonsynthetic	Substance is created by burning biological matter.
Calcium carbonate (limestone)	Nonsynthetic	Substance is produced from a natural source (mined mineral) and does not undergo chemical change.
Calcium oxide (quicklime)	Synthetic	Substance is produced from a natural source (mined mineral), but undergoes chemical change caused by heating the mineral.
Citric acid	Nonsynthetic	Substance is created from a naturally occurring biological process (microbial fermentation of carbohydrate substances).
Gibberellic acid	Nonsynthetic	Substance is extracted from a natural source without further chemical change
Newspaper	Synthetic	Substance is manufactured via a chemical process.
Raw manure	Nonsynthetic	Substance is from a natural source and used without further processing.



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NOP 5033-2 Agricultural/Nonagricultural Decision Tree

- Is the substance derived from a plant, animal, microorganism, or mineral?
- Is the substance a microorganism (e.g., yeast, bacteria, fungi) or an enzyme; or is the substance isolated from the product of a microorganism or an enzyme?
- Has the substance been processed to the extent that its chemical structure has been changed?



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NOP 5033-2 Agricultural/Nonagricultural Decision Tree (continued)

- Is the chemical change a result of naturally occurring biological processes such as fermentation or use of enzymes; or a result of mechanical/physical processes?
- Have any other ingredients (e.g., additives, carriers, preservatives) been added to the substance that remain in the final product?
- Are the ingredients consistent with sections 205.605 or 205.606?



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Table of Example Classifications with Explanations

Substance	Classification	Explanation
Colors derived from agricultural products	Agricultural	Substances are derived from plants or animals and have not been chemically changed
Bentonite	Nonagricultural	Substance is a mineral (not from a plant or animal source)
Citric acid	Nonagricultural	Substance is created from a naturally occurring biological process (microbial fermentation of carbohydrate substances)
Diatomaceous earth	Nonagricultural	Derived from a mineral
Enzymes	Nonagricultural	Derived from a plant, animal, or microorganism



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Timeline – Next Steps

- NOP to publish draft guidance (expect to put in clearance in summer of 2012)
- Publication will coincide with draft guidance NOP 5034, Permitted Substances for Organic Crop Production
- Public comment period (min. 60 days)
- NOP to review comments, amend text, and publish final guidance



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Thank you!

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