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Guidance **Classification of Materials**

1. Purpose

This guidance describes the procedure used to classify materials as synthetic or nonsynthetic, and as agricultural or nonagricultural, under the USDA organic regulations.

2. Scope

This guidance applies to all National Organic Program (NOP) certifying agents, certified operations, material evaluation programs, and other organic industry stakeholders.

3. Background

3.1 The National List of Allowed and Prohibited Substances

The Organic Foods Production Act of 1990 (OFPA) authorizes the USDA to establish the National List of Allowed and Prohibited Substances (National List). The National List is implemented in the USDA organic regulations at 7 CFR 205.600-607. Because industry typically uses the word "material" to describe "substance," for the purposes of this guidance, "substance" and "material" are synonymous and interchangeable. Under the OFPA, the National List must contain an itemization of each synthetic substance that is permitted and each natural substance that is prohibited for organic production.

For organic crop and livestock production, nonsynthetic (natural) materials are allowed unless specifically prohibited. Synthetic materials are prohibited unless they appear on the National List at section 205.601 for crop production or section 205.603 for livestock production.

For handling, the National List includes nonorganic substances that may be used in or on processed products. Section 205.605 lists the nonagricultural substances allowed as ingredients in or on processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))." Nonagricultural substances may be classified as either nonsynthetic at paragraph (a) or synthetic at paragraph (b). Section 205.606 of the National List includes the nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic." Substances included in section 205.606 may be used in organic products only when the product is not commercially available in organic form.

Due to this construction of the National List, the NOP, the National Organic Standards Board (NOSB), accredited certifying agents, and material evaluation programs conduct substance classifications to determine (1) whether a substance is allowed or prohibited in organic production, (2) whether the substance needs to be considered for the National List, and (3) where on the National List the substance should be placed.

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For the majority of materials, classification as synthetic or nonsynthetic, or as agricultural or nonagricultural, is straightforward; however, other materials are more complicated to classify. Industry interpretation may be inconsistent. Some substances have been classified as synthetic due to chemical changes that occur during manufacturing, while others substances have been classified as synthetic due to addition of small amounts of synthetic ingredients.

For livestock production, the classification of a substance used in livestock feed as agricultural or nonagricultural is important for determining whether the feed ingredient must be sourced in a certified organic form. For example, agricultural feed ingredients that must be certified organic include all feed and forage crops, and additives such as molasses, rice hulls, and vegetable oils.

For the handling or processing of organic agricultural products, the National List includes a list of agricultural and nonagricultural substances that are allowed in the handling of organic agricultural products. Nonagricultural substances are differentiated as either nonsynthetic (natural) or synthetic. Thus, the proper determination of a substance as agricultural or nonagricultural, or as synthetic or natural, is important for determining its permitted uses.

This guidance further describes and expands on the previous recommendations and existing practices of the National Organic Standards Board (NOSB) on the classification of materials. This guidance also describes a method for the NOSB, accredited certifying agents, and material evaluation programs to use to classify materials.

NOP has not amended the regulations, but has provided explanatory definitions within the guidance document to be used when appropriate. Some definitions that were provided in the April 2011 NOSB Formal Recommendation on Classification of Materials have been updated or amended within this guidance for clarity.

4. Policy

4.1 Inputs for Organic Crop Production

The classification decision tree, NOP 5033-1 provides a method to classify input materials for organic crop production as nonsynthetic or synthetic. Synthetic substances allowed for use in organic crop production are included on the National List at section 205.601. Natural substances prohibited for use in organic crop production are included on the National List at section 205.602.

An illustrative list of allowed natural and synthetic materials for organic crop production is available at NOP 5034-1, Materials for Organic Crop Production. For more information on the use of this list, refer to NOP 5034.

4.2 Inputs for Organic Livestock Production

The classification decision tree, NOP 5033-1 provides a method to classify inputs for organic livestock production as nonsynthetic or synthetic. Synthetic substances allowed for use in organic livestock production are included on the National List at section 205.603. Natural substances prohibited for use in organic livestock production are included on the National List at section 205.604.

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Agricultural livestock feed ingredients must be certified organic (§ 205.237(a)). Livestock feed ingredients should be first classified as agricultural or nonagricultural according to the classification decision tree, NOP 5033-2, to determine whether they are required to be certified organic. Substances that are determined to be nonagricultural may be further classified according to NOP 5033-1 to determine whether they are synthetic or nonsynthetic.

4.3 Inputs for Organic Handling and Processing

Petitioned ingredients and processing aids for handling and processing are classified by the NOSB to determine placement of substances on the National List, sections 205.605-205.606.

The classification decision tree, NOP 5033-2, provides a method to classify substances as agricultural or nonagricultural. The NOSB may further classify nonagricultural substances as nonsynthetic or synthetic to determine placement on section 205.605(a) or 205.605(b), respectively.

4.4 Eligibility for Organic Certification

This guidance does not determine the eligibility of a substance for organic certification.

If a substance contains or is made up of agricultural ingredients and can meet the USDA organic production, handling, processing and labeling standards, it may be eligible to be certified under the USDA organic regulations.

4.5 Materials Derived from Agricultural Products

Materials derived from agricultural products may be agricultural or nonagricultural, depending on the manufacturing and processing methods used.

The decision tree, NOP 5033-1, includes questions to differentiate between chemical reactions caused by naturally occurring biological processes, such as composting, fermentation, use of enzymes, and by heating or burning biological matter (e.g., cooking, baking, etc.).

Agricultural materials which are chemically changed due to allowed agricultural processing methods (e.g., cooking, baking, etc.) do not result in classification of the processed agricultural product as synthetic.

4.6 Extraction of Nonorganic Materials

Some materials are produced using manufacturing processes that involve separation techniques, such as the steam distillation of oil from plant leaves. Separation and extraction methods may include, but are not limited to, distillation, solvent extraction, acid-base extraction, and physical or mechanical methods (e.g., filtration, crushing, centrifugation, or gravity separation).

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For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets all of the following criteria:

- At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
- The material has not been altered into a form that does not occur in nature; and
- 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.

4.7 Products of Naturally Occurring Biological Processes

Products of naturally occurring biological processes, such as fermentation and composting, are statutorily considered natural and nonsynthetic. Examples of nonsynthetic materials produced from naturally occurring biological processes include vinegar, citric acid, compost, gibberellic acid, and spinosad. Additional examples are provided in Table 1 of NOP 5033-1.

4.8 Burning or Combustion

Heating or burning of biological matter (e.g., plant or animal material) is considered a natural process that does not result in classification of ash as synthetic. For example, ash from manure burning is classified as a prohibited nonsynthetic substance at section 205.602 of the National List. The use of other types of ash must comply with the soil fertility and crop nutrient management practice standard at section 205.203 of the USDA organic regulations.

Heating or burning of non-biological matter (e.g., minerals) to cause a chemical reaction has resulted in classification of the substance as synthetic. For example, limestone (calcium carbonate, CaCO₃) heated to release carbon dioxide and produce quicklime (calcium oxide, CaO) is classified as a synthetic process.

For purposes of classification of materials, pyrolysis (i.e., high temperature decomposition of substances in the absence of oxygen) may be treated as equivalent to burning or combustion.

5. Procedure

5.1 Inputs for Organic Crop Production

The decision tree in NOP 5033-1 (synthetic or nonsynthetic) classifies input materials for use in organic crop production.

5.2 Inputs for Organic Livestock Production

The decision tree NOP 5033-1 (synthetic or nonsynthetic) classifies input materials used for organic livestock production.

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For animal feed ingredients, substances should be classified first as agricultural or nonagricultural according to decision tree NOP 5033-2. Feed ingredients classified as agricultural do not need to be further classified since they are required to be used in organic form (7 CFR 205.237(a)).

5.3 **Inputs for Organic Handling and Processing**

The decision trees of NOP 5033-1 and NOP 5033-2 classify input materials used for organic handling or processing. For handling materials, classification as nonagricultural or agricultural according to NOP 5033-2, NOSB may first to determine permitted uses or placement on section 205.605 or 205.606. NOSB may further classify nonagricultural substances as nonsynthetic or synthetic for determining placement on section 205.605(a) or 205.605(b), respectively.

When used in products labeled "organic," materials classified as agricultural must be certified organic, except that, according to the provisions in section 205.301(b), agricultural ingredients included at section 205.606 may be used if those ingredients are not commercially available as organic.

Materials classified as agricultural may be used in products labeled "made with organic (specified ingredients or food group(s))" according to the provisions in section 205.301(c).

Examples of classification decisions are provided in each decision tree.

National List Sections	Type of Use	Classification Determination	Decision Tree
205.601/205.602	Crop Production	Synthetic / Nonsynthetic	NOP 5033-1
205.603/205.604	Livestock Production	Synthetic / Nonsynthetic	NOP 5033-1
205.603/205.604	Livestock Feed Ingredients	Agricultural / Nonagricultural	NOP 5033-2
205.605/205.606	Handling	Agricultural / Nonagricultural	NOP 5033-2
205.605(a)/205.605(b)	Handling – Nonagricultural	Nonsynthetic / Synthetic	NOP 5033-1

6. References

6.1 USDA Organic Regulations (7 C.F.R. Part 205)

§ 205.2 Terms defined.

Allowed synthetic. A substance that is included on the National List of synthetic substances allowed for use in organic production or handling.

National List. A list of allowed and prohibited substances as provided for in the Act.

Nonsynthetic (natural). A substance that is derived from mineral, plant, or animal matter and does not undergo a synthetic process as defined in section 6502(21) of the Act (7 U.S.C. 6502(21)). For the purposes of this part, nonsynthetic is used as a synonym for natural as the term is used in the Act.

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6.2 Organic Foods Productions Act of 1990 (as amended)

SEC. 2103 [7 U.S.C. 6502] DEFINITIONS.

(21) SYNTHETIC.—The term "synthetic" means a substances that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

6.3 NOP Program Handbook: Guidance and Instructions for Accredited Certifying Agents and Certified Operations

NOP 5034: Materials for Organic Crop Production (Guidance) NOP 5034-1: Materials for Organic Crop Production (Guidance)

NOP 5034-2: Appendix of Prohibited Materials for Organic Crop Production (Guidance)

NOP 3012: Material Review - Interim Instruction, August 30, 2016

6.4 NOSB Recommendations

NOSB Formal Recommendation, Classification of Materials, April 29, 2011

NOSB Formal Recommendation, Classification of Materials, May 24, 2010

NOSB Formal Recommendation, Classification of Materials, November 5, 2009

NOSB Formal Recommendation, NOSB guidance for the review of synthetic and non-synthetic substances, August 27, 2005

6.5 Other

NOP Memorandum to the National Organic Standards Board, Request for Clarification of "Other Ingredients" in Processed Organic Products, November 23, 2011;

 $\frac{https://www.ams.usda.gov/sites/default/files/media/NOSB\%20Memo\%20Request\%20for\%20Clarification\%20of\%20Other\%20Ingredients.pdf.$

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