National Organic Standards Board
Handling Committee
Recommendations Relative to "Agricultural" and "Nonagricultural" Substances
Final – July 14, 2005

Introduction:

In the interest of clarity and consistency, the National Organic Standards Board (NOSB) Handling Committee (HC) recommends to the NOSB a modification to the definition of "nonagricultural substances." The HC also recommends 2 guidance documents 1.) a "Decision Tree" for use in deciding upon the classification of substances as "agricultural" or "nonagricultural." 2.) A document defining agriculture as it applies to agricultural products.

Background:

In regards to determination and classification of substances as "agricultural" or "nonagricultural," the definitions found in the National Organic Program (NOP) Final Rule can be vague and sometimes even conflicting. Also, the rule does not provide a definition for agriculture. The net result of this is inconsistent application, and possible misclassification of substances as "agricultural" or "nonagricultural."

The distinction between "agricultural" and "nonagricultural" originated with the NOSB. The Organic Foods Production Act (OFPA) was approved by Congress as part of the 1990 Farm Bill. USDA published the first Proposed Rule in 1997. Between OFPA becoming law and the first proposed rule being published, the NOSB was organized, functioning and by 1994 already developing the first proposed National List. It was at that time that the NOSB introduced the distinction between "agricultural products" and "nonagricultural substances."

The NOSB adopted this distinction based on its understanding of OFPA requirements. Specifically that inclusion on the National List was required for any substance that "is used in handling and is non-synthetic but is not organically produced."[1] The NOSB did not believe it was necessary to send products for a Technical Advisory Panel (TAP) review that were merely non-organic agricultural products. Therefore, the NOSB recommended that non-organic agricultural products appear on the National List as a general category, rather than requiring TAP reviews for each specific agricultural product. NOSB also recommended that non-synthetic ingredients that were non-agricultural did not need to appear on the National List,[2] although this was later refuted as explained by NOP in the preamble to the second proposed rule of March 2000.[3]

At its meeting in Washington, DC, January 30-February 2, 1994, the NOSB voted unanimously to submit a list of materials for TAP review, but purposely excluded from the list "the category of non-synthetic, non-organic agricultural products."[4] The USDA

[1] 7 US Code § 6517(c)(1)(B)(iii)
[2] NOSB Final Rec. Add. No. 10 General Food Labeling Standards, Oct. 31, 1995. p. 54 Green Book
[3] NOP proposed rule, March 13 2000, p. 13588
[4] NOSB Full Board Meeting Minutes, Washington, DC, Jan. 30-Feb. 2, 1994, p. 10.

ratified that decision in 1997 in the First Proposed Rule. In the Preamble, the Department pointed out that it was "in concurrence with the NOSB."[5]

Accordingly, in that First Proposed Rule, the USDA set up two separate sections for ingredients in processed foods under the National List: Section 205.26 to list "nonagricultural substances" and Section 205.27 for nonorganically produced agricultural products. Section 205.27 provided that in general, non-organically produced agricultural product are allowed in products labeled "organic" or "made with organic."[6] These are the sections currently numbered as 205.605 and 205.606, respectively, in the Final Rule.

The root of the "agricultural" versus "nonagricultural" distinction traces directly back to the recommendations of the NOSB. OFPA's definition of "organically produced"[7] specifically references agricultural products; the NOP Final Rule, in the definition section, defines organic specifically as "an agricultural product produced in accordance with [OFPA]." In the history of OFPA, and in the current NOP regulations, the working thought has been substances that can be organic must be agricultural.

The definition of an "agricultural product" in OFPA and in the NOP rule is consistent. 7 CFR Part 205 section 205.2 *Terms Defined*: "**Agricultural product** – any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock, that is marketed in the United States for human or livestock consumption."

However, OFPA did not define "nonagricultural;" therefore creating confusion regarding the definition of agricultural. The NOP Rule defined "nonagricultural substances" in the first National List that appeared in 1994. The definition in section 7 CFR Part 205, section 205.2 *Terms Defined*: "**Nonagricultural substance** – A substance that is not a product of agriculture, such as a mineral or bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate or fraction."

These definitions in the Final Rule are inconsistent, and do not provide clear guidelines on how to evaluate a substance as "agricultural" verses "nonagricultural." The substance "gums" is subject to the confusion caused by the inconsistent definitions. Gums, by the current definition of nonagricultural in 205.2, should not be considered agricultural or organic (since they are listed as a specific example of a nonagricultural item). Yet water extracted gums are listed in 205.606 as agricultural items. Compounding the matter, gums are available as certified organic products. This by definition means they must be agricultural.

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[5] Preamble to First Proposed Rule, 62 Fed.Reg. 65895 (Dec. 16, 1997), pp 65895
[6] [Federal Register: December 16, 1997 (Volume 62, Number 241)], [Proposed Rules], [Page 65849-65898]
[7] (14) ORGANICALLY PRODUCED.—The term ''organically produced'' means an agricultural product that is produced and handled in accordance with this title from Title XXI of the Food, Agriculture, Conservation, and Trade Act of 1990

Inconsistencies have continued because of the conflicts with the current definition of "nonagricultural" substances. Many processed agricultural products have been extracted, isolated, or fractioned during processing to a point where the product no longer resembles the starting agricultural material. Examples of organic products in potential conflict with the definition include, but are not limited to: whey protein concentrate, milk protein concentrate, evaporated cane juice, and maltodextrin. All of these ingredients are "extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate or fraction"[8] and by definition would not be agricultural.

Clarifying the existing definition of "nonagricultural substance," defining agriculture as it applies to agricultural products, and incorporating a tool such as a "Decision Tree," would assist in resolving the confusion and provide guidance for current and ongoing review of substances.

Discussion:

The HC proposed and discussed a) two potential Rule changes for clarifying the definition of "nonagricultural substances" and b) guidance for reviewing substances.

To clarify the issue surrounding the definition of "nonagricultural substance," the HC first discussed the possibility of recommending the complete removal of the definition currently found in 7 CFR section 205.2 *Terms Defined* for "nonagricultural substance." The thinking was that OFPA did not provide a definition for a "nonagricultural substance" and with a guidance document supporting a process for determining what is an agricultural product, then by default you identify a nonagricultural substance.
Then the HC also discussed the following modification to the definition of "nonagricultural substance:"

Nonagricultural substance: A substance that is not a product of agriculture, such as a mineral or a bacterial culture. ~~that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.~~

The Committee preferred the second option because it still retains a definition for "nonagricultural substance," a term that is used throughout the Rule.

In addition, the HC felt that it would be helpful to provide guidance for defining agriculture to be used in determining the substance's status as "agricultural" or "nonagricultural." There was wide support for the use of a "Decision Tree" to assist in providing guidance. The Decision Tree used by the HC as a model was initially proposed to the NOSB in October 2004, via public comment, by Oregon Tilth (a USDA accredited certification agency). The HC acknowledges it as a working document that may need modification prior to acceptance.

[8] 7 CFR Part 205, section 205.2 *Terms Defined*: "**nonagricultural substance"**

Recommendations:

There are three recommendations from the HC:

1. A guidance document for defining agriculture as it applies to agricultural products.
2. The re-definition of "nonagricultural substance"
3. Assistance in defining a "nonagricultural substance" by use of the Decision Tree. The goal of these recommendations are for a more uniform, transparent system for decision making related to "agricultural" or "nonagricultural" determinations.

Recommendation #1:

The HC Recommends the adoption of the attached guidance document for defining agriculture as it applies to agricultural products.

Recommendation #2:

The HC recommends a Rule change for the current definition of "nonagricultural substance" as listed in 7 CFR section 205.2 *Terms Defined.* HC recommends the definition be modified to read:

Nonagricultural substance: A substance that is not a product of agriculture, such as a mineral or a bacterial culture~~. that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.~~

Recommendation #3:

The HC recommends the adoption of the attached Decision Tree as guidance in determining a substance's "agricultural" or "nonagricultural" status. This is a practical solution which could work with both the current or modified definition of "nonagricultural substance" and the guidance document referred to in recommendation #1. The decision tree should be used in conjunction with NOSB clarification regarding the definitions of "synthetic" and "nonsynthetic." (in development)

Conclusion:

The organic industry is an innovative industry with continued opportunities for growth and change. The modification of the definition of "nonagricultural substance" and providing guidance for what is agriculture will provide greater consistency and clarity in application and will allow the Final Rule to accurately serve this growing and innovative industry, without compromising the effectiveness of the definition.

The "Decision Tree" will be used as a tool to help strengthen the consistency of the National Organic Standards in regards to "nonagricultural" substances. It will provide a basis for certifying agencies, certified entities, and the NOSB to verify a substance's "agricultural" or "nonagricultural" status.

<u>Committee vote:</u>

Yes -- 5

No – 0

Abstentions – 0

Absent - 0

Proposed Guidance Document Defining Agriculture
as it applies to Agricultural Products.

Agricultural products are those that are managed by humans and derived from living organisms that are capable of photosynthesis including plants (Kingdom Plantae), cyanobacteria (Kingdom Monera) and the multi-cellular algae (Kingdom Protitsa) or derive their energy by absorption including animals (Kingdom Animalia) and the edible, fungi that produce multi-cellular fruiting bodies (ascocarp and basidiocarp) commonly referred to as mushrooms (Kingdom Fungi).

Managed by humans -- the intentional act of gathering, producing, raising, or growing, domestically or in designated wild-harvest areas, by persons for human or livestock consumption.

Background and Justification on the development of the types of organisms that shall be considered agricultural

Agriculture can be broadly defined as the science of using crops and animals to transform sunlight energy into products that can be stored and used by humans. The definition implies that there is some level of management imposed by humans in the practice of agriculture. This is consistent with the NOP standards which describe those practices which shall be followed in order to label an agricultural product organic. Central to this definition is the ability of humans to utilize products that have been generated from the direct or indirect transformation of energy from the sun. Products that directly transform energy from the sun, use water and carbon dioxide from the environment and can form carbohydrates and oxygen through the process known as photosynthesis. In this process light energy is converted to chemical energy. Types of organisms that can carry out photosynthesis include all photosynthetic eukaryotes which include all vascular plants (Kingdom Plantae), green algae (Kingdom Protista), euglenoid algae (Kingdom Protista), and prokaryotic cyanobacteria (Kingdom Monera).

Members of the plant kingdom are commonly considered agricultural if they are edible (grains, vegetables, fruits, coffee, tea), used for fiber (cotton, trees species, rice, sisal), have medicinal properties (herbs, Echinaceae, St. John Wort) or have special properties that can be used in industry (rubber, indigo). Additionally, members of the Kingdoms Protista and Monera that are capable of photosynthesis have been managed by humans for food, medicinal and industrial products. In the Kingdom Monera only the cyanobacteria, commonly known as blue-green algae could be considered agricultural.

Members of the Kingdom Protista that are capable of photosynthesis include the eukaryotic algae. In both fresh and salt water systems algae form the nutritional basis for all the animals within the ecosystem. Some species have been commercially cultured or naturally harvested to provide protein, vitamin and minerals for humans. The Kingdom Protista is comprised on six divisions, three which consist almost entirely of unicellular

organisms and three include groups that are multi-cellular. The red and brown algae are multi-cellular organisms that have been utilized by humans. *Porphyra* (nori) is an example of a red algae. Another example of an edible sea weed is kelp which is also used to produce iodine and fertilizer. Alginates, which are a group of substances derived from kelps are widely used as thickening agents and colloid stabilizers in the food, textile, cosmetic, pharmaceutical, paper and welding industries. One of the most useful direct commercial applications of alga is the preparation of agar which is made from a material extracted from the cell walls. Agar is a component of capsules for vitamins and other drugs, anti-drying agent in bakery goods, in the preparation of rapid-setting jellies and desserts and as a temporary preservative for meat and fish in tropical regions. A similar algal colloid called carrageenan is used for the stabilization of emulsions in dairy products. Currently, Kelp is listed on 205.606 and the by-products of algae (alginates) are listed on 205.605 as an allowed synthetic. The NOSB considers members of the Kingdom Protista that are commercially produced or wild harvested as agricultural.

There are a number of non-photosynthetic organisms that are considered agricultural. These organisms are members of the Kingdoms Animalia and Fungi. Members of the Kingdom Animalia that are utilized in agriculture typically derive their energy by consuming other organisms such as plants which produce their own energy via photosynthesis. Their nutrition is primarily derived from ingesting and digesting within an internal cavity, however some members derive food from absorption and lack and internal digestive cavity. Members of the Kingdom Animalia are used in agriculture primarily for food, medicinal, industrial and fiber products.

Members of the Kingdom Fungi are nonmotile filamentous eukaryotes that lack plastids and photosynthetic pigments and absorb their nutrients from either dead or living organisms. Their primary role in the ecosystem is decomposition. A number of fungi have food, medicinal and industrial uses. The edible fungi are sometimes referred to as higher fungi because their edible portion is actually a multi-cellular fruiting body that is commonly called a 'mushroom'. These edible portions or fruiting bodies arise from the mycelium. Some of the edible fungi or mushrooms can be cultivated while others are only harvested in the wild. Edible, multi-cellular mushrooms are considered agricultural.

There are other simple fungi (form no fruiting bodies that arise from mycelium) that are utilized by humans in food, industry and medicinally include yeasts, *Aspergillus and Penicillium.* The yeasts are distinguished from the mycellium forming fungi. They are predominantly unicellular and they reproduce asexually by fission or by the pinching off of small buds rather than spore formation. Yeasts do not produce mycellium or fruiting bodies they are unicellular and this is a way to biologically distinguish them from what most people consider the edible fungi. The commercial production of yeasts, *Aspergillus* and *Penicillium* is usually done by culturing the microorganism in a sterile, closed container system which contains a nutrient broth containing a sugar source, essential mineral and vitamins and a source of amino nitrogen. These containers are maintained at specific temperatures, pH is controlled and sterile air is pumped in to maintain aerobic conditions. Yeasts have been considered nonagricultural and listed in section 205.605 along with other non-synthetics such as dairy cultures. Fungi that do not produce true fruiting bodies as the edible fungi (mushrooms) are not considered agricultural.

Criteria for Determining Agricultural vs. Non-agricultural Substances for Use in Organic Processed Products

1. Is the substance in question derived from an agricultural product (plant, animal, or cyanobacteria, multicellular algae or fungi that produce multi-cellular fruiting bodies)?

no → Non-agricultural

yes ↓

2. Is the substance a metabolic product isolated from a microbial culture?

yes → Non-agricultural product

no ↓

3. Has the substance been processed to the extent that its chemical structure has been changed ("chemically changed")* (decomposed, re-arranged or added to) from its naturally occurring state?

no → Agricultural product

yes ↓

4. Is the change in chemical structure a result of a naturally occurring biological process such as fermentation or enzymatic hydrolysis, or a result of a mechanical/physical process described under 205.270(a)?

no → Non-agricultural product

yes ↓

5. Agricultural product

* A "chemical change" occurs when one or more atoms are removed or added to a molecule. (see NOSB clarification of definition of "synthetic")