



406 S. Pennsylvania Ave • Centre Hall, PA 16828
(814) 364-1344 • fax (814) 364-4431
info@paorganic.org www.paorganic.org

Public Comments to the National Organic Standards Board
October 17, 2006

Agricultural and Nonagricultural Substances

Thank you for the opportunity to comment on the NOSB's Recommendations relative to "Agricultural" and "Nonagricultural" Substances for National List Consideration. Pennsylvania Certified Organic appreciates the NOSB's continued efforts to provide clarity and consistency regarding this issue.

Summary

We understand and support the need for correction to the definition of the term "nonagricultural substance" to be consistent with items currently on the National List, and support the development of a decision tree that aids NOSB and certifiers in making this determination in future.

We question the need to omit mention of bacterial cultures in the current definition of nonagricultural substances. PCO does **not** support the NOSB recommendation to change the listing of "dairy cultures" and "yeast" from 205.605 (a) – Nonagricultural (nonorganic) substances to 205.606 – Nonorganic agricultural substances allowed at this time.

This proposed change has many un-addressed consequences, including impact on dairy processors, impact on many microorganism products also on the national list at 205.605, impact on use of microorganisms fed to animals, possible impact on organic mushroom standards. It also does not follow required OFPA procedures or NOSB policies for amending the National List. Most problematically for certifiers, it would require organic forms of microorganisms used in food when no standards or guidelines exist for organic certification of microorganisms.

This recommendation should be amended to drop any changes in the National List pending receipt of petitions and TAP reviews, and public input on impacts to various sectors.

1. Additional Consequences Have Not Been Considered

Dairy cultures are microorganism grown to exact specifications, in a sterile laboratory setting. If these are considered agricultural, it means that handlers are required to use organic forms when available. This is an extra burden, considering that no explicit standards have been recommended

and products will inconsistently be marketed as "organic". Processors will be expected to document the availability of a product that is produced according to various interpretations of NOP standards. Yogurt and cheese makers will be seriously impacted by this sudden change, and should be consulted as to the impact on their industry. Other sectors utilizing microorganisms, including wine and brewing, and baking industries have not been consulted or notified of this potentially large change in the requirements.

Many species of bacteria and other microorganisms are routinely fed to livestock as "direct fed microorganisms". These serve the purpose of adding beneficial flora to the rumen and aid in digestion. If microorganism as a whole category are shifted to the 205.606 as "agricultural" ingredients, than it would seem that microorganisms fed to animals must be "organic" also, as an agriculture product in a component of a total feed ration (205.237). Yet there are no standards, and no guidance to certifiers as to what type of bacteria, method of manufacture, and ingredients permitted as additives are candidates for organic status.

Mushrooms are currently considered to be an agricultural commodity by the USDA, and meet the definition of "agricultural product." Yet they are fungi, not plants yet this has not warranted classifying them as "livestock" for the purposes of NOP standards. If yeast is considered livestock, does this impact standards for mushroom culture also? Livestock standards are definitely not appropriate for mushrooms, which are grown as food crops on compost and agricultural products. If mushrooms are livestock, then all materials permitted in crop production are not sanctioned for mushrooms, and must be petitioned and amended on to the livestock list.

2. Consistency is Needed on the National List

This proposal is inconsistent with NOSB recommendation of 2003, and recent NOP rule amendment of Sept. 11, 2006 that adds "microorganisms" to the National List as a nonsynthetic, nonagricultural substance. Does the Board intend that yeast and dairy cultures be moved and that "microorganisms" stay on 205.605? This will cause great confusion if so.

The proposal does also states that enzymes and vitamins that are products of microorganisms should be considered agricultural also, although it fails to recommend this change to the list also. Note that there have been no petitions or other requests to change the status of these substances. In addition there are many other substances derived from microorganism currently listed at 205.606, including citric acid, lactic acid, enzymes, glucono delta lactone, L-malic acid, and tartaric acid. These have all been subject of previous review and are in wide use in the organic processing industry. If yeast and dairy cultures are to be changed, then there should be similar consideration and notice provided for any changes applied to all of those ingredients as well.

3. Existing Standards are not Adequate for Organic Microorganisms

Microorganisms do not fit into the regulatory categories provided by the NOP rule as crop, livestock, or wild crafting. If microorganisms are considered agricultural products, as opposed to substances used as ingredients in products, this means they can be certified. If so, what are the requirements for initial organic cultures or "seed"? Which materials are permitted? How long on the organic substrate must a non-organic inoculum be cultured before it is considered "organic"?

The committees have recommended that fungi and bacteria be considered "livestock" according to the NOP regulations. In this case, how should livestock rules be applied? Do microorganisms require 100% organic "feed"? Where do the "breeding stock" come from, must the source organisms be "organic from last third of gestation"? Must microbe growers provide "access to the outdoors, including shade, shelter and exercise areas"? Which parts of the livestock rules apply and which don't? Can substances approved as ingredients in human food be used for "raising" organic microorganisms? (Currently, only substances in 205.603 are permitted in livestock production) Without direct guidance or regulations for production of "organic" yeast, bacteria, or other fungi, there will be products marketed under different systems of production, that are not adhering to uniform standards, causing inequity in the market place.

The sterile conditions and exacting specifications required for bacterial culture production have not been reviewed or considered by the NOSB in this proposal. Bacteria have specific media requirements, including nutrient level, pH buffers, stabilizers, etc. These require much more study to evaluate if organic production systems are even remotely possible, much less commercially available. Certifiers need specific guidance if they are to certify these products in a consistent manner.

4. This change is not a technical correction, and requires procedures as mandated by OFPA

The current recommendation proposed to move "Dairy cultures" and "yeast" to 205.606 as a "technical correction." These two substances were reviewed by NOSB in 1995, recommended for the National List as a nonsynthetic substance, and incorporated into the final NOP rule at 205.605(a) of December 2000. There has been no petition to remove or change the status of these substances. The NOSB did not recommend removing these substances as part of the mandated sunset review. There has been no Technical Advisory Panel review of these substances and re-evaluation to warrant a change in status. NOSB must follow the procedures in OFPA:

7 USC 6518(l)

"In establishing the proposed National List or proposed amendments to the National List, the Board **shall** – [emphasis added]

- 1) review available information from the Environmental Protection Agency, the National Institute of Environmental Health Studies, and such other sources as appropriate, concerning the potential for adverse human and environmental effects of substances considered for inclusion in the proposed National List; [and]
- 3) submit to the Secretary, along with the proposed National List or any proposed amendments to such list, the results of the Board's evaluation and the evaluation of the technical advisory panel of all substances considered for inclusion in the National List."

The NOSB has adopted procedures for considering changes to the National List, and included this in the Board Policy Manual. These state: "formalized procedures to facilitate the NOSB's role in reviewing and approving materials for the National List include:

- New petition procedures.
- Formalized Decision Criteria Forms from the NOSB for providing feedback to NOP on their recommended decisions.
- Sunsetting of materials every five years.

- New Technical Advisory Panel (TAP) contractor training for TAP contractors to facilitate quality TAP reviews to provide essential information.”¹

The Board has been very careful to follow this procedure, and has not made other changes requested without petitions or TAP reviews. The Board declined, for example, to modify annotations during the sunset process, claiming that even changing a restriction requires a petition. If a major change in status of a substance is deemed necessary, then these careful procedures for review and documentation should be applied.

4. Other Organic Regulatory Systems Do Not Consider Microorganisms to be Agricultural Ingredients, or Require Organic Sources

The US will be differing with international laws and regulation if it declares microorganisms are agricultural. It will create an unfair situation if US producers must source “organic” microorganisms, while imported products sold as organic in the US are not required to do this. Will foreign agencies accredited by the USDA be held to the same standard for documenting the attempts at sourcing organic microorganism derived products? The EU (EEC 2092-91) and FAO/WHO Codex Alimentarius standards consider microorganisms to be nonagricultural and permitted, provided not from genetically engineered sources. IFOAM, a non-governmental organization has published standards that state that microorganisms be produced on organic substrate when possible, however they offer no specific standards for certification of microbes. (See Appendix for International standards.)

Conclusion:

At this time we are not convinced that microbial or bacterial substances and their derivatives should be classed as agricultural. We are not aware of any country that considers them to be an “agricultural commodity”, as described in the definition of an agricultural product. There will be many impacts not considered by this proposal on the marketplace and the benefits achieved are not clear. If the purpose is to encourage use of organic ingredients in the substrates used to produce microorganisms, and limit further the synthetic substances used, then a less disruptive solution would be consider modifying the annotations for these substances to restrict their production to a manner that encourages use of organic materials.

We suggest the following changes to the definition, which should include reference to the criteria included in the decision tree in order for the decision tree to have any authority.

Suggested Change to Definition:

Non-agricultural 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 and is not chemically changed other than the result of a naturally occurring biological process. ~~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 means in the extract, isolate, or fraction.~~

¹ Aug 22, 2005. Board Policy Manual p. 19

We support the additional clarifying steps proposed for the decision tree as proposed by our colleagues at Oregon Tilth Certified Organic, that limit an agricultural product to formulations including substances consistent with the National List.

NOSB should remind the public that petitions and Technical Advisory Panel reviews are required in order to amend the National List. If NOSB decides to reclassify any substances on 205.605, then the established procedures should be followed in order to provide public input and Technical Advisory Panel expertise on the subject. If microorganisms or their derivatives are classed as agricultural, then we expect the NOSB to assist the NOP in developing standards and guidance regulating this type of organic production.

Respectfully submitted,

Leslie Zuck, Executive Director

Emily Brown Rosen, Materials Review Manager

APPENDIX

International Standards For Microorganisms used in Organic Food Production

1. European Union - EEC No 2092/91

Annex VI.

For the purposes of this Annex, the following definitions will apply:

2. ingredients of agricultural origin:
 - (a) single agricultural products and products derived therefrom by appropriate washing, cleaning, thermic and/or mechanical processes and/or by physical processes having the effect of reducing the moisture content of the product;
 - (b) also, products derived from the products mentioned under (a) by other processes used in food processing, unless these products are considered food additives or flavourings as defined under points 5 or 7 hereunder;
3. ingredients of non-agricultural origin: ingredients other than ingredients of agricultural origin and belonging to at least one of the following categories:
 - 3.1. food additives, including carriers for food additives, as defined under points 5 and 6 hereunder;
 - 3.2. flavourings, as defined under point 7 hereunder;
 - 3.3. water and salt;
 - 3.4. micro-organism preparations;
 - 3.5. minerals (including trace elements) and vitamins;

SECTION A — INGREDIENTS OF NON-AGRICULTURAL ORIGIN (REFERRED TO IN ARTICLE 5(3)(c) AND ARTICLE 5(5a)(d) OF REGULATION (EEC) No 2092/91)

A.4. Micro-organism preparations

(i) Any preparations of micro-organisms normally used in food processing with the exception of micro-organisms genetically modified within the meaning of Article 2 (2) of Directive 90/220/EEC.

2. Codex Alimentarius Guidelines For The Production, Processing, Labelling And Marketing Of Organically Produced Foods (GL 32 – 1999, Rev. 1 – 2001)

TABLE 3: INGREDIENTS OF NON AGRICULTURAL ORIGIN REFERRED TO IN SECTION 3 OF THESE GUIDELINES

3.4 Preparations of Microorganisms and Enzymes

Any preparations of microorganisms and enzymes normally used in food processing, with the exception of microorganisms genetically engineered/modified or enzymes derived from genetic engineering.

3. IFOAM Basic Standards 2005

6.2.4 Preparations of micro-organisms and enzymes commonly used in food processing may be used, with the exception of genetically engineered micro-organisms and their products.

Processors shall use micro-organisms grown on substrates that consist entirely of organic ingredients and substances on Appendix 4, if available. This includes cultures that are prepared or multiplied in-house

Appendix 4 - Table 1: List of Approved Additives and Processing Aids

Where the substances listed in this annex can be found in nature, natural sources are preferred. Substances of certified organic origin are preferred.

Preparations of Micro-organisms and Enzymes for use in food processing (see 6.2.4.)

These may be used as ingredient or processing aids with approval based on the criteria in Appendix 1.

- Organic certified micro-organisms
- Preparations of micro-organisms
- Enzymes and enzyme preparations