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Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.,
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: Fermentation processes; Yeast, microorganisms, dairy cultures, L-lactic acid, citric acid, enzymes

MS: Workplan

These comments to the National Organic Standards Board (NOSB) on its Spring 2015 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

Fermentation Processes

Fermentation is a biological process by which sugars are metabolized to acids, gases, and/or alcohol. Depending on the fermenting organism and the food source, other byproducts may be produced. Fermentation processes used for agricultural inputs and food processing are both in need of clarification, but the issues surrounding them are different. Here we address fermentation with respect to food processing.

Fermentation and food processing

Fermentation processes produce foods or food ingredients in several ways:

1. **Foods and ingredients that are organisms grown by fermentation—that is, the biomass produced by the fermentation process.** These include nutritional yeast and baking yeast. Yeast may be certified organic when produced in compliance with an approved organic systems plan.¹ Marroquin International petitioned to have yeast reclassified as agricultural and listed on §205.606. It made the argument that yeast, like mushrooms, should be considered livestock under OFPA. “Microorganisms” are listed on §205.605(a).

¹ NOP, Certification of Organic Yeast. NOP 5014 issued March 2, 2010.

2. **Food processing changes raw agricultural ingredients into new products defined by the products of fermentation.** These include wine, beer, vinegar, lactic acid pickles, yogurt, and miso.
3. **Production of food additives through fermentation of specific strains of microorganisms.** These include nucleotides, various vitamins, etc. that are isolated from the products of fermentation. They may be either **primary metabolites** –substances produced by the fermenting organism that are essential to its growth, such as nucleotides, nucleic acids, amino acids, proteins, carbohydrates, lipids, etc.—or **secondary metabolites** –which have no obvious role in the metabolism of the cultured organisms, such as antibiotics and other drugs.

There are products of fermentation permitted in organic food in all of these categories. A number of them are up for sunset review. Those up for sunset in 2016 below are marked with +, those up for sunset in 2017 are marked with *.

Materials on §205.605(a) that are products of fermentation include:²

1. Food organisms: yeast.*
2. Fermented foods do not need to be listed, but yeast,* microorganisms,+ and dairy cultures,* which are the agents that ferment the food, are listed.
3. Metabolites: L-lactic acid,* citric acid,* L-malic acid,+ gellan gum, glucono delta-lactone, enzymes.*

Materials on §205.605(b) that are products of fermentation include metabolites:³ glycerin,* xanthan gum,* various vitamins that may be produced by fermentation (B2, B12, C, D2, E, K2, biotin, and some combinations).*

Finally, there are metabolites of fermentation listed on §205.606:⁴ fructooligosaccharides (FOS),* Inulin –oligosaccharide enriched (IOE),* whey protein concentrate.* The Handling Subcommittee proposal now claims that glycerin should have been included in this list.

Classification: agricultural vs. non-agricultural

The fact that products of fermentation are included on three different lists for processing is a sign that the classification of products of fermentation needs to be clarified. In particular, the Handling Subcommittee (HS) states, “Glycerin, produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch.” This is also consistent with the NOP draft classification decision tree, which preserves the nonagricultural classification through fermentation.

² Materials on §205.605(a) that are up for sunset in 2016 are addressed in separate comments. Those up for sunset in 2017 are addressed below.

³ These materials are all address in our comment on materials on §205.605(b) that have uses prohibited by §205.600(b)(4).

⁴ Materials on §205.606 are addressed in comments on that section.

However, it is not consistent with the definition of a “nonagricultural substance” in the regulations.

The regulations define “agricultural products” (following the OFPA definition) and “nonagricultural” (without a definition in OFPA) in §205.2:

Agricultural Products. 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” (§2103(1)).

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. [Emphasis added.]

Perhaps some of the inconsistency in the classification of materials as agricultural or nonagricultural could be resolved by asking, “What makes a product of fermentation agricultural?” If the product of fermentation is agricultural, then it can be certified organic, and we need to define acceptable practices in organic fermentation processes.

The NOP policy on organic yeast allows yeast to be a certified organic nonagricultural ingredient. Following that approach would allow other organic substances on 205.605(a). It is tempting to view yeast and other products of fermentation as agricultural. Issues surrounding the classification and listing of food additives produced by fermentation or extracted from fermentation products would be easier to resolve if fermentation processes were regarded as agricultural production systems. It may be argued that defining what organic production means in the context of vat fermentation is no more difficult than defining organic aquaculture.

However, the NOSB has been clear that soil-less systems are not organic.⁵ Organic agriculture is premised on a belief that the foundation of healthy plants and animals is healthy soil. This, indeed, is a problem in defining organic aquaculture.

Thus, the draft materials classification guidance, which treats fermentation as a processing method that does not change the classification of the substrate from agricultural to non-agricultural only works if both the substrate and the product of fermentation meet the definition of agricultural, and not nonagricultural substances. Thus pickles, wine, and cheese are all agricultural, but substances whose relationship to the substrate is unrecognizable – such as glycerin, as a product of fermenting cornstarch—are nonagricultural. Fructooligosaccharides (FOS), a product of fermenting glucose, and inulin enriched with oligosaccharides (which contains FOS) are also inappropriately listed on §205.606 because they are nonagricultural.

⁵ NOSB recommendation, Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses), April 29, 2010.

Classification: Synthetic vs. Nonsynthetic

The classification of some “nonsynthetic” substances needs to be revisited. For example, citric acid and L-lactic acid were originally added to the National List based on TAP reviews that gave a simplified version of their production using fermentation. Commercial production of these acids, however, involves synthetic chemical reactions that were not considered in the original classification decision.

Other issues

A number of products of fermentation that are on the National List may be made using genetically engineered organisms or genetically engineered substrate. Both of these issues should be addressed by annotation or in a general policy.

In some cases, fermentation may create undesirable byproducts. The TAP review for glucono delta-lactone, for example, recommended annotating to ensure that it is not produced by a strain that produces a toxin. (This was not included in the listing.)

Therefore, in addition to the material-specific comments below, we request that the Materials/GMO Subcommittee add to its workplan the development of criteria for evaluating products of fermentation processes.

Material-Specific Comments: Products of Fermentation on §205.605(a)

Yeast

Current listing:

§205.605(a) Yeast—When used as food or a fermentation agent in products labeled as “organic,” yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

One ancillary substance that was identified by the HS is butylated hydroxytoluene (BHT). There is a TAP review of BHT as an “inert” in pheromone products. The following comes from that and other sources, as indicated:

1. **Environmental impacts from its use or manufacture.** BHT: An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.⁶ Another review cites classifications as hazardous.⁷
2. **Effects on human health.** “Butylated Hydroxytoluene (BHT) is classified as irritating to the eyes, respiratory system, and skin under European classification. Allergic contact dermatitis and contact urticaria are associated with exposure to BHT (HAZ-MAP). It is

⁶ EPA, Office of Prevention, Pesticides, and Toxic Substances. Memo from Pauline Wagner, Inert Ingredients Branch, to Lois Rossi, Registration Division. Inert Reassessment of Butylated Hydroxyanisole (250 13- 16-5) and Butylated Hydroxytoluene (128-37-0). September 29, 2005.

⁷ Safety Review of Checkmate Chemicals, by Don't Spray California.

<http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf>

currently listed as “unclassifiable” in regard to its carcinogenicity in humans (due to limited human test data), however a variety of in vitro and animal studies have shown it to have carcinogenic, tumorigenic, mutagenic, and teratogenic effects in animals as well as in human cells (Sigma-Aldrich MSDS). Studies have also confirmed BHT to have estrogenic activity (Miller et al. 2001; Wada et al. 2004) and MSDS sheets state that chronic exposure to BHT may cause reproductive and fetal effects (Acros MSDS).”⁸

Yeast is produced by fermentation, separated by physical methods from the culture. Yeast *per se* meets OFPA requirements However, there are many ancillary substances that have not been reviewed, some of which may be problematic.

Dairy cultures

Current listing:

§205.605(a) Dairy cultures.

Dairy cultures are a subset of microorganisms. Unless there is information available specifically relating to dairy cultures, it does not seem worthwhile to address dairy cultures separately. On the other hand, there are reasons to divide up microorganisms into groups if they differ in manufacturing methods, purposes, or ancillary substances. The early TAP review on dairy cultures gave little information specific to the specific microorganisms used in dairy cultures. The microorganisms TR indicates that dairy cultures are produced on milk and not separated using chemical methods, so the nonsynthetic classification is appropriate.

Dairy cultures *per se* meet OFPA requirements, but there are many ancillary substances that must be reviewed.

L-lactic acid

Current listing:

§205.605(a)

Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).

L-lactic acid is commercially produced by fermentation, with additional steps that involve synthetic chemical reactions. The process creates a surplus of calcium sulfate waste, which some producers are trying to market as a fertilizer. Some substrates may be derived from genetically modified organisms. Although fermentation is a biological process, the additional reactions should result in a classification of synthetic. The earlier judgment that L-lactic acid is nonsynthetic was based on a much less complete description of the fermentation and purification processes than is available in the TR. It should be revisited.

⁸ Safety Review of Checkmate Chemicals, by Don't Spray California.

<http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf>.

L-lactic acid should be reclassified as synthetic and considered for listing on §205.605(b). L-lactic acid is also present in some foods by virtue of *in situ* fermentation, and this is not synthetic. The microorganisms responsible for the fermentation are on the National List.

Citric acid

Current listing:

§205.605(a)

Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).

Citric acid is commercially produced by fermentation, and several different processes are used. Fermentation uses large quantities of water and creates much waste with high BOD and many contaminants. Some substrates may be derived from genetically modified organisms. Although fermentation is a biological process, there are many chemical reactions involved in most methods, including the most common, of purifying the citric acid. Citrates are formed as a result of reactions of citric acid with the appropriate bases. The earlier judgment that citric acid is nonsynthetic was based on a much less complete description of the fermentation and purification processes than is available in the TR. It should be revisited.

Citric acid should be classified as synthetic unless it is possible to define nonsynthetic citric acid by annotation. If it is possible to define nonsynthetic citric acid, then it should be annotated on §205.605(a). Otherwise, it should be removed from §205.605(a) and considered for listing on §205.605(b).

Enzymes

Current listing:

§205.605(a) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

The review of enzymes as a class—even with a few specific representatives— is insufficient to address classification and all of the OFPA criteria. The classification of all commercial enzymes as nonsynthetic is questionable, given that the TR says that chemical changes involving reactions with synthetic chemical are sometimes involved in the manufacture, extraction, or purification of enzymes.

The HS summary lists some ancillary substances and requests comment on whether there are others. It also says, “[T]his list does not include ancillary substances that are already on the National List (NL). From the Technical Report and spec sheets,” which is confusing, since some of those on the list are on the NL (for example, magnesium stearate and silicon dioxide). Boric acid, which is mentioned in the TR as a preservative in enzyme preparations, is on §205.601(e), “(3) Boric acid—structural pest control, no direct contact with organic food or crops,” a listing that would preclude its use in organic food.

Enzymes should be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change. The review of ancillary substances should include all such substances, including those on the National List.

Annotations and Changed Lists

Some of our recommendations above call for annotations or correcting the listing by moving the substance to a different section of the National List. We believe that these actions are necessary to ensure that OFPA criteria are met. The classification –and hence placement within the proper section of the list—is important because different restrictions apply to synthetic as opposed to nonsynthetic materials. Annotations are important to ensure that if a material may be synthetic or nonsynthetic, then only the nonsynthetic version will be allowed by a listing on §205.605(a). The NOP’s sunset policy does not allow these changes to be made as part of the sunset process. Therefore, the NOSB must make these changes through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.⁹

Thank you for your consideration of these comments.

Sincerely,



Terry Shistar, Ph.D.
Board of Directors

⁹ The November 2009 NOSB recommendation on chlorhexidine said, “In terms of the board recommending a substance to be added to the national list without a petition, (An OGC person sees) nothing in the OFPA or NOP regulations that would prohibit such action. (Another OGC person) agrees as well, and indicated that he believes the original NL was created by the board without any petitions. In either event, it would seem like the board's primary function is to make recommendations concerning the NL (to add, remove, renew, etc.) and that petitions are just one mechanism through which the board can make such recommendations.”

<http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081492&acct=nosb>