



BEYOND PESTICIDES

701 E Street, SE ■ Washington DC 20003
202-543-5450 phone ■ 202-543-4791 fax
info@beyondpesticides.org ■ www.beyondpesticides.org

October 3, 2014

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: Glycerin; MS: Workplan

These comments to the National Organic Standards Board (NOSB) on its Fall 2014 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.

Beyond Pesticides agrees with the Handling Subcommittee (HS) that the issues raised by the glycerin petition are complex. We believe that the approach to listing glycerin needs to recognize that complexity. We do not support the classification of glycerin made by hydrolysis of fats and oils as agricultural and therefore oppose its listing on §205.606. Glycerin made by fermentation of agricultural products should be listed separately, but we believe that further work is needed to address criteria for products of fermentation processes. One option is to wait to take definitive action until there is final guidance on classification and some guidance on fermentation processes, in which case, the NOSB must include an expiration date on the listing.

In addition, we believe that some issues raised by the petition are beyond the purview of the HS and we request that the Materials/GMO Subcommittee (MS/GMO) add them to its workplan. (See "Fermentation Processes" below.)

1. Listing of Glycerin

As shown by the HS, glycerin is made by a number of processes. Currently, the product of one process, hydrolysis of fats and oils, is listed on the National List (§205.603 and §205.605(b)) as a synthetic. The petitioner, who is asking to delist synthetic glycerin, produces "organic" glycerin through fermentation of organic cornstarch. This glycerin is considered "organic" because it is considered a processed form of organic cornstarch, and because "fermentation" is an allowed form of processing.

The HS proposes to list all glycerin on §205.606 –apparently accepting the argument of the petitioner that it should be so listed in order to impose the commercial availability restriction. While we applaud the motivation, glycerin made by hydrolysis of fats and oils is classified as synthetic and has not been classified as agricultural, which is a prerequisite for §205.606. In addition, as we read the regulations, commercial availability also applies to §205.605.

Although it is not clear to us that glycerin produced by fermentation of cornstarch is agricultural, we agree that conclusion is consistent with the application of NOP's draft classification guidelines.

We suggest separate listings for glycerin made by hydrolysis of fats and oil and glycerin made by fermentation. We do not support the classification of glycerin made by hydrolysis of fats and oils as agricultural and therefore oppose its listing on §205.606. Commercial availability does apply to §205.605, according to §205.270(b), "(b) Nonagricultural substances allowed under §205.605 and nonorganically produced agricultural products allowed under §205.606 may be used: (1) In or on a processed agricultural product intended to be sold, labeled, or represented as "organic," pursuant to §205.301(b), if not commercially available in organic form."

Glycerin made by fermentation of agricultural products should be listed separately. As we suggest below, there are larger issues that should be addressed in decisions involving fermentation products. Given the fact that commercial availability does apply to §205.605, one option is to wait until there is final guidance on classification and some guidance on fermentation processes. In this case, the NOSB must include an expiration date on the listing.

Both listings should address ancillary substances by either stating that there are none or by listing those allowable. In considering what other substances might be present in glycerin made by fermentation, residues of processing aids in cornstarch or other substrates should be included.

2. Fermentation Processes

This material raises issues that should be addressed by the NOSB: What criteria must be applied to determine whether fermentation products are acceptable as inputs in organic production and processing? What criteria must be applied in classifying the products of fermentation as agricultural/nonagricultural or synthetic/nonsynthetic? The draft materials classification guidance treats fermentation as a processing method that does not change the classification of the substrate from agricultural to non-agricultural or from nonsynthetic to synthetic. Yet fermentation processes vary widely from pickling, wine-making, and cheese-making to manufacture of substances that have no apparent relationship to the substrate. Glycerin made by fermentation of cornstarch is an example of the last. Whole algal flour and gellan gum are other examples. The processes vary in nutrients added, physical methods of isolating the product, solvents used, and ancillary substances added. The fact that all of these processes involve the growth of microorganisms does not seem to be sufficient to treat them the same.

Therefore, we request that the Materials/GMO Subcommittee add to its workplan the development of criteria for evaluating products of fermentation processes.

3. Ancillary Substances

According to the recommendation passed by the NOSB in the spring of 2013, the board defined “ancillary substances” as “additives added during the manufacturing of a non-organic substance and **not** removed.”

The NOSB went on to recommend the following policy:

The NOSB intends to review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. Comprehensive review does not require these substances to be individually listed on the National List, however. The Board intends to follow the request by NOP to consider ancillary ingredients contained in substances as they come up for review or as new petitions are considered.

In each NOSB review checklist and recommendation cover sheet there will be a clear space to indicate what other ingredients are being reviewed and what restriction if any are placed on them as a result of the review. Restrictions on other ingredients will be included in an annotation and may be for specific individual components, for functional classes of ingredients, or by regulatory reference to another governmental agency such as FDA. The other ingredients restrictions may be incorporated into a permitted substances database for Handling, such as the one that is coming out for crops.

The NOSB recommendation will include a note that the other ingredients were reviewed and accepted. The review of other ingredients will distinguish between synthetic and nonsynthetic ones, as well as agricultural ingredients that might be able to be organically produced. Any additional restrictions will be specified in an annotation.

Ancillary substances in general product categories that are currently on §205.605 and §205.606 and currently used in certified organic processed product will continue to be allowed until they go through their next sunset review and subsequent Rule amendment.

The ancillary substances associated with this material have not been reviewed or even listed. This is an important piece that needs to be incorporated into the review of every material during review of petitions –including petitions to remove.

4. Annotation

It is critical that the listing of this material as an exempt prohibited material on the National List include an annotation with a 5-year expiration date –especially in view of the uncertainties surrounding manufacturing processes and classification. The Board has the statutory

prerogative to adopt annotations when it recommends a national listing with language that takes into account concerns it has about health and the environment, essentiality, and other issues of compatibility with organic production and processing. The statute does not prohibit the Board from adopting a specific time frame in which it determines it would like to reassess a material's use, update its evaluation, and vote with the same standards of review that are applied to the petition review to allow initial use.

The specific time frame for an expiration date allows the Board to monitor the use of the material, incentivize alternatives, update its scientific and essentiality review, and vote on the continuation of use pending the receipt of a petition requesting that use be continued. This process, as we saw with tetracycline, allows sufficient time for the Board to vote before the expiration would go into effect, so, if it is approved, there would be no break in market availability. Expiration simply puts on notice those who use or produce the substance that the material will be reviewed with the same rigor in looking for new information that it used when it was initially listed. Under the new sunset policy, an expiration date on a petition is necessary to ensure the kind of periodic rigorous review and vote that many in the organic community have come to expect and depend on to maintain organic integrity and trust in the organic label.

Thank you for your consideration of these comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Terry Shistar". The signature is fluid and cursive, with a long horizontal stroke at the end.

Terry Shistar, Ph.D.
Board of Directors