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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: Microorganisms Ancillary Substances

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 the world.

The following comments relate mostly to the process that the Handling Subcommittee has used to review ancillary substances in microorganisms. We conclude that the process does not live up to the standards of the procedure established by the NOSB.

The NOSB established policy on ancillary substances that said:

- *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.*

BP Comment: Last fall, the HS stated it would not include in its review ancillary substances that are already on the National List (NL), and we commented that ancillary substances already on the NL should be included if they are not listed for the same purpose. We appreciate the HS including ancillary substances that are on the NL –which was mentioned in the microorganisms review, but not the proposal on ancillary substances in microorganisms.

The HS proposal provided the responses to evaluation criteria enumerated below:

1. **Impact on Humans and Environment**: Is there any evidence the substance(s) may be harmful to human health or the environment?

"There is no literature to suggest that the manufacture or use of microbial preparations with ancillary substances is harmful to the environment or biodiversity." (2014 TR page 26). There is no literature to suggest that microbial preparations with ancillary substances have negative effects on human health. (2014 TR page 28)

BP Comment: The NOSB must review each ancillary substance for impacts on human health and the environment rather than microbial products containing them. OFPA requires a finding that the substance "would not be harmful to human health or the environment," rather than a statement that no literature was found.

2. **Essential & Availability**: Is the substance necessary to the handling of the product because of unavailability of wholly natural substitute products, or essential for the handling of an organic product?

   All the substances in the chart above are necessary because they are what keep the microorganism alive, pure and able to perform its function. Formulations of the desired microorganism products are not available without some of these ancillary substances. The availability of organic carriers and substrates is sometimes possible and the NOSB encourages the use of organic ancillary substances whenever possible. Therefore a second motion is proposed below to recommend that organic sources of ancillary substances must be used when available.

BP Comment: This is not the kind of analysis that the NOSB or the public can use. The checklists ask for alternative materials and methods. These should be provided for each ancillary substance, or a reason that none is available for that substance.

3. **Compatibility & Consistency**: Is the substance's use consistent and compatible with organic handling practices?

   "There is no literature to suggest preservatives used in microbial preparations as ancillary substances exert any technical or functional preservative effect in the final fermented product. Typically, Good Manufacturing Practices (GMP) dictate that preservatives are added at a maximum level of 0.1% by weight of the finished product to exert the desired effect (FDA 2013b)." (2014 TR page 23)

BP Comment: As with health and environmental impacts above, the NOSB must review each ancillary substance for consistency and compatibility. The question demands a positive response rather than a statement that no literature was found, and it requires that the NOSB consider more factors than the preservative effect. Substances that are made with genetically engineered organisms, for example, should not be considered compatible with organic production.

Two ancillary substances on the list –potassium sorbate and propylene glycol—have been petitioned for inclusion on §603 and denied. In May 2012, the NOSB voted to change the

annotation of cellulose to remove microcrystalline cellulose. Although NOP chose to ignore this recommendation, it should be taken into account in evaluating the compatibility of this substance.

The TR states (lines 632-633), “Both synthetic and nonsynthetic growth media components are used to provide carbohydrate and nitrogen sources.” The HS does not appear to have identified any synthetic nutrients as ancillary substances that might appear in microorganisms, though other food sources are on the list. Is it possible that some might carry over?

The NOSB policy also stated:

- *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.*

BP Comment: The HS review has not distinguished between synthetic and nonsynthetic ancillary substances. It has not identified agricultural ingredients that might be able to be organically produced. It has not applied restrictions that are on some ancillary substances that appear on the NL (nitrogen and magnesium sulfate). It has not prohibited GMO substances.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors