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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: Microorganisms; MS/GMO: 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 cannot support the relisting of microorganisms without documentation to show that the listing meets the criteria of the Organic Foods Production Act (OFPA). The principal document of support is a technical review (TR) that does not address the manufacture of microorganisms by fermentation.

Our role as public interest commenters on the NOSB materials review process is to ensure that NOSB decisions are based on OFPA criteria, backed up with adequate documentation. We are disappointed that given the inadequacies of the documentation that the Handling Subcommittee (HS) has not requested a supplemental TR to document environmental and health impacts of the manufacturing process, including generation and disposal of wastes. Nor has it requested any information from the industry or public concerning the manufacturing process. This lack of information and failure to request more information is especially disturbing because any information received after this meeting will be considered "untimely" according to the new NOP sunset policy. We urge the HS to seek more information. In addition, we believe that some issues raised by the consideration of microorganisms are beyond the purview of the HS and we request that the Materials/GMO Subcommittee (MS/GMO) add them to its workplan.

1. Identification of "microorganisms" as listed on the National List

The listing on §205.605(a) is "Microorganisms—any food grade bacteria, fungi, and other microorganism." This listing is not clear. It is apparent that it is intended to cover those microorganisms present as living organisms in foods such as cheese, yogurt, vinegar, pickles, tempeh, wine, and so forth. However, there are other products that are made from (or with the assistance of) microorganisms, and it is not clear whether the listing is intended to cover them. These include nutritional yeast and spirulina, both cultured microorganisms that are no longer

living. They also include products of fermentation that have been isolated from the fermentation organisms, including glycerin, gellan gum, L-malic acid, and others. We assume that the listing does not cover the last group, but that those organisms and their manufacture should be evaluated in the course of evaluating their products that are on the National List (NL). If the listing is intended to cover the group of killed microbial products, then the evaluation should include algae as well as the other organisms addressed in the technical review.

2. Ancillary substances

In choosing microorganisms as the "test case" for identifying and evaluating ancillary substances, the HS has set itself a large task whose boundaries are not well-defined. First of all, there is the problem identified above of clarifying the intended coverage of the term "microorganism." Secondly, the universe of microorganisms used in food is large, and it does not appear that the HS has sought to create a complete inventory. Thirdly, each of those microorganisms may be cultured in different ways, each of which may have its own set of ancillary substances. Finally, "ancillary substances" must be defined in terms of each National List substance, and it is not clear that the HS has accomplished that task.

According to the recommendation passed by the NOSB in the spring of 2013, the board defined "ancillary substances" as follows,

> The term "other ingredients," as described in the NOP Memo to NOSB, is not a recognized regulatory term with a legal definition. However since the term was used in the NOP Memo, it was used throughout this discussion document, but in the final recommendation is changed to "Ancillary Substances". For this purpose, "other ingredients" will be defined as additives added during the manufacturing of a non-organic substance and ***not*** removed. They may be considered "incidental additives" by FDA, depending on use and type of end product being considered.
>
> "Ancillary Substances" have the following characteristics:
> • They are added during the manufacturing of a non-organic substance and ***not*** removed.
> • They are not added directly by the certified handler.
> • They are present in a food at insignificant levels and have no technical or functional effect in that food.
> • They are not required by FDA to be listed on the ingredient panel in that food.
> • "Other ingredients" are substances that are present because they were incorporated into an allowed substance on the National List.

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 microorganisms TR and the HS summary give some examples of ancillary substances that might be found in microorganisms. They do not attempt to give a complete list. They do not review those materials.

This does not provide a good test case for the NOSB consideration of ancillary substances. The policy calls for the NOSB to indicate what ancillary substances are being reviewed and what restrictions are proposed. It also states, "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." None of these processes can take place without a complete list and a review of the ancillary substances.

In addition,

- Some ancillary substances in the table have been petitioned and denied (propylene glycol, potassium sorbate), some are on the National List (NL) with restrictions (yeast, nitrogen, magnesium sulfate), and there has been board/HS action on some not reflected on the NL (microcrystalline cellulose, inulin).
- Those ancillary substances that are on the NL should not be accepted without review if they are listed for another purpose.
- The TR did not address GRAS status of ancillary ingredients.

We conclude that the HS has a long way to go to achieve a satisfactory analysis of ancillary substances. If the HS had chosen a less complex listing as a pilot, it might have produced a more acceptable result.

3. Environmental and Health Impacts

In order to evaluate impacts on human health and the environment, the HS must evaluate the production practices for microorganisms. (See "Fermentation" below.) Some examples of questions that have not been addressed are:

- What are conditions for workers within buildings holding fermentation vats?
- Are there discharges from fermentation vats?
- How/where are remains from fermentation, bad batches, etc. disposed of? Do they compete with natural organisms?

In addition, the TR indicates a potential for some microorganisms to concentrate heavy metals.

4. Essentiality

We support the use of microbially fermented agricultural products as health-supporting and eliminating the use of some chemical preservatives and other antimicrobial agents.

5. Compatibility

The HS documentation does not address compatibility. We believe that in principle, the use of microorganisms to produce microbially fermented agricultural products is compatible with organic practices. HS documentation should address this issue. Our main concern is with the specifics of production practices.

6. Fermentation

The consideration of microorganisms raises additional 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. L-malic acid is an example of the last. Whole algal flour, glycerin, 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.

7. Conclusion

Beyond Pesticides cannot support the relisting of microorganisms without documentation to show that the listing meets the criteria of the Organic Foods Production Act (OFPA).

A word about the process of the Handling Subcommittee. it is critical that the subcommittee and Board prepare a more robust review for public discussion at the first meeting on a Sunset 2016

material. We believe that a supplemental Technical Review is critical to an assessment that evaluates compliance with OFPA criteria, particularly as it relates to manufacturing of the microorganisms in this case, and should have been available and critiqued for this meeting. Since the Fall 2014 meeting is scheduled to be the only public NOSB meeting during which the Handling Subcommittee and Board members can share their thinking and receive "timely" public input on the checklist and assessment of the material in accordance with OFPA criteria, the lack of prepared written analysis by the subcommittee for this meeting makes for an incomplete and truncated assessment process. Had this been done, the Subcommittee would have discovered that it needed a more complete TR to enable a complete assessment in accordance with OFPA criteria. Or, conversely, with a written prepared review, the subcommittee would have been able to share with the organic community its thinking on its decision on TR sufficiency and compliance with OFPA criteria. We appreciate the subcommittee's question on defining the universe of ancillary materials and their essentiality, but believe that the subcommittee and Board have a responsibility to bring to the public a comprehensive set of questions that address all OFPA criteria with a preliminary assessment of the data it has and should have prepared a prepared a preliminary checklist.

Under the current process, information brought to the Board at the Spring 2015 meeting will be considered "untimely." While we recognize that the Board has embarked on a new two-stage process, the first stage, or first meeting on sunset materials, must be a more robust review process if the Board's assessment of exempt prohibited materials, like this one, on the National List is to be viewed by the public, including users and consumers, as credible. The process requires this, if there is to be continuing and building public trust in the assessment process and the organic food label.

We have attached a checklist in which we provide the Board with answers to questions, based on the available technical review, that are required to be considered as a part of a sunset review that is in compliance with the Organic Foods Production Act (OFPA) and the implementing regulations.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors

National Organic Standards Board
Handling Subcommittee
Petitioned Material Checklist
Microorganisms

[Date of Vote]

Summary of Proposed Action:
[Insert narrative describing vote, review of material, discussion, etc.]

Evaluation Criteria (see attached checklist for criteria in each category)

		Criteria Satisfied?
1.	Impact on Humans and Environment	☐ Yes ☐ No ☐ N/A
2.	Essential & Availability Criteria	☐ Yes ☐ No ☐ N/A
3.	Compatibility & Consistency	☐ Yes ☐ No ☐ N/A
4.	Commercial Supply is Fragile or Potentially Unavailable as Organic (only for §205.606)	☐ Yes ☐ No ☐ N/A

Substance Fails Criteria Category: [ ] **Comments:**

Subcommittee Action & Vote, including classification proposal (state actual motion):

Classification Motion: Move to classify [substance] as [synthetic, nonsynthetic, agricultural]
Motion by:
Seconded by:
Yes: # No: # Absent: # Abstain: # Recuse: #

Listing Motion: Move to list [substance] on section **205.6xx** of the National List [with the annotation]
Motion by:
Seconded by:
Yes: # No: # Absent: # Abstain: # Recuse: #

Proposed Annotation (if any):

Basis for annotation: ☐ To meet criteria above ☐ Other regulatory criteria ☐ Citation
Notes:

Approved by Subcommittee Chair to Transmit to NOSB

Name , Subcommittee Chair **Date**

NOSB Evaluation Criteria for Substances Added To the National List
Handling

Category 1. Adverse impacts on humans or the environment? **Substance:**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Are there adverse effects on the environment, or is there a probability of environmental contamination during use or misuse of the substance? [§205.600(b)(2), [§6518(m)(3)]	?			Discharges from fermentation vats?
2. Are there adverse effects on the environment or is there a probability of environmental contamination during manufacture or disposal of the substance? [§6518(m)(3)]	?			Disposal? How/where are remains from fermentation, bad batches, etc. disposed of? Do they compete with natural organisms?
3. Are there any adverse impacts on biodiversity? (§205.200)	?			Disposal? How/where are remains from fermentation, bad batches, etc. disposed of? Do they compete with natural organisms?
4. Does the substance contain inerts classified by EPA as 'inerts of toxicological concern'? [§6517 (c)(1)(B)(ii)]			X	See ancillary substances.
5. Is there undesirable persistence or concentration of the material or breakdown products in the environment? [§6518(m)(2)]		?		Ancillary substances?
6. Are there any harmful effects on human health from the main substance or the ancillary substances that may be added to it? [§6517(c))(1)(A)(i); 6517 (c)(2)(A)(i); §6518(m)(4), 205.600(b)(3)]	?			Need to check out ancillary substances. Some have been petitioned and denied (propylene glycol, potassium sorbate), some are on NL with restrictions (yeast, nitrogen, magnesium sulfate), and there has been board/HS action on some not reflected in NL (microcrystalline cellulose, inulin). Those on NL should not be accepted without review.
7. Is the substance, and any ancillary substances, GRAS when used according to FDA's good manufacturing practices? [§205.600(b)(5)]		?		TR did not address GRAS status of ancillary ingredients.
8. Does the substance contain residues of heavy metals or other contaminants in excess of FDA tolerances? [§205.600 (b)(5)]				TR (lines 946-956) indicates a potential for some microorganisms to concentrate heavy metals.

NOSB Evaluation Criteria for Substances Added To the National List
Handling

Category 2. Is the Substance Essential for Organic Production? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance agricultural? [§6502(1)]		X		"Microorganisms—any food grade bacteria, fungi, and other microorganism" are listed on 605(a) and hence are considered non-agricultural.
2. Is the substance formulated or manufactured by a chemical process? [§6502(21)]		X		
3. Is the substance formulated or manufactured by a process that chemically changes a substance extracted from naturally occurring plant, animal, or mineral sources? [§6502(21)]	X			TR lines 611-701
4. Is the substance created by naturally occurring biological processes? [§6502(21)]	X			TR lines 703-728.
5. Is there a natural source of the substance? [§ 205.600(b)(1)]	X			TR lines 730-736.
6. Is there an organic substitute? [§205.600(b)(1)]	?			"No alternatives to the petitioned substance were found among current organic products used for food processing and handling. While microorganisms are not commercially available in organic form, microorganisms are considered a non-agricultural substance. Similar to yeast, microorganisms can potentially be produced organically, depending on substrate and nutrient inputs." (TR lines 1138-1141)
7. Is the substance essential for handling of organically produced agricultural products? [§205.600(b)(6)]	X			Essential for certain products. (TR lines 1097-1099)
8. Is there a wholly natural substitute product? [§6517(c)(1)(A)(ii)]			X	Microorganisms are natural.
9. Are there any alternative substances? [§6518(m)(6)]		X		Not for fermentation.
10. Is there another practice (in farming or handling) that would make the substance unnecessary? [§6518(m)(6)]	X			Organic carriers could be substituted for nonorganic carriers. TR lines 1101-1103.
11. Have the ancillary substances associated with the primary substance been reviewed? Describe, along with any proposed		X		TR and HS review give examples of ancillary substances, but do not examine them.

limitations.				

NOSB Evaluation Criteria for Substances Added To the National List
Handling

Category 3. Is the substance compatible with organic handling practices? Substance:

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the substance consistent with organic handling? [§6517(c)(1)(A)(iii); 6517(c)(2)(A)(ii)]	X			
2. Is the manner of the substance's use, manufacture, and disposal compatible with organic handling? [§205.600(b)(2)]	?			Varied methods.
3. Is the substance compatible with a system of sustainable agriculture? [§6518(m)(7)]	X			
4. Are the ancillary substances reviewed compatible with organic handling [?		X		Not all have been reviewed. Some are not.
5. Is the nutritional quality of the food maintained with the substance? [§205.600(b)(3)]	X			TR lines 360-363. This addresses fermented food containing active cultures.
6. Is the primary use as a preservative? [§205.600(b)(4)]		X		One use is to preserve food, but the preserved product has a unique identity. TR lines 360-363
7. Is the primary use to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law)? [§205.600(b)(4)]	X			TR lines 846-847

NOSB Evaluation Criteria for Substances Added To the National List: Handling
Category 4. Is the commercial supply of an organic agricultural substance fragile or potentially unavailable? [§6610, 6518, 6519, §205.2, § 205.105(d), §205.600(c)] **Substance:**

Question	Yes	No	N/A	Comments/Documentation. (TAP; petition; regulatory agency; other)
1. Is the comparative description as to why the non-organic form of the material /substance is necessary for use in organic handling provided?		X		TR Lines 1139-1141
2. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **form** to fulfill an essential function in a system of organic handling?				
3. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quality** to fulfill an essential function in a system of organic handling?				
4. Does the current and historical industry information, research, or evidence provided explain how or why the material /substance cannot be obtained organically in the appropriate **quantity** to fulfill an essential function in a system of organic handling?				
5. Does the industry information about unavailability include (but is not limited to) the following?: a. Regions of production (including factors such as climate and number of regions);				
b. Number of suppliers and amount produced;				
c. Current and historical supplies related to weather events such as hurricanes, floods, and droughts that may temporarily halt production or destroy crops or supplies;				
d. Trade-related issues such as evidence of hoarding, war, trade barriers, or civil unrest that may temporarily restrict supplies; or				
e. Other issues which may present a challenge to a consistent supply?				