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October 2, 2015

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: ancillary substances in microorganisms, pectin, and yeast

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

Beyond Pesticides opposes all three proposals on ancillary substances because they are inconsistent with OFPA and the process adopted by the NOSB for review of ancillary substances.

An Abbreviated History

On Nov. 23, 2011, National Organic Program (NOP) Deputy Administrator Miles McEvoy sent a Memorandum to the National Organic Standards Board (NOSB) requesting clarification of "other ingredients" contained within handling materials on the National List of Allowed and Prohibited substance used in processed organic products. Since OFPA requires that each non-agricultural ingredient be specifically listed, and because the National List does not specifically list "other ingredients" commonly found in formulated products, the NOP identified the need for clarity and requested that the NOSB develop a policy that specifies that all allowed non-organic constituents of organic foods be on the National List in some form.

The term "Ancillary Substances" is now being used to refer to these other ingredients.

In response to the memo, the NOSB Handling Subcommittee developed a policy for ancillary substances that may be included in permitted handling materials. It defines "ancillary substances" and the scope of their review. The policy was included in a recommendation that was discussed at the April 2013 NOSB meeting, amended in response to comments from the board and the public, and passed unanimously.

The central issue in the discussion involved ensuring that ancillary ingredients would be allowed only if they meet OFPA criteria.[1]

The HS defined "ancillary Substances" as having 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.
- They are present because they were incorporated into an allowed substance on the National List.
- They may be considered "incidental additives" by FDA, depending on use and type of end product being considered.
- They are not the same as "ingredients" or "processing aids" used for a specific purpose directly by a certified handler in or on processed organic products. The regulations are clear that non-organic 'ingredients' or 'processing aids' used directly by a certified handler in or on a certified organic processed product must be on the National List at §205.605 or §205.606.

The NOSB recommendation said that the evaluation of ancillary substances would be "based on the existing requirements that are already imposed by OFPA and 7 CFR Part 205." And again:

> 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.
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> 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.
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> 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.

[1] See transcript, http://www.ams.usda.gov/sites/default/files/media/transcriptor.pdf. For example, testimony on pages 82, 140, 171-172, 179, 241-242, 1113-1116, 1125-1126; colloquy at pages 1074-1075, 1082-1083.

NOP summary of April 2013 NOSB meeting agreed: "The NOSB recommended a policy by which ancillary substances, as described in the recommendation, would be reviewed by the NOSB against the OFPA criteria."[2]

As did the NOP response memo:

> The NOP has reviewed the NOSB's recommendation and supports a review of these ancillary substances according to OFPA requirements. The NOP also agrees that the review does not require these substances to be individually listed on the National List, and reiterates that the NOP could communicate any restrictions or prohibitions in an annotation for the generic substance or in published guidance regarding permitted substances for organic handling.

So, it was not unreasonable to expect that the HS would present us with lists of ancillary substances accompanied by evaluations against OFPA criteria (e.g., checklists) and proposals to allow some and restrict or prohibit others.

The HS proposals are not based on evaluations of the ancillary substances according to OFPA criteria and ignore a clear previous board recommendation.

The proposals contain sweeping statements like,

- "There is no literature to suggest that microbial preparations with ancillary substances have negative effects on human health."
- "Yeasts are very precise strains for the desired end product and great pains are taken to maintain product purity when it is grown. Yeast from natural sources is not a feasible choice for most uses. The ancillaries are necessary to help maintain the purity and to enable the yeast to be a consistent performer."
- "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."

There is no evidence presented for these sweeping statements. Although the microorganisms proposal refers to the technical review (TR), statements in the TR itself are unsupported statements that "[t]here is no evidence to suggest that microbial preparations with ancillary substances" have effects on human health, the environment, etc. In addition, the TR does not consider factors required by OFPA such as "the probability of environmental contamination during manufacture, use, misuse or disposal of such substance," or "the effect of the substance on human health," which must be applied to the ancillary substance itself, not the product containing it. The TR should not have been read as sufficient by the subcommittee.

[2] http://www.ams.usda.gov/sites/default/files/media/summaryor.pdf

Furthermore, the HS proposes to approve chemicals that are not mentioned directly in the proposal, but are in the category "defoaming agents," which are referred to as "many in TR." Only in reading the TR do we see that chemicals like formaldehyde, several petroleum compounds, BHA, and BHT would be allowed.

This is not the review that is required by OFPA and not the review that is required by the policy on ancillary substances passed by the NOSB.

More ancillary substances would be allowed without review.

Each of the proposals contains the statements, "Additional ancillaries that fall within one of the functional classes below do not need to be reviewed further to be used. Any new functional class of ancillaries however will have to be petitioned." This allowance of new chemicals without review rewards those who have kept silent. To allow additional substances without review is totally unjustifiable and contrary to the legal requirements and spirit of organic.

The proposals offer no incentive for formulating product with only organic ingredients.

In the NOSB ancillary substances policy recommendation, the NOSB said,

> Increasing the use of organic ingredients and processing aids has been a very explicit goal of the organic community since early on. The NOSB has already endorsed the concept of a pro-active approach to the development and creation of organic analogs to replace nonorganic and synthetic items. By making the policy and procedure clearer for review of minor ingredients there will be more incentive for product development of superior choices within these ingredient categories. This would likely stimulate the use of "other ingredients" in 205.605 substances that are either organic or on the National List.

Instead of implementing the proposal to evaluate ancillary substances, subjecting them to the rigorous review expected for every non-organic ingredient in organic foods, the HS proposes to grandfather all known existing ancillary substances, as well as unknown materials in the same functional categories. This moves organic in the wrong direction, creating disincentives to produce organic-compatible ingredients.

Conclusion

We urge the NOSB to reject all three ancillary ingredients proposals. We believe that this experiment has been shown to result in inadequate control over chemicals added to organic foods, and we therefore recommend that the NOSB require that all ingredients allowed in organic foods –ancillary or otherwise– be either organic or listed on the National List.

Having said this, we don't believe that the board is precluded from reviewing classes of materials in groups to expedite the process, but ensure consumers that the materials are given the scrutiny that is expected and deserved to earn the organic label and their trust in it.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors