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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: Ancillary Substances

These comments to the National Organic Standards Board (NOSB) on its Spring 2016 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 proposal on ancillary substances does not meet the statutory requirements of the Organic Foods Production Act (OFPA), falling short in several areas to ensure compliance with the law. **Definitions are needed.** In order to be meaningful and useful, the ancillary substances policy must define terms it uses: technical or functional effect, direct food additive, incidental food additive, food contact substance, functional class, and significant amount. **Each ancillary substance must be reviewed and approved for each particular use.** Whether the approval of ancillary substances is communicated by means of listing on the National List of Allowed and Prohibited Substances –which we believe to be required by OFPA– or by other means, each ancillary substance must be reviewed according to OFPA criteria, as required by law. The NOSB must not categorically allow substances in a functional class that have not been specifically reviewed and it must not rubber stamp ancillary substance because they are currently in use, although essentiality is certainly a factor to be considered along with adverse effects and compatibility with organic systems.

Background

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 Substances (NL) 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, 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 are only allowed 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 recommended that the evaluation of ancillary substances 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.

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.

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.

The NOP summary of the 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 for public comment lists of ancillary substances (or categories of substances) accompanied by evaluations against OFPA criteria (e.g., checklists) and proposals to allow some and restrict or prohibit others.

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

The proposals contained 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

² <http://www.ams.usda.gov/sites/default/files/media/summaryor.pdf>.

preservatives are added at a maximum level of 0.1% by weight of the finished product to exert the desired effect."

There was no evidence presented for these sweeping statements. Although the microorganisms proposal referred to the technical review (TR), statements in the TR itself are unsupported (uncited) statements, such as, "[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 approved as sufficient by the subcommittee.

Furthermore, the HS proposed 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.

That was 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 contained 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 and the previous recommendation of the NOSB.

[The proposals offered 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 proposed to

grandfather all known existing ancillary substances, as well as unknown materials in the same functional categories. This would move organic in the wrong direction, creating disincentives to produce organic-compatible ingredients. We view this policy as an opportunity to ensure continuous improvement, but the HS recommendation would accomplish just the opposite by allowing an increasing number of synthetic materials that are not reviewed to OFPA criteria for their specific use.

The intent of the current proposal is unclear.

It is not clear whether the HS intends the proposal to be a supplement to the recommendation adopted by the NOSB in Spring 2013 or a substitute for it. The fact that it is incomplete in not specifying review procedures suggests that it is a supplement, but the fact that it conflicts with the 2013 recommendation suggests that it is a substitute. See side-by-side comparison in the attached table.

Definitions are needed.

In order to be meaningful and useful, the ancillary substances policy must define terms it uses: technical or functional effect, direct food additive, incidental food additive, food contact substance, functional class, and significant amount.

The following are potential definitions:

Technical or functional effect 21CFR170.3(o) The following terms describe the physical or technical functional effects for which direct human food ingredients may be added to foods. They are adopted from the National Academy of Sciences/National Research Council national survey of food industries, reported to the Food and Drug Administration under the contract title "A Comprehensive Survey of Industry on the Use of Food Chemicals Generally Recognized as Safe" (September 1972), which is incorporated by reference. Copies are available from the National Technical Information Service (NTIS), 5285 Port Royal Rd., Springfield, VA 22161, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

(1) *Anticaking agents and free-flow agents* : Substances added to finely powdered or crystalline food products to prevent caking, lumping, or agglomeration.

(2) *Antimicrobial agents* : Substances used to preserve food by preventing growth of microorganisms and subsequent spoilage, including fungistats, mold and rope inhibitors, and the effects listed by the National Academy of Sciences/National Research Council under "preservatives."

(3) *Antioxidants* : Substances used to preserve food by retarding deterioration, rancidity, or discoloration due to oxidation.

(4) *Colors and coloring adjuncts* : Substances used to impart, preserve, or enhance the color or shading of a food, including color stabilizers, color fixatives, color-retention agents, etc.

(5) *Curing and pickling agents* : Substances imparting a unique flavor and/or color to a food, usually producing an increase in shelf life stability.

- (6) *Dough strengtheners* : Substances used to modify starch and gluten, thereby producing a more stable dough, including the applicable effects listed by the National Academy of Sciences/National Research Council under "dough conditioner."
- (7) *Drying agents* : Substances with moisture-absorbing ability, used to maintain an environment of low moisture.
- (8) *Emulsifiers and emulsifier salts* : Substances which modify surface tension in the component phase of an emulsion to establish a uniform dispersion or emulsion.
- (9) *Enzymes* : Enzymes used to improve food processing and the quality of the finished food.
- (10) *Firming agents* : Substances added to precipitate residual pectin, thus strengthening the supporting tissue and preventing its collapse during processing.
- (11) *Flavor enhancers* : Substances added to supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.
- (12) *Flavoring agents and adjuvants* : Substances added to impart or help impart a taste or aroma in food.
- (13) *Flour treating agents* : Substances added to milled flour, at the mill, to improve its color and/or baking qualities, including bleaching and maturing agents.
- (14) *Formulation aids* : Substances used to promote or produce a desired physical state or texture in food, including carriers, binders, fillers, plasticizers, film-formers, and tableting aids, etc.
- (15) *Fumigants* : Volatile substances used for controlling insects or pests.
- (16) *Humectants* : Hygroscopic substances incorporated in food to promote retention of moisture, including moisture-retention agents and antidusting agents.
- (17) *Leavening agents* : Substances used to produce or stimulate production of carbon dioxide in baked goods to impart a light texture, including yeast, yeast foods, and calcium salts listed by the National Academy of Sciences/National Research Council under "dough conditioners."
- (18) *Lubricants and release agents* : Substances added to food contact surfaces to prevent ingredients and finished products from sticking to them.
- (19) *Non-nutritive sweeteners* : Substances having less than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.
- (20) *Nutrient supplements* : Substances which are necessary for the body's nutritional and metabolic processes.
- (21) *Nutritive sweeteners* : Substances having greater than 2 percent of the caloric value of sucrose per equivalent unit of sweetening capacity.
- (22) *Oxidizing and reducing agents* : Substances which chemically oxidize or reduce another food ingredient, thereby producing a more stable product, including the applicable effect listed by the National Academy of Sciences/National Research Council under "dough conditioners."
- (23) *pH control agents* : Substances added to change or maintain active acidity or basicity, including buffers, acids, alkalies, and neutralizing agents.
- (24) *Processing aids* : Substances used as manufacturing aids to enhance the appeal or utility of a food or food component, including clarifying agents, clouding agents, catalysts, flocculents, filter aids, and crystallization inhibitors, etc.
- (25) *Propellants, aerating agents, and gases* : Gases used to supply force to expel a product or used to reduce the amount of oxygen in contact with the food in packaging.

(26) *Sequestrants* : Substances which combine with polyvalent metal ions to form a soluble metal complex, to improve the quality and stability of products.

(27) *Solvents and vehicles* : Substances used to extract or dissolve another substance.

(28) *Stabilizers and thickeners* : Substances used to produce viscous solutions or dispersions, to impart body, improve consistency, or stabilize emulsions, including suspending and bodying agents, setting agents, jellying agents, and bulking agents, etc.

(29) *Surface-active agents* : Substances used to modify surface properties of liquid food components for a variety of effects, other than emulsifiers, but including solubilizing agents, dispersants, detergents, wetting agents, rehydration enhancers, whipping agents, foaming agents, and defoaming agents, etc.

(30) *Surface-finishing agents* : Substances used to increase palatability, preserve gloss, and inhibit discoloration of foods, including glazes, polishes, waxes, and protective coatings.

(31) *Synergists* : Substances used to act or react with another food ingredient to produce a total effect different or greater than the sum of the effects produced by the individual ingredients.

(32) *Texturizers* : Substances which affect the appearance or feel of the food.³

Direct food additive “Direct food additive” is not a term defined in the law or the regulations. It is used by FDA and others to identify food additives which are not food contact substances as defined in the Food, Drug, and Cosmetic Act.⁴

Incidental food additive 21CFR100(a)(3) [In section listing exemptions from labeling requirements.] For the purposes of this paragraph (a)(3), incidental additives are:

(i) Substances that have no technical or functional effect but are present in a food by reason of having been incorporated into the food as an ingredient of another food, in which the substance did have a functional or technical effect.

(ii) Processing aids, which are as follows:

(a) Substances that are added to a food during the processing of such food but are removed in some manner from the food before it is packaged in its finished form.

(b) Substances that are added to a food during processing, are converted into constituents normally present in the food, and do not significantly increase the amount of the constituents naturally found in the food.

(c) Substances that are added to a food for their technical or functional effect in the processing but are present in the finished food at insignificant levels and do not have any technical or functional effect in that food.

(iii) Substances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.

Food contact substance 21CFR170.3(e)(3) *A food contact substance* is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging,

³ <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=170.3&SearchTerm=definition>

⁴ http://www.pewtrusts.org/~media/legacy/uploadedfiles/wwwpewtrustsorg/reports/food_additives/fdasupplementalmaterialspdf.pdf

transporting, or holding food if such use is not intended to have any technical effect in such food.

Functional class See list under “Technical or Functional Effect.”

Significant amount “Significant amount” is defined in different ways in FDA regulations. It is not defined in organic regulations. We suggest that “detectable amount” is a suitable definition.

21CFR170.10(d) (4) An ingredient that is specifically required by the standard as defined in parts 131 through 169 of this chapter, shall be present in the product in a significant amount. A significant amount of an ingredient or component of an ingredient is at least that amount that is required to achieve the technical effect of that ingredient in the food.

21CFR101.100(a) (4) For the purposes of paragraph (a)(3) of this section, any sulfiting agent (sulfur dioxide, sodium sulfite, sodium bisulfite, potassium bisulfite, sodium metabisulfite, and potassium metabisulfite) that has been added to any food or to any ingredient in any food and that has no technical effect in that food will be considered to be present in an insignificant amount only if no detectable amount of the agent is present in the finished food.

Each ancillary substance must be reviewed and approved for each particular use.

Although we support the listing of ancillary substances on the National List, the alternative adopted by the NOSB in 2013 was an acceptable compromise that was supported only because it required all ancillary substances to be reviewed according to OFPA criteria. The HS, in bringing forth proposals that did not abide by this policy, broke faith with those who agreed to the compromise.

NOSB must not categorically allow substances in a functional class that have not been specifically reviewed.

Although the NOSB review may be structured by functional class, it is totally unacceptable to propose approving unknown members of a functional class, as was done in Spring 2015 proposals.

NOSB must not rubber stamp ancillary substance just because they are currently in use.

The practice of listing known ancillary substances for approval without evaluating them according to OFPA criteria is not consistent with OFPA or the policy previously adopted by the NOSB.

Thank you for your consideration of these comments.

Sincerely,



Terry Shistar, Ph.D.
Board of Directors

Attachment: Comparison of 2013 NOSB Recommendation and Current HS Proposal

	2013 NOSB Recommendation	2016 HS Proposal
Definition of Ancillary Substances	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. 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.	Additives intentionally added to a non-organic substance on the National List that are not removed and have a technical or functional effect on the non-organic substance , not on the final organic product that the non-organic substance is used in. Ancillary substances may be present in the final organic product but only in insignificant amounts. Ancillary substances fall under the FDA definition and labeling regulations for “incidental additives,” which do not need to be declared on the label of the final food (including organic product) (CFR Title 21 101.22(h)(3) and 101.100 (a)(3 i to iii4).
Criteria for Allowance	<ol style="list-style-type: none"> 1. Must be legal for use in food in the United States, (appearing with a regulated status in the FDA database "Everything Added to Food in the United States" (EAFUS)), or be subject of a FDA “no objections” response in the GRAS Notification Inventory published by FDA. 2. Not prohibited by federal regulatory action [7 U.S.C. § 6517(d)] 3. Is not required by the FDA to be on an ingredient label of the product to which the substance is being added, and therefore does not meet FDA’s definition of an ‘incidental additive.’ 4. NOSB to review ancillary substances “in accordance with OFPA criteria.” 	<ol style="list-style-type: none"> 1. The ancillary ingredient was considered part of the manufacturing process that has already been reviewed by the NOSB; or is certified organic, on the National List 205.605 or 205.606; or is agricultural; or is approved by FDA as GRAS for the particular use; or is approved by FDA as a direct food additive or incidental additive for the particular use; or is approved by FDA as a food contact substance for the particular use, as evidenced by a Food Contact Notification (FCN). 2. Is not a known or probable carcinogen according to the International Agency for Research on Cancer (IARC) or the National Toxicity Program (NTP).
Process	1. Review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. The Board intends to follow the request by NOP to consider ancillary ingredients contained in substances as they	1. At the time of requesting a TR for a new or sunset substance, the NOSB will ask that information about identity and functional classes of ancillary substances be reviewed along with the other evaluation questions.

	<p>come up for review or as new petitions are considered.</p> <p>2. 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.</p> <p>3. 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.</p>	<p>2. For new substances, a chart of the ancillary substances by functional class will be incorporated in the checklist document or whatever review template is used.</p> <p>3. For sunset substances, a chart of the ancillary substances by functional class will be included in the first posting along with a request for new information about existing ancillaries and/or additional ancillary substances to be brought forward in public comment.</p> <p>4. The vote to approve a new substance will be considered to also approve the ancillaries that are associated with that substance unless the NOSB specifically states that one is not approved. Similarly, the vote to finalize the sunset review after the second posting will be considered to also approve ancillaries unless one is pulled out as not approved.</p> <p>5. Any ancillary substances that the NOSB wishes to prohibit (that are not already on the IARC and NTP lists) will have to come before the board in a separate proposal that can be voted on at the same meeting or a subsequent meeting of the board.</p>
<p>NOSB Review Procedure</p>	<p>1. NOSB identifies “ancillary substances” as disclosed in the petition and previous TRs, and through the public comment process.</p> <p>2. For sunset materials the NOSB will additionally request input from ACAs, MROs, and industry on additional other ingredients in a substance before commissioning the TR, so that all can be reviewed at once.</p> <p>3. TR identifies commonly used ancillary substances and describes them.</p> <p>4. Must meet Criterion 1 (above).</p>	

	<p>5. Special questions on the checklist used by the NOSB will be developed by the fall of 2013 to assess the role, essentiality and viability of alternatives to the ancillary ingredients in a substance.</p> <p>6. NOSB may recommend ancillary substances individually, categorically or a combination of the two.</p> <p>7. The NOSB may or may not stipulate in a review that any agricultural ancillary substances must be organically produced.</p> <p>8. Materials listed on § 205.605(a) and 205.606 may contain synthetic or nonsynthetic ancillary substances. Specific restrictions or prohibitions will be communicated in an annotation or in NOP Guidance.</p>	
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