



BEYOND PESTICIDES

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National Organic Standards Board
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Re. HS: “Other Ingredients” Proposal

These comments are submitted on behalf of Beyond Pesticides. 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, 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.

We have a lot to say about many issues raised by this proposal, but we do not want the central point to be lost, so here it is:

- **All ingredients of a product labeled “organic” must be either organic or on the National List for that purpose.**

Overview

The Handling Subcommittee (HS) proposes a procedure for dealing with “other ingredients” – that is, ingredients in organic food that get there by virtue of being ingredients in an ingredient. One of the beautiful things about the *Organic Foods Production Act* (OFPA) is that the criteria are very simple: Does it harm people or the environment (related to its source, production, and use)? Is it essential? Is it compatible with organic principles? OFPA says nothing about risk assessment, whether something is an “incidental” or “other” ingredient, whether it's added by a certified handler or someone else. It simply requires us to take a hard look at all inputs in processed food. The Handling Subcommittee proposal for dealing with “other” ingredients would circumvent the necessary review of all non-organic the ingredients in processed food. There is nothing in OFPA that justifies making the distinction between “ingredients” and “other ingredients,” and the proposal does not point to underlying statutory language that would waive this responsibility for review. We support the option “D” we presented in comments to the discussion document last fall (see Appendix) –no ingredient of any kind can be in processed food labeled organic unless it is organic or on the National List.

Comments on Recommendation Document

There are many issues raised by the recommendation document that do not necessarily have a direct bearing on the proposal itself, but nevertheless must be addressed because the subcommittee is putting forth a framework in which this and other issues are discussed –and we find this framework to be inconsistent with OFPA.

1. Distinguishing and Defining “Other Ingredients”

The first paragraph of the discussion document states, Since OFPA requires that each non-organic ingredient be specifically allowed, and because the National List does not specifically list “other ingredients” commonly found in formulated products, the NOP [National Organic Program] identified the need for clarity and requested that the NOSB develop a policy that specifies whether these “other ingredients” are allowed.

OFPA requires that each non-organic ingredient be specifically evaluated before being allowed for use in processed food labeled organic and does not differentiate between “ingredients” and “other ingredients.” The distinction seems to have arisen after so-called “other ingredients” had made their way into organic food without specific approval. This failure of process, contrary to OFPA, does not mean that a new definition is needed for these ingredients in organic processing. The NOP and HS have compared “other ingredients” to so-called “inert” ingredients in crop inputs. Yes, there are some similarities —both are secret, not listed on the label, for example— but OFPA specifically provides for the consideration and evaluation of “inert” ingredients, while making no special category for “other ingredients” as described by the NOP or HS. The authors of OFPA also hoped —and this Board is in the process of making that hope a reality—that “inert ingredients” as a special class would eventually be abolished. The idea of a “special class” of materials that is held to a different (lower) standard is not consistent with OFPA. In fact, the fact that the statute specifically cites “inerts that are not of classified by the Administrator of the Environmental Protection Agency as inerts of toxicological concern,” but is silent on “other ingredients” suggests that a special category of exemption from review was not envisioned in the statute. It is helpful to make the analogy to inerts, but only to support the need for full review under the provisions of the law.

The recommendation background states,

Currently, the allowance of “other ingredients” in substances on the National List used in processed organic products is unclear, particularly in contrast with crop and livestock substances. For organic crop and livestock production, specific categories of “other ingredients” are allowed as inert ingredients in pesticides and excipients in animal drugs.

While inert ingredients used in pesticide products, and excipients used in animal drugs are addressed, the regulations are silent on “other ingredients” used in *non*-pesticide and *non*-drug products.

These statements lead us to the conclusion that the addition of these “other ingredients” skirts the law and is contrary to OFPA. Later, the subcommittee states,

In contrast, the National List for processed products does not include a provision that provides allowances for any “other ingredients.” Instead, certain substances on the National List, such as flavors, colors and fish oil, specify a *restriction* on the use of “other ingredients.” This has led some to believe that “other ingredients” used in handling materials are allowed unless specifically prohibited.

It seems counterintuitive to conclude that materials would be allowed if not specifically prohibited when OFPA creates a clear default against the use of synthetic substances unless approved.

As the recommendation background says, “The term ‘other ingredients,’ as described in the NOP Memo to NOSB, is not a recognized regulatory term with a legal definition.” The document proceeds to define “other ingredients” as “additives added during the manufacturing of a non-organic substance and **not** removed.” It adds, “They may be considered ‘incidental additives’ by FDA.” This creates a fuzzy link between “other ingredients” and “incidental additives.” What is the legal connection? (The commingling of OFPA and FDA terminology is problematic—the term “additive,” for example, does not include Generally Recognized as Safe (GRAS) materials.)

The following bullet list from the background expands on the definition of “other ingredients”:

- They are added during the manufacturing of a non-organic substance and **not** removed.
- They are not added directly by the certified handler.

We have difficulty seeing how it is relevant to the evaluation of an ingredient in a processed organic food whether it is added by a certified handler or someone else.

- They are present in a food at insignificant levels and have no technical or functional effect in that food.

This is not helpful to us, since the Board has no definition of “insignificant” or “technical or functional effect.”

- 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 recommendation background adds, “An incidental additive is usually present because it is an ingredient within another ingredient used in the final product, or it is a processing aid added to a food for its technical or functional effect in the processing and present only in insignificant amounts in the final food.” Again, we have a definition depending on “insignificant” and “technical or functional effect,” that have never been defined by the Board. Furthermore, under “Relevant areas in OFPA and Regulations,” the document states,

OFPA prohibits a certified handler from adding “any synthetic **ingredient** not appearing on the National List during processing or any postharvest handling.” The National List heading in the regulations at § 205.605 and § 205.606 also specify the use of non-agricultural substances and agricultural products, respectively, referred to as ‘**ingredients.**’ While OFPA does not reference processing aids, the regulations under § 205.301(f)(4) prohibit the use of ‘**processing aids**’ during the handling of an organic product unless they are approved on the National List. Both terms are included under 205.2 (Terms Defined). Furthermore, in the final ruling on the Harvey II case (Nov. 2, 2006, the District Court of Maine¹) the Courts determined that Congress did not

¹OFPA does not refer to ‘processing aids.’ However, in the final ruling on the Harvey II case Nov. 2, 2006, the District Court of Maine ruled that the OFPA change of 2005 that allowed synthetic “ingredients” also allowed

distinguish between the general term “ingredients” and “processing aids,” and authorized the use of synthetic substances, whether ingredients or processing aids, for the use in handling operations so long as they appear on the National List (Memorandum Decision on Motion to Enforce Judgment and Cross Motion for Relief from Judgment, U.S. District Court, District of Maine, Civil Docket 2:02cv216).

Is the distinction between “ingredients” and “processing aids” relevant to OFPA? Apparently, the courts think not.

The crux of the HS position is:

- “It should be clear that ‘other ingredients’ discussed in this paper 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.”
- “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 may be considered “incidental additives” by FDA...”

The distinction that the HS attempts to make in these excerpts is extraneous to the purposes of OFPA. The distinction between direct and indirect additives is not found in OFPA, and §205.301(b) contradicts this distinction:

(b) Products sold, labeled, or represented as “organic.” A raw or processed agricultural product sold, labeled, or represented as “organic” must contain (by weight or fluid volume, excluding water and salt) not less than 95 percent organically produced raw or processed agricultural products. Any remaining product ingredients must be organically produced, unless not commercially available in organic form, or must be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part. If labeled as organically produced, such product must be labeled pursuant to §205.303. [Emphasis added.]

Furthermore, §205.105 states,

To be sold or labeled as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food group(s)),” the product must be produced and handled without the use of:

synthetic “processing aids” as long as they appear on the National List. The Court determined that Congress did not distinguish between the general term “ingredients” and “processing aids,” and authorized the use of synthetic substances, whether ingredients or processing aids, for the use in handling operations so long as they appear on the National List (Memorandum Decision on Motion to Enforce Judgment and Cross Motion for Relief from Judgment, U.S. District Court, District of Maine, Civil Docket 2:02cv216). [Footnote in recommendation document.]

- (c) Nonagricultural substances used in or on processed products, except as otherwise provided in §205.605;
- (d) Nonorganic agricultural substances used in or on processed products, except as otherwise provided in §205.606;

The fact that most of these ingredients may be exempt from FDA's labeling requirements may pose a problem for some processors in determining all of the ingredients in their products, but it is irrelevant to OFPA. OFPA requires that all ingredients must be organic or on the National List. A reference to an FDA allowance in the non-organic market does not override the Board responsibility to review ingredients labeled organic in accordance with OFPA.

2. Baseline Criteria

The HS's "baseline criteria," which would be the only criteria applied under the proposal, are described as "the existing requirements that are already imposed by OFPA and 7 CFR Part 205." This is a misleading description because they have nothing to do with the OFPA criteria. The criteria used by FDA to approve a substance as a food additive, allowed as (possibly self-) affirmed as GRAS, or issue a letter of no objection to the substance being listed as GRAS have nothing to do with OFPA criteria. Criterion #3 would prohibit a substance already prohibited by federal action. Criterion #4, "It ... does not meet FDA's definition of an 'incidental additive'," is irrelevant to OFPA, since "incidental additive" is not defined by OFPA or the NOP regulations, has nothing to do with the OFPA criteria of no harm to people or the environment, essentiality, and compatibility with organic principles.

3. Policy and Procedure

The section on policy and procedure begins, "NOSB currently evaluates materials on a case-by-case basis without an overarching policy for 'other ingredients.'" Actually, there is a policy in place—the policy established by OFPA that all ingredients must be either organic or listed on the National List. It is unfortunate that, for whatever reason, that policy has not always been followed. The issue should not be "How can we draft a new policy that codifies our mistakes?," but "How can we correct the mistakes of the past to ensure organic integrity as we move forward?"

The recommendation states: "The NOSB intends to review "other ingredients" found in substances on and petitioned for the National List. Comprehensive review does not require "other ingredients" to be individually listed on the National List, however." The problem with this statement is that, as shown above, it is not consistent with the law.

4. Confidential Business Information (CBI)

The recommendation states, "Petitions that contain CBI ingredients run the risk of not having those ingredients reviewed. Please see the NOSB's CBI recommendation." This statement is not very clear. There is no NOSB CBI recommendation at this time. At this point, we have a CBI discussion document. Lacking a clear general policy on CBI, the HS should state in this proposal how it proposes to address CBI claims with respect to "other ingredients." We suggest that the identity of an "other ingredients" is not an appropriate CBI claim for organic food.

5. Other Considerations

The subcommittee recommends, “moving cleaners, sanitizers, disinfectants and other non-food substances such as boiler additives to their own designated section of the National List and develop policy specific to these types of items. This section should apply to Crops, Livestock and Processing materials.” There is no reason to create another section of the National List. §205.601 deals with crop inputs as diverse as hydrogen peroxide, newspaper mulch, sticky traps, pheromones, and cheese wax. There is no reason that §205.605 cannot list a variety of nonagricultural inputs into processing and handling and §205.606 a variety of agricultural inputs. Similar to what we have stated above, all ingredients of these materials should be organic or on the National List.

We disagree with the HS suggestion in closing that the proposal, “would likely stimulate the use of “other ingredients” in 205.605 substances that are either organic or on the National List.” We believe that the best way to encourage “other ingredients” that are either organic or on the National List is to require compliance with OFPA from the start.

In conclusion, we repeat our central point:

- **All ingredients of a product labeled “organic” must be either organic or on the National List for that purpose.**

Thank you for your consideration of these comments on the Handling Subcommittee’s other ingredients recommendation.

Sincerely,



Terry Shistar, Ph.D.
Board of Directors

Appendix: Description of Option D

Our proposed Option D is a clear, straightforward OFPA-compliant alternative. “Other ingredients” are ingredients. They are evaluated under OFPA criteria of health and environmental impacts, essentiality, and compatibility with organic principles, just like any ingredient. They are petitioned and possibly approved for listing on §205.605 or §205.606, just like any ingredient. The proposal eliminates distinctions that are extraneous and irrelevant to OFPA.

All ingredients in a processed product labeled as organic must either be organically produced or on the National List on §205.605 or §205.606, making who adds them irrelevant.

Review Criteria for NOSB

- Review all petitions for all ingredients. Petitioners must disclose ingredients, or materials will not be listed.
- Processors must ensure that all ingredients (including those added by others) are either organically produced or on the National List.
- Review during Sunset the ingredients not previously petitioned or allowed or disclosed.
- A petitioner for an ingredient must ensure —by petition or reformulation if necessary— that all subingredients are on the National List.
- Secondary direct or indirect additives not used in direct contact with certified product must be reviewed under OFPA criteria since environmental impacts, essentiality, and compatibility, taking into account the cradle-to-grave life of the substances, are still relevant.