

BEYOND PESTICIDES

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Re. HS: "Other Ingredients" Discussion Document

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 discussion document, but we do not want the central point to be lost, so here it is:

<u>All ingredients</u> of a product labeled "organic" must be either organic or on the National List <u>for that purpose</u>.

Overview

The Handling Subcommittee (HS) asks for comments on options 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--just take a hard look at all inputs. It looks like all of these options for dealing with "other" ingredients are just putting things in the way of taking a hard look at all the ingredients –as was done years ago when it was decided to call some pesticide ingredients" and "other ingredients." We support a fourth option –no ingredient of any kind can be in food labeled organic unless it is on the National List. This fourth option, which we will call "Option D," is very similar to Option C, which *almost always* requires all ingredients to be on the National List.

Comments on Discussion Document

There are many issues raised by the discussion document that do not necessarily have a direct bearing on the questions raised by the HS, but nevertheless must be addressed because they are 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 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 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.

The discussion document 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.

All of these facts 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 discussion document 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 are defined as "incidental additives" by FDA." (As we will note below, the commingling of OFPA and FDA terminology is problematic – the term "additive," for example, does not include GRAS materials.)

The next paragraph has a very different definition of "incidental additives": "ingredients that are present in a food at insignificant levels and do not have any technical or functional effect in that food." This is not helpful to us, since we have no definition of "insignificant" or "technical or functional effect." It 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." According to the full definition in the appendix, "insignificant" applies to the ingredient within an ingredient as well as the processing aid. Furthermore, the discussion 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 nonagricultural 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 the Courts 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.¹

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

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 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 from discussion document.]

organic processed product must be on the National List at § 205.605 or § 205.606. "Other ingredients" are substances that are present by way of having been incorporated into an allowed substance on the National List. As such, most, if not all "other ingredients," will fall under FDA's definitions for incidental additives and, if present at only insignificant levels, are exempt from FDA's labeling requirements.

The distinction that the HS attempts to make in this paragraph 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. <u>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.]</u>

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:

(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 <u>all ingredients must be organic or on the National List.</u>

2. Baseline Criteria

The HS's "baseline criteria," which under Option A would be the only criteria applied, are described as "the existing requirements that are already imposed by OFPA and 7 CFR Part 205." This is a misleading description because it is a list of <u>alternative</u> (that is, separated by "or") criteria, most of which have nothing to do with the OFPA criteria. Criteria 1 or 2 are legal requirements –that is, if the ingredient is not organic then it must either be on the National List (#1) or required by another statute (#2). Criteria #3-5 are meaningless in this context. Criteria #6-8 mention prohibitions in OFPA. Criterion #9, "It provides a technical or functional effect in the final certified organic product and therefore does not meet FDA's definition of an 'incidental additive'," is irrelevant to OFPA, since "technical or functional effect" and "incidental additive" are not defined by OFPA or the NOP regulations, and neither has anything to do with

the OFPA criteria of no harm to people or the environment, essentiality, and compatibility with organic principles.

3. Policy Options

The section on policy options begins, "NOSB currently evaluates materials on a case-bycase 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, as we move forward?"

A major "Con," or a critical flaw, of both Options A and B is that they do not meet the legal requirements of OFPA. Option C comes much closer to meeting the minimum legal requirements, with the exception of the provision:

Secondary direct or Indirect additives not used in direct contact with certified product are allowed provided the operator has clear intervention/contamination prevention measures detailed in their OSP.

This provision does not meet the requirements of OFPA. Regardless of whether the material is in direct contact with food, it must still meet the OFPA criteria of no harm to humans or the environment (related to its source, production, and use), essentiality, and compatibility with organic principles.

We will have more to say about policy options below.

4. "Other Considerations"

We agree with the HS suggestion, "It would be helpful if the NOP creates a publicly available database that documents material review and specifies 'other ingredients' that were reviewed and approved." This is true whether or not any of the suggested options are adopted. The NOSB and the public need to know what ingredients have been approved that are not on the National List.

The HS suggests, "If no hurdles exist, we will consider drafting a recommendation that would assign commercial availability to all §205.605 listed substances." §205.270(b) states,

(b) Nonagricultural substances allowed under §205.605 and nonorganically produced agricultural products allowed under §205.606 may be used:

(1) In or on a processed agricultural product intended to be sold, labeled, or represented as "organic," pursuant to §205.301(b), if not commercially available in organic form....

And §205.301(b) states,

(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.

Thus, it appears that the HS suggestion is already in effect.

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.

1. Description of Option D

All ingredients in a processed product labeled as organic must either be organically produced or on the National List on §205.605 or §205.605, 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.

Pros

- Most clarity about the regulation because it is the same regulation for all ingredients.
- Most protective in terms of what non-organic ingredients can be used.
- Reduced number of options for non-organic ingredients and corresponding growth of organic minor ingredients that would lead to increased organic acreage and increased business opportunity.

- Customers who buy and eat organic foods can be certain that all the ingredients in an organic product, whether or not required by law to be listed on the finished product label, are either organic or on the National List.
- ACAs and MROs and processors have a clear rule for making materials decisions.
- Promotes a strong incentive to use organic ingredients.
- Clear and simple process for retailers and marketers to explain to consumers.
- Most likely to meet most consumer advocates' expectations for organic food.
- Could reduce the number of synthetic ingredients used in organic processing as processors seek alternatives.

Cons

• All ingredients (carriers, standardizing agents, stabilizers, pH adjusters, diluents, etc.) that are not on the National List or "organic" will need to be petitioned which could result in significant review and rulemaking.

• NOP and NOSB may need additional resources and could be burdened by the time needed to review petitions and complete necessary rulemaking.

- Could potentially increase the number of synthetic substances on the National List.
- Reduced number of options for non-organic ingredients and corresponding loss of products currently on the market due to limited options.

• Would have commercial and cost implications for certified manufacturers that could lead to loss of organic products, which would lead to reduced organic acreage.

- Many products currently on the market may be non-compliant.
- Compliance on an international level must be ensured.
- Would have commercial and cost implications for certified manufacturers.

• May result in certified organic products currently on the market becoming unavailable because a manufacturer of an ingredient chooses not to reformulate to meet these new requirements.

2. Comparison of Options C and D

For your convenience, we provide a side-by-side comparison of Options C and D. Italic and bold formatting are used to distinguish aspects that are the *Same* or **Different**. In most cases, we adopted the HS assignment of "Pros" and "Cons."

Option C	Option D
All ingredients in a processed product labeled	Option D is the clearest, most
as organic must either be organically produced	straightforward interpretation of OFPA.
or on the National List. NOSB creates three	"Other ingredients" are ingredients. They are
new sections to the National List that are	evaluated under OFPA criteria of health and
designated for incidental additives only	environmental impacts, essentiality, and
(other ingredients). They may not be used	compatibility with organic principles, just like
directly by a certified handler in or on a	any other ingredient. They are petitioned and
certified product. They are allowed only by	possibly approved for listing on §205.605 or
way of having been incorporated into a	§205.606, just like any other ingredient. We
substance appearing on § 205.605 or §	forget distinctions that are extraneous and

205.606 of the National List.	irrelevant to OFPA.
 Review Criteria for NOSB Review all petitions for other ingredients according to the Baseline Criteria, the regulations and guidance. Review during Sunset the "other ingredients" not previously petitioned or allowed. Suspend all new petitions for final ingredients until there are petitioners of final ingredients. (Or: Require petitioners of final ingredients to submit petitions for other ingredients if not previously petitioned or allowed.) NOSB creates three new sections to the National List that are designated for incidental additives only (other ingredients). The new sections would be as follows: o § 205.607(a) Non-synthetic nonagricultural incidental additives allowed only in substances that appear on § 205.605(a) or § 205.607 (c) Non-organic agricultural incidental additives allowed only in substances that appear on § 205.605(b); and o § 205.607 (c) Non-organic agricultural incidental additives allowed only in substances that appear on § 205.605(b); and o § 205.607 (c) Non-organic agricultural incidental additives allowed only in substances that appear on § 205.605(b); and o § 205.605(b); or § 205.606. 	 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 for that purpose. 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 for that purpose. All ingredients in a processed product labeled as organic must either be organically produced or on the National List on §205.605 or §205.605. It is irrelevant who adds them. 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. A transition time should not be necessary,
sanitizers, disinfectants and secondary direct food additives: o "Other ingredients" contained in sanitizers or cleaners or other similar non-food inputs that are used in direct contact with certified product must be on the National List or their allowance must be specified through an annotation via a CAS number or reference to another agency's regulation, (e.g. peracetic acid), or their use must be mandated by law or specifically allowed through NOP Policy.	since Option D is just the law as it stands. However, currently listed substances will have until their sunset date to bring products into compliance.

 o Secondary direct or Indirect additives not used in direct contact with certified product are allowed provided the operator has clear intervention/contamination prevention measures detailed in their OSP. • NOSB recommends a transition time for currently listed substances that will allow manufactures and non-organic ingredients and certified handlers adequate time to bring products into compliance. NOP will specify this transition or implementation time in their draft and final guidance. 	
 Pros: More clarity about the regulation. Reduced number of options for non-organic ingredients and corresponding growth of organic minor ingredients that would lead to increased organic acreage and increased business opportunity. Customers who buy and eat organic foods can be certain that all the incidental ingredients, which by law are not required to be listed on the finished product label, in an organic product are either organic or on the National List. ACAs and MROs have a clear rule to make materials decisions. Promotes a strong incentive to use organic ingredients. Clear and simple process for retailers and marketers to explain to consumers. Most likely to meet many if not most consumer advocates expectations for organic food. 	 Pros Most clarity about the regulation because it is the same regulation for all ingredients. Most protective in terms of what non- organic ingredients can be used. (Listed as "Con" for Option C.) Reduced number of options for non- organic ingredients and corresponding growth of organic minor ingredients that would lead to increased organic acreage and increased business opportunity. Customers who buy and eat organic foods can be certain that all the ingredients in an organic product, whether or not required by law to be listed on the finished product label, are either organic or on the National List for that purpose. ACAs and MROs and processors have a clear rule for making materials decisions. Promotes a strong incentive to use organic ingredients. Clear and simple process for retailers and marketers to explain to consumers. Most likely to meet most consumer advocates expectations for organic food.

	• Could reduce the number of synthetic ingredients used in organic processing as processors seek alternatives.
 Cons: Most restrictive in terms of what ingredients can be used. (Listed as "Pro" for Option D.) All "other ingredients" (carriers, standardizing agents, stabilizers, pH adjusters, diluents, etc.) that are not on the National List or "organic" will need to be petitioned which could result in significant review and rulemaking. NOP and NOSB have limited time and resources and could be overly burdened by the time needed to review petitions and complete necessary rulemaking. Could potentially increase the number of synthetic substances on the National List, which may be misunderstood by consumers. Reduced number of options for non-organic ingredients and corresponding loss of products currently on the market due to limited options, especially for materials like pectin and gums. Would have commercial and cost implications for certified manufacturers that could lead to loss of organic acreage. Many products currently on the market may be non-compliant. Product from countries with an equivalency agreement won't need to comply. Product from countries without an equivalency agreement may file a Technical Barrier to Trade complaint with the World Trade Organization. Would have commercial and cost implications for certified manufacturers Similar "cons" related to varying interpretations of annotations and the potential for the NOSB to list "other ingredients" that are petitioned by a select few. 	 Cons All ingredients (carriers, standardizing agents, stabilizers, pH adjusters, diluents, etc.) that are not on the National List or "organic" will need to be petitioned which could result in significant review and rulemaking. NOP and NOSB have limited time and resources and could be burdened by the time needed to review petitions and complete necessary rulemaking. Could potentially increase the number of synthetic substances on the National List. Reduced number of options for non-organic ingredients and corresponding loss of products currently on the market due to limited options, especially for materials like pectin and gums. Would have commercial and cost implications for certified manufacturers that could lead to reduced organic acreage. Many products currently on the market may be non-compliant. Compliance on an international level must be ensured. Would have commercial and cost implications for certified manufacturers May result in certified organic products currently on the market becoming unavailable because a manufacturer of an ingredient chooses not to reformulate to meet these new requirements.

• May result in certified organic products	
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chooses not to reformulate to meet these new	
requirements.	

Responses to questions in the discussion document

- 1. Which is your preferred option? Please answer with the following in mind:
- a. Which option best captures the intent of the law?
- b. Which option best captures the expectation of the consumer?
- c. Which option is best for the growth of the organic industry?
- d. Which option will be the most difficult to implement? Describe the obstacles.

Option D, which we describe in these comments, is our preferred option. It is the only option that fully complies with the law and captures the expectation of the consumer that all non-organic ingredients in organic food will be on the National List and comply with OFPA criteria. We believe it is the best for the growth of the organic industry because it is fully transparent and hence easy to comply with. It also encourages the development of organic solutions.

Implementation of different options will be difficult for different people. Option D will be less difficult than option C for the NOP because it creates consistency and straightforward implementation of the rules already on the books. Options C and D should have similar difficulty for the NOSB in terms of review. Option D, because of its transparency, should be easy for processor compliance. Options A and B may be easier in some ways, but, since they do not meet the standards of OFPA, are not worth discussing.

2. Do you think that in general, *nonsynthetic* incidental additives should be allowed without further petitioning, review or rulemaking if they meet baseline criteria?

No. The "baseline criteria" are far from OFPA criteria. All ingredients should comply with OFPA.

3. Should the use of organic substitutes be required of § 205.605 substances when they are commercially available?

As we understand the regulations, this is the current requirement.

4. Should organic preference (synthetic allowed when nonsynthetic is not available; nonsynthetic allowed when organic is not available) be assigned to "other ingredients"? Is this practical? How would it be enforced?

Certainly, organic processors should always use organic preference for all ingredients. The preference for nonsynthetic over synthetic can be enforced if the NOSB does not approve synthetics when nonsynthetic alternatives exist. Certifiers should enforce preference for organic over nonorganic.

5. Is it acceptable to allow "other ingredients" as incidental components of an allowed substance on the National List? Does it make a difference knowing they are present at amounts typically below 10ppm?

All ingredients, including so-called "other ingredients" must be either organic or listed on the National List for the specific use. The quantity is irrelevant. OFPA is not a risk assessment statute, but requires <u>all ingredients</u> to be judged on a qualitative basis on their cradle-to-grave impacts.

6. Should sanitizers, cleaners and disinfectants be moved to their own section of the National List and dealt with separately from ingredients and processing aids?

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.

7. Should "other ingredients" used in sanitizers, cleaners, or disinfectants be organic or on the National List?

<u>All ingredients</u> must be organic or on the National List.

8. How can the system of reviewing non-organic ingredients used in processed organic products be improved?

The system of review would be greatly improved if everyone involved read OFPA and took it seriously.

Thank you for considering these lengthy comments to the (even more lengthy) discussion document.

Sincerely,

Jeresalha Hit

Terry Shistar, Ph.D. Board of Directors