

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date:

Subject:

Chair:

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement:

Other:

Statement of Recommendation: (Motion # 1)

The NOSB intends to review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. Comprehensive review, however, does not require these substances to be individually listed on the National List. 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. A procedure is presented to carry out this review that includes identification of ancillary substances, Technical Review support, NOSB checklist revisions, and process for annotation or guidance implementation of the policy.

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

The NOP requested clarification on this issue in a memorandum to the NOSB in November of 2011. OFPA and the Rule are not very specific regarding this subject and a policy and procedure is needed because the reviews of handling materials have been inconsistent with regard to ancillary substances. The recommendation adopted unanimously is consistent with OFPA by calling for review to OFPA criteria. It is consistent with what some ACAs are doing now, and makes it clearer what petitioners and NOSB member should expect for future ingredient reviews.

Committee Vote:

Moved:

Seconded:

Yes:

No:

Abstain:

Absent:

Recuse:

**National Organic Standards Board
Handling Subcommittee
Recommendation
Ancillary Substances ("Other Ingredients")**

April 11, 2013

Introduction

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 the memo to NOSB, NOP requested the following:

The NOP is requesting that the NOSB develop a policy on “other ingredients” in § 205.605 substances that is comparable to the comprehensive policy for crop and livestock materials. From this point forward, NOP is requesting that NOSB consider the presence of any “other ingredients” as part of its processes. As substances on the National List come up for sunset review, or as new petitions are considered, NOP requests that NOSB clarify whether any restrictions are warranted for “other ingredients” in § 205.605 substances. Any third-party technical report that NOP provides will include information on any “other ingredients” commonly found in the substance under review.

NOP is requesting that NOSB specify any allowed “other ingredients” in the background section of its recommendations for substances recommended for listing on § 205.605, so that these allowances are clear to the organic trade, certifying agents, and NOP. Any “other ingredients” not listed on § 205.605 or not referenced in the background section of the recommendation, would not be allowed in formulations of substances on § 205.605 that are used in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The memo continues:

NOSB may want to address the subject further in the future with a comprehensive policy for “other ingredients” that may be included in permitted handling materials. Some questions that could be addressed in a future recommendation could include the following:

1. Should all agricultural ingredients that are “other ingredients” be organically produced?
2. Are synthetic preservatives allowed as “other ingredients”?

In response to the memo, the NOSB Handling Subcommittee has developed a policy for “other ingredients” that may be included in permitted handling materials. This recommendation defines “other ingredients” and the scope of their review.

Background

The NOP regulations require that all certified organic producers and handlers use materials that comply with the applicable parts of the Standards [7 CFR Part 205]. The Standards include Subpart G (The National List), which specifies allowed and prohibited non-organic inputs for use in organic crop and livestock production and nonorganic substances allowed in organic food processing and handling.

In general, for crop and livestock production, non-synthetic materials are allowed unless prohibited. Synthetic substances may be used provided they are on the National List and used in accordance with any specified restrictions. In contrast, the handling standards require that all non-organic non-agricultural substances, whether synthetic or non-synthetic, be included on the National List. Non-organic agricultural ingredients used in the 5% of an “organic” product must also be on the National List AND commercially unavailable in organic form.

Some items on § 205.605 and on § 205.606, however, are sold as multicomponent substances or mixtures wherein the “active” or listed substance is combined with “other ingredients,” (e.g. carriers, stabilizers and antioxidants) to provide a **necessary** technical effect on the National List substance. In certain cases, small amounts of standardizing agents may be incorporated to ensure the substance meets the specifications required by their standards of identity. Examples of § 205.605 substances that generally contain “other ingredients” include, but are not limited to, biological substances such as enzymes, dairy cultures and microorganisms; cleaners, sanitizers and disinfectants such as peracetic acid; and nutrient vitamins. Examples of § 205.606 items that generally contain “other ingredients” include, but are not limited to, casings from processed intestines, colors, fish oil, pectin, and whey protein concentrate.

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 drugs are addressed, the regulations are silent on “other ingredients” used in **non**-pesticide and **non**-drug products. The NOP memo states that for other crop and livestock materials a synthetic “other ingredient” is prohibited unless it appears on the National List and non-synthetic “other ingredients” are allowed unless prohibited by the National List. Livestock vitamins and minerals often include other ingredients, but these may be considered approved by certifiers as part of the vitamin or mineral due to lack of restrictions or further clarification on permitted sources of vitamins and minerals

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.

Relevant areas in OFPA and Regulations (see **Appendix 1** for full references)

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 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).

There is inconsistent use of the term ‘substance’ used throughout OFPA and the regulations. OFPA clearly states that other ingredients should be evaluated as part and parcel of the consideration of substances for inclusion on the list. In establishing the criteria for what should be included on the national list and how items on the National List should be evaluated, OFPA uses the term “substance” to describe these items. It does not use terms like “single ingredient” or even “ingredient” in Sections 2118 or 2119 and it does not state that substances with more than one ingredient must be evaluated individually. Indeed, Sec. 2119 (l)(2) makes it clear that it was understood that substances might contain multiple ingredients where it says:

- “Sec. 2119 (l)(2) work with manufacturers of substances considered for inclusion on the National List to obtain a complete list of ingredients and determine whether such substances contain inert materials that are synthetically produced;” {emphasis added}

However, the Federal Register Notice on Procedures for Submitting National List Petitions [72 *Federal Register* 2167] has not fostered a clear and consistent approach to the issue. The Notice reads:

Any person may submit a petition requesting a substance to be reviewed by the NOP and NOSB at any time. Each substance to be evaluated for the National List must be submitted in a separate petition. **Only single substances may be petitioned for evaluation; formulated products cannot appear on the National List.**

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).

Furthermore, the NOSB recommendation of November 2009 in the context of classification of materials uses the following definition for "substance":

"*Substance*. A generic type of material, such as an element, molecular species, or chemical compound that possesses a distinct identity (e.g. having a separate Chemical Abstracts Service (CAS) number, Codex International Numbering System (INS) number, or FDA or other agency standard of identity)."

Discussion

Defining Ancillary Substances ("other ingredients")

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. **See Appendix 2** for other relevant FDA Definitions.

"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.

It should be clear that ancillary substances 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.

The NOP memo only requested a policy on § 205.605 listings on the National List. However non-organic ***agricultural*** ingredients or products listed on § 205.606 of the National List often contain "other ingredients" also. The Handling Subcommittee believes it will be more efficient and result in overall better comprehension to address both sections of the National List at the same time.

Baseline Criteria

We believe that baseline criteria should be used for the evaluation of ancillary substances, based on the existing requirements that are already imposed by OFPA and 7 CFR Part 205. As baseline we propose that all ancillary substances must be legal for use in food in the United States, (appears 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. The NOSB is aware that some ingredients are legally used in food products that are deemed GRAS by manufacturers who

do not disclose the safety information by submitting a notification to FDA, but finds that ingredients used in organic food, should at a minimum, be reviewed for safety by the FDA, with such information publicly disclosed.²

The **baseline criteria** are as follows:

Ancillary substances (“Other ingredients”) are those that are authorized for use in materials on the National List at § 205.605 and § 205.606 according to the following criteria:

1. Any substance either approved as a food additive or listed or affirmed as GRAS in the FDA Database “Everything Added to Food in the United States (EAFUS)” [<http://www.fda.gov/Food/FoodIngredientsPackaging/ucm115326.htm>]
2. Any substance listed in the GRAS Notification Inventory published by FDA, with a letter of no objection.
[see <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=grasListing>]

AND any component or ingredient would be disallowed if:

3. Prohibited by federal regulatory action [7 U.S.C. § 6517(d)] or;
4. It is 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’.

Recommendation

Policy and Procedure

NOSB currently evaluates materials on a case-by-case basis without an overarching policy for ancillary substances. Additionally, ACAs and MROs have no overall guidance on other ingredients from the NOP, varying capacities for materials review and wide latitude to make decisions unless specific decisions are overruled by the NOP. While the review of materials in general for use in organic production and handling is currently quite rigorous, there is need for improvement and harmonization of the system to assure continued confidence and growth of the industry.

NOP clearly recognizes the need to improve review of non-organic ingredients as reflected by their declaration in the memo that third party technical reviews will include information on “ancillary substances” and their request that NOSB consider their presence as part of their review process “from this point forward.” This recommendation clarifies the policy to be used for review and sets out a set of procedures to achieve a more consistent and transparent review of these ingredients.

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

² As [FDA notes](#): “The EAFUS list of substances contains ingredients added directly to food that FDA has either approved as food additives or listed or affirmed as GRAS. Nevertheless, it contains only a partial list of all food ingredients that may in fact be lawfully added to food, because under federal law some ingredients may be added to food under a GRAS determination made independently from the FDA. The list contains many, but not all, of the substances subject to independent GRAS determinations.”

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 non-synthetic 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.

Procedure

The following procedure will be used in review of all new petitions to add substances to the National List. It will also be used during the sunset review of existing listings. The sunset process on the more complex groups of substances mentioned below will need to start about six months earlier than normal to allow for stakeholders to submit input on other ingredients before a TR is commissioned.

This procedure refers only to the NOSB review, but not ACA procedures. It is anticipated that following adoption of this proposal the NOP will issue guidance for ACAs, MROs and handlers about their procedures in this matter.

NOSB Review:

- 1) NOSB identifies “ancillary substances” as disclosed in the petition and previous Technical Reports, and through the public comment process.
- 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.
- 3) TR identifies commonly used ancillary substances and describes them.
- 4) All ingredients must meet Baseline Criteria (above).
- 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.
- 6) NOSB may recommend ancillary substances individually, categorically or a combination of both.
- 7). The NOSB may or may not stipulate in a review that any agricultural ancillary substances must be organically produced.
- 8). Materials listed on § 205.605(a) and 205.606 may contain synthetic or non-synthetic ancillary substances. Specific restrictions or prohibitions will be communicated in an annotation or in NOP Guidance.

Appendix 1 – Regulatory References

OFPA

SEC. 2111. [7 U.S.C. 6510] HANDLING.

- (a) IN GENERAL.—For a handling operation to be certified under this title, each person on such handling operation shall not, with respect to any agricultural product covered by this title—
- (1) add any synthetic ingredient not appearing on the National List during the processing or any postharvest handling

SEC. 2118. [7 U.S.C. 6517] NATIONAL LIST.

- (a) IN GENERAL.—The Secretary shall establish a National List of approved and prohibited substances that shall be included in the standards for organic production and handling established under this title in order for such products to be sold or labeled as organically produced under this title.
- (b) CONTENT OF LIST.—The list established under subsection (a) shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2).

NOP Regulations

§ 205.2. Terms Defined.

Ingredient. Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.

Processing aid.

- (1) Substance that is added to a food during the processing of such food but is removed in some manner from the food before it is packaged in its finished form;
- (2) a substance that is added to a food during processing, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and
- (3) a substance that is added to a food for its technical or functional effect in the processing but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.

§ 205.301 Product composition.

(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.

(c) *Products sold, labeled, or represented as “made with organic (specified ingredients or food group(s)).”* Multi-ingredient agricultural product sold, labeled, or represented as “made with organic (specified ingredients or food group(s))” must contain (by weight or

fluid volume, excluding water and salt) at least 70 percent organically produced ingredients which are produced and handled pursuant to requirements in subpart C of this part. No ingredients may be produced using prohibited practices specified in paragraphs (f)(1), (2), and (3) of §205.301. Nonorganic ingredients may be produced without regard to paragraphs (f)(4), (5), (6), and (7) of §205.301. If labeled as containing organically produced ingredients or food groups, such product must be labeled pursuant to §205.304.

(f) All products labeled as “100 percent organic” or “organic” and all ingredients identified as “organic” in the ingredient statement of any product must not:

(4) Be processed using processing aids not approved on the National List of Allowed and Prohibited Substances in subpart G of this part: Except, That, products labeled as “100 percent organic,” if processed, must be processed using organically produced processing aids;

§ 205.605 Nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

The following nonagricultural substances may be used as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s))” only in accordance with any restrictions specified in this section.

[Examples of specified restrictions addressing “other ingredients”:]

(a) Nonsynthetics allowed:

Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(b) Synthetics allowed:

Peracetic acid/Peroxyacetic acid (CAS # 79–21–0)—for use in wash and/or rinse water according to FDA limitations. For use as a sanitizer on food contact surfaces.

§ 205.606 Nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as “organic.”

Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.

[Examples of specified restrictions addressing “other ingredients”:]

(d) Colors derived from agricultural products—Must not be produced using synthetic solvents and carrier systems or any artificial preservative.

(f) Fish oil (Fatty acid CAS #'s: 10417–94–4, and 25167–62–8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.

Appendix 2 – FDA references

Food additive. A substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, either in the substance becoming a component of food or otherwise affecting the characteristics of food. A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container. A substance that does not become a component of food, but that is used in preparing an ingredient of the food to give a different flavor, texture, or other characteristic in the food, may be a food additive. 21 CFR § 170.3.

Secondary Direct Food Additive. This term is in the title of 21 CFR 173, which was created during recodification of the food additive regulations in 1977. A secondary direct food additive has a technical effect in food during processing but not in the finished food (e.g., processing aid). Some secondary direct food additives also meet the definition of a food contact substance. For more on food contact substances, consult the Food Contact Substance Notification Program.

Indirect Food Additive - In general, these are food additives that come into contact with food as part of packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on the food. Indirect food additives mentioned in Title 21 of the U.S. Code of Federal Regulations (21CFR) used in food-contact articles, include adhesives and components of coatings (Part 175), paper and paperboard components (Part 176), polymers (Part 177), and adjuvants and production aids (Part 178). Currently, additional indirect food additives are authorized through the food contact notification program. In addition, indirect food additives may be authorized through 21 CFR 170.39.

Incidental additive. (3) Incidental additives that are present in a food at insignificant levels and do not have any technical or functional effect in that food. 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 4.

GRAS - "GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the FD&C Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. GRAS substances are distinguished from food additives by the type of information that supports the GRAS determination, that it is publicly available and generally accepted by the scientific community, but should be the same quantity and quality of information that would support the safety of a food additive. Additional information on GRAS can be found on the GRAS Notification Program page.

Appendix 3 – Other Considerations

In the course of developing policy, several other considerations became apparent. The Handling Sub-Committee hopes to do further work on some of these subjects in the future and brings them up here because they are relevant to reviewing handling materials.

- If a new policy is adopted there will be need for transition time for operators to bring products into compliance. NOP will need to specify this transition or implementation time in their draft and final guidance
- We recommend 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.
- The Handling Subcommittee recommends that the CACS take up the issue of a standardized template that is required for non-organic ingredient affidavits. The template could include legal language vetted with the NOP that would hold ingredient manufacturers more accountable about avoiding excluded methods, technical effects of other ingredients and other issues.