National Organic Standards Board
Handling Subcommittee
"Other Ingredients" Discussion Document
August 21, 2012

Introduction[1]

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-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.

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 Sub-Committee is currently working to develop a policy for "other ingredients" that may be included in permitted handling materials. This discussion document defines "other ingredients" and the scope of their review,

[1] The NOSB Handling Subcommittee wishes to thank the members of the ad hoc Materials Working Group for providing a framework for this Discussion Document. Their names are in Appendix 3.

provides historical and regulatory background, and proposes a range of policy options for consideration along with an assessment of their impact on the organic sector.

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 dictates allowed synthetic and prohibited nonsynthetic 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.

The chart in Appendix 4 lists the substances currently on §205.605, the specific list of non-agricultural substances that are the subject of the NOP request; the agricultural substances currently listed at §205.606, which were not mentioned in the NOP request but some of which share the characteristic of containing "other ingredients"; and those substances recommended by NOSB but which have not yet completed the process, along with those "other ingredients" identified in the original petition, a Technical Advisory Panel (TAP) review or a Technical Report (T)R). The chart also references examples of "other ingredients" that are disclosed on specification sheets that certifiers use when determining compliance for a formulated ingredient.

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. As stated in the NOP memo of November 23, 2011, for crop and livestock

products, 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. The Handling Subcommittee believes that exceptions have been made for livestock vitamins and minerals due to the fact that they commonly contain “other ingredients” but their use is required to fulfill the nutritional needs of certified livestock.

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 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.[2].

The Federal Rule § 205.301 determines that product composition for products labeled as "organic" must contain only ingredients that are organically produced (95%) or "be nonagricultural substances or nonorganically produced agricultural products produced consistent with the National List in subpart G of this part".

Examples of specified restrictions addressing "other ingredients" in § 205.605 include:

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

Examples of specified restrictions addressing "other ingredients" in § 205.606 include:

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

[2]OFPA 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).

(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.

The inconsistent use of the term 'substance' used throughout OFPA and the regulations, and 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.**

Discussion

Defining "other ingredients"

This discussion paper focuses on the use and allowance of "**other ingredients**" contained in § 205.605 items. 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 will be used throughout this discussion document. For this purpose, "other ingredients" will be defined as additives added during the manufacturing of a non-organic substance and ***not*** removed. They are defined as "incidental additives" by FDA.

FDA defines "incidental additives" as ingredients that are present in a food at insignificant levels and do not have any technical or functional effect in that food. 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. In such cases, per FDA labeling regulations, incidental additives and processing aids do not need to be declared on the label of the final food (certified product) (CFR Title 21 101.22(h)(3) and 101.100 (a)(3i to iii4). **See Appendix 2** for other relevant FDA Definitions.

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. "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 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 Sub-Committee believes it will be more efficient and result in overall better comprehension to address both sections

of the National List at the same time. Therefore, we have incorporated § 205.606 into our policy options in this discussion paper.

We have not presented policy options for synthetic solvents and processing aids used during the production of non-organic ingredients on § 205.605 and § 205.606 in this document. This topic is part of the overall 'Classification of Materials' discussion, thus we believe it is outside the scope of the "other ingredients" discussion provided the processing aids or solvents undergo a removal step.

Baseline Criteria

We believe that baseline criteria that should be used for the evaluation of "other ingredients," based on the existing requirements that are already imposed by OFPA and 7 CFR Part 205. This would parallel those identified in the NOP Memo for Inerts in crop pesticides and Excipients in Livestock drugs. These baseline criteria would apply to all policy options for review of ingredients.

The **baseline criteria** are as follows:
"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. The National List [7 CFR 205.605 – 606] or;
2. Mandatory federal requirements [7 U.S.C. §6519(f)] or;
3. FDA (GRAS) or otherwise [7 U.S.C. § 6517(c) and 7 U.S.C 6519(f)]; or
4. EPA [7 U.S.C. § 6517(c) and 7 U.S.C 6519(f)] or;
5. Any other federal regulatory agency with primary jurisdiction over that substance [7 U.S.C 6519(f)].

AND any component or ingredient would be disallowed if:

6. Prohibited by federal regulatory action [7 U.S.C. § 6517(d)] or;
7. Produced using excluded methods [7 CFR 205.105(e) and 7 CFR 205.2] or;
8. Contain any heavy metals or toxic residues in excess of established tolerance levels set by FDA or EPA [7 U.S.C. § 6510(a)] or;
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'.

Policy Options

NOSB currently evaluates materials on a case-by-case basis without an overarching policy for "other ingredients." 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 reports will include information on "other ingredients" and their request that NOSB consider their presence as part of their review process "from this point forward." In acknowledgement of this request, the options

presented all include NOSB review of “other ingredients”. A fundamental variation between the options however is the method by which NOSB specifies the allowance of “other ingredients” after they have conducted their review.

Option A simply includes NOSB review of “other ingredients” as requested by NOP, but allows for the presence of all “other ingredients” unless they are restricted or prohibited by an annotation. Option B aligns with the request in the NOP memo, but includes suggestions to help facilitate review by certifiers and MROs and includes additional criteria that are specific to the various categories of materials on § 205.605 and § 205.606. Option C presents a blanket policy that while easy to understand would be very challenging to implement. The pros and cons of each option are described in further detail below.

Option A

For all newly petitioned non-organic ingredients, the NOSB considers "other ingredients" identified in the petition and Technical Report and documents the review in the background section of their recommendation. Items already on the National List are not subject to this provision, unless the NOSB explicitly requests a Technical Report to address the ‘other ingredient’ question of a particular item subject to Sunset Review. Unless restrictions are specified in an annotation, any “other ingredient” that meets Baseline Criteria is permitted.

Review Criteria for NOSB

Other ingredients must meet Baseline Criteria (above). NOSB will determine whether any specific prohibitions that should be specified in an annotation based on their review of “other ingredients” discussed or disclosed in the petition or Technical Report or presented in further research or public comment.

Pros:

- Processors, handlers and their suppliers have the greatest possible latitude to formulate ingredients and develop organic products.
- ACAs and MROs have a minimum amount of documentation to review.
- All products that meet the current standard and policy comply unless NOP specifies otherwise.
- Policy is the least likely to cause inconsistencies with major trading partners.
- Greater number of options for non-organic ingredients.
- Less time and energy spent on the allowed non-organic portion freeing up more time to advocate and work towards increased organic production.

Cons:

- Little incentive to source organic alternatives to ingredients on 7 CFR 205.605.
- There is no transparent way to be able to look up all of the non-organic substances that might be contained in a certified product containing non-organic ingredients.
- Potential decline in the value of the organic label due to dilution and loss of consumer confidence.

Option B

The NOSB would follow the request by NOP to consider “other ingredients” during their review as substances come up for sunset review or as new petitions are considered. The NOSB would review “other ingredients” included in the petition and Technical Report. The

NOSB recommendation includes a note that the other ingredients were reviewed and accepted. The “other ingredient” is entered into a database maintained on the NOP Website. Materials listed on § 205.605(a) and § 205.606 must not contain any "synthetic" incidental additives unless they are on the National List at § 205.605(b) or specifically allowed by NOSB. Non-synthetic incidental additives are allowed unless specifically prohibited. Synthetic incidental additives are allowed in 205.605(b) items if they are included and documented in the NOSB review. Any additional restrictions are specified in an annotation.

Other ingredients in general product categories that are currently on § 205.605 and § 205.606 and currently used in certified organic processed product will be grandfathered for one sunset period recommendations, including vitamins, minerals, enzymes, dairy cultures, yeast, microorganisms, natural flavors, and colors. NOSB can recommend exceptions for new materials that are petitioned as appropriate. The National List is restructured to create a separate category and exceptions for cleaners, sanitizers, disinfectants and other substances that are secondary direct and indirect food additives subject to a separate Baseline Criteria.

Review Criteria for NOSB:

- Other ingredients must meet Baseline Criteria (above).
- NOSB considers “other ingredients” as disclosed in the petition and Technical Report.
- If the substance is recommended for inclusion on the National List, the NOSB may specify implicit allowance of all other ingredients, deny allowance of other ingredients, or prohibit those other ingredients in the recommendation.
- NOSB may recommend “other ingredients” individually, categorically or a combination of both.
- Non-synthetic ingredients used as other ingredients in items are allowed unless specifically prohibited.
- The NOSB may stipulate in a review that any agricultural "other ingredients" must be organically produced.
- Materials listed on § 205.605(a) and 205.606 must not contain any "synthetic" incidental additives unless they are on the National List at § 205.605(b) or specifically allowed by NOSB.
- Synthetic incidental additives are allowed in 205.605(b) substances if they were reviewed, approved and documented by NOSB.
- NOSB specifies any additional restrictions or allowances in an annotation.
- As a part of the Sunset Review process, the NOSB should request Technical Reports on the following product categories currently on the National List:
    - Vitamins/Minerals
    - Enzymes (including animal enzymes)
    - Microorganisms
    - Dairy Cultures
    - Natural Flavors
    - Agricultural Colors

  The TR will help the NOSB determine whether other ingredients that are not “organic” or on the National List are currently being used in these categories and whether to recommend annotation or documentation in the database.

- "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.

- Substances classed by FDA as 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.

Pros:

- Greater consistency amongst ACA's and MRO's.
- Having the NOSB provide relevant annotations for each material would enable each material to be looked at in its context.
- The NOSB assessment would be open for review and public comment, bringing greater transparency.
- Would clarify the review process for most materials that contain carriers, stabilizers, standardizing agents.
- Most likely to meet many if not most consumer advocates expectations for organic food.
- Individual ingredients would be assessed according to use and type.
- Other regulatory agencies would be referred to for legally approved formulas for cleaners, sanitizers, boiler additives.

Cons:

- Annotations can still be interpreted differently and may not always be clear.
- Annotations are verified through desk audit. Increased paperwork for verification purposes.
- This option could only work if there is a consistent policy/decision tree on how to determine nonsynthetic vs. synthetic.
- More work for the NOSB.
- More work for ACAs and MROs to collect and review the necessary information.
- Only certain specific formulas will be petitioned and receive Technical Reports. Some Branded formulations currently used in organic processed products may include other ingredients not reviewed because the manufacturer is unable or unwilling to disclose all of the ingredients.
- The NOP may not keep up the aforementioned database

Option C

All ingredients in a processed product labeled as organic must either be organically produced or on the National List. NOSB creates three new sections to the National List that are designated for incidental additives only (other ingredients). They may not be used directly by a certified handler in or on a certified product. They are allowed only by way of having been incorporated into a substance appearing on § 205.605 or § 205.606 of the National List.

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 petitions for other 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:

    - § 205.607(a) Non-synthetic nonagricultural incidental additives allowed only in substances that appear on § 205.605(a) or § 205.605(b);
    - § 205.607(b) Synthetic nonagricultural incidental additives allowed only in substances that appear on § 205.605(b); and
    - § 205.607 (c) Non-organic agricultural incidental additives allowed only in substances that appear on § 205.605(a), § 205.605(b), or § 205.606.

- Exceptions are made for cleaners, sanitizers, disinfectants and secondary direct food additives:
    - “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.

    - 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.

Cons:

- Most restrictive in terms of what ingredients can be used.
- 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 products, which would lead to reduced 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.
- 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.

Other Considerations

In the course of developing policy options for this paper, 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 under any of these policy options.

- 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.
- 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 would like to explore a recommendation to move 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.
- We would like to ask NOP to report on what legal and regulatory hurdles exist that prevent assigning commercial availability to all § 205.605. If no hurdles exist, we will consider drafting a recommendation that would assign commercial availability to all § 205.605 listed substances.

Increasing the use of organic ingredients and processing aids has been a very explicit goal of the organic community since early on. The key to increasing organic ingredients lies in the interpretation of the phrase, commercial availability. The NOSB has already endorsed the concept of a pro-active approach to the development and creation of organic analogs to

replace non-organic and synthetic items. Implementation of the pro-active program that would apply to both § 205.605 and § 205.606 substances would help encourage and further the development of organic minor ingredients. In turn this would likely stimulate the use of “other ingredients” in 205.605 substances that are either organic or on the National List.

Comments Requested

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.

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

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

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?

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?

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?

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

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

Sub-Committee Vote

Motion: The Handling Sub-Committee moves to accept this document and present it for full board discussion at the Fall 2012 NOSB meeting

Motion by: Zea Sonnabend Second: Tracy Favre
Yes: 7 No: 0 Absent: 0 Abstain: 0 Recuse: 0

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”:

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

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 terms

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), adjuvants and production aids and sanitizers (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. 21 CFR101.100(a)(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 constitutents 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 – Materials Working Group

The Materials Working Group is an unaffiliated ad hoc committee of volunteers with technical and regulatory background. The MWG was initiated in November, 2007 following the NOSB meeting to work on clarifying the issues surrounding the definitions of “nonagricultural,” “synthetic” and “nonsynthetic,” and to provide the NOSB with recommendations and guidance documents relating to those definitions. Participation in the group is voluntary, open and available to any interested party.

The NOSB Handling Subcommittee wishes to thank members of the Materials Working Group for their help in putting together this Discussion Document.

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Appendix 4 – Chart of § 205.605 and § 205.606 substances along with “other ingredients” identified in Technical Reviews and Petitions.

FDA Regulatory citation & Category	7 CFR 205.605	Other Ingredients (TAP, TR, Petition, NOSB Recommendation)	Comments
(a) *Nonsynthetics allowed:*			
Biological Materials			

	Animal enzymes—(Rennet—animals derived; Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin)	2000 TAP: Enzyme preparations usually contain diluents, preservatives (to prevent microbial growth In liquid preparations), antioxidants, and other food grade substances consistent with current good manufacturing practice. Among the substances used in commercial rennet preparations include salt (sodium chloride), propylene glycol, sodium benzoate, and sodium propionate.	
21 CFR 184.1685	Rennet		
21 CFR 184.1034	Catalase		
21 CFR 184.1415	Animal lipase		
21 CFR 184.1583	Pancreatin		
21 CFR 184.1595	Pepsin		
21 CFR 184.1914	Trypsin		
21 CFR 184.	**Dairy cultures.**	No mention of "other ingredients" (other than milk)	See specification sheets for Enzymes and Dairy Cultures
21 CFR 184.	**Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.**		See specification sheets for Enzymes and Dairy Cultures
	Plant enzymes	1995 TAP: ". . . Carriers and stabilizers used to keep them mold-free and stable . . ."	
	Microbial enzymes	1995 TAP: "Preparations from microbial sources are the most important source of commercial enzymes and are produced from the fermentation of specifically selected nonpathogenic and nontoxicogenic strains of microorganisms. These microorganisms are **grown on natural food grade substances (such as starch and corn meal)**	Specification sheets lists calcium sulfate and wheat (carrier) as ingredients used in combination with enzymes. See spec sheet

		under controlled conditions which prevent the introduction of undesirable microorganisms or other substances. Enzymes are recovered from the fermentation broth under mild conditions usually by mechanical separation means, such as filtration or centrifugation and then concentrated using ultrafiltration or evaporation. **Any carriers, diluents, or processing aids used in the production of enzyme preparations are acceptable for general use in food**, and the levels used do not exceed specified limits." "**Preservatives** are almost always added during processing, and optionally in the final preparation, to prevent microbial growth and to stabilize and maintain the desired enzymic activity. Proper and appropriate use of **preservatives and stabilizers** serve to protect the consumer from unsafe or ineffective enzyme products. When the enzyme is intended for addition to food, **all such additives and diluents** must be acceptable to the FDA for use in food. They must be of food grade quality and the levels used must not exceed specified limits." 2011 Enzymes TR: "Microbial enzymes used in food processing and are typically sold as enzyme preparations, which are mixtures with the desired enzyme activity that contain preservatives (such as boric acid and natamycin), stabilizers (such as salts and aminoacetic acid), and other metabolites of the production strain." "Substances used in commercial rennet preparations include salt (sodium chloride), propylene glycol, sodium benzoate, boric acid, and sodium propionate."	for Watson Enzymes. Example spec sheet for Marzyme Enzyme lists Sodium chloride, acetic acid and sodium acetate
	Microorganisms—any food grade bacteria, fungi, and other	TAP: Only discusses enzymes, dairy cultures, and yeasts; PETITION: Miso - non-pathogenic fungi used for fermentation; Pre-gelatinized starch	

	microorganism.	added.	
21 CFR 184.	**Yeast—nonsynthetic, growth on petrochemical substrate and sulfite waste liquor is prohibited**	Yeast, Autolysate, Brewer's, Nutritional - nothing added Yeast, Bakers - Yeast cake is mixed with oils, emulsifiers and water... (From TAP 1996) Yeast, Smoked - Hickory smoke added for flavor. Spec sheet included with TAP (1996) showing only yeast and Hickory smoke flavor.	**(Autolysate; Bakers; Brewers; Nutritional; and Smoked—non-synthetic smoke flavoring process must be documented)**
Defined Substances			
	Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).	no "other ingredients"	
21 CFR 184.1011	Alginic acid	no "other ingredients"	
21 CFR 184.1033	Citric acid	1995 TAP: "pure substance"	
21 CFR 184.1061	Lactic acid	TAP: NO additives noted; MSDS Indicates impurities in mfg proess possible (10-20% Lactic Acid lactate)	
21 CFR 184.1115	Agar-agar.	1995 TAP: no "other ingredients." 2011 TR: no "other Ingredients."	
21 CFR 184.1155	Bentonite.	1995 TAP: no "other ingredients."	
21 CFR 184.1191	Calcium carbonate.	no "other ingredients"	
21 CFR 184.1193	Calcium chloride.	No TAP; no "other ingredients"	
21 CFR 184.1230	Calcium sulfate—mined.	2001 TAP: Terra Alba as mined may contain certain impurities (limestone (calcium carbonate) and various naturally occurring forms of silica). No "added ingredients."	

21 CFR 172.620	Carrageenan.	1995 TAP: Carrageenan precipitated isopropyl alcohol may contain traces of residual isopropyl alcohol (21 CFR refers only to water extraction); may contain residues of epichlorhydrin from chlorinated antimicrobials. If recovered by drum drying, may contain up to mono- and diglycerides or up to 5% polysorbate 80. Chemicals may be added when standardizing carrageenan: sugar, sodium chloride, potassium chloride, phosphate salts, other hydro-colloids. 2011 TER: No mention of "added ingredients."	Example Specification sheet: Standardized with Sucrose
21 CFR ??? GRAS	Diatomaceous earth—food filtering aid only.	Some DE is calcined in the presence of suitable flux (soda ash (sodium carbonate) or other alkaline salt)	
21 CFR ??? GRAS	Egg white lysozyme (CAS # 9001–63–2)	No specific combination products were identified for egg white lysozyme (or bromelain). Lysozyme is directly added to foods as a hydrochloride salt.	
21 CFR 184.	**Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.**	The natural flavor does not contain propylene glycol, any artificial preservative, and is not extracted with hexane. Manufacturers must provide written documentation in their Organic Handling Plan, which shows that efforts were made toward the ultimate production of an organic natural flavor as listed in the stepwise progression below: 1. Natural flavor constituents and non-synthetic carrier base and preservative agents; 2. Organic flavor constituents, organic carrier base, and organic preservative agents; and 3. Organic flavor constituents extracted using organically produced solvent, organic carrier base, and organic preservative agents.	
21 CFR 172.665	Gellan gum (CAS # 71010–52–1)—high-acyl form only.	None shown in TAP, committee recommendation or petition	
21 CFR 184.1318	Glucono delta-lactone—	None shown inTAP. No committee recommendation. MSDS shows 99%	

	production by the oxidation of D-glucose with bromine water is prohibited.	GDL in petition.	
21 CFR 186.1256	Kaolin.	TAP MSDS shows 90-100% kaolin. No petition, or recommendations given	
21 CFR 184.1069	L-Malic acid (CAS # 97–67–6).	TAP: No other ingredients identified; must be from microbial fermentation.	
21 CFR 184.1443	Magnesium sulfate, nonsynthetic sources only.	TR: No other ingredients	
21 CFR 184.1540	Nitrogen—oil-free grades.	No other Ingredients	
21 CFR ??? GRAS	Oxygen—oil-free grades.	No other Ingredients	
21 CFR ??? GRAS	Perlite—for use only as a filter aid in food processing.	No other Ingredients	
21 CFR 184.1622	Potassium chloride.	No documents available on NOP website	
21 CFR 184.1634	Potassium iodide.	No other Ingredients	
21 CFR 184.1736	Sodium bicarbonate.	1995 TAP: No combinations listed. One reviewer states: "As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic element concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adopted.	
21 CFR 184.1742	Sodium carbonate.	1995 TAP: No combinations listed. One reviewer states: "As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic element concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adopted.	
21 CFR 184.1099	Tartaric acid—made from grape wine.	1995 TAP:	

	Waxes—nonsynthetic (Carnauba wax; and Wood resin).	Wax 2007 TAP: "Shellac is used as a hard protective coat, and will rapidly harden if not kept in a solvent. Aqueous lac will also be combined with various synthetic preservatives such as phenol, or the mixed methyl and propyl esters of p-hydroxybenzoic acid. It is almost always used with pure ethyl alcohol, but will occasionally isopropyl alcohol is used as a solvent. Often used with wood resins. Ammonium soap is used as a flowing and solidifying agent with wood resin and shellac."	
21 CFR 184.1978	Carnauba wax	1996 TAP ("Fruit Waxes"): No other Ingredients	
21 CFR 172.210	Wood rosin	1996 TAP ("Fruit Waxes"): No other Ingredients	
(b) *Synthetics allowed:*			
Sanitizers, other Secondary Direct Food Additives			Sanitizer examples and common "other ingredients" are not presented here.
21 CFR 186.1750	**Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.**		
21 CFR 173.325	**Chlorine materials—disinfecting and sanitizing food contact surfaces, (Calcium hypochlorite;**	2006 TR: "products contain no other active ingredients and contain no inert ingredients other than water"	***Except,* That, residual chlorine levels in the water shall not exceed the maximum residual**

	Chlorine dioxide; and Sodium hypochlorite).		**disinfectant limit under the Safe Drinking Water Act**
21 CFR ???	Calcium hypochlorite		
21 CFR 186.1750	Sodium hypochlorite		
21 CFR 178.1010	Chlorine dioxide		
21 CFR 184.1366	Hydrogen peroxide.		
21 CFR 184.1563	Ozone.	Petition includes oxygen and air as potential secondary ingredients; no other ingredients noted	
21 CFR 178.1010	**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.**	Original petition unable to obtain from NOP website; TAP Crops and Livestock: Stabilizers are acknowledged to be not considered in the review; TAP Processing: HEDP, dipicolini acid (2, 6-pyridinedicarboxylic acid), sulfuric acid, octanoic acid, peroxyoctanoic acid, sodium 1-octanesulfonate - mentioned in TAP but not evaluated to OFPA and the NL; HEDP mentioned in TAP reviews Committee recommendation.	
21 CFR 173.370	Acetic acid		
21 CFR 184.1005	Hydrogen peroxide	No TAP, committee recommendation, or petition shown.	
21 CFR 184.1366	HEDP (1-hydroxyethylidene-1,1-diphosphonic acid)		
21 CFR 178.1010	Sulfuric acid		
21 CFR 184.1095	Octanoic acid		
21 CFR 184.1025			
21 CFR 182.1073	Phosphoric acid—cleaning of food-contact surfaces and	TAP: Always combined with surfactant. Naphthalenesulfonic acid, sodium dodecylbenzene sulfonic acid, carboxylic acids, citric acid, lactic acid,	

	equipment only.	isopropyl alcohol, mention of FDA approved solutions, EDTA ethylenediaminetetraacetic acid	
21 CFR 173.310	Cyclohexylamine (CAS # 108–91–8)—for use only as a boiler water additive for packaging sterilization.	No "other ingredients"	
21 CFR 173.310	Diethylaminoethanol (CAS # 100–37–8)—for use only as a boiler water additive for packaging sterilization.	No "other ingredients." Blended with sodium zeolite softened water.	
21 CFR 173.310	Octadecylamine (CAS # 124–30–1)—for use only as a boiler water additive for packaging sterilization.	No "other ingredients"	
Nutrient vitamins and minerals			
	Nutrient vitamin ingredients		
21 CFR 184.1930	**Vitamin A**	No other ingredients mentioned in TAP	
21 CFR 184.1950	**Vitamin D**	No other ingredients mentioned in TAP	
USP/FCC	Vitamin K_1 (Phylloquinone) [required per 21 CFR 107.100(c)]	No other ingredients mentioned in TAP	
	Vitamin K [Menaquinone-7]	No other ingredients mentioned in TAP	[GRN No. 245 submitted & withdrawn]
21 CFR 182.8890	Vitamin E [tocopherols]	No other ingredients mentioned in TAP	
21 CFR 182.8892	Vitamin E [alpha-tocopherol acetate]	No other ingredients mentioned in TAP	
21 CFR	Ascorbic acid	No other ingredients mentioned in	

182.8013		TAP	
21 CFR 182.3189	Calcium ascorbate	No other ingredients mentioned in TAP	
21 CFR 182.3731	Sodium ascorbate	No other ingredients mentioned in TAP	
21 CFR 184.1875	Thiamine hydrochloride	No other ingredients mentioned in TAP	
21 CFR 184.1878	Thiamine mononitrate	No other ingredients mentioned in TAP	
21 CFR 184.1695	Riboflavin	No other ingredients mentioned in TAP	
21 CFR 184.1697	Riboflavin-5'-phosphate, sodium	No other ingredients mentioned in TAP	
21 CFR 184.1676	Pyridoxine hydrochloride	No other ingredients mentioned in TAP	
21 CFR 184.1945	**Vitamin B12**	No other ingredients mentioned in TAP	
21 CFR 184.1530	Niacin	No other ingredients mentioned in TAP	
21 CFR 184.1535	Niacinamide	No other ingredients mentioned in TAP	
21 CFR 172.345	Folic acid	No other ingredients mentioned in TAP	
21 CFR 184.1212	Calcium pantothenate	No other ingredients mentioned in TAP	
21 CFR 182.8159	Biotin	No other ingredients mentioned in TAP	
21 CFR 182.8890	Tocopherols—derived from vegetable oil when rosemary extracts are not a suitable alternative.	No other ingredients mentioned in TAP	
21 CFR ??? GRAS	Activated charcoal (CAS #s 7440–44–0; 64365–11–3)—only from vegetative sources; for use only as a filtering aid.	Pure carbon; no other ingredients	
	Alginates.	Alginates are produced from alginic acid and various alkaline elements (pH control agents). The pH control agents (are) ammonia, calcium	

		hydroxide, potassium hydroxide, sodium hydroxide. No "other ingredients" mentioned.	
21 CFR 184.1133	Ammonium alginate		
21 CFR 184.1187	Calcium alginate		
21 CFR 184.1610	Potassium alginate		
21 CFR 184.1721	Sodium alginate		
21 CFR 184.1135	Ammonium bicarbonate—for use only as a leavening agent.	No TAP Review available; this substance is a single entity	
21 CFR 184.1137	Ammonium carbonate—for use only as a leavening agent.	No TAP Review available; this substance is a single entity	
21 CFR 182.8013	Ascorbic acid.	1995 TAP: no "other ingredients"	
21 CFR 184.1195	Calcium citrate.	1995 TAP: no "other ingredients"	
21 CFR 184.1205	Calcium hydroxide.	1995 TAP: no "other ingredients"	
21 CFR 182.8217	Calcium phosphates (monobasic, dibasic, and tribasic).	1995 TAP: no "other ingredients"	
21 CFR 182.6215	Monobasic calcium phosphate	1995 TAP: no "other ingredients"	
21 CFR 182.1217	Dibasic calcium phosphate	1995 TAP: no "other ingredients"	
21 CFR 182.1217	Tribasic calcium phosphate	1995 TAP: no "other ingredients"	
21 CFR 184.1240	Carbon dioxide.	1995 & 2006 Tap: No "other ingredients"	
21 CFR ??? GRAS	Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.	Petition: 100% cellulose (no "other ingredients"). 2001 TAP: "All additives must appear on the National List"	

21 CFR 184.	Ethylene—allowed for postharvest ripening of tropical fruit and degreening of citrus.	No "other ingredients"	
21 CFR 184.1307	Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).	MSDS in TAP states composed of Iron II sulfate hydrate and sulfuric acid (2+) salt. No petition, or committee recommendation.	
21 CFR 184.1505	Glycerides (mono and di)—for use only in drum drying of food.	None listed in TAP, or petition. No committee recommendation.	
21 CFR 182.1320	Glycerin—produced by hydrolysis of fats and oils.	No TAP, committee recommendation, or petition shown.	
21 CFR 184.1425	Magnesium carbonate—	No" other ingredients" mentioned in TAP; but various grades mentioned	for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))”
21 CFR 184.1426	Magnesium chloride—derived from sea water.	No" other ingredients" mentioned in TAP	
21 CFR 184.1440	Magnesium stearate—	No" other ingredients" identified in TAP, but identified as a potential "incidental" additive itself in the TAP review	for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))”
21 CFR 184.1595	Pectin (low-methoxy).	No "other ingredients"	

21 CFR 184.1077	Potassium acid tartrate.	No "other ingredients"	
21 CFR 184.1619	Potassium carbonate.	No "other ingredients"	
21 CFR 184.1625	Potassium citrate.	1995 TAP: no "other ingredients"	
21 CFR 184.1631	Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches during the Individually Quick Frozen (IQF) production process.	No "other ingredients"	
21 CFR 184.1634	Potassium iodide—	No "other ingredients"	for use only in agricultural products labeled “made with organic (specified ingredients or food group(s))”
21 CFR 184.	Potassium phosphate—	No "other ingredients"	for use only in agricultural products labeled “made with organic (specific ingredients or food group(s))”
21 CFR 184.	Monobasic potassium phosphate	No "other ingredients"	
21 CFR 182.6285	Dibasic potassium phosphate	No "other ingredients"	
21 CFR 184.	Tribasic potassium phosphate	No "other ingredients"	
21 CFR 172.480	Silicon dioxide.	Petition: The 2010 petition to remove does not mention other ingredients. TR: The 1995 and 2010 TRs do not mention other ingredients.	

21 CFR 182.1087	Sodium acid pyro-phosphate (CAS # 7758–16–9) –for use only as a leavening agent.	Petition: The 2002 petition and 2009 petition to for expanded use do not mention other ingredients. TR: The 2002 and 2010 TRs do not mention other ingredients.	
21 CFR 184.1751	Sodium citrate.	TR: The 1995 TAP lists no other ingredients.	
21 CFR 184.1763	Sodium hydroxide—prohibited for use in lye peeling of fruits and vegetables.	1995 TAP: No combinations listed. One reviewer states: "As with all synthetic inorganic salts, source must be food grade. In addition each lot should be analyzed for toxic elemnt concentrations (mercury, lead, cadmium, arsenic, thallium and antimony) and a near zero tolerance adpted.	
21 CFR 182.8778	Sodium phosphates—for use only in dairy foods.	Petition: The 2001 petition for sodium hexametaphosphate mentions other sodium phosphates. TR: The 2001 TAP review states: Sodium phosphates are combined with calcium phosphates as leavening agents (Horsford, 1864; Ellinger, 1972; FMC, no date). Sodium orthophosphates are often combined with insoluble sodium metaphosphate (IMP) and various polyphosphates (Ellinger, 1972; FMC, no date). The addition of other salts, such as sodium chloride, can have a synergistic effect on water-holding capacity (Gordon and Klimek, 2000). Typical commercial mixtures contain 30-60% soluble orthophosphates and 40-70% IMP (Gard, 1996). Starches are often used as carriers (Ashford, 1994). Trisodium phosphate used for cleaning is often combined with sodium hypochlorite (bleach) (Ashford, 1994). Sodium aluminum phosphate and sodium acid pyrophosphates are also used as a leavening agents (Food Chemicals Codex, 1996). The sodium phosphates are often used in combination with various gels such as agar, alginates, carageenan, pectins, and various gums (Ellinger, 1972).	

		The previous sodium phosphates TAP Review (NOSB, 1995) only reviewed the forms mono-, di-, and tri-sodium phosphates. . This TAP Review does not cover other forms such as metaphosphates, pyrophosphates, polyphosphates, or combinations of sodium phosphates with any elemental constituents other than hydrogen.	
21 CFR 182.3862	Sulfur dioxide—for use only in wine labeled “made with organic grapes,”.	Petition: The 2010 petition does not mention other ingredients. TR: The 1995 TAP does not mention combinations. The 2011 TR mentions citric acid and carbon dioxide, both of which appear on 205.605.	Provided, That, total sulfite concentration does not exceed 100 ppm
21 CFR 184.1099	Tartaric acid—made from malic acid.		
21 CFR 182.6789	Tetrasodium pyrophosphate (CAS # 7722–88–5)—for use only in meat analog products.	Petition not linked on the NOP website. The 2002 TAP review states: "Tetrasodium pyrophosphate is combined with calcium phosphates as leavening agents (Ellinger, 1972; FMC, no date). TSPP has a synergistic effect on various foaming agents, such as alkyl polycarboxylates and triethyl citrate (Sutton, 1960). Other salts, such as sodium chloride, can have a synergistic effect on water-holding capacity of sodium phosphates (Gordon and Klimek, 2000)."	
21 CFR 172.695	Xanthan gum.	1995 TAP review by Steven Harper mentions that isopropyl alcohol is used to extract and purify xanthan gum and it is possible that trace amounts remain. FDA has limits for residual isopropyl.	

7 CFR 205.606	Other Ingredients (TAP, TR, Petition, NOSB Recommendation)
a) Casings, from processed intestines.	No technical report requested. No other ingredients mentioned in the petition.
(b) Celery powder.	The fresh celery is cleaned, concentrated by evaporation, heated and dried. There are no other chemicals or preserving agents used in the manufacture process.

(c) Chia (*Salvia hispanica L.*).	Spanish sage. Petition: No other ingredients mentioned. No TR requested.
(d) Colors derived from agricultural products.	See specific colors as follows:
(1) Annatto extract color (pigment CAS # 1393–63–1)—water and oil soluble.	NOSB recommended removal from the NL
(2) Beet juice extract color (pigment CAS # 7659–95–2).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(3) Beta-carotene extract color, derived from carrots or algae (CAS # 1393–63–1).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73." "Beta-carotene and maltodextrin" in CWS powder. 2009 Petition: "The main articles of commerce are suspensions in food grade vegetable oil or the liquids in oil made dispersable in water using food grade emulsifiers."
(4) Black currant juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: ". . . contains only the natural constituents of the processed black currant. Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(5) Black/Purple carrot juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petitions: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73." pH of flavor is less than 4.0; since carrots are a low-cid food, a food grade acid is being added (presumably citric acid).
(6) Blueberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(7) Carrot juice color (pigment CAS # 1393–63–1).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(8) Cherry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(9) Chokeberry—Aronia juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and	Petitioner A: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."

134–04–3).	Petitioner B: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(10) Elderberry juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(11) Grape juice color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(12) Grape skin extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(13) Paprika color (CAS # 68917–78–2)—dried, and oil extracted.	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73." NOSB: "Organic Oil must be used for the oil extraction."
(14) Pumpkin juice color (pigment CAS # 127–40–2).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(15) Purple potato juice (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(16) Red cabbage extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petitioner A: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73." Petitioner B: "Citric acid and invert sugar may be used for standardization purposes and these ingredients are GRAS."
(17) Red radish extract color (pigment CAS #'s: 528–58–5, 528–53–0, 643–84–5, 134–01–0, 1429–30–7, and 134–04–3).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(18) Saffron extract color (pigment CAS # 1393–63–1).	Petition: "Specific formulation is withheld as a trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(19) Turmeric extract color	2007 Petition: "Specific formulation is withheld as a

(CAS # 458–37–7).	trade secret pursuant to 21CFR20.61. The characterizing principles and/or other components of this color blend are approved and are in compliance with 21CFR73."
(e) Dillweed oil (CAS # 8006–75–5).	No "other ingredients."
(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.	None of the other ingredients are disclosed in the Petition.
(g) Fortified cooking wines.	
(1) Marsala.	No sulfites; grapes and yeast fermented, salt added, bentonite filtered.
(2) Sherry.	No sulfites; grapes and yeast fermented, salt added, bentonite added, filtered with diatomaceous earth.
(h) Fructooligosaccharides (CAS # 308066–66–2).	Sucrose is converted by a fermentation reaction to short-chain molecules containing two, three, or four fructose units. No “other ingredients.”
(i) Galangal, frozen.	
(j) Gelatin (CAS # 9000–70–8).	Specifically states in TAP that it is often combined with other ingredients and each of these other ingredients would need to appear on the NL or be organic. Isinglass (made from fish bladders) can contain tartaric acid to balance pH as a preservative. Metabisulfite as a stabilizer. Bentonite for juice clarification. Sucrose added to increase set time. Capsules use hardening agents like glycerine, various alcohols, propylene glycol, sucrose and acacia. Starches for secondary as disintegrants. Formaldehyde and glutaraaldehyde used as hardening agents for encapsulation of flavors. Surfactants such as polysorbates used for increased dispersion. Substances considered GRAS for use in geletin capsules succinylated gelatin, arabinogalactan, silicon dioxide, glutataldehyde, n-Octyl alcohol, petroleum wax, polyacrylamide, and terpine resin.
(k) Gums—water extracted only (Arabic; Guar; Locust bean; and Carob bean).	None shown in TAP. No petition, or committee recommendation.
Gum Arabic	
Guar Gum	
Locust bean gum	
Carol bean gum	
(l) Hops (*Humulus luplus*).	
(m) Inulin-oligofructose enriched (CAS # 9005–80–5).	
Kafir Lime Leaves	None shown in petition, committee proposal, or formal

	recommendation. No TAP.
(n) Kelp—for use only as a thickener and dietary supplement.	None shown in TAP. No committee recomendationm, or petition.
(o) Konjac flour (CAS # 37220–17–0).	No petition, TAP, or committee recommendation.
(p) Lecithin—de-oiled.	No" other ingredients"
(q) Lemongrass—frozen.	No" other ingredients"
(r) Orange pulp, dried.	No" other ingredients"
(s) Orange shellac-unbleached (CAS # 9000–59–3).	No information available on NOP website
(t) Pectin (high-methoxy).*	TAP on NOP website is for low-methoxy pectin; No "other ingredients" mentioned
(u) Peppers (Chipotle chile).	No" other ingredients"
(v) Seaweed, Pacific kombu.	
(w) Starches.	
(1) Cornstarch (native).	No "other ingredients"
(2) Rice starch, unmodified (CAS # 977000–08–0)—for use in organic handling until June 21, 2009.	Petition: "Rice starch interacts with the other thickening agents to create a unique gelation agent. The combination of rice starch, locust bean gum, pectin, and carrageenen reinforce the gels of each component, provide an elastic texture and prevents syneresis separation of water). " No TR requested.
(c) Chia (*Salvia hispanica L.*).	Spanish sage. Petition: No other ingredients mentioned. No TR requested.
(3) Sweet potato starch—for bean thread production only.	Petition: Is not linked on the NOP's website. No TR requested.
(x) Tragacanth gum (CAS #–9000–65–1).	Petition: The 2007 petition mentions other gums on 606. TR: The 1995 TAP review lists no combinations. No TR requested for the 2007 petition.
(y) Turkish bay leaves.	Petition: The 2006 petition does not mention other ingredients. No TR requested.
(z) Wakame seaweed (*Undaria pinnatifida*).	
(aa) Whey protein concentrate.	No other ingredients mentioned in petition or recommendation

*Specification sheets often indicate pectin is standardized with sugar