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Re. HS: Sunset §605, 606

These comments to the National Organic Standards Board (NOSB) on its Spring 2024 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers, and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

Some general issues pertain to a number of materials. General issues concerning technical reviews (TRs), ancillary substances, fermentation processes, and §606 will be addressed in separate sections of these comments.

Technical Reviews

In a number of cases (for example, microorganisms), the Handling Subcommittee (HS) has cited information from a TR that has not been made available to the public. That is not acceptable--the public should have access to the TR and be able to comment on it and conclusions drawn by the subcommittee.

Ancillary Substances

A Little History

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, NOP identified the need for clarity and requested that the NOSB develop a policy that specifies that all allowed non-organic constituents of organic foods be on the National List in some form. The term “Ancillary Substances” is now being used to refer to these other ingredients.

In response to the memo, the NOSB Handling Subcommittee developed a policy for ancillary substances that may be included in permitted handling materials. It defines “ancillary substances” and the scope of their review. The policy was included in a recommendation that was discussed at the April 2013 NOSB meeting, amended in response to comments from the Board and the public, and passed unanimously.

The central issue in the discussion involved ensuring that ancillary ingredients would be allowed only if they meet OFPA criteria.¹

The HS defined “ancillary Substances” as having the following characteristics:

- They are added during the manufacturing of a non-organic substance and not removed.
- They are not added directly by the certified handler.
- They are present in a food at insignificant levels and have no technical or functional effect in that food.
- They are not required by FDA to be listed on the ingredient panel in that food.
- They are present because they were incorporated into an allowed substance on the National List.
- They may be considered “incidental additives” by FDA, depending on use and type of end product being considered.
- They are not the same as “ingredients” or “processing aids” used for a specific purpose directly by a certified handler in or on processed organic products. The regulations are clear that non-organic ‘ingredients’ or ‘processing aids’ used directly by a certified handler in or on a certified organic processed product must be on the National List at §205.605 or §205.606.

The NOSB recommendation said that the evaluation of ancillary substances would be “based on the existing requirements that are already imposed by OFPA and 7 CFR Part 205.” And again:

The NOSB intends to review ancillary substances found in substances on and petitioned for the National List in accordance with OFPA criteria. Comprehensive review does not require these substances to be individually listed on the National List, however. The Board intends to follow the request by NOP to consider ancillary ingredients contained in substances as they come up for review or as new petitions are considered.

¹ See transcript, <http://www.ams.usda.gov/sites/default/files/media/transcript.pdf>. For example, testimony on pages 82, 140, 171-172, 179, 241-242, 1113-1116, 1125-1126; colloquy at pages 1074-1075, 1082-1083.

In each NOSB review checklist and recommendation cover sheet there will be a clear space to indicate what other ingredients are being reviewed and what restriction if any are placed on them as a result of the review. Restrictions on other ingredients will be included in an annotation and may be for specific individual components, for functional classes of ingredients, or by regulatory reference to another governmental agency such as FDA. The other ingredients restrictions may be incorporated into a permitted substances database for Handling, such as the one that is coming out for crops.

The NOSB recommendation will include a note that the other ingredients were reviewed and accepted. The review of other ingredients will distinguish between synthetic and nonsynthetic ones, as well as agricultural ingredients that might be able to be organically produced. Any additional restrictions will be specified in an annotation.

NOP summary of April 2013 NOSB meeting agreed: “The NOSB recommended a policy by which ancillary substances, as described in the recommendation, would be reviewed by the NOSB against the OFPA criteria.”²

As did the NOP response memo:

The NOP has reviewed the NOSB’s recommendation and supports a review of these ancillary substances according to OFPA requirements. The NOP also agrees that the review does not require these substances to be individually listed on the National List, and reiterates that the NOP could communicate any restrictions or prohibitions in an annotation for the generic substance or in published guidance regarding permitted substances for organic handling.

At the Spring 2015 meeting, the HS brought forward a motion concerning ancillary substances in microorganisms. It was withdrawn and the issues sent back to the HS. At the Fall 2015 meeting, HS proposals for ancillary substances in microorganisms, yeast, and pectin were again sent back to the HS.

Current NOSB Policy

At the Spring 2016 meeting, the NOSB adopted a new procedure for ancillary substances. The proposal included:

1. A definition of Ancillary Substance
2. Criteria used to review ancillary substances that can be used by both the NOSB in initial review and ACAs in subsequent verifications.
3. Procedures for the NOSB to follow for those materials that may have ancillary substances to be reviewed.

The resulting definition is:

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

Ancillary Substance: Additives intentionally added to a non-organic substance on the National List that are not removed and have a technical or functional effect on the non-organic substance, not on the final organic product that the non-organic substance is used in. Ancillary substances may be present in the final organic product but only in insignificant amounts. Ancillary substances fall under the FDA definition and labeling regulations for “incidental additives,” which do not need to be declared on the label of the final food (including organic product) (CFR Title 21 101.22(h)(3) and 101.100 (a)(3 i to iii4). To illustrate: Enzymes are listed on 205.605(a). The enzymes might contain the following additives, which are considered by the organic industry as “ancillary ingredients”: calcium silicate (anticaking agent), calcium phosphate (carrier and/or filler), stearic acid (preservative), sorbitol (stabilizer), sodium citrate (pH control, buffer).

The criteria for compliance approved by the NOSB are:

- At least one must apply:
 1. The ancillary ingredient was considered part of the manufacturing process that has already been reviewed by the NOSB.
 2. The ancillary ingredient is certified organic, on the National List 205.605 or 205.606, or is agricultural (e.g., sugars as standardizing agents in pectin).
 3. The ancillary ingredient is approved by FDA as GRAS for the particular use.
 4. The ancillary ingredient is approved by FDA as a direct food additive or incidental additive for the particular use.
 5. The ancillary ingredient is approved by FDA as a food contact substance for the particular use, as evidenced by a Food Contact Notification (FCN).
- Additionally, the ancillary ingredient cannot be a known or probable carcinogen according to the International Agency for Research on Cancer (IARC) or the National Toxicity Program (NTP). A compiled list is published by the American Cancer Society at <http://www.cancer.org/cancer/cancercauses/othercarcinogens/generalinformation/aboutcarcinogens/known-and-probable-human-carcinogens>. Examples of ancillaries that are listed on the IARC and/or NTP list, and would therefore be prohibited, include formaldehyde and butylated hydroxyanisole (BHA).

The procedure for NOSB review of ancillary substances that was adopted includes these steps:

- At the time of requesting a TR for a new or sunset substance, the NOSB will ask that information about identity and functional classes of ancillary substances be reviewed along with the other evaluation questions.
- For new substances, a chart of the ancillary substances by functional class will be incorporated in the checklist document or whatever review template is used.
- For sunset substances, a chart of the ancillary substances by functional class will be included in the first posting along with a request for new information about existing ancillaries and/or additional ancillary substances to be brought forward in public comment.

- The vote to approve a new substance will be considered to also approve the ancillary substances that are associated with that substance unless the NOSB specifically states that one is not approved. Similarly, the vote to finalize the sunset review after the second posting will be considered to also approve ancillaries unless one is pulled out as not approved.
- Any ancillary substances that the NOSB wishes to prohibit (that are not already on the IARC and NTP lists) will have to come before the board in a separate proposal that can be voted on at the same meeting or a subsequent meeting of the board.

The HS has identified many ancillary substances in the sunset materials under review. We believe that it is past time to review these substances and allow them only if they meet OFPA criteria.

Fermentation Processes

Fermentation is a biological process in which sugars are metabolized to acids, gases, and/or alcohol. Depending on the fermenting organism and the food source, other byproducts may be produced. Fermentation processes used for agricultural inputs and food processing are both in need of clarification, but the issues surrounding them are different. Here we address fermentation with respect to food processing.

Fermentation and food processing

Fermentation processes produce foods or food ingredients in several ways:

1. Foods and ingredients that are organisms grown by fermentation—that is, the biomass produced by the fermentation process.

These include nutritional yeast and baking yeast. Yeast may be certified organic when produced in compliance with an approved organic systems plan.³ Marroquin International petitioned to have yeast reclassified as agricultural and listed on §205.606. It made the argument that yeast, like mushrooms, should be considered livestock under OFPA. “Microorganisms” are listed on §205.605(a).

2. Food processing changes raw agricultural ingredients into new products defined by the products of fermentation.

These include wine, beer, vinegar, lactic acid pickles, yogurt, and miso.

3. Production of food additives through fermentation of specific strains of microorganisms.

These include nucleotides, various vitamins, etc. that are isolated from the products of fermentation. They may be either **primary metabolites**—substances produced by the fermenting organism that are essential to its growth, such as nucleotides, nucleic acids, amino acids, proteins, carbohydrates, lipids, etc.—or **secondary metabolites**—which have no obvious role in the metabolism of the cultured organisms, such as antibiotics and other drugs.

³ NOP, Certification of Organic Yeast. NOP 5014 issued March 2, 2010.

There are products of fermentation permitted in organic food in all of these categories. A number of them are up for sunset review. Those up for sunset in 2019 are marked with *. Materials on §205.605(a) that are products of fermentation include:

1. Food organisms: yeast.*
2. Fermented foods do not need to be listed, but yeast,* microorganisms,* which are the agents that ferment the food, are listed.
3. Metabolites: L-lactic acid,* citric acid,* gellan gum, glucono delta-lactone, enzymes.*

Materials on §205.605(b) that are products of fermentation include metabolites: glycerin, xanthan gum, various vitamins that may be produced by fermentation (B2, B12, C, D2, E, K2, biotin, and some combinations).*

Finally, there are metabolites of fermentation listed on §205.606: fructooligosaccharides (FOS), inulin—oligosaccharide enriched (IOE), whey protein concentrate. The NOSB has added glycerin to this list.

Classification: agricultural vs. non-agricultural

The fact that products of fermentation are included on three different lists for processing is a sign that the classification of products of fermentation needs to be clarified. In particular, the Handling Subcommittee (HS) stated, “Glycerin, produced organically by fermentation is an agricultural product as defined in 7 CFR 205.2, since it is a processed product produced from an agricultural commodity, e.g. cornstarch.” This is also consistent with the NOP classification decision tree, which preserves the nonagricultural classification through fermentation. However, it is not consistent with the definition of a “nonagricultural substance” in the regulations. The regulations define “agricultural products” (following the OFPA definition) and “nonagricultural” (without a definition in OFPA) in §205.2:

Agricultural Products. Any agricultural commodity or product, whether raw or processed, including any commodity or product derived from livestock that is marketed in the United States for human or livestock consumption.

Nonagricultural substance. A substance that is not a product of agriculture, such as a mineral or a bacterial culture that is used as an ingredient in an agricultural product. For the purposes of this part, a nonagricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product **so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.** [Emphasis added.]

Perhaps some of the inconsistency in the classification of materials as agricultural or nonagricultural could be resolved by asking, “What makes a product of fermentation agricultural?” If the product of fermentation is agricultural, then it can be certified organic, and we need to define acceptable practices in organic fermentation processes.

The NOP policy on organic yeast allows yeast to be a certified organic nonagricultural ingredient. Following that approach would allow other organic substances on 205.605(a). It is tempting to view yeast and other products of fermentation as agricultural. Issues surrounding the classification and listing of food additives produced by fermentation or extracted from fermentation products would be easier to resolve if fermentation processes were regarded as agricultural production systems. It may be argued that defining what organic production means in the context of vat fermentation is no more difficult than defining organic aquaculture.

However, the NOSB has been clear that soil-less systems are not organic.⁴ Organic agriculture is premised on a belief that the foundation of healthy plants and animals is healthy soil. This, indeed, is a problem in defining organic aquaculture.

Thus, the materials classification guidance, which treats fermentation as a processing method that does not change the classification of the substrate from agricultural to non-agricultural only works if both the substrate and the product of fermentation meet the definition of agricultural, and not nonagricultural, substances. Thus, pickles, wine, and cheese are all agricultural, but substances whose relationship to the substrate is unrecognizable—such as glycerin, as a product of fermenting cornstarch—are nonagricultural. Fructooligosaccharides (FOS), a product of fermenting glucose, and inulin enriched with oligosaccharides (which contains FOS) are also inappropriately listed on §205.606 because they are nonagricultural.

Classification: Synthetic vs. Nonsynthetic

The classification of some “nonsynthetic” substances needs to be revisited. For example, citric acid and L-lactic acid were originally added to the National List based on TAP reviews that gave a simplified version of their production using fermentation. Commercial production of these acids, however, involves synthetic chemical reactions that were not considered in the original classification decision. The 2019 Technical Review (TR) of L-malic acid illustrates the complexity of classifying a product of fermentation. The TR identifies three major processes of producing L-malic acid by fermentation. Although two of these processes involve microbial fermentation of nonsynthetic substrates, the third—most commonly used—is a two-step process that starts with a synthetic substrate. The TR also notes, “It is worth noting that the starting material or the type of growth medium has not consistently been used to categorize whether a fermentation process or extraction is synthetic or nonsynthetic. For instance, the *Aspergillus* production of citric acid by fermentation uses synthetic mineral salts and synthetic reagents, but the overall process is considered nonsynthetic (USDA 2015c). NOSB has recognized that nonsynthetic microorganisms used in handling have synthetic ancillary substances in the formulation but described leftover substrate as natural substances (USDA 2015c, USDA 2015d).”⁵ This TR also relies on the classification of citric acid—which we believe to be mistaken (see below)—as a precedent, lacking a clear statement of policy.

⁴ NOSB recommendation, Production Standards for Terrestrial Plants in Containers and Enclosures (Greenhouses), April 29, 2010.

⁵ L-Malic Acid TR, 2019. Lines 418-423.

Other issues

A number of products of fermentation that are on the National List may be made using genetically engineered organisms or genetically engineered substrate. Both of these issues should be addressed by annotation or in a general policy.

In some cases, fermentation may create undesirable byproducts. The TAP review for glucono delta-lactone, for example, recommended annotating to ensure that it is not produced by a strain that produces a toxin. (This was not included in the listing.)

Therefore, in addition to the material-specific comments below, we request that the Materials Subcommittee add to its workplan the development of criteria for evaluating products of fermentation processes.

§605(a) Nonsynthetic, nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).”

Citric and lactic acids

205.605(a) Acids (Citric – produced by microbial fermentation of carbohydrate substances; and Lactic).

See above comments on fermentation.

A limited scope TR was found sufficient on November 21, 2023, but has not been made available to the public.

Citric Acid

Citric acid is commercially produced by fermentation, and several different processes are used. Fermentation uses large quantities of water and creates much waste with high biological oxygen demand (BOD) and many contaminants. Some substrates may be derived from genetically modified organisms. Although fermentation is a biological process, there are many chemical reactions involved in most methods, including the most common, of purifying the citric acid. Citrates are formed as a result of reactions of citric acid with the appropriate bases. The earlier judgment that citric acid is nonsynthetic was based on a much less complete description of the fermentation and purification processes than is available in the 2015 TR. It should be revisited.

Citric acid should be classified as synthetic unless it is possible to define nonsynthetic citric acid by annotation. If it is possible to define nonsynthetic citric acid, then it should be annotated on §205.605(a). Otherwise, it should be removed from §205.605(a) and considered for listing on §205.605(b). Since certified organic citric acid is now available, it should be required when commercially available.

L-Lactic Acid

L-lactic acid is commercially produced by fermentation, with additional steps that involve synthetic chemical reactions. The process creates a surplus of calcium sulfate waste, which some producers are trying to market as a fertilizer. Some substrates may be derived from genetically modified organisms. Although fermentation is a biological process, the additional reactions should result in a classification of synthetic. The earlier judgment that L-lactic acid is nonsynthetic was based on a much less complete description of the fermentation and purification processes than is available in the 2015 TR. It should be revisited.

L-lactic acid should be reclassified as synthetic and considered for listing on §205.605(b). L-lactic acid is also present in some foods by virtue of *in situ* fermentation, and this is not synthetic. The microorganisms responsible for the fermentation are on the National List.

Calcium chloride

Reference: 205.605(a)

The OxyChem safety data sheet(SDS)⁶ for food grade calcium chloride gives this analysis of the product:

Component	Percentage
Calcium chloride	94 - 97
Potassium chloride	2 - 3
Sodium chloride	>1 - <2
Water	<1
Calcium bromide	<1

The SDS notes, “Potassium chloride, sodium chloride, and calcium bromide are impurities from the naturally-occurring source material, brine solution.” Since, as noted by the HS, some processes for manufacturing calcium chloride result in a synthetic product, it should be annotated to ensure a nonsynthetic process.

The TR requested by the HS has not been made public.

Conclusion

We consider the level of impurities—up to 6%—to be high for a food grade material. The presence of calcium bromide,⁷ which is not on the National List, is troublesome. We recommend that the HS investigate this more closely and propose an appropriate annotation.

Enzymes

Reference: §205.605(a) Enzymes—must be derived from edible, nontoxic plants, nonpathogenic fungi, or nonpathogenic bacteria.

⁶ <https://sds.oxy.com/private/document.aspx?prd=M48003~~PDF~~MTR~~ANSI~~EN~~01-01-0001~~~>.

⁷ <https://pubchem.ncbi.nlm.nih.gov/compound/Calcium-bromide#section=Symptoms>.

See above comments on fermentation.

The review of enzymes as a class—even with a few specific representatives—is insufficient to address classification and all the OFPA criteria. The classification of all commercial enzymes as nonsynthetic is questionable, given that the 2011 TR says that chemical changes involving reactions with synthetic chemicals are sometimes involved in the manufacture, extraction, or purification of enzymes.⁸

The limited scope TR requested by the HS has not been made available to the public. Two TRs are available—a 2011 TR addresses enzymes as a class, and a 2015 TR addresses ancillary substances in enzymes.

Conclusion

Enzymes should be classified as synthetic unless annotated to define those that have not undergone synthetic chemical change. The review of ancillary substances should include all such substances, including those on the National List.

L-Malic acid

Beyond Pesticides opposes the relisting of L-malic acid because the database does not support the decision to relist on §605(a). The 2019 TR raises important issues. In addition to the helpful discussion of manufacturing processes, the additional information based on a patent, included below, should be considered. In addition, we believe that some issues raised by the petition are beyond the purview of the HS and we request that the Materials/GMO Subcommittee (MS/GMO) add fermentation processes to its workplan.

Classification

The TR identifies three major processes of producing L-malic acid by fermentation. Although two of these processes involve microbial fermentation of nonsynthetic substrates, the third—most commonly used—is a two-step process that starts with a synthetic substrate. A fourth method of producing L-malic acid is entirely synthetic. Since the listing on §605(a) does not specify a production method, L-malic acid must be assumed to be synthetic—and hence it should be removed from §605(a) and petitioned for §605(b)—or annotated to ensure that it is nonsynthetic.

Health and Environmental Impacts

Documentation contained in the TR on the health and environmental impacts of producing L-malic acid is incomplete. The following information comes from the patent⁹ for manufacturing L-malic acid by fermentation. There are no restrictions on feedstock or fermenting organisms in the National List listing.

⁸ Lines 540-545.

⁹ 3,063,910 Method of Producing L-Malic Acid by Fermentation <http://www.google.com/patents/US3063910>.

The patent says, “[A] substantial amount of l-malic acid can be accumulated in a culture medium by cultivating a strain of the species *Aspergillus parasiticus* Speare, *Aspergillus flavus* Link and *Aspergillus oryzae* (Ahl’ourg) Cohn.” The carbon source may be glucose, sucrose or molasses, fructose, maltose, mannose, galactose, sorbose, xylose, starch, sorbitol, glycerol, etc.” It continues, “Peptone, ammonium chloride, ammonium nitrate, urea, ammonium sulfate or sodium nitrate can be used in an amount of from 0.2 to 1.5% as nitrogen source. In addition to the carbon and nitrogen sources, 0.015% of potassium dihydrogen phosphate (KH PO 0.015% of Patented Nov. 13, 1962 dipotassium hydrogen phosphate (Kg-IP0 0.01% of magnesium sulfate (MgSO 7H O), 0.01% of calcium chloride (CaCl-2H O), as well as 5 mgr./l. each of ferrous sulfate (FeSO-7H O) and sodium chloride are added to the culture medium. Further, 0.5 to 10% of organic acid, such as pyruvic and fumaric acid, or the salts thereof may be advantageously used together with the carbon source as fermentation accelerator. Additionally, 1 to 10% of sterile calcium carbonate or magnesium carbonate may be added.... After cultivation is completed, the mycelium is separated from the broth, containing l-malic acid, by filtration. The filtrate is then concentrated in vacuo, thereby yielding l-malic acid salt, such as calcium salt or magnesium salt.”

It appears, therefore, that quite a variety of chemicals may be used in the manufacture of L-malic acid, and the NOSB should review them and the process for its impacts on human health and the environment.

Ancillary substances

The ancillary substances associated with this material have not been reviewed or even listed. This is an important piece that needs to be incorporated into the review of every material during sunset. Maleic (<500 ppm) and fumaric (7.5 ppm) acids are impurities that should be considered.¹⁰

Essentiality

L-malic acid is used to acidify fruit juices, though it is not restricted to that use by its listing. As an acidulant, the TAP review points out that there are several alternatives available, including organic vinegar and lemon juice, as well as the nonsynthetic lactic acid and citric acid, which are also on the National List—and also produced by fermentation.

Compatibility

Although the main use of L-malic acid is acidification, the choice of L-malic acid as an acidulant is based on its ability to re-create and improve flavors, which—for a synthetic additive—is not consistent with organic processing. The TR defines its action, “Malic acid also intensifies and extends the impact of flavors, allowing producers to reduce the amount of added flavoring. For example, adding malic acid to jams, jellies, and fruit preparations results in a more natural flavor profile.” It distinguishes this action from re-creating and improving flavors lost during processing. If the NOSB accepts this distinction, it must still ask whether it is compatible with organic production to create artificial flavors.

¹⁰ <http://pubchem.ncbi.nlm.nih.gov/summary/summary.cgi?cid=222656#x321>.

Conclusion

We conclude that there is not sufficient information to support the relisting of L-malic acid on §605(a). Information from the TR challenges the classification of L-malic acid as nonsynthetic and raises issues of compatibility. Ancillary substances have not been identified or assessed. Therefore, L-malic acid should not be relisted.

Magnesium sulfate

Reference: 205.605(a) - nonsynthetic sources only.

The Technical Review (TR) characterizes magnesium sulfate from nonsynthetic sources as synthetic, based upon dehydration and purification reactions.¹¹ The TR does not give details allowing the reader to compare the process to the NOP classification of materials guidance. The limited scope TR requested by the HS has not been made available to the public.

The HS review states, “During the last sunset review, there were no comments on this listing,” which ignores the comments submitted by Beyond Pesticides.

Conclusion

If the NOSB accepts the judgment of TR authors, then magnesium sulfate should be classified as synthetic, removed from §205.605(a), and (if there is support) petitioned for §205.605(b).

Microorganisms

Reference: 205.605(a) - Microorganisms—any food grade bacteria, fungi, and other microorganism.

Beyond Pesticides cannot support the relisting of microorganisms without documentation to show that the listing meets the criteria of the Organic Foods Production Act (OFPA). The principal document of support is a technical review (2014 TR) that does not address the manufacture of microorganisms by fermentation. The limited scope TR requested by the HS has not been made available to the public.

Identification of “microorganisms” as listed on the National List

The listing on §205.605(a) is “Microorganisms—any food grade bacteria, fungi, and other microorganism.” This listing is not clear. It is apparent that it is intended to cover those microorganisms present as living organisms in foods such as cheese, yogurt, vinegar, pickles, tempeh, wine, and so forth. However, there are other products that are made from (or with the assistance of) microorganisms, and it is not clear whether the listing is intended to cover them. These include nutritional yeast and spirulina, both cultured microorganisms that are no longer living. They also include products of fermentation that have been isolated from the fermentation organisms, including glycerin, gellan gum, L-malic acid, and others. We assume

¹¹ 2011 Technical Evaluation Report, <https://www.ams.usda.gov/sites/default/files/media/MGSu%20Technical%20Evaluation%20Report%20Handling.pdf>. Lines 256-258.

that the listing does not cover the last group, but that those organisms and their manufacture should be evaluated in the course of evaluating their products that are on the National List (NL). If the listing is intended to cover the group of killed microbial products, then the evaluation should include algae as well as the other organisms addressed in the technical review.

Ancillary substances

The microorganisms TR gives some examples of ancillary substances that might be found in microorganisms. It does not attempt to give a complete list. It does not review those materials. The ancillary substances review process cannot take place without a complete list and review of the ancillary substances.

Environmental and Health Impacts

In order to evaluate impacts on human health and the environment, the HS must evaluate the production practices for microorganisms. Some examples of questions that must be addressed are:

- What are conditions for workers within buildings holding fermentation vats?
- Are there discharges from fermentation vats?
- How/where are remains from fermentation, bad batches, etc. disposed of? Do they compete with natural organisms? In addition, the TR indicates a potential for some microorganisms to concentrate heavy metals.

Essentiality

We support the use of microbially fermented agricultural products as health-supporting and eliminating the use of some chemical preservatives and other antimicrobial agents.

Compatibility

The HS documentation must address compatibility. In principle, the use of microorganisms to produce microbially fermented agricultural products is compatible with organic practices. HS documentation should address this issue. Our main concern is with the specifics of production practices.

Fermentation

The consideration of microorganisms raises additional issues that should be addressed by the NOSB. See the section on fermentation above.

Conclusion

Beyond Pesticides cannot support the relisting of microorganisms without documentation to show that the listing meets the criteria of the Organic Foods Production Act (OFPA).

Perlite

Reference: 205.605(a) —for use only as a filter aid in food processing.

Perlite is amorphous volcanic glass. It is an excellent filter aid and often substitutes for diatomaceous earth in filtering beer. In the past, the subcommittee received indications from a range of stakeholders that perlite continues to be necessary.

A TR requested by the HS has not been made available to the public. When we have reviewed it, we will be able to make some comments.

Potassium iodide

Reference: 205.605(a)

Potassium iodide is used as a sanitizing agent and a supplemental source of iodine. The NOSB must restrict supplemental vitamins and minerals to those required by law. A review of sanitizers is needed to determine which are needed and compatible with organic practice.

A TR requested by the HS has not been made available to the public. When we have reviewed it, we will be able to provide updated conclusions. Since the HS describes both synthetic and nonsynthetic methods of manufacture, we will be looking for assurance that the material as used in organic processing is nonsynthetic as listed.

Pullulan

Reference 205.605(a) Pullulan—for use only in tablets and capsules for dietary supplements labeled “made with organic (specified ingredients or food group(s)).

Pullulan was added to the National List in 2021, based on a 2019 recommendation from the NOSB.

Pullulan is an extracellular polysaccharide excreted by the yeast-like fungus *Aureobasidium pullulans* in vat fermentation. It is another example of the need for NOSB guidance on the classification and listing of products of fermentation.

Pullulan was classified as an agricultural material and used in products labeled “made with organic,” but it was not listed on §205.606 and had not been reviewed by the NOSB until being petitioned.

The petition, which characterizes *Aureobasidium pullulans* as “non-pathogenic and non-toxicogenic,” is a vast oversimplification. *Aureobasidium pullulans* exists in many strains with a large variety of ecological niches, including (as stated in the petition) “forest soil, fresh and sea

water, plant and animal tissues.” It is known as a human pathogen,¹² a human allergen,¹³ a biological control agent in plants,¹⁴ and in biotechnology for production of the polysaccharide pullulan and the antifungal aureobasidin A.¹⁵

A review of pullulan by the European Food Safety Authority (EFSA) found no evidence of acute toxicity and some effects in subchronic tests that were possibly due to large doses of non-digestible carbohydrate. EFSA found no available data on carcinogenicity, reproductive toxicity, or developmental toxicity. Experiments in human volunteers resulted in increased feeling of fullness, increased carbohydrate malabsorption, and increased bifidobacteria in feces. Although *Aureobasidium pullulans* is associated with allergic reactions and infections in immunocompromised individuals, there is no evidence that pullulan causes such reactions.¹⁶

Beyond Pesticides continues to call for NOSB guidance on classification and listing of products of vat fermentation. In view of the problems that may arise from exposure to the parent organism, *Aureobasidium pullulans*, the use of pullulan should not be expanded beyond the current use, and pullulan must be listed on labels of made with organic supplement tablets and capsules.

The HS asks, “Does pullulan have the potential to be produced organically, and if so, would a commercial availability requirement help drive commercialization of organic pullulan?” Since it is unclear what it means for a product of fermentation to be produced organically, organic pullulan must await the creation of guidance on the classification and listing of products of fermentation. Furthermore, it is doubtful that pullulan belongs on 205.605(a), based on the TR findings cited by the HS: “Nitrogen is provided in the growth medium in the form of inorganic nitrogen sources such as ammonium salts and nitrates and biological sources such as glutamate, peptone, yeast extract, and corn steep liquor. Essential nutrient minerals are provided as phosphates, magnesium salts, and the sulfates of iron, manganese, and zinc.” Pending policy on fermentation, products of fermentation in which macronutrients are supplied in synthetic form should be classified as synthetic.

¹² See, for example, van Houghenhouck-Tulleken, W.G., Mathole, G., Karstaedt, A., Govind, N., Moodley, M., Seetharam, S., Govender, N.P. and Menezes, C.N., 2016. Disseminated fungal infection in an HIV-infected patient due to *Aureobasidium pullulans*. *Southern African Journal of Infectious Diseases*, 31(3), pp.71-73.

¹³ Niedozytko, M., Chełmińska, M., Jassem, E. and Czestochowska, E., 2007. Association between sensitization to *Aureobasidium pullulans* (*Pullularia* sp) and severity of asthma. *Annals of Allergy, Asthma & Immunology*, 98(2), pp.153-156.

¹⁴ See, for example, Di Francesco, A., Calassanzio, M., Ratti, C., Mari, M., Folchi, A. and Baraldi, E., 2018. Molecular characterization of the two postharvest biological control agents *Aureobasidium pullulans* L1 and L8. *Biological Control*, 123, pp.53-59.

¹⁵ Gostinčar, C., Ohm, R.A., Kogej, T., Sonjak, S., Turk, M., Zajc, J., Zalar, P., Grube, M., Sun, H., Han, J. and Sharma, A., 2014. Genome sequencing of four *Aureobasidium pullulans* varieties: biotechnological potential, stress tolerance, and description of new species. *BMC genomics*, 15(1), p.549.

¹⁶ EFSA, 2004. Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to Pullulan PI-20 for use as a new food additive. *EFSA Journal* (2004) 85: 1-32.

Conclusion

Therefore, pullulan should be sunsetted from 205.605(a) and petitioned for 205.605(b).

Yeast

Reference: 205.605(a) - When used as food or a fermentation agent, yeast must be organic if its end use is for human consumption; nonorganic yeast may be used when equivalent organic yeast is not commercially available. Growth on petrochemical substrate and sulfite waste liquor is prohibited. For smoked yeast, nonsynthetic smoke flavoring process must be documented.

See above comments on fermentation.

The HS must examine ancillary substances in yeast. One ancillary substance that was identified earlier by the HS is butylated hydroxytoluene (BHT). There is a TAP review of BHT as an “inert” in pheromone products. The following comes from that and other sources, as indicated:

1. Environmental impacts from its use or manufacture. An EPA memo states that BHT is moderately to slightly toxic to aquatic organisms.¹⁷ Another review cites classification as hazardous.¹⁸

2. Effects on human health. “Butylated Hydroxytoluene (BHT) is classified as irritating to the eyes, respiratory system, and skin under European classification. Allergic contact dermatitis and contact urticaria are associated with exposure to BHT. It is currently listed as “unclassifiable” in regard to its carcinogenicity in humans (due to limited human test data), however a variety of in vitro and animal studies have shown it to have carcinogenic, tumorigenic, mutagenic, and teratogenic effects in animals as well as in human cells. Studies have also confirmed BHT to have estrogenic activity, and MSDS sheets state that chronic exposure to BHT may cause reproductive and fetal effects.”¹⁹

Conclusion

Yeast is produced by fermentation, separated by physical methods from the culture. Yeast *per se* meets OFPA requirements However, there are many ancillary substances that have not been reviewed, some of which may be problematic.

¹⁷ EPA, Office of Prevention, Pesticides, and Toxic Substances. Memo from Pauline Wagner, Inert Ingredients Branch, to Lois Rossi, Registration Division. Inert Reassessment of Butylated Hydroxyanisole (250 13- 16-5) and Butylated Hydroxytoluene (128-37-0). September 29, 2005.

¹⁸ Safety Review of Checkmate Chemicals, by Don't Spray California.

<http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf>.

¹⁹ Safety Review of Checkmate Chemicals, by Don't Spray California.

<http://www.dontspraycalifornia.org/Safety%20of%20Checkmate%20Chemicals%202-06-08.pdf>.

§605(b) Synthetic, nonagricultural (nonorganic) substances allowed as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group(s)).

Activated charcoal

Reference: § 205.605(b) (2) Activated charcoal (CAS #s 7440-44-0; 64365-11-3)—only from vegetative sources; for use only as a filtering aid.

Activated charcoal is a substance that could meet the requirements of the Organic Foods Production Act with few restrictions, including limiting its use to filtering water and requiring steam activation. However, without those restrictions, we find it to present environmental and health problems and issues with compatibility. A TR requested by the HS has not been made available to the public. When available, it may modify the views presented below.

Environmental and Health Impacts

According to the Technical Advisory Panel (TAP) review, activated carbon can be produced from a number of agricultural commodities, including hardwoods, grain hulls, corn cobs, and nutshells. Activation can be achieved by a number of methods, including treatment with steam or acids, bases, and other substances. Activated carbon can be recycled, reactivated, or regenerated from spent activated carbon. “[A] number of solvents, acids, and alkalis may be employed to remove the adsorbed substances. These include such things as carbon tetrachloride, hydrochloric acid, hydrogen peroxide, potassium hydroxide, sodium hydroxide.” According to a study not included in the TAP review, “Although this process results in small uniform pores with high adsorption capacity, the carbon is usually contaminated with the dehydrating agent.”²⁰

In view of the large number of chemicals that can be used in the activation and reactivation of charcoal, TAP reviewers suggested the annotation, “Must meet Food Chemicals Codex purity requirement and be manufactured from agricultural products by steam activation.” We concur with this recommendation.

Essentiality

The petitioned use was to clarify and improve the flavor of organic fruit juices. The TAP review proposed that better harvesting and processing methods could eliminate the need for activated charcoal. The review also suggested that the use is not compatible with organic practices. (See below.) On the other hand, activated charcoal is often used to remove chlorine and other chemicals from tap water, which may be essential in some cases. Thus, TAP reviewers also suggested the annotation, “Processing material for filtering water, only.” We agree with that recommendation as well.

²⁰ M.D. Sufnarski, 1999. The Regeneration of Granular Activated Carbon Using Hydrothermal Technology, master’s thesis in Chemical Engineering at the University of Texas. <http://www.dtic.mil/dtic/tr/fulltext/u2/a362534.pdf>.

Compatibility

The use, as petitioned, to improve the color and flavor of grape juice, is not compatible with organic production and handling. Moreover, although the nutritional value of the juice may be improved, it may also be diminished. According to the TAP review, “This depends on a number of complex factors: the nature of the activation of the carbon, the nutritional quality and chemical properties of the adsorbate, the preparation, and the various factors related to adsorption.”

Ancillary substances

The ancillary substances associated with this material must be reviewed. This is an important piece that needs to be incorporated into the review of every material during sunset.

Conclusion

Beyond Pesticides opposes the relisting of activated charcoal as currently allowed. We would support a listing that limits its use to filtering water and requires steam activation.

Ascorbic acid

Reference: §205.605(b) Ascorbic acid.

Ascorbic acid is added to many foods to fortify them to original, pre-processing Vitamin C levels. It is a synthetic antioxidant/preservative. There are natural and organic alternatives. As a vitamin, it should be addressed under nutrient vitamins and minerals. **Ascorbic acid should be removed from the National List.**

Calcium citrate, potassium citrate, sodium citrate

Reference: §205.605(b):

Calcium citrate.

Potassium citrate

Sodium citrate

Citric acid is commercially produced by fermentation, and several different processes are used. Fermentation uses large quantities of water and creates much waste with high biological oxygen demand (BOD) and many contaminants. Some substrates may be derived from genetically modified organisms. Although fermentation is a biological process, there are many chemical reactions involved in most methods, including the most common, of purifying the citric acid. Citrates are formed as a result of reactions of citric acid with the appropriate bases. The earlier judgment that citric acid is nonsynthetic was based on a much less complete description of the fermentation and purification processes than is available in the 2015 TR. It should be revisited.

A limited scope TR has been requested by the HS but is not available to the public. We look forward to reviewing it.

Collagen gel

Reference: § 205.605(b)(13) Collagen gel—as casing, may be used only when organic collagen gel is not commercially available.

Non-organic collagen gel casings are not necessary.

Collagen gel is made from the skins of cows, pigs, chickens and/ or turkeys. All of these are produced organically. In discussing the common casings (made from intestines), there is an issue with sausage made from chicken/turkey, since casings are not made from their intestines. However, collagen is made from the skins, so the issue of having enough collagen from organic animals should not be an issue.

Non-organic collagen gel casings contaminate organic products.

Non-organic cows, pigs, chickens, and turkeys consume corn and soy produced by chemical-intensive agriculture. These feed ingredients are largely genetically engineered, many pesticides are used on these feeds, and residues can be expected in the feed and meat.

There appears to be a practical issue of isolating organic intestines to use for organic collagen gel. Instead of petitioning for the use of casings made from meat contaminated with pesticide and antibiotic residues, those who wish to use collagen gel casings for organic sausage should devote their efforts to eliminating these practical obstacles.

Ferrous sulfate

§205.605(b) Ferrous sulfate—for iron enrichment or fortification of foods when required by regulation or recommended (independent organization).

Ferrous sulfate is a synthetic nutrient added to recreate nutritive values lost in processing and should be addressed under nutrient vitamins and minerals. Its use could be avoided by using natural whole foods. It should be added to organic food only when required by law.

Iron sulfate as a listing separate from nutrient vitamins and minerals should not be relisted.

Hydrogen peroxide

Reference: 205.605(b)

Hydrogen peroxide is relatively nontoxic in low concentrations, though it is a powerful oxidizer and may damage soil biota. Repeated exposure to vapor is harmful. It breaks down quickly to oxygen and water, and therefore does not have a residual effect.

Conclusion

Beyond Pesticides supports the relisting of hydrogen peroxide. The advantage of hydrogen peroxide is its nontoxic residue, but concentrated hydrogen peroxide is a powerful

oxidizer. EPA's Design for the Environment program has listed l-lactic acid, citric acid, hydrogen peroxide, and peracetic acid—all on §205.605—as meeting its criteria for use as disinfectants.

Nutrient vitamins and minerals

Reference: 205.605(b) Nutrient vitamins and minerals, in accordance with 21 CFR 104.20, Nutritional Quality Guidelines for Foods.

AMS issued a Federal Register (FR) notice on January 12, 2012, in response to the NOSB sunset action at the April 2011 NOSB meeting, though also (according to AMS) signaling its intent to propose an annotation to the listing at the following (November 2011) meeting. The proposed rule in the January 2012 FR notice would have revised the regulatory reference in the listing to read, "Vitamins and minerals. For food—vitamins and minerals identified as essential in 21 CFR 101.9. For infant formula—vitamins and minerals as required by 21 CFR 107.100 or 107.10."

For food, this proposed rule would allow processed products labeled as "organic" or "made with organic (specified ingredients or food group(s))" to be randomly supplemented with vitamins and minerals identified as "essential" by the U.S. Food and Drug Administration (FDA). We commented that this provision is inconsistent with the regulations implementing the Organic Foods Production Act (OFPA) (7 CFR Part 205), and specifically §205.600(a)-(c). These sections of the regulations establish the evaluation criteria for allowed and prohibited substances, methods and ingredients and do not support the categorical allowance for ingredients (vitamins and minerals, in this instance). Additionally, these regulations require that the National Organic Standards Board (NOSB) determine that a substance is, among other criteria, essential for the handling of the organically produced agricultural products (§205.600(b)(6)), and it cannot be produced from a natural source, and there is no organic substitute (§205.600(b)(1)) before the synthetic version may be added to the National List. Therefore, rather than listing a category of "vitamins and minerals," we stated that the proposed rule should be amended to list specific vitamins and minerals—only after full consideration of the criteria in OFPA as well as their availability from nonsynthetic and/or organic sources by the NOSB.

On September 27, 2012, AMS issued another FR notice, this time promulgating an interim rule on nutrient vitamins and minerals. The interim rule is the same as the rule that had been in place—and had been recommended for relisting by the NOSB—and it is the listing that is up for sunset consideration now.

In order to meet the requirements of §205.600(b)(4), the addition of the nutrients must be required by law, not merely allowed by law. The fact that FDA has designated a vitamin or mineral as "essential" is not sufficient reason for adding it to any food product. The FDA's fortification policy **does not require** the supplementation of all foods with the vitamins and minerals that it has designated as "essential." FDA uses additional and more restrictive criteria for determining when fortification or enrichment of a specific food with specific nutrients is

required—such as adding certain vitamins and minerals to “enriched white flour.” Fortification is required in very few cases.

We recommend amending this listing to restrict the use of any supplemental vitamins and minerals to only those instances in which FDA regulations require such supplementation.

Additional information provided by the TR

“Unlike the current NOP regulation and the latest NOP proposal, the other four international regulations [EEC, Codex, Canada, IFOAM] only permit nutrient vitamin and mineral addition when legally required.”²¹ The list of vitamins actually required is very small:

Food class	Regulation	Specific vitamins or minerals required by FDA
Infant formula	21 CFR 107.10 21 CFR 107.100	All nutrients known to be essential and listed therein.
Bakery products	21 CFR Part 136	Thiamine, riboflavin, niacin, folic acid, iron*
Cereal flours	21 CFR Part 137	Thiamine, riboflavin, niacin, folic acid, iron*
Macaroni & noodles	21 CFR Part 139	Thiamine, riboflavin, niacin, folic acid, iron*
Margarine	21 CFR 166.110	Vitamin A

* For food labeled as “enriched.”

Food class	Regulation	Specific vitamins or minerals required for WIC Package Foods
Fruit juice	7 CFR 246.10	Minimum of 30 mg of Vitamin C per 100 mL of juice
Infant cereals	7 CFR 246.10	Minimum of 45 mg of Iron per 100 g of dry cereal
Breakfast cereals	7 CFR 246.10	Minimum of 28 mg of Iron per 100 g of dry cereal
Soy-based beverage (milk alternative)	7 CFR 246.10	Vitamins A & D, calcium, magnesium, phosphorus, riboflavin, vitamin B12
Iodized salt	21 CFR 100.155	Iodine
Milk for WIC	7 CFR 246.10 21 CFR Part 131	Vitamins A & D
Fruit juice for WIC	7 CFR 246.10	Vitamin C
Infant cereals (WIC)	7 CFR 246.10	Iron
Adult cereals (WIC)	7 CFR 246.10	Iron

Conclusion

Beyond Pesticides supports amending this listing to restrict the use of any supplemental vitamins and minerals to only those instances in which FDA regulations require such supplementation.

²¹ 2015 Technical Review, Nutrient Vitamins and Minerals, lines 406-407.

Peracetic acid

Reference: § 205.605(b)(22) 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.

Beyond Pesticides supports the relisting of peracetic acid for use in handling. Compared to alternatives, it is relatively harmless, effective, and compatible with organic handling practices.

Environmental and Health Impacts

Peracetic acid exists as a solution in an equilibrium of hydrogen peroxide and acetic acid. According to the 2009 sunset recommendation, “These reaction components of peracetic acid—hydrogen peroxide and acetic acid—have various production methods, including (for acetic acid) oxidation of acetaldehyde, hydrolysis of acetylene, or fermentation of plant sources. For hydrogen peroxide, the Riedl-Pfleiderer process uses a polycyclic aromatic hydrocarbon derived from coal tar along with oxygen and hydrogen gases to produce the material.” Breakdown products are acetic acid (same acid found in vinegar at 5% level) and hydrogen peroxide that breaks down to O₂ and H₂O. The 2009 recommendation also states that peracetic acid is an irritant of the skin, eyes, mucous membranes, and respiratory tract, and it is on the EPA Extremely Hazardous Substance list.

Ancillary Substances

According to the 2000 Technical Advisory Panel review, “Stock commercial preparations usually contain a synthetic stabilizer such as 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) or 2,6-pyridinedicarboxylic (dipicolinic) acid to slow the rate of oxidation or decomposition (Kurschner and Diken, 1997). According to FDA regulations, HEDP may be used with PAA at a level not to exceed 4.8 ppm in water used to wash fresh fruits and vegetables (21 CFR 173.315(a)(5)). Sanitizing combinations approved by 21CFR 178.1010 to be used with PAA under (b)(38) include: hydrogen peroxide; acetic acid; sulfuric acid; and 2,6-pyridinedicarboxylic (dipicolinic) acid. Under (b)(45) they include: hydrogen peroxide; acetic acid; octanoic acid; peroxyoctanoic acid; sodium 1-octanesulfonate; and 1-hydroxyethylidene-1,1-diphosphonic acid.” The HS should investigate these potential ancillary substances.

The HS review identifies 1-hydroxyethylidene-1,1-diphosphonic acid (HEDP) and 2,6-pyridinedicarboxylic (dipicolinic) acid as “‘inerts’ for EPA registration as an antimicrobial and not subject to review as an ancillary substance.” However, dipicolinic acid is a former List 3 “inert” and not allowed in products used in organic production. As stated by the HS, only products with allowable “inerts” should be used.

Essentiality

According to the TAP review, alternatives include: fresh, clean water; rapid cooling; and reducing the time between harvest and consumption. Physical methods such as heat and steam can also be used in some situations. Other alternatives on the National List include hydrogen

peroxide, chlorine bleach, phosphoric acid, and sodium hydroxide. Peracetic acid is superior to hydrogen peroxide in antimicrobial activity.

Compatibility

Peracetic acid is relatively compatible with organic practices. The TAP review says,

In comparison to other most-used sanitizers in the food industry, peracetic acid may be more compatible with organic handling than the use of halogen-based sanitizers and disinfectants such as chlorine bleach, iodine-phosphorous (iodophors), or quaternary ammonia products (quats). For example, chlorination can seriously damage aquatic life and form chlorinated hydrocarbons with carcinogenic and mutagenic properties (Arturo-Schaan et al., 1996). Quats have the longest residual activity (Block, 1991). PAA degrades rapidly, leaves little residue, and decomposes into relatively harmless naturally-occurring substances (Evans, 2000).

Conclusion

We agree with the TAP review's assessment of the relative compatibility of peracetic acid, especially compared with chlorine-based materials. Since physical methods may not always appear to be workable, peracetic acid appears to be the safest, most effective, and most compatible of the chemical approaches. Only products with allowable "inert" ingredients should be used.

Potassium phosphate

Reference: 205.605(b) —for use only in agricultural products labeled "made with organic (specific ingredients or food group(s))," prohibited in agricultural products labeled "organic."

Phosphate food additives should not be used if they are merely "useful" to processors, given their impact on human health. If the additive is not essential, it should not be allowed, in order to protect organic consumers from high phosphorus load. These additives do not appear to be essential and fail the criteria in OFPA for inclusion on the National List.

Conclusion

The NOSB should seek to eliminate the use of inorganic phosphates in organic food. If it is not possible to totally eliminate them, the NOSB should seek to identify those that are essential.

Sodium acid pyrophosphate

Reference: § 205.605(b) (30) Sodium acid pyrophosphate (CAS # 7758-16-9)—for use only as a leavening agent.

Beyond Pesticides opposes the relisting of sodium acid pyrophosphate (SAPP), based on the information available to us and the Handling Subcommittee (HS). We note that the principal document available to the committee is a technical advisory panel (TAP) review of sodium phosphates in response to a petition for use in soy milk. The technical review (TR) focuses on a proposed expanded use of SAPP and does not address the current listed use.

Health and Environmental Impacts

The TR says no data was found on the material itself that indicated it posed potential negative impact on human health or the environment, but it did discuss that one of the primary inputs in the manufacture of SAPP, phosphoric acid, does pose a threat if waste is not carefully managed. According to the TAP review for sodium phosphates, the manufacture of food grade phosphoric acid involves the removal of heavy metals and radioactive waste. This creates a hazardous waste stream. A primary environmental concern of sodium phosphates is their release into water, though this is only likely to be a problem with this use in the case of a spill. When heated to decomposition, it emits toxic fumes.

Sodium pyrophosphate has similar subacute effects to the more toxic orthophosphates, including kidney damage and calcium deposits in test animals. According to the TAP review, “The toxicity of sodium phosphates is generally related to the sequestration of calcium and the subsequent reduction of ionized calcium. It is an irritant, and ingestion may injure the mouth, throat, and gastrointestinal tract, resulting in nausea, vomiting, cramps, and diarrhea.”

Essentiality

SAPP is an acid that reacts with baking soda to act as a leavening agent. Other sources of acid—buttermilk, yogurt, molasses, lemon juice, vinegar—are commonly used alternatives. Besides those above, other acids on the National List for use in food include potassium acid tartrate (cream of tartar) and ammonium bicarbonate. Whipped egg whites and yeast are alternative methods of leavening.

Compatibility

SAPP is a synthetic chemical that is not essential for organic processing and whose manufacture creates a hazardous waste stream. It should therefore be viewed as incompatible with organic production and handling.

Ancillary Substances

The ancillary substances associated with this material must be reviewed. This is an important piece that needs to be incorporated into the review of every material during sunset.

Conclusion

Beyond Pesticides opposes the relisting of sodium acid pyrophosphate because it does not meet the criteria of lack of harm to the environment and human health, essentiality, and compatibility.

Tocopherols

Reference: 205.605(b) derived from vegetable oil when rosemary extracts are not a suitable alternative.

A limited scope TR that was requested by the HS is not available to the public.

The minority report on the tocopherols proposal for aquaculture, which was considered at the spring 2014 NOSB meeting said:

The minority also has concerns about the unnecessary presence of volatile synthetic solvents in tocopherols. The Livestock Subcommittee received a letter from Oh Oh Organics supporting the consistent availability of natural tocopherols extracted without synthetic solvents. The letter states,

I have sold Non-GMO, non-solvent extracted tocopherol since 2005. Both BASF, an international ingredient manufacturer out of Germany and BTSA, a company specializing in non-GMO Tocopherols supply this material. It is consistently available and is broadly used in the food, cosmetic and household cleaning business. Additionally, I have seen ISO certified documents for a supplier in China...so, I believe it available around the world.

The 2016 Technical Review states, “At least one manufacturer of a mixed tocopherols product claims to manufacture its product using physical process only. Specifically, the Spanish manufacturer BTSA produces a mixed tocopherols product—Tocobiol®—through short path molecular distillation of vegetable oils, claiming that no solvents or chemicals are added during the manufacturing process (BTSA, 2014a; Piñol del Olmo, date unknown).”

Conclusion

The Handling Subcommittee must investigate the availability of natural tocopherols. If natural tocopherols are available, then they should be removed from §205.605(b) and petitioned for §205.605(a). The NOSB should encourage the production of organic tocopherols by placing an expiration date on the §205.605(a) listing.

§606

It is time to stop adding listings to §606 and phase out current listings.

Organic production is grown up now, and any agricultural commodity can be produced organically. Listing on §606 only stifles organic production of new organic crops and promotes chemical-intensive production. Finally, in the time that it takes to add new regulations, petitioners could develop the demand for the organic product.

Pesticide exposure poses tremendous health threats to humans, especially the farmworkers who work in chemical-intensive operations.²² Given the human impacts, the crash of insect populations worldwide,²³ the vulnerability of pollinators to synthetic pesticides,²⁴ and habitat destruction in nonorganic agriculture, it is crucial that we move away from any

²² See Beyond Pesticides databases, Pesticide-Induced Diseases Database <https://beyondpesticides.org/resources/pesticide-induced-diseases-database/overview>, Eating With a Conscience <https://beyondpesticides.org/resources/eating-with-a-conscience/overview>, and the Pesticide Gateway <https://beyondpesticides.org/resources/pesticide-gateway>.

²³ <https://beyondpesticides.org/dailynewsblog/2019/02/study-predicts-demise-of-insects-within-decades-if-pesticide-dependence-continues/>.

²⁴ <https://beyondpesticides.org/programs/bee-protective-pollinators-and-pesticides/what-the-science-shows>.

dependence on non-organic ingredients. Thus, our reviews of sunsets for §606 materials summarize some impacts of producing these materials in a chemical-intensive system.

Celery powder

Reference: 205.606(b)

Environmental and Health Effects of Nonorganic Celery Production

California Farmworker Poisonings, 1992–2010: 70 reported (CA acreage: 26,400). These poisoning incidents only represent the tip of the iceberg because it only reflects reported incidents in one state. It is widely recognized that pesticide incidents are underreported and often misdiagnosed.

Pesticide Tolerances—Health and Environmental Effects: The database shows that while celery grown with toxic chemicals show low pesticide residues on the finished commodity, there are 62 pesticides with established tolerance for celery, 27 are acutely toxic creating a hazardous environment for farmworkers, 57 are linked to chronic health problems (such as cancer), 15 contaminate streams or groundwater, and 56 are poisonous to wildlife.

Pollinator Impacts: In addition to habitat loss due to the expansion of agricultural and urban areas, the database shows that there are 28 pesticides used on celery that are considered toxic to honey bees and other insect pollinators. For more information on how to protect pollinators from pesticides, see Beyond Pesticides' BEE Protective webpage. This crop is dependent on pollinators. This crop is foraged by pollinators.

The evaluation of celery powder must take into consideration the use of pesticides in the non-organic production of celery.

Celery Powder and Nitrates

Cultured celery powder is a way of adding "natural" nitrites. The quotation marks are appropriate since it is not possible to achieve the high levels of nitrate needed through organic celery production.²⁵ Given the known health effects of nitrates, we do not believe there is a good reason for keeping celery powder on the National List. Agency for Toxic Disease Registry (ATSDR)/Centers for Disease Control and Prevention (CDC) lists, for example, methemoglobinemia, hypotension, risk of pregnancy complications, a number of reproductive effects, and cancer, among others. Regarding cancer, ATSDR says:²⁶

Some study results have raised concern about the cancer-causing potential of nitrates and nitrites used as preservatives and color-enhancing agents in meats [Norat et al. 2005; Tricker and Preussmann 1991]. Nitrates can react with amino acids to form

²⁵ CROPP comments in Spring 2015, and J.J. Sindelar and T.A. Houser, *Alternative Curing Systems*, in Tarté, R. (Ed.). (2009). *Ingredients in meat products: properties, functionality and applications*. Springer Science & Business Media. pp. 398–399.

²⁶ ATSDR, 2001. *Case Studies in Environmental Medicine: Nitrate/Nitrite Toxicity*. https://www.atsdr.cdc.gov/csem/nitrate_2013/docs/nitrite.pdf.

nitrosamines, which have been reported to cause cancer in animals [Bruning-Fann and Kaneene 1993]. Elevated risk of non-Hodgkin's lymphoma [Ward et al. 1996] and cancers of the esophagus, nasopharynx, bladder, colon, prostate and thyroid have been reported [Cantor 1997; Eichholzer and Gutzwiller 1998; Barrett et al. 1998; Ward et al. 2010].

An increased incidence of stomach cancer was observed in one group of workers with occupational exposures to nitrate fertilizer; however, the weight of evidence for gastric cancer causation is mixed [Van Loon et al. 1998; Xu et al. 1992]. Epidemiological investigations and human toxicological studies have not shown an unequivocal relationship between nitrate intake and the risk of cancer [Alexander et al. 2010; Mensinga et al. 2003].

The International Agency for Research on Cancer (IARC) classifies nitrates and nitrites as "probably carcinogenic to humans" (Group 2A) under certain conditions (i.e. ingested nitrate or nitrite under conditions that result in endogenous nitrosation) which could lead to the formation of known carcinogens such as N-nitroso compounds [IARC 2010].

Finally, recent work demonstrates serious hormonal impacts of nitrate exposure.²⁷

OFPA §6510(a)(2)-(3) makes it illegal to:

- (2) add any ingredient known to contain levels of nitrates, heavy metals, or toxic residues in excess of those permitted by the applicable organic certification program;
- (3) add any sulfites, except in the production of wine, nitrates, or nitrites;

The regulations at §205.301(f)(5) state that organic products must not "Contain sulfites, nitrates, or nitrites added during the production or handling process, Except, that, wine containing added sulfites may be labeled 'made with organic grapes.'"

Celery powder is used in such a way that it adds significant nitrite, in light of the following.

Celery powder prepared from celery juice has been shown to have a nitrate content of approximately 2.75%. When using juice powder added at 0.2%, 0.35%, or 0.4% (on a total formulation basis), and assuming 100% nitrate-to-nitrite conversion, ingoing nitrite concentrations of approximately 69, 120, and 139 ppm (based on meat block), respectively, could be expected. As the amount of celery juice powder in the formulation increases, higher amounts of generated nitrite can be expected. ...From these results it was determined an uncured product with nitrite replaced with a source

²⁷ Guillette, L. J., & Edwards, T. M. (2005). Is nitrate an ecologically relevant endocrine disruptor in vertebrates?. *Integrative and Comparative Biology*, 45(1), 19-27. Guillette, L. J. (2006). Endocrine disrupting contaminants-beyond the dogma. *Environmental health perspectives*, 114, 9.

containing naturally occurring nitrate could result in a product with higher levels of residual nitrite than one in which nitrite was originally and intentionally added.²⁸

The concentrations above should be compared to the limit of 10 ppm in drinking water and the European Commission's (EC) Scientific Committee for Food (SCF) Acceptable Daily Intake (ADI) for the nitrate ion of 3.65 mg/kg body weight (equivalent to 219 mg/day for a 60 kg person).

Consumer Reports (CR) and Center for Science in the Public Interest (CSPI) petitioned USDA to change labeling of meats in which nonsynthetic sources of nitrates and nitrites are used. The petition gives additional scientific information about how sources such as celery powder affect health and mislead the consumer. The petition presents research—as well as conclusions by expert bodies, including the World Health Organization, American Cancer Society, and American Heart Association—finding increased risk of colorectal cancer associated with the consumption of cured meats and recommending limiting consumption of them. Consumers of organic “uncured” meat that has been treated with celery powder are doubly deceived—they believe that organic products have no added nitrates, and they believe that celery powder is an innocuous additive. We refer the NOSB to the CSPI/CR petition for details.²⁹ (In response, USDA said in a letter³⁰ that it will stop requiring the terms “Uncured” and “No Nitrate or Nitrite Added” on labels for meat processed with nitrates or nitrites from non-synthetic sources, such as celery powder.)

Conclusion

Beyond Pesticides opposes the relisting of celery powder. Its production in chemical-intensive agriculture results in health and environmental hazards. In considering the relisting of celery powder on §205.606, the NOSB must consider (a) whether its use is a direct violation of OFPA and the regulations, and (b) whether the hazards associated with the added nitrate/nitrite exposure—in addition to the hazards associated with nonorganic celery production—result in the a failure to meet OFPA criteria. The use of celery powder is a way of artificially adding nitrate as a preservative at levels not possible to achieve through use of organic celery. Nitrates pose dangers to health when artificially enhanced in food.

Fish oil

Reference: §205.606(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.

Fish oil raises two major issues: depletion of fish in the ocean and the presence of persistent contaminants, including DDT, PCBs, mercury, and dioxins.

²⁸ *Ingredients in Meat Products: Properties, Functionality and Applications*. pp. 398–399.

²⁹ CSPI/CR Petition to Require Accurate and Non-Misleading Labeling on Meat Processed with Non-Synthetic Nitrates and Nitrites.

<https://cspinet.org/sites/default/files/attachment/2019%20Petition%20No%20Nitrates%20Added%20CSPI%20UCOMPLETE.pdf>.

³⁰ https://www.cspinet.org/sites/default/files/19-03_CSPI_Nitrite_Response_121020.pdf.

Fish are known to bioconcentrate a number of toxic substances. Several studies have examined contaminants in fish oil supplements. They have found a wide variation in contaminant levels, even in those products labeled “purified.”³¹ The Food and Drug Administration (FDA) says,

In the case of components or extracts of whole fish (e.g., dietary supplements, dietary ingredients, and flavors), the component or extract may contain higher or lower concentrations of environmental chemical contaminants and pesticides than the whole fish from which it was derived. For example, organochlorine contaminants, such as PCBs, are oil soluble. When producing fish oil and fish meal, any PCBs present will become more concentrated in the oil fraction and less concentrated in the water fraction, as compared with the levels in the whole fish.³²

FDA also gives guidance to those using fish for reducing contamination in their products.³³

Currently, most fish oil for human consumption comes from marine pelagic oil fish, including mackerel, salmon, anchovy, sprat, pilchard, and herring, but the sought-after omega-3 oils are also found in deep sea fish and predators such as cod, swordfish, spearfish, marlin and tuna. Many people have expressed concerns over the depletion of populations of top-level predators, but extensive harvesting of marine fauna at lower trophic levels is also likely to have substantial impacts on the food supplies of predators.³⁴ Production of fish oil today often violates the fundamental tenets of organic food production to “promote ecological balance and conserve biodiversity.”

³¹ “Purified” -- <http://www.webmd.com/diet/news/20111206/some-fish-oil-supplements-fishy-on-quality> reporting on Consumers Reports study. Press release on ConsumerLab study: http://www.consumerlab.com/news/ReviewofFishOilandOmega-3SupplmentsbyConsumerLab.com/8_22_2012/ Also: Rawn DF, Breakell K, Verigin V, Nicolidakis H, Sit D, Feeley M., 2009. Persistent organic pollutants in fish oil supplements on the Canadian market: polychlorinated biphenyls and organochlorine insecticides. *J Food Sci.* Jan-Feb; 74(1):T14-9 <http://onlinelibrary.wiley.com/doi/10.1111/j.1750-3841.2008.01020.x/pdf>; Storelli MM, Storelli A, Marcotrigiano GO, 2004. Polychlorinated biphenyls, hexachlorobenzene, hexachlorocyclohexane isomers, and pesticide organochlorine residues in cod-liver oil dietary supplements. *J Food Prot.* Aug; 67(8):1787-91. Covaci, A., Voorspoels, S., Vetter, W., Gelbin, A., Jorens, P. G., Blust, R., & Neels, H., 2007. Anthropogenic and naturally occurring organobrominated compounds in fish oil dietary supplements. *Environmental science & technology*, 41(15), 5237-5244.

³² FDA Guidance: Environmental Chemical Contaminants and Pesticides. <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM252404.pdf> P. 1 (pdf numbering, p. 155 in original).

³³ FDA Guidance: Environmental Chemical Contaminants and Pesticides. <http://www.fda.gov/downloads/Food/GuidanceRegulation/UCM252404.pdf> Pp. 4-23 (pdf; 158-177 in original.)

³⁴ Brunner, E. J., Jones, P. J., Friel, S., & Bartley, M., 2009. Fish, human health and marine ecosystem health: policies in collision. *International journal of epidemiology*, 38(1), 93-100. <http://ije.oxfordjournals.org/content/38/1/93.full.pdf+html>.

The NOSB must consider whether organic consumers are adequately protected from contaminants in fish oil by the current listing. In addition, the NOSB must consider whether the allowance of fish oil from wild fish has a negative impact on fish populations.

Conclusion

Many organic consumers do want the benefits they could get from fish oil, but others are sensitive to the problems of contamination and overfishing. And organic fish, even if available, would be a net negative impact under current production practices, given that 81% of the world's supply of fish oil goes to feed fish. Although processing of fish oils reduces the levels of contaminants, many of those present in fish oil have no threshold for their negative effects (e.g., cancer).

Beyond Pesticides is strongly committed to the conservation of biodiversity, and until sustainable practices can be defined to conform to organic standards in compliance with OFPA, we oppose the relisting of fish oil.

Gelatin

Reference: 205.606(j) Gelatin (CAS # 9000-70-8)

Non-organic gelatin is made from a variety of meat and fish sources. Conventional meat production and aquaculture rely on chemically-intensive grain production. Nonorganic meat production typically results in air and water pollution from feedlots. Disposal of hides used in manufacture may result in toxic chemical pollution. Other effluents create high biological oxygen demand (BOD). The issue of BSE (bovine spongiform encephalopathy) transmission is raised by the TAP review, and FDA guidance addresses the sourcing and processing of gelatin to avoid BSE. Organic gelatin would promise better control over environmental and health issues. The TAP review raises the question of whether any gelatin is essential, but the issue of essentiality of non-organic gelatin is addressed by a simple internet search. The compatibility of some of the uses of gelatin with organic handling is questionable, particularly if organic gelatin is available.

Non-organic meat production is dependent on chemically-intensive production of corn and soybeans.

Corn

Non-organic corn production is an intensive user of pesticides and synthetic fertilizers. Most of the non-organic corn is also genetically modified.

Pesticide Tolerances—Health and Environmental Effects: The database shows that while field corn products grown with toxic chemicals show low pesticide residues on the finished commodity, there are 140 pesticides with established tolerance for field corn products,. Of these, at least 37 are acutely toxic creating a hazardous environment for **farmworkers**, 97 are linked to chronic health problems (such as cancer), 31 contaminate streams or groundwater, and 87 are poisonous to wildlife.

Pollinator Impacts: In addition to habitat loss due to the expansion of agricultural and urban areas, the database shows that there are 29 pesticides used on field corn products that are considered toxic to honey bees and other insect pollinators. This crop is foraged by pollinators.

Soybeans

California Farmworker Poisonings, 1992–2010: 1 reported. This poisoning incident represents only the tip of the iceberg because it only reflects reported incidents in one state. It is widely recognized that pesticide incidents are underreported and often misdiagnosed.

Pesticide Tolerances—Health and Environmental Effects: The database shows that while soybeans grown with toxic chemicals show low pesticide residues on the finished commodity, there are 83 pesticides with established tolerance for soybeans, 37 are acutely toxic creating a hazardous environment for farmworkers, 76 are linked to chronic health problems (such as cancer), 28 contaminate streams or groundwater, and 75 are poisonous to wildlife.

Pollinator Impacts: In addition to habitat loss due to the expansion of agricultural and urban areas, the database shows that there are 31 pesticides used on soybeans that are considered toxic to honey bees and other insect pollinators. This crop is dependent on pollinators. This crop is foraged by pollinators.

The evaluation of gelatin must take into consideration the use of pesticides in the non-organic production of corn and soybeans and ensure that GMO grains are not used in producing organic products. The NOSB must consider the availability of organic meat byproduct for this purpose, as well as the potential availability of gelatin if the demand was enhanced by removal of this listing.

Conclusion

The harm to organic consumers is only one part of the harm caused by dependence on non-organic inputs.

A previous HS proposal made a useful distinction between fish gelatin and other gelatin. It says, “Fish gelatin is widely preferred for uses in kosher foods and is never available as organic.” It is not clear whether the HS believed there to be an adequate supply of organic non-fish gelatin for the purposes for which fish gelatin is not needed. In either case, it appears that there is a need to separate the listing into two listings—for fish gelatin and gelatin from any or mixed sources. If the NOSB believes that a listing for the latter is still necessary, then the change of annotation should be put on the HS agenda. If the supply of organic gelatin is sufficient to meet the needs for gelatin not necessarily derived from fish, then the separate listings should be proposed during this sunset cycle.

Orange pulp, dried

Reference: 205.606(q) Orange pulp, dried

Health and Environmental Impacts

California Farmworker Poisonings, 1992–2010: 508 reported (CA acreage: 180,000). These poisoning incidents only represent the tip of the iceberg because they only reflect reported incidents in one state. It is widely recognized that pesticide incidents are underreported and often misdiagnosed.

Pesticide Tolerances —Health and Environmental Effects: The database shows that while oranges grown with toxic chemicals show low pesticide residues on the finished commodity, there are 73 pesticides with established tolerance for oranges, of which 30 are acutely toxic creating a hazardous environment for farmworkers, 66 are linked to chronic health problems (such as cancer), 19 contaminate streams or groundwater, and 60 are poisonous to wildlife.

Pollinator Impacts: In addition to habitat loss due to the expansion of agricultural and urban areas, the database shows that there are 25 pesticides used on oranges that are considered toxic to honey bees and other insect pollinators. For more information on how to protect pollinators from pesticides, see Beyond Pesticides' BEE Protective webpage. This crop is dependent on pollinators. This crop is foraged by pollinators.

The evaluation of dried orange pulp must take into consideration the use of pesticides in the non-organic production of oranges and the availability of organic oranges for this purpose, as well as the potential availability of the dried pulp if the demand existed.

The HS states, "A search in September 2023 of the Organic Integrity Database for orange pulp, dried, or dried orange pulp, resulting in zero results. However, when searching for orange pulp, 6 entities were found and when searching for orange powder, 29 entities were found." These findings require follow-up to determine whether the listed entities can provide adequate dried orange pulp.

Conclusion

Beyond Pesticides opposes the relisting dried orange pulp, which is produced by practices dangerous to workers and the environment.

Seaweed, Pacific kombu

Reference: 205.606(u) Seaweed, Pacific kombu.

Kombu is a brown seaweed and concentrates heavy metals including arsenic³⁵ and cadmium.³⁶ Since seaweeds concentrate iodine (kombu by a factor of 1000x), those grown in water contaminated by radioactivity have high radioactive iodine concentrations.³⁷

Conclusion

³⁵ Sartal, C. G., del Carmen Barciela-Alonso, M., & Bermejo-Barrera, P. (2012). Effect of the cooking procedure on the arsenic speciation in the bioavailable (dialyzable) fraction from seaweed. *Microchemical Journal*, 105, 65-71.

³⁶ Kikuchi, Y., Nomiya, T., Kumagai, N., Uemura, T., & Omae, K. (2002). Cadmium concentration in current Japanese foods and beverages. *Journal of Occupational Health*, 44(4), 240-247.

³⁷ Daiichi Weiss, D. (2011). Contamination of water, sediments and biota of the Northern Pacific coastal area in the vicinity of the Fukushima NPP. In *Paris, France, November: EUROS SAFE Forum*.

Annotations requiring testing for heavy metals and radioactivity and prevention of overharvesting would protect organic consumers and the environment. The NOSB must consider the question of whether the allowance of the use of wild kombu is adequately protective. The NOSB should examine the use of marine plant and animal products as ingredients in organic foods and how to apply standards protecting the marine environment.

Some kombu might be certified as wildcrafted organic in order to prevent overharvesting and minimize contamination. The HS says, "Most kombu is from the species *Saccharina japonica* (*Laminaria japonica*), and is extensively cultivated on ropes in the seas of Japan and Korea." In view of the tendency of seaweeds to concentrate radioactivity, seaweed harvested from ocean waters that received a high input of radioactivity from Fukushima should not be permitted in organic food without screening for radioactivity.

Because of the issues of contamination and overharvesting, Beyond Pesticides opposes the relisting of Pacific kombu.

Seaweed, Wakame (*Undaria pinnatifida*)

Reference: 205.606(y) Wakame seaweed (*Undaria pinnatifida*)

Like other seaweeds, wakame concentrates heavy metals, including arsenic.³⁸

Conclusion

Annotations requiring testing for heavy metals and prevention of overharvesting would protect organic consumers and the environment. The NOSB must consider the question of whether the allowance of the use of wild wakame is adequately protective. The NOSB should also examine the use of marine plant and animal products as ingredients in organic foods and how to apply standards protecting the marine environment.

Because of the issues of contamination and overharvesting, Beyond Pesticides opposes the relisting of wakame.

Thank you for your consideration of these comments.

Sincerely,



Terry Shistar, Ph.D.
Board of Directors

³⁸ García-Sartal, C., Romarís-Hortas, V., del Carmen Barciela-Alonso, M., Moreda-Piñeiro, A., Dominguez-Gonzalez, R., & Bermejo-Barrera, P. (2011). Use of an in vitro digestion method to evaluate the bioaccessibility of arsenic in edible seaweed by inductively coupled plasma-mass spectrometry. *Microchemical Journal*, 98(1), 91-96.