



BEYOND PESTICIDES

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April 3, 2015

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW.,
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Re. HS: Ascorbic acid, citric acid and citrates, lactic acid and lactates, sulfur dioxide, tocopherols, magnesium carbonate, magnesium chloride, glycerin, alginates, calcium hydroxide, calcium phosphates, glycerin, sodium phosphates, xanthan gum, ferrous sulfate, calcium hydroxide, nutrient vitamins and minerals.

These comments to the National Organic Standards Board (NOSB) on its Spring 2015 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 reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and groups around the world.

These comments address a number of materials on §205.605(b) that are used for purposes not permitted for synthetic materials. The organic regulations state at §205.600(b)(4):

The following criteria will be utilized in the evaluation of substances or ingredients for the organic production and handling sections of the National List:

(b) In addition to the criteria set forth in the Act, any synthetic substance used as a processing aid or adjuvant will be evaluated against the following criteria:

...

(4) The substance's primary use is not as a preservative or to recreate or improve flavors, colors, textures, or nutritive value lost during processing, except where the replacement of nutrients is required by law;

In accordance with this regulation, colors are on the National List on §205.606 (non-organic agricultural materials), and flavors are listed on §205.605(a) (nonsynthetic non-agricultural materials), but a number of materials on §205.605(b) (synthetic materials) have been added to the National List for their use as preservatives, texturizing agents, and synthetic nutrients.

This regulation is consistent with NOSB's "Principles of Organic Production and Handling" and guidance on "Compatibility with a System of Sustainable Agriculture and Consistency with Organic Farming and Handling," which stress the importance of maintaining the integrity,

quality, and authenticity of organic products. Synthetic preservatives threaten the integrity, quality, and authenticity of organic products by artificially extending shelf-life and making products appear fresher than they are. Texturizers create artificial foods that lack the authenticity and integrity that consumers expect from organic foods. Consumers also expect superior nutrition from organic food that comes from its production in “an ecological production management system that promotes and enhances biodiversity, biological cycles, and soil biological activity,”¹ and artificial nutrients are inconsistent with that expectation.

Preservatives

Substances on §205.605(b) primarily for their preservative function include ascorbic acid, sulfur dioxide (only in wine made with organic grapes), and tocopherols. In addition, glycerin’s functions include use as a preservative. Magnesium carbonate and magnesium chloride both include “color retention” among their uses.

Ascorbic acid

Current listing:

§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. **Ascorbic acid should be removed from the National List.**

Citric acid and its salts (calcium citrate, potassium citrate, and sodium citrate)

Current listings:

§205.605(a) Nonsynthetics allowed:

Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).

§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 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 TR. It should be revisited.

¹ NOSB’s “Principles of Organic Production and Handling.”

Many, if not all, of the uses of the citrates are prohibited by §205.600(b)(4) –preservative, flavors, color enhancement, and nutritional fortification—and if citric acid were judged to be synthetic, those prohibitions should apply to it as well.

Citric acid should be re-classified as synthetic, or annotated to require use of processes that do not involve synthetic chemical reactions. If truly nonsynthetic citric acid is available, then synthetic citric acid should not be allowed. If nonsynthetic citric acid is not available, then the use of synthetic citric acid –and the citrates—should be restricted to uses that are in compliance with §205.600(b)(4). Although NOP’s sunset policy does not allow this change to be made as part of the sunset process, we suggest that in this case, the change should be made to make the listing consistent with §205.600(b)(4) and ensure that OFPA criteria are met. Therefore, the NOSB must make the change through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.²

Lactic acid (and sodium lactate and potassium lactate)

Current listing:

§205.605(a)

Acids (Alginic; Citric—produced by microbial fermentation of carbohydrate substances; and Lactic).

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 citric acid is nonsynthetic was based on a much less complete description of the fermentation and purification processes than is available in the TR. It should be revisited. Lactates, which NOP has requested the NOSB to address, are formed as a result of reactions of lactic acid with the appropriate bases and are synthetic.

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.

The NOSB needs guidance on products of fermentation to help decide whether the materials under consideration are synthetic or nonsynthetic and agricultural or nonagricultural.

² The November 2009 NOSB recommendation on chlorhexidine said, “In terms of the board recommending a substance to be added to the national list without a petition, (An OGC person sees) nothing in the OFPA or NOP regulations that would prohibit such action. (Another OGC person) agrees as well, and indicated that he believes the original NL was created by the board without any petitions. In either event, it would seem like the board's primary function is to make recommendations concerning the NL (to add, remove, renew, etc.) and that petitions are just one mechanism through which the board can make such recommendations.”

<http://www.ams.usda.gov/AMSv1.0/getfile?dDocName=STELPRDC5081492&acct=nosb>.

The proposed decision tree for agricultural/nonagricultural is at odds with the definition of nonagricultural in §205.2.

Many, if not all of the uses of these materials are prohibited by §205.600(b)(4) –preservative, flavor enhancement, and creation of texture—and if lactic acid were judged to be synthetic, those prohibitions should apply to it as well.

Lactic acid should be re-classified as synthetic, or annotated to require use of processes that do not involve synthetic chemical reactions. If truly nonsynthetic lactic acid is available, then synthetic lactic acid should not be allowed. If nonsynthetic lactic acid is not available, then the use of synthetic lactic acid –and the lactates—should be restricted to uses that are in compliance with §205.600(b)(4). Although NOP’s sunset policy does not allow this change to be made as part of the sunset process, we suggest that in this case, the change should be made to make the listing consistent with §205.600(b)(4) and ensure that OFPA criteria are met. Therefore, the NOSB must make the change through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.³

Sulfur dioxide

Current listing:

§205.605(b) Sulfur dioxide—for use only in wine labeled “made with organic grapes,” Provided, That, total sulfite concentration does not exceed 100 ppm.

Sulfur dioxide is a major air pollutant and has significant impacts upon human health as well as plants and animals. Inhaling sulfur dioxide is associated with increased respiratory symptoms and disease, difficulty in breathing, and premature death. It is estimated that anywhere between 0.4 and 1 percent of the general population is sensitive to sulfites, and a person who is sensitive to sulfite may suffer effects that range from moderate to life-threatening ones. There are small amounts of B vitamins in wine, and sulfur dioxide depletes them. Organic wine is made without sulfur dioxide. **Sulfur dioxide is a synthetic preservative, but it is limited in the listing to use only in wine labeled “made with organic grapes,” which does not threaten the integrity of the organic label.**

Tocopherols

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,

³ See footnote 2 above.

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 Handling Subcommittee must investigate the availability of natural tocopherols. If, as the comment quoted above states, 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. Although NOP’s sunset policy does not allow this change to be made as part of the sunset process, we suggest that in this case, the change should be made to make the listing consistent with §205.600(b)(4) and ensure that OFPA criteria are met. Therefore, the NOSB must make the change through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.⁴

Magnesium carbonate

Current listing:

§205.605(b) Magnesium carbonate—for use only in agricultural products labeled “made with organic (specified ingredients or food group(s)),” prohibited in agricultural products labeled “organic”.

Magnesium carbonate was petitioned as a filtration aid, but other uses include pH adjustment, drying agent, anti-caking agent, and color-retention agent.

Since this use is allowed only in “made with organic” foods, it does not threaten organic integrity.

Magnesium chloride

Current listing:

§205.605(b) Magnesium chloride—derived from sea water.

According to the Petitioned Substances Database, magnesium chloride for use in crops is “classified as nonsynthetic when extracted from brine, seawater, and salt deposits.” The TAP reviews for both Crops and Handling say that magnesium chloride obtained from sea water “by concentration of the liquor by solar evaporation and then fractional crystallization of other salts.” This appears to be a nonsynthetic process, so magnesium chloride does not belong on §205.605(b). If it is to appear on the National List for Handling, it should be on §205.605(a).

⁴ See footnote 2 above.

While the coagulant use for making tofu is consistent with organic practices, the use for color enhancement is not if magnesium chloride is correctly listed as synthetic on §205.605(b), so if magnesium chloride derived from sea water remains on §205.605(b), an annotation should be added, “as a coagulant in making tofu.”

The HS should revisit the classification decision for magnesium chloride derived from sea water. If it is found to be nonsynthetic, then it should be petitioned for listing on §205.605(a) and removed from §205.605(b). Although NOP’s sunset policy does not allow this change to be made as part of the sunset process, we suggest that in this case, the change should be made to make the listing consistent with §205.600(b)(4) and ensure that OFPA criteria are met. Therefore, the NOSB must make the change through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.⁵

Glycerin

Current listing:

§205.605(b) Glycerin—produced by hydrolysis of fats and oils.

Glycerin as listed is made by hydrolysis of fats and oils, a chemical process. Glycerin as listed is not agricultural. The classification of glycerin made by fermentation of cornstarch is unclear. Additional nutrients may be added. Glycerin from fermentation involves some steps (eg, ion exchange) that may be chemical processes. If organic cornstarch is used and other nutrients are organic, it is possible that the resulting glycerin may be organic. There are many alternatives for the many uses of glycerin. Some of the uses are not permitted uses of synthetic food additives in organic food –preservative, improving texture, a synthetic ingredient in colors and flavors. Some of the uses are not consistent –preservative, improving texture, a synthetic ingredient in colors and flavors. Nonsynthetic glycerin would be compatible in all uses. Even as a synthetic, glycerin can be a sustainable input.

The classification of glycerin made by fermentation must be clarified. To this end, it would be helpful to develop guidance on fermentation processes. The TR for citric acid and citrates is a helpful first step, since it identifies variants on the fermentation process, including synthetic inputs, reactants, extractants, and processes that could affect the classification of the fermentation product. The approach taken in the NOP draft classification guidance –that fermentation is a food processing method that does not change the classification as the substrate is transformed—is not adequate for more complex processes, and is not consistent with the definition of “Nonagricultural substance” in §205.2:

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

⁵ See footnote 2 above.

an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

Meanwhile, glycerin as listed is synthetic and should not be used for those purposes prohibited by §205.600(b)(4) –as a preservative, or to recreate or improve flavors, colors, textures, or nutritive value lost during processing. The relisting of glycerin must be justified in terms of uses that are not prohibited. Although NOP’s sunset policy does not allow this change to be made as part of the sunset process, we suggest that in this case, the change should be made to make the listing consistent with §205.600(b)(4) and ensure that OFPA criteria are met. Therefore, the NOSB must make the change through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.⁶

Texturizers

The National List includes a number of substances to give or preserve texture in foods. Those on §205.605(b) include alginates, calcium hydroxide, calcium phosphate monobasic, glycerin, sodium phosphates, and xanthan gum.

Alginates

Current listing:
§205.605(b) Alginates.

Alginates are synthetic derivatives of brown seaweeds. They are extracted through a method that causes chemical changes. Brown algae concentrate heavy metals and radioactivity, so those contaminants will be present either in the finished product, the waste stream, or both. The use of alginates is to create textures, and is therefore incompatible with organic regulations.

Alginates should be removed from the National List unless they have allowed uses for which they are essential.

Calcium hydroxide

Current listing:
§205.605(b) Calcium hydroxide.

Calcium hydroxide is used as a pH buffer and as the alkaline substance in aluminum-free baking powder. It is also used to fortify foods with calcium, clarify sugar cane or beet juice, for making hominy and masa, and as a firming agent.

The use as a firming agent is not compatible. It may be essential in making hominy and masa, where it causes the loss of some nutritional value, but adds calcium.

⁶ See footnote 2 above.

The listing should clarify which uses are permitted. Although NOP’s sunset policy does not allow this change to be made as part of the sunset process, we suggest that in this case, the change should be made to make the listing consistent with §205.600(b)(4) and ensure that OFPA criteria are met. Therefore, the NOSB must make the change through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.⁷

Calcium phosphate monobasic

Current listing:

§205.605(b) Calcium phosphates (monobasic, dibasic, and tribasic).

Calcium phosphates are used as leavening agents, dough conditioners, and yeast food. Monobasic is also used as a buffer, sequestrant, and firming agent. Tribasic is also used as an anti-caking agent and a buffer.

Phosphate refining releases heavy metals and radioactivity. Phosphates have a number of impacts when used as food additives. According to the TAP review for sodium phosphate, “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.”

More recent studies have shown that inorganic forms of phosphate, such as calcium and sodium phosphates, cause hormone-mediated harm to the cardiovascular system. A review found that they “may harm the health of persons with normal renal function. This judgment has been made on the basis of large-scale epidemiological studies and is supported by the latest findings of basic research.”⁸ This is an important line of research that should be investigated by the HS.

The NOSB should seek to eliminate the use of inorganic phosphates in organic food. If it is not possible to totally eliminate them, the listings should be annotated to eliminate uses prohibited by §205.600(b)(4). Although NOP’s sunset policy does not allow this change to be made as part of the sunset process, we suggest that in this case, the change should be made to make the listing consistent with §205.600(b)(4) and ensure that OFPA criteria are met. Therefore, the NOSB must make the change through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.⁹

⁷ See footnote 2 above.

⁸ Ritz, E., Hahn, K., Ketteler, M., Kuhlmann, M. K., & Mann, J. (2012). Phosphate Additives in Food—a Health Risk. *Deutsches Ärzteblatt International*, 109(4), 49–55.

⁹ See footnote 2 above.

Glycerin

See above.

Sodium phosphates

Current listing:

§205.605(b) Sodium phosphates—for use only in dairy foods.

Sodium phosphates are used in dairy products as emulsifiers, stabilizers, preservatives, and to create certain textures. They can lead to imbalances in the calcium:phosphorus ratio in the body. Phosphate refining releases heavy metals and radioactivity, but some heavy metal contamination may remain in the sodium phosphate products.

Subacute effects include 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.”

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The NOSB should seek to eliminate the use of inorganic phosphates in organic food. If it is not possible to totally eliminate them, the listings should be annotated to eliminate uses prohibited by §205.600(b)(4). Although NOP’s sunset policy does not allow this change to be made as part of the sunset process, we suggest that in this case, the change should be made to make the listing consistent with §205.600(b)(4) and ensure that OFPA criteria are met. Therefore, the NOSB must make the change through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.¹¹

Xanthan gum

Xanthan gum is produced by fermentation of crop pathogenic bacteria in a complex nutrient broth, extracted by a difficult process involving a number of synthetic solvents. Effluents from manufacture are unknown, as are ancillary substances. Xanthan gum can cause respiratory symptoms in workers; necrotizing enterocolitis in infants; allergies, depending on source of fermentation medium; and intestinal distress, including bloating and diarrhea, in consumers.¹²

¹⁰ Ritz, E., Hahn, K., Ketteler, M., Kuhlmann, M. K., & Mann, J. (2012). Phosphate Additives in Food—a Health Risk. *Deutsches Ärzteblatt International*, 109(4), 49–55.

¹¹ See footnote 2 above.

¹² http://en.wikipedia.org/wiki/Xanthan_gum#Health

Xanthan gum is a good example of the need for guidance regarding the classification and acceptability of products of fermentation. Xanthan is the product of fermentation that uses a plant pathogenic organism. The fermentation medium is a complex chemical mixture, and the recovery of xanthan gum from the fermentation broth is a difficult and expensive process that depends on a number of synthetic solvents:

The main steps of the recovery process (Fig. 2) are deactivation and removal (or lysis) of the microbial cells, precipitation of the biopolymer, dewatering, drying, and milling. Processing must be done without degrading the biopolymer. The final product is usually a dry powder or a concentrated solution. Numerous methods have been developed to deactivate, lyse, or remove cells from the broth. Treatment with chemicals (e.g. alkali, hypochlorite, enzymes), by mechanical means, and thermal treatment are used. Chemical treatment at elevated pH can cause depyruvylation of the product. When enzymes are used, they must be removed from the medium and this adds to costs. Usually, the fermentation broth is pasteurized or sterilized to kill the cells (Smith and Pace, 1982; Garcia-Ochoa et al., 1993). These thermal treatments also enhance xanthan removal from the cells. Pasteurization of the fermentation broth at a high temperature often causes thermal degradation of the microbial exopolysaccharides. When the broth is treated under proper conditions ($80 \pm 130^\circ\text{C}$, 10 ± 20 min, $\text{pH } 6.3 \pm 6.9$) enhanced xanthan dissolution occurs without thermal degradation and disruption of cells is observed (Smith and Pace, 1982). The increased temperature also reduces the viscosity of the broth to ease removal of the insolubles by centrifugation or filtration.

For highly viscous xanthan broths, viscosity reduction must precede filtration. Viscosity is reduced by dilution or heating. The fermentation broth is usually diluted in water, alcohol, or mixtures of alcohol and salts in quantities lower than those needed for xanthan precipitation (Smith and Pace, 1982; Garcia-Ochoa et al., 1993). The diluted and/or heated broth is filtered to remove the solids. Filtration is improved in presence of alcohol.

Xanthan in solution can be viewed as a hydrophilic colloid forming a true solution in water (Smith and Pace, 1982). Precipitation of polymer is achieved by decreasing the solubility of the dissolved colloid using methods such as addition of salts, water-miscible non-solvents, and concentration by evaporation. Recovery options that have been studied include precipitation with organic solvent such as ethanol (Gonzalez et al., 1989) and isopropyl alcohol (IPA) (Galindo and Albiter, 1996); the use of mixtures of salts and alcohol (Garcia-Ochoa et al., 1993); and precipitation with trivalent or tetravalent salts (Kennedy and Bradshaw, 1984). Also, the use of ultrafiltration has been reported (Lo et al., 1997). The most common technique used for the primary isolation and purification of polysaccharides is precipitation using water miscible non-solvents such as alcohols (Smith and Pace, 1982). Both the cost of alcohol for recovery and the inevitable losses contribute significantly to the total cost of production. A knowledge of the mechanisms controlling phase separation is useful for devising alternatives to alcohol precipitation and for determining the conditions under which alcohol usage can be minimized.

The lower alcohols (methanol, ethanol, isopropanol) and acetone, which are non-solvents for the polysaccharide, can be added to the fermentation broth not only to decrease the solubility until phase separation occurs, but also to wash out impurities such as colored components, salts, and cells.¹³

So, unlike glycerin, which may be made by fermenting an agricultural product, xanthan gum is the result of fermenting a broth that may or may not be synthetic by OFPA standards, but is certainly not an agricultural product. Two of the TAP reviewers considered xanthan gum to be synthetic by virtue of the use of synthetic solvents to purify it, and the other considered it to be nonsynthetic.¹⁴ Absent guidance on fermentation processes, however, it is not clear what criteria the NOSB should apply in classifying materials like xanthan gum. In addition, it is not clear how the NOSB should evaluate the manufacture and compatibility of a product made by such a process.

Xanthan gum should be removed from the National List unless it has allowed uses for which it is essential.

Synthetic nutrients

Synthetic nutrients listed on §205.605(b): ascorbic acid, ferrous sulfate, and nutrient vitamins and minerals. Those with “nutrient” as one of several uses include calcium citrate, calcium hydroxide, calcium phosphates (monobasic, dibasic, and tribasic), potassium citrate, sodium citrate, and tocopherols.

Since there are very few cases in which added nutrients are required by law, the materials below should almost never be added to organic food. Their continued listing for nutrient purposes must be justified by reference to a regulation that requires their use.

Ascorbic acid

See above.

Calcium citrate

See “Citric acid and its salts” above.

Ferrous sulfate

Current listing:

§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. It oxidizes fats and oils and vitamin E in products in which it occurs. Its use could be avoided by

¹³ Garcia-Ochoa, F., Santos, V. E., Casas, J. A., & Gomez, E. (2000). Xanthan gum: production, recovery, and properties. *Biotechnology advances*, 18(7), 549-579.

¹⁴ TAP, pp. 5, 7.

using natural whole foods. When absolutely necessary to fortify with iron, a less destructive chemical should be used.

Ferrous sulfate should be phased out. Iron fortification is required for “enriched” cereal and flour products, but in those cases, a form of iron that is less destructive of other food values should be substituted. Alternatively, less processed forms can be used that do not require fortification.

Calcium hydroxide

See above.

Calcium phosphates (monobasic, dibasic, and tribasic)

See above calcium phosphate monobasic.

Nutrient vitamins and minerals

Current listing:

§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”. The 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. Although such a change –or the changes proposed by AMS—could occur only through a petition under the current sunset policy, we suggest that in this case, the change should be made to make the listing consistent with §205.600(b)(4) and ensure that OFPA criteria are met. Therefore, the NOSB must make the change through a two-stage process of removing the listing and creating a new listing. The USDA Office of General Counsel has previously ruled that a petition is not necessary for this process. In fact, the first National List did not arise based on petitions.¹⁵

Tocopherols

See above.

Thank you for your consideration of these comments.

Sincerely,



Terry Shistar, Ph.D.
Board of Directors

¹⁵ See footnote 2 above.