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

Re. HS: 2018 Sunset

These comments to the National Organic Standards Board (NOSB) on its Spring 2016 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 the world.

Agar-agar

205.605(a)

Synthetic vs. Nonsynthetic Agar

Agar (or agar-agar) may be nonsynthetic or synthetic. Nonsynthetic agar is made from *Gellidium* species of seaweed. It may be pretreated with an acid (vinegar or a mineral acid) to improve penetration. Synthetic agar is made from *Graciliara* species, which is subject to alkaline pretreatment to bring about a chemical change in the polysaccharides (L-galactose-6-sulfate groups are converted to 3,6-anhydro-L-galactose), producing agar with increased gel strength.

In the spring of 2012, the Handling Subcommittee (HS) concluded from the Technical Evaluation Report (TR):

> While the Technical Review does list several methods of extraction, it does state that only 1 -2 % of the Agar- Agar supply is from the natural form of extraction. Furthermore, the product from the natural extraction method does not appear to be readily available in the U.S. market, or at least on a very limited basis.

We are not certain that the TR says what the subcommittee thinks it says, and we ask that the subcommittee recheck its conclusions. The TR states:[1]

> 'Natural' agar refers to products sold in strips or squares that are produced on a small scale using traditional methods for extraction and freezing. First, the algae are boiled in water for several hours, sometimes in the presence of vinegar or dilute mineral acid. Then the extract is filtered through a cotton cloth and poured into wooden trays to cool. The resulting gel is cut into strips that are placed outside to freeze at night and thaw during the day, a process that may be repeated. Modern refrigeration is sometimes used as a substitute. Finally, the strips are dried and bleached in the sun. The agar-agar produced by this process has a weak gelling capacity and currently accounts for only ~1.5% of the world's production.

However, nonsynthetic agar also may be made by syneresis, which is:[2]

> "the separation of a liquid from a gel. During this process, mechanical pressure is applied to the agar-agar gels to increase the rate of separation. The polymer chains that make up agar-agar associate together and water is expressed from the gel. The resulting gels have an agar-agar concentration of about 20% making this method much more efficient than the freeze-thaw process."

The agar concentration from this process (20%) is about twice that of the gels made through the "natural" process (10-12%). The source for much of the information in the TR, McHugh (2003),[3] may be helpful to the committee in checking its conclusions. Agar made from *Gellidium* species is nonsynthetic, while agar made from *Graciliara* species is synthetic, and there is probably adequate production of nonsynthetic agar to meet the needs of organic processors.

Is there a need?

The TR states,[4]

> Several agricultural products could be used as alternatives for agar-agar depending on the function required for a specific food application as well as compatibility with other ingredients.
>
> Possible agricultural alternatives to agar-agar in food applications include (1) gelling agents, such as pectin high methoxy), gelatin, unmodified starches, and konjac flour, and (2) thickeners, emulsifiers, and stabilizers, such as vegetable gums (Arabic, locust/carob bean, guar), unmodified starches, tragacanth gum, konjac flour. All of these products are included on the National List as nonorganically produced agricultural products allowed as ingredients in or on processed products labeled as "organic" (7 CFR 205.606). Suppliers of organic forms

[1] Lines 202-209.
[2] TR lines 192-196.
[3] 1 McHugh, D.J. 2003. Ch. 2 Seaweeds used as a source of agar and Ch. 3 Agar. In: McHugh, D.J. 2003. A Guide to the Seaweed Industry. FAO Technical Fisheries Paper No. 441. Food and Agricultural Organization of the United Nations, Rome, Italy. Available online at http://www.fao.org/docrep/006/y4765e/y4765e00.htm.
[4] Lines 335-345.

of these products were found in most cases (as noted below). Organically-produced forms of these products are only allowed when organic forms are not commercially available.

However, the HS conclusion of 2012, "Agar continues to be an important material used by the organic community" should be re-evaluated in light of the information in the TR regarding alternatives.

What are the human health and ecological impacts?

The TR did not identify any adverse impacts on human health. However, it did identify ecological impacts, particularly with the synthetic form of agar. As we stated above, synthetic forms of agar are produced from different species than those used for nonsynthetic forms. The ecological impacts identified in the TR come from the production of synthetic agar—both from overharvesting of *Graciliara* and from alkaline wastewaters.

Is it consistent with principles of organic production and handling?

Assuming that the conclusions of the TR are valid, we find no areas of inconsistency with the use of nonsynthetic agar.

Conclusion

We support the continued listing of agar-agar on §205.605(a) Nonsynthetics allowed, with the annotation, "from *Gellidium* species, processed without alkaline pretreatment." We oppose the proposed listing of agar-agar on §205.605(b) Synthetics allowed.

Animal enzymes

205.605(a) Animal enzymes– (Rennet–animals derived; Catalase–bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin).

The use of enzymes from animals produced by chemical-intensive agriculture carries with it impacts of that form of production. With regard to animal enzymes, it appears that animal rennet from non-organic sources is probably not essential, since according to the 2011 Technical Review (TR), non-animal sources account for 95% of the rennet used in the U.S.[5] Animal-based rennet could also be made from organic livestock.[6]

Questions for further review.

The 2011 and 2015 TRs –the latter addressing ancillary substances– leave unanswered some important questions. The most important of these questions are:

1. Are organic forms of each animal enzyme available?
2. Which of the identified ancillary ingredients are necessary?
3. Of the necessary ancillary ingredients, which are available as organic agricultural products?

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[5] 2011 TR, lines 834-835.

[6] 2011 TR, lines 829-830.

4. Of the necessary ancillary ingredients, which are available as synthetic substances already on §205.605(b) and allowed to be added to organic food?
5. Other animal enzymes ("Catalase—bovine liver; Animal lipase; Pancreatin; Pepsin; and Trypsin") should be addressed in TR.

Calcium sulfate –mined

205.605(a) Calcium sulfate—mined.

What are the human health and ecological impacts?

As stated by one TAP reviewer,

> Calcium sulfate derived from natural sources impacts the environment in that mining operations are needed to obtain it. This involves quarrying or blasting, and the use of heavy equipment. In addition to the direct impact of the mining operations on the Earth, there is a negative impact caused by the generation of gypsum dust in the process. This dust can affect air quality, and can be a potential exposure hazard to humans and other animals. There are no other known negative effects of toxicity and/or persistence in the environment caused by production of calcium sulfate from these methods, as long as standard regulations for proper mining activities are followed.

Calcium sulfate is an irritant to eyes and skin, and when inhaled. We have not seen any reports indicating that problems associated with Chinese gypsum in drywall are problems for food-grade calcium sulfate.

Is there a need?

Calcium sulfate has been used as a coagulant for tofu for over 2000 years in China. Although there are other coagulants that may be used, calcium sulfate is essential for traditional Chinese tofu. Other uses are allowed under this listing, and the need for them has not been established. They include: nutrient, yeast food, dough conditioner, firming agent, sequestrant, jelling agent, baking powder ingredient, carrier, pH buffer, and abrasive agent. One of the three TAP reviewers in 2001 recommended that calcium sulfate be approved only for use in making tofu.

Is it consistent with principles of organic production and handling?

We ask the board to consider Table 4 from the TAP review. We agree that the use of calcium sulfate as a coagulant in tofu production is compatible with organic principles, but other uses should be considered individually. The information in this table might support the use of calcium sulfate in brewing, but not in other possible uses.

Conclusion

We have not seen sufficient evidence to support the use of calcium sulfate for all food uses. Therefore we support renewing the listing of calcium sulfate with the annotation, *"For use only as a coagulant in bean curd (tofu and similar products)."*

Carrageenan

205.605(a)

We oppose the relisting of carrageenan on §205.605(a) and believe that the substance should be removed from the National List. Carrageenan should be reclassified as a synthetic. As we will explain below, this use does not meet the requirements of the Organic Food Production Act – carrageenan may have adverse effects on the health of consumers, its production results in adverse ecological impacts, there are alternatives to its use, and its use is inconsistent with a system of organic and sustainable production.

Carrageenan is synthetic.

The 2011 TR says,[7] "No information was found to indicate that any form of commercially-available carrageenan is extracted without chemical modifications."

Carrageenan may have adverse effects on the health of consumers.

After a discussion of the impacts of "degraded carrageenan," the 2011 TR continues,[8]

> Today, both concern and debate exists over human health hazards from not only direct use of degraded carrageenan in foods, but also based on the idea that acid hydrolysis in the stomach following consumption of non-degraded carrageenan could result in formation of degraded carrageenan, which could then potentially promote colon cancer (Tobacman, 2001; Carthew, 2002). In 2001, Joanne K. Tobacman published a review of 45 studies dated from 1969 through 1997, that showed that exposure to degraded and/or undegraded carrageenan was associated with intestinal lesions such as ulcerations and neoplasms in several different animal models, including ferret, guinea pig, monkey, mouse, rat, and rabbit (Tobacman, 2001). Animal studies published since 1997 that were not included in Tobacman's review have shown conflicting results. While some studies have verified that carrageenan is associated with induction or promotion of gastrointestinal tract inflammation, ulcerations and/or neoplasms in animal models (e.g., Benard et al., 2010 and human tissues (e.g., Borthakur et al., 2007; Bernard et al., 2010), other studies have contradicted this finding (e.g., *in vivo:* Weiner et al., 2007; and *in vitro:* Tobacman and Walters, 2001).

Even taking into account the two negative studies, this is a considerable weight of evidence of harm to humans from carrageenan. The standards of the Organic Foods Production Act are distinct from the Federal Food Drug and Cosmetic Act and the determinations of FDA, requiring that a hazard analysis be incorporated into a decision making process that is precautionary. The TR contains several cautions beyond the two studies cited above. "JECFA [Joint FAO/WHO Expert Committee on Food Additives] advised that carrageenan should not be used in infant formula intended for children under 13 months of age based on a concern over the narrow margin of exposure between the level of carrageenan consumed through infant formula and the lowest doses reported to cause

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[7] Lines 387-388.

[8] Lines 571-582.

inflammatory responses in laboratory rats and mice." "[C]arrageenan has a high tendency to sequester metal ions such as arsenic, lead, zinc, and copper (Piculell, 2006)."

The more recent (2015) technical review specifically examined potential health impacts of carrageenan. The review came up with a verdict of mixed results on virtually every issue. On the question of whether less hazardous high molecular weight carrageenan can be degraded in the digestive system to more hazardous lower molecular weight forms: "The research is not fully conclusive but seems to suggest that degradation is possible."[9] On the association between food-grade carrageenan and inflammation or ulceration: "Several conclusions in the literature for animal feeding studies did not associate food-grade carrageenan fed in the diet with inflammation or ulceration, although some research does suggest an association."[10] On the impact of carrageenan administered through drinking water: "Results are mixed in animal studies that administered carrageenan through drinking water."[11] On effects on cell-signaling leading to inflammation: "Several in vitro studies have been performed to investigate carrageenan-induced effects on cell signaling pathways that contribute to inflammation, but without consensus among the reviewed research."[12] On the inflammatory effects of carrageenan in humans, "Definitive conclusions regarding the varying degrees of human susceptibility to inflammation effects of carrageenan cannot be made from the available literature."[13] On absorption of carrageenan: "Although these studies indicate that there may be a small percentage that is not excreted, there is no apparent evidence in the literature of animal feeding studies that carrageenan fed in the diet is absorbed in the gastrointestinal tract in toxicologically significant quantities."[14] On carcinogenic risk: "From the above studies on the role of carrageenan in tumor promotion of existing carcinogenic activity, it is difficult to draw conclusions about how carrageenan may contribute hazardous risk to humans."[15] And, "Carrageenan-induced cell signaling pathways that contribute to proliferation disorders have been studied in human colonic epithelial cells. A mechanism of carrageenan-induced Wnt signaling can lead to proliferative disorders and contribute to colon carcinogenesis as demonstrated in a study by Bhattacharyya, Feferman, Borthakur, et al. (2014)."[16] On insulin resistance and diabetes, the results appear more definitive: "The mechanisms of the cell-signaling pathway are demonstrated in a recent study by Bhattacharyya, Feferman, and Tobacman (2015), wherein carrageenan-induced inflammatory and transcriptional cell-signaling cascades impair glucose tolerance resulting in insulin resistance."[17] On the relevance of non-dietary studies in which the link between carrageenan and inflammation is non-controversial: "The relevancy of nearly all of the in vitro studies performed on the health effects of carrageenan is contested by McKim (2014), an in vitro toxicologist, in a review article prepared

[9] Lines 40-41.
[10] Lines 103-104.
[11] Line 138.
[12] Lines 146-147.
[13] Lines 173-174.
[14] Lines 202-205.
[15] Lines 228-230.
[16] Lines 238-241.
[17] Lines 247-250.

for and funded by FMC Corporation, a manufacturer of carrageenan."[18] Virtually every study purporting to refute findings of health effects was performed by the same group of industry-supported scientists.

The NOSB must take a precautionary approach in light of these studies. Even giving equal weight to industry-supported and independent peer-reviewed research, the NOSB must accept the existence of science pointing to serious health consequences associated with the consumption of carrageenan and act to protect organic consumers.

The production of carrageenan results in adverse ecological impacts.

The 2011 TR examined ecological impacts of carrageenan production in detail. Overharvesting of a cold water species of seaweeds used to make carrageenan resulted in a population crash of the wild species. Warm water species are cultivated and present "serious bio-invasive risks for nearby marine communities" –not only spreading beyond cultivation sites, but also smothering coral ecosystems and contributing to reef degradation. Other adverse impacts are detailed in the TR.[19] Furthermore, "The industrial manufacture of carrageenan is a process that produces large amounts of alkaline waste water which may pose environmental problems."[20]

Carrageenan is unnecessary.

The use of carrageenan is widespread, but that does not make it necessary. The 2011 TR lists a number of substitutes that "may be substituted for carrageenan to achieve a similar functionality when used either alone or in combinations." The Cornucopia Institute has published a shopping guide showing that every product made with carrageenan can be made without it.[21] Food processors have been removing carrageenan from organic food since the last sunset decision in 2012.

The use of carrageenan is inconsistent with a system of organic production and handling.

Carrageenan is an unnecessary synthetic material. Volatile synthetic solvents are used in at least some of its manufacturing processes.[22] Depending on the production method, it may contain residues of other synthetic materials including polysorbate 80 and epichlorohydrin. (TAP review pages 3, 4, 7) In some cases, it is used as a preservative.[23]

Conclusion

Therefore, we ask that the NOSB remove carrageenan from the National List. This is made more urgent by the fact that the National Organic Program ignored the recommendation of the NOSB in spring of 2012 to remove carrageenan from infant foods.

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[18] Lines 299-302.
[19] Lines 469-551.
[20] Lines 533-534.
[21] http://www.cornucopia.org/shopping-guide-to-avoiding-organic-foods-with-carrageenan/.
[22] 2011 TR lines 287-294.
[23] 2011 TR line 415.

Glucono delta- lactone

205.605(a) Glucono delta-lactone—production by the oxidation of D-glucose with bromine water is prohibited.

Classification

The 2016 technical review (TR) suggests that the current annotation is not sufficient to ensure that the glucono delta-lactone (GDL) in use is nonsynthetic.[24] It also states that some enzymes used in the production of GDL may be genetically engineered. If it decides to relist GDL, the NOSB should consider an annotation change to correct these issues.

Glucono delta-lactone is not essential to organic production and handling.

GDL was originally listed because of its use in making "silken" tofu. However the TR says, "Silken tofu can be produced with coagulants other than GDL, but the process is not as convenient, because the soymilk must be chilled to slow coagulation. However, the flavor may be better."[25] The TR also lists alternative materials and/or practices for other uses of GDL.

Tartaric acid

205.605(a) Tartaric acid—made from grape wine.

The HS should investigate whether tartaric acid from organic grape wine is available or would be available if this listing did not discourage its use. Since tartaric acid is a waste product from winemaking, its sale could provide additional revenue to organic vintners.

Cellulose

205.605(b) Cellulose—for use in regenerative casings, as an anti-caking agent (non-chlorine bleached) and filtering aid.

At the spring 2012 meeting, the NOSB recommended relisting with the following annotation, in order to ensure that microcrystalline cellulose is not used in food, "for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid." The NOP refused to make the annotation change and renewed the listing as originally written.

The manufacture of cellulose causes adverse impacts on the environment, and evidence is not conclusive about health impacts of microcrystalline cellulose.

Cellulose may be derived from many sources, but the usual source is wood pulp. The production of wood pulp involves the clearing of natural ecosystems, which threatens biodiversity, high energy use, and emission of pollutants into the air and water.[26]

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[24] Lines 281-287.

[25] Lines 761-763.

[26] 2016 Cellulose TR, lines 373-391.

Although no health impacts were associated with it, a World Health Organization paper pointed out that the assumption that microcrystalline cellulose (MCC) particles are too large to be absorbed by the body is not true:

> Rats, pigs and dogs were used to study the persorption of microcrystalline cellulose. The animals were not fed for 12 hours prior to oral administration of the test compound. Rats, dogs and pigs were given 0.5, 140 and 200 g, respectively, of the test compound. Venous blood was taken from the animals 1-2 hours after administration of the test compound, and examined for particles. Persorbed particles were demonstrated in the blood of all three species. The average maximum diameter for persorbed particles was greater in rats than in dogs or pigs (Pahlke & Friedrich, 1974).[27]

Cellulose is not necessary for organic production and handling.

The 2016 Technical Review (TR) identified alternative materials and practices for all listed uses of cellulose.[28] In addition, none of the original TAP reviewers supported adding microcrystalline cellulose to food as an anti-caking agent.[29]

Some uses of cellulose are incompatible with organic production and handling.

Microcrystalline cellulose is a highly processed material not compatible with organic handling systems.[30]

Conclusion

It appears that cellulose can be removed from the National List as unnecessary. As an alternative, the recommendation for an annotation change passed by the board in 2012 should be revisited.

Potassium hydroxide

205.605(b) Potassium hydroxide—prohibited for use in lye peeling of fruits and vegetables except when used for peeling peaches.

Potassium hydroxide is hazardous to humans and the environment.

As summarized in the 2001 TAP review, health effects may be severe:[31]

> The substance is highly corrosive and can cause severe burns of eyes, skin, and mucous membranes. Generally, studies and surveys regarding the toxicity of potassium hydroxide are included with studies of sodium hydroxide, and they are collectively known as 'caustics' or 'lye.' Lye poisoning results in numerous deaths annually, generally as accidents involving cleaners. Lyes are particularly penetrating and corrosive with

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[27] World Health Organization, 1998. Food Safety Additives Series 40. http://www.inchem.org/documents/jecfa/jecmono/v040je03.htm.
[28] Lines 429-471.
[29] 2001 TAP review, lines 414-426.
[30] 2001 TAP review, lines 21-22.
[31] Lines 118-122.

> tissue. This is due to the solubilizing reactions with protein, saponification of fats, and dehydration of tissue.

Regarding environmental impacts, the TAP review says, "A lye peeling processing method is of concern to the agroecosystem due to handling of waste from the plant. Large volumes of water are used, which enter the waste stream along with the soluble potassium and alkali ions."[32] "Disposal of KOH can be potentially dangerous. Mercury cells are used to produce most of the KOH in the United States."[33]

Reviewer #2 adds, "As an industrial chemical whose manufacture does employ the use of other toxic materials, i.e., mercury cells, by-products of chlorine production, etc., KOH does impact the environment. The mere transportation of these chemicals poses a risk. Note the restrictions placed on facilities using this technology based on waste water requirements. In the textile industry, there is growing concern about the disposal of bleaching products and more and more communities are requiring closed systems for KOH & NaOH bleaching."[34]

Is potassium hydroxide essential for organic processing?

OFPA states, "The [National List] shall contain an itemization, by specific use or application, of each synthetic substance permitted under subsection (c)(1) or each natural substance prohibited under subsection (c)(2)." The annotation is unclear in that it specifies uses that are <u>not allowed</u> rather than those that are allowed. Nevertheless, the HS notes say, "A member added that it is used extensively and is also used for nectarines,"[35] and this is clearly not allowed by the listing.

The 2016 Technical Review (TR) identifies a number of food processing uses of potassium hydroxide:[36]

> Uses of potassium hydroxide that are Generally Recognized As Safe (GRAS) by the U.S. Food and Drug Administration (FDA) include use as a formulation aid, pH control agent, processing aid, stabilizer and thickener [21 CFR 184.1631(b)].
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> Potassium hydroxide's main food processing uses include use as a pH adjuster, cleaning agent, stabilizer, thickener, fruit and vegetable peeling agent, and poultry scald agent. It is used in dairy products, baked goods, cocoa, fruits, vegetables, soft drinks and poultry. The main foods processed with potassium hydroxide are chicken, cocoa, coloring agents, ice cream and black olives.
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> Soft soap is manufactured with potassium hydroxide.

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[32] Lines 165-166.
[33] Lines 185-186.
[34] Lines 369-374.
[35] HS notes for January 19, 2016.
[36] Lines 52-61.

Is potassium hydroxide used for all these purposes in organic processing? Is it necessary?

The TR says, "Peaches peeled for canning or pickling use a 1.5% solution of lye at a temperature slightly below 145°F (<62°C) for about 60 seconds, followed by a wash and dip into a solution of 0.5-3.0% citric acid. ***Because hot water cannot be used for freezing peaches***, they require a higher solution –about 10%– and a treatment time of about four minutes to be peeled. Lye is removed by thorough washing, and again citric acid is used to neutralize the pH of the fruit (Woodroof 1986)."[37] (Emphasis added.) Most home freezing uses hot water treatment,[38] and although heat in a certain range is avoided in commercial preparation using potassium hydroxide, steam treatment is a possibility for peeling peaches commercially.[39]

TAP Reviewer #3 said, "Suitable equipment exists to remove the peels and pits by mechanical means."[40]

Is potassium hydroxide compatible with organic processing?

The 2001 TAP review summarizes the issues with regard to peeling peaches, "The use of a synthetic substance to perform a mechanical function such as peeling can be seen as not consistent with objectives of minimizing synthetic substances in handling of organic food. However, use of this material will allow the availability of an organic product otherwise not available, as hand peeling of peaches will not be viable on a commercial scale. Pureed peach products can be produced without chemical peeling techniques, but canned and frozen peaches cannot."[41]

Conclusion

Potassium hydroxide is a hazardous material, possibly (with sodium hydroxide) one of the most hazardous and toxic on the National List.[42] The 2016 TR does not seem to have resolved the issue of the essentiality for potassium hydroxide in processing peaches, but the essentiality of other allowed uses also needs to be examined. We suggest that the HS address the following questions:

1. For what purposes is potassium hydroxide used in organic processing?
2. What are the alternatives for those uses?
3. Is further annotation necessary?

Silicon dioxide

205.605(b) Silicon dioxide –Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.

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[37] TR lines 88-92.
[38] https://extension.purdue.edu/extmedia/HHS/HHS-808-W.pdf.
[39] https://archive.org/stream/commercialfreezi0703josl/commercialfreezi0703josl_djvu.txt.
[40] Lines 557-558.
[41] Lines 239-243.
[42] TAP lines 376-378.

In 2011, the NOSB voted to annotate the listing to recognize and encourage the use of organic rice hulls as an alternative for most uses of silicon dioxide. The NOSB recommended the following annotation: "Allowed for use as a defoamer. May be used in other applications when non-synthetic alternatives are not commercially available.'' The NOP proposed and put into regulation instead this annotation: "Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available." NOP justified this change as follows, "AMS understands that the intent of the NOSB's recommendation is to allow the continued use of silicon dioxide as a defoamer and to require the use of a nonsynthetic substance instead of silicon dioxide when possible. To ensure clarity and consistency within the USDA organic regulations, AMS is proposing a modification to the NOSB's recommendation." The annotation in the final rule is less restrictive than the NOSB recommendation, and therefore allows the use of the synthetic silicon dioxide in cases where there is a nonsynthetic alternative other than organic rice hulls," which is contrary to OFPA §6517(d)(2).[43] According to the 2010 Technical Review (TR), other plant materials may be the basis for biogenic silica products.[44]

Therefore, the NOSB should revisit the annotation to determine whether it should be changed to the language as originally passed by the NOSB or to a slightly less restrictive version (but still more restrictive than the version adopted into the regulations), "Permitted as a defoamer. Allowed for other uses when an organic substitute is not commercially available."

Colors: Beta- carotene extract

205.606(d)(2) Beta-carotene extract color –derived from carrots or algae (pigment CAS# 7235-40-7).

Health and Environmental Impacts

The NOSB must take into consideration pesticide use on nonorganic carrots. This information is derived from the Beyond Pesticides web-based database *Eating with a Conscience*.[45]

California Farmworker Poisonings, 1992–2010: 35 reported (CA acreage: 63,000). 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 carrots grown with toxic chemicals show low pesticide residues on the finished commodity, there are 42 pesticides with established tolerance for carrots, 16 are acutely toxic creating a hazardous environment for farmworkers, 39 are linked to chronic health problems (such as cancer), 13 contaminate streams or groundwater, and 42 are poisonous to wildlife.

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[43] "The Secretary may not include exemptions for the use of specific synthetic substances in the National List other than those exemptions contained in the Proposed National List or Proposed Amendments to the National List."
[44] Lines 438-448.
[45] http://www.beyondpesticides.org/organicfood/conscience/index.php?pid=610.

Pollinator Impacts: In addition to habitat loss due to the expansion of agricultural and urban areas, the database shows that there are 17 pesticides used on carrots 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. Carrots are dependent on pollinators and foraged by pollinators. The following pesticides may be used on non-organic carrots. *(**A** = acute health effects, **C** = chronic health effects, **SW** = surface water contaminant, **GW** = ground water contaminant, **W** = wildlife poison, **B** = bee poison, **LT** = long-range transport)*

2,4-D (C, SW, GW, W, B)
Azoxystrobin (A, SW, GW, W)
Bensulide (A, C, W, B)
Boscalid (C, W)
Captan (A, C, W)
Carbaryl (A, C, SW, GW, W, B)
Carfentrazone-ethyl (W)
Chlorothalonil (A, C, GW, W, LT)
Cyazofamid (C, W)
Cyfluthrin (A, C, W, B)
Cypermethrin (A, C, W, B)
Diazinon (A, C, SW, GW, W, B, LT)
Dicloran (DCNA) (C, W)
Diquat Dibromide (A, C, W)
Endosulfan (A, C, GW, W, B, LT)
Ethofumesate (W)
Fenamidone (C, W)
Fenvalerate (C, W, B)
Fluazifop-P-butyl (C, W)
Fludioxonil (C, W, B)
Glyphosate (C, SW-URBAN, W)
Imidacloprid (A, C, W, B)
Iprodione (C, W)
Linuron (C, W)
Malathion (A, C, SW-URBAN, GW, W, B)
Mancozeb (C, W, B)
Maneb (C, W)
Metalaxyl (A, C, W)
Methoxyfenozide (W)
Metribuzin (A, C, SW, W)
O-Phenylphenol (C, W)
Oxamyl (A, C, GW, W, B)
Paraquat/Paraquat dichloride (A, C, GW, W)
Pendimethalin (C, GW, W)
Prometryn (C, W, B, LT)
Propiconazole (A, C, W)
Pyriproxyfen (C, W)
Sethoxydim (C, B)
Spinetoram (C, B)
Spinosad (C, W, B)
Thiabendazole (C, W)
Trifluralin (C, SW, GW, W, LT)

The evaluation of beta carotene from carrots must take into consideration the use of pesticides in the non-organic production of carrots and the availability of organic carrots for this purpose, as well as the potential availability of the color if the demand existed.

Extraction of beta carotene from algae involves the use of solvents that may include carbon dioxide, acetone, methanol, propan-2-ol, hexane, ethanol, and vegetable oil.[46] Although the petitioner claimed to use carbon dioxide, ethanol, or vegetable oil,[47] the annotation does not restrict extraction to those solvents. Ethanol may be synthetic or nonsynthetic, and if nonsynthetic, may be derived from non-organically produced corn.

Vegetable oil may be extracted from a number of oil-rich seeds, but about 80 percent of the vegetable oil comes from soybeans.[48] Below are the pesticides with established tolerances (residue limits for pesticides used in the U.S. or by countries exporting to the U.S.) for soybeans.

[46] STR line 296.
[47] STR lines 303-305.
[48] https://www3.epa.gov/ttnchie1/ap42/ch09/final/c9s11-1.pdf.

While not all the pesticides on the list are applied to all soybeans, there is no way to tell which pesticides are applied to any given piece of conventional produce on your store shelf.

California Farmworker Poisonings, 1992–2010: One reported. This poisoning incident only represents 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, of which 38 are acutely toxic creating a hazardous environment for farmworkers, 75 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 32 pesticides used on soybeans 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.[49] Soybeans are dependent on pollinators and foraged by pollinators.

*(**A** = acute health effects, **C** = chronic health effects, **SW** = surface water contaminant, **GW** = ground water contaminant, **W** = wildlife poison, **B** = bee poison, **LT** = long-range transport)*

2,4-D (C, SW, GW, W, B)
Acephate (C, SW, W, B)
Acetamiprid (A, C, B)
Acetochlor (C, SW, W, B)
Acifluorfen Sodium (A, C, SW, GW, W)
Alachlor (SW, GW, W)
Aldicarb (A, C, GW, W, B)
Azoxystrobin (A, SW, GW, W)
Bentazon (C, SW, GW)
Cyfluthrin (A, C, W, B)
Cypermethrin (A, C, W, B)
Dacthal (DCPA) (C, SW, GW, W, B, LT)
Deltamethrin (A, C, W, B)
Dicamba (A, C, GW, W)
Difenoconazole (C, W)
Diflubenzuron (C, W)
Dimethenamid (A, C, W)
Dimethoate (A, C, GW, W, B)
Endothall (A, C, W)
Glyphosate (C, SW-URBAN, W)
Halosulfuron-methyl (C)
Imazethapyr
Imidacloprid (A, C, W, B)
Indoxacarb (A, C, W, B)
Lactofen (A, C, W)
Lambda-cyhalothrin (A, C, W, B)
Malathion (A, C, SW-URBAN, GW, W, B)
Metalaxyl (A, C, W)
Metconazole (C, W)
Methomyl (A, C, W, B)
Methoxyfenozide (W)
Methyl bromide (A, C, W)
PCNB (Quintozene, Pentachloronitrobenzene) (GW, W)
Pendimethalin (C, GW, W)
Permethrin (A, C, GW, W, B)
Phorate (A, C, GW, W, B)
Phosphine (A, C)
Propiconazole (A, C, W)
Pyraclostrobin (C, W)
Pyraflufen-ethyl (C, W, B)
Quizalofop-ethyl (C, W)
Rimsulfuron (C)
Sethoxydim (C, B)
Spinetoram (C, B)
Spinosad (C, W, B)
Spiromesifen (W)
Spirotetramat (C, W)
Sulfentrazone (C, W)
Thiabendazole (C, W)

[49] http://beyondpesticides.org/programs/bee-protective-pollinators-and-pesticides/what-the-science-shows.

Bifenazate (C, W, B)
Bifenthrin (A, C, SW, W, B)
Boscalid (C, W)
Carbaryl (A, C, SW, GW, W, B)
Carboxin (C, W)
Carfentrazone-ethyl (W)
Chloroneb (C)
Chlorothalonil (A, C, GW, W, LT)
Chlorpyrifos (A, C, SW, GW, W, B, LT)
Clethodim (A, C)
Clomazone (A, C, W)
Clothianidin (A, C, SW-URBAN, W, B)
Esfenvalerate (A, C, W, B)
Ethalfluralin (A, C, W)
Fluazifop-P-butyl (C, W)
Flubendiamide (C)
Flufenacet (C, W)
Flumioxazin (C, W)
Fluometuron (C, W, B)
Fluoxastrobin (C, W)
Fluthiacet-methyl (C, W)
Flutolanil (W)
Glufosinate ammonium (C, SW, W)
Methyl parathion (A, C, W, B)
Metolachlor (C, SW, GW, W)
Metribuzin (A, C, SW, W)
Myclobutanil (C, W)
Norflurazon (C, GW, W)
Oxamyl (A, C, GW, W, B)
Oxyfluorfen (C, W)
Paraquat/Paraquat dichloride (A, C, GW, W)
Thiodicarb (A, C, W, B)
Tralomethrin (A, C, W, B)
Trifloxystrobin (C, W)

In addition to the impacts of chemical-intensive culture –including the use of genetically-engineered varieties– the process of turning soybeans (or other oilseeds) into vegetable oil involves extraction with a solvent like hexane and refining using alkali.[50]

Beta carotene extract is not essential for organic processing.

Organic consumers do not expect their food to be artificially colored, whether or not the color is "synthetic" according to the NOP classification of materials, so a color additive is not necessary. In addition, the 2012 Supplemental Technical Review identifies organic annatto coloring as an alternative. **The HS should determine whether organic annatto does indeed perform the function of beta carotene extract.**

Beta carotene extract coloring is incompatible with organic production and handling.

As mentioned above, organic consumers do not expect their food to be artificially colored. Beta carotene may be extracted using volatile synthetic solvents, vegetable extracted using volatile organic solvents, or solvents derived from genetically engineered plants, all of which are incompatible with organic production and handling.

[50] https://www3.epa.gov/ttnchie1/ap42/ch09/final/c9s11-1.pdf.

Conclusion

The NOSB must take into account all of the impacts of beta carotene extract. The HS should investigate the availability and suitability of organic substitutes, as well as why an artificial color is needed.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors