BEYOND PESTICIDES
701 E Street, SE ▪ Washington DC 20003
202-543-5450 phone ▪ 202-543-4791 fax
info@beyondpesticides.org ▪ www.beyondpesticides.org

March 22, 2021

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

Docket ID # AMS-NOP-20-0089

Re. HS: Sunset

These comments to the National Organic Standards Board (NOSB) on its Spring 2021 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 2016, the Handling Subcommittee (HS) concluded from the Technical Evaluation Report (TR) that a reevaluation of the classification of agar might be needed once the NOP finalizes the classification of materials guidance. We do not believe that the reevaluation must wait on the NOP's long-delayed guidance. That guidance is now considered final, though we believe it is flawed. 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

[1] Lines 202-209.

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. It is clear that agar made from *Gelidium* species is nonsynthetic, while agar made from *Gracilaria* species is synthetic, and the HS should determine whether there is 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 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.

The need for agar should be re-evaluated in light of the information in the TR regarding alternatives.

---

[2] TR lines 192-196.
[3] 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.

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. In addition, the 2016 TR on Marine Plants and Algae says, “In shallow waters, seaweed farms for Gracilaria or Eucheuma can result in additional damage through trampling and accidental damage. Physical shading of an area by seaweed farms can affect benthic communities and primary production in the water column.”[5] 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 *Gracilaria* and from alkaline wastewaters.

At the Fall 2021 NOSB meeting, the board passed a recommendation designed to protect marine ecosystems from damage from harvesting marine macroalgae. The NOSB recommended an annotation to listings of synthetic macroalgae products used in crop production:

> Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules2, holdfasts, and reproductive structures are available to maintain the abundance and size structure of the population and its ecosystem functions. Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height) of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service.

In addition, “A new listing at 205.602 is further recommended to prohibit marine macroalgae unless harvested to the same parameters, with an exemption for non-commercial harvests.” These protections should also be applied to macroalgae used for organic food inputs.

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.

Questions to address

1. Given the alternatives identified in the TR, is agar still needed?
2. Please reassess the classification of agar.

---

[5] 2016 TR on Marine Plants and Algae, lines 972-974.

3. If agar is still needed, can the need be met by nonsynthetic agar from *Gellidium*?

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 listing of synthetic forms of agar-agar.

Animal enzymes

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

The HS summary and the Technical Reviews are both inadequate to support this listing. The 2011 TR on enzymes covers enzymes from both animal and plant sources, but the only animal enzymes addressed are rennet and egg white lysozyme. The 2015 addresses ancillary substances, and again the only animal enzymes addressed are rennet and egg white lysozyme. The only animal enzyme addressed in the HS summary is rennet. A more thorough examination is required to support relisting.

Animal enzyme production causes harm to humans and the environment.

A number of solvents, acids, and bases are used in extraction and formulation. Disposal methods and accidental releases are unknown.[6]

The use of enzymes from animals produced by chemical-intensive agriculture carries with it impacts of that form of production. Cows raised in a chemical-intensive system are fed corn and soybeans.

Field corn impacts

The following information is extracted from Beyond Pesticides' *Eating with a Conscience* database.[7]

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 109 pesticides with established tolerances for field corn products, 39 are acutely toxic creating a hazardous environment for farmworkers, 96 are linked to chronic health problems (such as cancer), 34 contaminate streams or groundwater, and 88 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 37 pesticides used on field corn products that are

---

[6] TR lines 523-545.

[7] https://www.beyondpesticides.org/resources/eating-with-a-conscience/choose-a-crop.

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 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)
Acetochlor (C, SW, W, B)
Alachlor (SW, GW, W)
Ametryn (C, W)
Aminopyralid (A, SW, GW, W)
Atrazine (C, SW, GW, W)
Azoxystrobin (A, SW, GW, W)
Bentazon (C, SW, GW)
Bifenthrin (A, C, SW, W, B)
Boscalid (C, W)
Bromoxynil (A, C, GW, W)
Butylate (C, W)
Captan (A, C, W)
Carbaryl (A, C, SW, GW, W, B)
Carboxin (C, W)
Carfentrazone-ethyl (W)
Chlorantraniliprole (C, GW, W, B)
Chlorpyrifos (A, C, SW, GW, W, B, LT)
Clethodim (A, C)
Clopyralid (A, C, GW, W)
Clothianidin (A, C, SW-URBAN, W, B)
Cryolite (C)
Cyfluthrin (A, C, W, B)
Cypermethrin (A, C, W, B)
Cyprosulfamide
Dacthal (DCPA) (C, SW, GW, W, B, LT)
Deltamethrin (A, C, W, B)
Dicamba (A, C, GW, W)
Diflufenzopyr (C)
Dimethenamid (A, C, W)
Dimethoate (A, C, GW, W, B)
Diquat Dibromide (A, C, W)
Diuron (C, SW, W, B)
Endothall (A, C, W)
EPTC (C, SW, W)
Esfenvalerate (A, C, W, B)
Ethoprop (ethoprophos) (A, C, W, B)
Etoxazole (C)
Fenamidone (C, W)
Fipronil (A, C, W, B)
Flubendiamide (C)
Fludioxonil (C, W, B)
Flufenacet (C, W)
Flumioxazin (C, W)
Fluometuron (C, W, B)
Fluoxastrobin (C, W)
Fluridone (C, W)
Fluroxypyr (C, W)
Fluthiacet-methyl (C, W)
Glufosinate ammonium (C, SW, W)
Glyphosate (C, SW-URBAN, GW, W, B)
Halosulfuron-methyl (C)
Hexythiazox (C)
Imazapyr (SW, GW, W, B)
Imazethapyr
Imidacloprid (A, C, SW, W, B)
Ipconazole (C)
Isoxadifen-ethyl
Lambda-cyhalothrin (A, C, W, B)
Linuron (C, W)
Malathion (A, C, SW-URBAN, GW, W, B)
Mancozeb (C, W, B)
Mesotrione (C, GW, W, B, LT)
Metalaxyl (A, C, W)
Metconazole (C, W)
Methomyl (A, C, W, B)
Methoxyfenozide (W)
Metolachlor (C, SW, GW, W)
Metribuzin (A, C, SW, W)
Myclobutanil (C, W)
Nicosulfuron (C, W)
Nitrapyrin (A, C, GW, W)
Oxyfluorfen (C, W)
Paraquat/Paraquat dichloride (A, C, SW, GW, W, B)
Pendimethalin (C, GW, W)
Permethrin (A, C, GW, W, B)
Phorate (A, C, GW, W, B)
Phosphine (A, C)
Piperonyl butoxide (PBO) (C, W)
Propargite (A, C, W)
Propiconazole (A, C, W)
Propyzamide (C, W)
Prosulfuron
Pyraclostrobin (C, W)
Pyraflufen-ethyl (C, W, B)
Pyrethrins (C, W, B)
Pyridate (C, W)
Pyriproxyfen (C, W)
Rimsulfuron (C)
Sethoxydim (C, B)
Simazine (C, SW, GW, W)
Spinetoram (C, B)
Spinosad (C, W, B)
Spiromesifen (W)
Sulfentrazone (C, W)
Sulfuryl fluoride (A, C)
Tebuconazole (A, C)
Tebufenozide (W)
Tefluthrin (A, C, W, B)
Tembotrione (C)
Terbufos (A, C, W, B)
Terrazole (C, W)
Tetraconazole
Thiabendazole (C, W)
Thiamethoxam (C, B)
Topramezone (C)
Triadimenol (A, C)
Trifloxystrobin (C, W)
Trifluralin (C, SW, GW, W, LT)

All tolerance data is based on the Environmental Protection Agency's *Tolerances by Commodity, Crop Group, or Crop Subgroup Index* (last updated July 2009). For more information, see our Methodology page.

Soybean impacts

The following information is extracted from Beyond Pesticides' *Eating with a Conscience* database.[8]

[8] https://www.beyondpesticides.org/resources/eating-with-a-conscience/choose-a-crop.

Pesticide Tolerances —Health and Environmental Effects: The database shows that while soy beans grown with toxic chemicals show low pesticide residues on the finished commodity, there are 83 pesticides with established tolerance for soy beans, 38 are acutely toxic creating a hazardous environment for farmworkers, 75 are linked to chronic health problems (such as cancer), 29 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 34 pesticides used on soy beans 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.

*(**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)
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)
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)
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)
Glyphosate (C, SW-URBAN, GW, W, B)
Halosulfuron-methyl (C)
Imazethapyr
Imidacloprid (A, C, SW, 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)
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, SW, GW, W, B)
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)
Thiodicarb (A, C, W, B)
Tralomethrin (A, C, W, B)
Trifloxystrobin (C, W)

All tolerance data is based on the Environmental Protection Agency's *Tolerances by Commodity, Crop Group, or Crop Subgroup Index* (last updated July 2009). For more information, see our Methodology page.

Not all animal enzymes are essential.

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.[9] This contradicts the statement in the HS review, "There are no true alternatives to animal enzymes. Enzymes can only be substituted with another enzyme with the same function."[10] The TR, for example, lists as examples of substitutes for rennet some plants with coagulating properties, nettles, cardoon thistle, and fig tree bark.[11] Animal-based rennet could also be made from organic livestock.[12]

The TR did not investigate catalase, animal lipase, pancreatin, pepsin, and trypsin, so we lack information about the essentiality of these enzymes. Nevertheless, the comments above relating to the impacts of chemical-intensive production practices do apply.

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? If not, what is the barrier to their availability?
2. Which of the identified ancillary ingredients are necessary?
3. Of the necessary ancillary ingredients, which are available as organic agricultural products?
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 a TR.

Conclusion

Unless the HS can perform an adequate review of animal enzymes, they should not be relisted.

Calcium sulfate – mined

205.605(a) Calcium sulfate—mined.

What are the human health and ecological impacts?

As stated by one TAP reviewer,[13]

---

[9] 2011 TR, lines 834-835.

[10] https://www.ams.usda.gov/sites/default/files/media/HS2018SunsetRvwMtg2SubcommReviewNov2016.pdf.

[11] 20011 TR, line 369.

[12] 2011 TR, lines 829-830.

[13] 2001 TAP Review. Reviewer 1.

> 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.

The HS review states, "Mining of calcium sulfate (as gypsum or alabaster) has exposed several public land areas, including Grand Staircase-Escalante National Monument in Utah, to extractive impacts. It is unclear the full extent of these activities to date, or landscape and critical area damage that could occur in the future. This question could potentially be addressed more fully in more current Technical Report (TR), as the most recent report on calcium sulfate is a 2001 Technical Advisory Panel (TAP), especially given that the sunset under consideration is the mined version." We agree with the HS that these environmental impacts should be examined, but disagree with the implication of the question, "Is there clear evidence of unacceptable environmental impacts from the mining of calcium sulfate?" The NOSB should take a precautionary approach, and it has offered presumptive evidence of environmental harm, which should be rebutted if calcium sulfate is to be relisted.

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.[14]

Is it consistent with principles of organic production and handling?

We ask the board to consider Table 4 from the TAP review.[15] 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.

[14] 2001 TAP Review. Reviewer 1.
[15] 2001 TAP Review. P. 10.

Conclusion

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

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 classified as a synthetic, and hence must be removed from §605(a) and considered for §605(b) if it is to remain on the National List. 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 may have adverse effects on the health of consumers.

We refer the NOSB to the detailed analyses of industry and independent science submitted by Joanne Tobacman, M.D., Cornucopia Institute, and Consumer Reports, which critique studies reviewed by the HS. Although we support those analyses, for the purpose of these comments we choose to concentrate on results that have been reviewed in the technical reviews commissioned for the NOSB.

Carrageenan is synthetic.

The 2011 TR says, "[I]ndustrial extraction methods use alkali treatment to facilitate rearrangements and modifications in the chemical structure of the polysaccharide for manufacture of commercial-grade products. Carrageenan that is produced using those methods is considered synthetic."[16] "[M]anufacturing of carrageenan results in chemical modifications to the seaweed extract. **No information was found to indicate that any form of commercially available carrageenan is extracted without chemical modifications.**"[17] In view of these statements from the commissioned technical report, the NOSB must justify its classification decision.

Carrageenan may have adverse effects on the health of consumers.

After a discussion of the impacts of "degraded carrageenan," the 2011 TR continues,[18]

> 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

---

[16] Lines 369-372.

[17] 2011 TR lines 386-388. Emphasis added.

[18] Lines 571-582.

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 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."[19] 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."[20] On the impact of carrageenan administered through drinking water: "Results are mixed in animal studies that administered carrageenan through drinking water."[21] 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."[22] 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."[23] 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

[19] Lines 40-41.
[20] Lines 103-104.
[21] Line 138.
[22] Lines 146-147.
[23] Lines 173-174.

animal feeding studies that carrageenan fed in the diet is absorbed in the gastrointestinal tract in toxicologically significant quantities."[24] 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."[25] 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)."[26] 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."[27] 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 for and funded by FMC Corporation, a manufacturer of carrageenan."[28] **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 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.

A point of agreement

Although there is some disagreement, as pointed out by the HS and the TRs, there is agreement that poligeenan (aka "degraded carrageenan" or "low molecular weight carrageenan") causes adverse health effects. It is important, therefore, that **when faced with the recommendation from the European Commission Scientific Committee on Food (now the European Food Safety Authority) that carrageenan with molecular weight below 50 kilodaltons be limited to no more than 5% of food-grade carrageenan, the industry was unable to comply**.[29] The 2015 TR states,[30] "It is possible that food-grade carrageenan may contain some low molecular weight fractions that are equivalent to poligeenan, although **validated analytical methods to accurately measure the low molecular weight distributions of carrageenan are not fully developed or available to the industry** (Cohen and Ito 2006). An

[24] Lines 202-205.
[25] Lines 228-230.
[26] Lines 238-241.
[27] Lines 247-250.
[28] Lines 299-302.
[29] Marinalg International, 2008. Status Report on the Work of Marinalg International to Measure the Molecular Weight Distribution of Carrageenan and PPESi n Order to Meet the EU Specification: Less Than 5% Below 50,000 Daltons. P. 2.
[30] 2015 TR lines 31-36. Emphasis added.

analysis of the molecular weight distributions of 29 types of commercially available food-grade carrageenan demonstrated that none of the food-grade samples contained molecular weight fractions equivalent to poligeenan **at a detection limit of about 5%** (Uno, Omoto, et al. 2001a)."

Thus, **regardless of other disagreements, the NOSB must assume a presence of 5% or more of poligeenan**, which is generally accepted to cause "ulcerations of the cecus and proximal colon in experimental animals, leading to its classification by the International Agency for Research on Cancer as a possible human carcinogen."[31] IARC classified poligeenan as a Class 2B carcinogen.[32] For reference, other chemicals that IARC has classified as 2B carcinogens include chlordane, chloroform, 2,4-D, hexachlorobenzene, and parathion.[33] **Since there is in general no safe level of exposure to a carcinogen,[34] poligeenan at 5% of the total carrageenan should not be dismissed.**

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.[35] Furthermore, "The industrial manufacture of carrageenan is a process that produces large amounts of alkaline waste water which may pose environmental problems."[36]

More recently, the NOSB commissioned a TR on Marine Plants and Algae, which also documented some impacts of carrageenan production.[37] This TR discusses site-specific overharvesting of *Chondrus* (cool water species), including potential regulation by the Canadian government.[38] This comment is also relevant to cultivated species used for carrageenan. Distributions of similar algal species can naturally vary geographically and over time. Habitat change producing conditions not well tolerated by resident species, can often lead to

---

[31] 2015 TR lines 26-28.

[32] IARC, List of Classifications, Volumes 1-116. http://monographs.iarc.fr/ENG/Classification/latest_classif.php.

[33] IARC, List of Classifications, Volumes 1-116. http://monographs.iarc.fr/ENG/Classification/latest_classif.php. Class 2B "is used for agents for which there is *limited evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals. It may also be used when there is *inadequate evidence of carcinogenicity* in humans but there is *sufficient evidence of carcinogenicity* in experimental animals. In some instances, an agent for which there is *inadequate evidence of carcinogenicity* in humans and less than *sufficient evidence of carcinogenicity* in experimental animals together with supporting evidence from mechanistic and other relevant data may be placed in this group. An agent may be classified in this category solely on the basis of strong evidence from mechanistic and other relevant data."
http://monographs.iarc.fr/ENG/Preamble/currentb6evalrationale0706.php.

[34] See, for example: Wigle, D. T., & Lanphear, B. P. (2005). Human Health Risks from Low-Level Environmental Exposures: No Apparent Safety Thresholds. *PLoS Medicine*, *2*(12), e350.
http://doi.org/10.1371/journal.pmed.0020350.

[35] Lines 469-551.

[36] Lines 533-534.

[37] 2016 TR Marine Plants and Algae.

[38] 2016 TR lines 588-596.

colonization by new species. Lack of competition or their inability to adjust to environmental changes can lead to the disappearance of one resident species from a particular region and replacement by another. Sometimes, the algae themselves cause these changing conditions. Many of the invasive algal species produce alien biomolecules that control competitive organisms in the new habitat.

A recent brief by the United Nations University and the Scottish Association for Marine Science also highlighted impacts of production of seaweed products.[39] In relation to cultivated species, it says,

> For example, the red seaweed *Kappaphycus* is one of the most valuable crops grown for its carrageenan content, a product used widely in food, pharmaceuticals and nutraceuticals. As a result, the cultivation of this crop has been promoted in over 30 countries worldwide. The occurrence of 'ice-ice' disease - a bacterial infection causing whitening of the sea - weed branches (Figure 2) and epiphyte infestations, however, have led to dramatic declines in the productivity of this crop in the Philippines, where this seaweed originated, in many of the other countries where it has been introduced (e.g. Madagascar and Tanzania). In the Philippines alone, disease caused a 15% loss in production of *Kappaphycus alvarezii* between 2011 and 2013 (a reduction of 268,000 tonnes), equating to a loss of over US$ 310 million based on a value of 1.09 USD/kg (farm-gate price). [40]

At the Fall 2021 NOSB meeting, the board passed a recommendation designed to protect marine ecosystems from damage associated with harvesting marine macroalgae. The NOSB recommended an annotation to listings of synthetic macroalgae products used in crop production:

> Prohibited harvest areas: established conservation areas under federal, state, or local ownership, public or private, including parks, preserves, sanctuaries, refuges, or areas identified as important or high value habitats at the state or federal level. Prohibited harvest methods: bottom trawling and harvest practices that prevent reproduction and diminish the regeneration of natural populations. Harvest practices should ensure that sufficient propagules2, holdfasts, and reproductive structures are available to maintain the abundance and size structure of the population and its ecosystem functions. Harvest timing: repeat harvest is prohibited until biomass and architecture (density and height)

---

[39] Cottier-Cook, E.J., Nagabhatla, N., Badis, Y., Campbell, M., Chopin, T, Dai, W, Fang, J., He, P, Hewitt, C, Kim, G. H., Huo, Y, Jiang, Z, Kema, G, Li, X, Liu, F, Liu, H, Liu, Y, Lu, Q, Luo, Q, Mao, Y, Msuya, F. E, Rebours, C, Shen, H., Stentiford, G. D., Yarish, C, Wu, H, Yang, X, Zhang, J, Zhou, Y, Gachon, C. M. M. (2016). Safeguarding the future of the global seaweed aquaculture industry. United Nations University (INWEH) and Scottish Association for Marine Science Policy Brief. ISBN 978-92-808-6080-1. 12pp. http://voices.nationalgeographic.com/files/2016/08/Final-unu-seaweed-aquaculture-policy-for-printing.pdf.

[40] Cottier-Cook, E.J., et al. (2016). Safeguarding the future of the global seaweed aquaculture industry. United Nations University (INWEH) and Scottish Association for Marine Science Policy Brief. ISBN 978-92-808-6080-1. 12pp. http://voices.nationalgeographic.com/files/2016/08/Final-unu-seaweed-aquaculture-policy-for-printing.pdf.

of the targeted species approaches the biomass and architecture of undisturbed natural stands of the targeted species in that area. Bycatch: must be monitored and prevented, or eliminated in the case of special status species protected by U.S. Fish and Wildlife Service or National Marine Fisheries Service.

In addition, "A new listing at 205.602 is further recommended to prohibit marine macroalgae unless harvested to the same parameters, with an exemption for non-commercial harvests." These protections should also be applied to macroalgae used for organic food inputs.

"Sensitivity" to carrageenan differs from food allergies.

The HS has suggested that varying sensitivity to carrageenan makes it similar to food ingredients to which consumers may be sensitive or have allergies. This suggestion ignores the fundamental difference between an unnecessary food additive and a food ingredient like "gluten, dairy, legumes, and many other foods." Gluten, dairy, and legumes are foods or food components that may be produced organically and do not require an exemption from a general OFPA rule to be allowed in organic food. Carrageenan is not an agricultural product. It is a highly processed food additive that is only allowed in organic food by virtue of its listing on the National List –a list of exceptions to the general rule that "organic" applies only to foods composed of organic ingredients.

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.**[41] Food processors have been removing carrageenan from organic food since the 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.[42] Depending on the production method, it may contain residues of other synthetic materials including polysorbate 80 and epichlorohydrin.[43] In some cases, it is used as a preservative.[44]

Conclusion

Therefore, we ask that the NOSB remove carrageenan from the National List. The evidence summarized by the 2015 Technical Review came up with a verdict of mixed results on virtually every issue regarding food grade (high molecular weight) carrageenan. However, there is widespread agreement that poligeenan, which contaminates food grade carrageenan

---

[41] http://www.cornucopia.org/shopping-guide-to-avoiding-organic-foods-with-carrageenan/

[42] 2011 TR lines 287-294.

[43] TAP review pages 3, 4, 7.

[44] 2011 TR line 415.

at unknown and uncontrollable levels, does cause adverse effects, including cancer. The production causes adverse environmental impacts. And it is not necessary –organic processors have been moving away from the use of carrageen because of consumer pressure since it was last considered for sunset. 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.

Glucono delta-lactone

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

Classification

The current annotation— "production by the oxidation of D-glucose with bromine water is prohibited"—was added to ensure that glucono delta-lactone would be produced by microbial or enzymatic processes and hence be nonsynthetic. However, the 2016 technical review (TR) states, "There are many chemical methods of gluconic acid synthesis other than bromine water." Hence, the current annotation is not sufficient to ensure that the glucono delta-lactone (GDL) in use in organic processing is nonsynthetic.[45] It also states that some enzymes used in the production of GDL may be genetically engineered. The NOSB should not relist GDL without 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."[46] The TR also lists alternative materials and/or practices for other uses of GDL. Other uses of GDL that are allowed by the listing: "a curing and pickling agent, a leavening agent, a pH control agent, and as a sequestrant."[47] The need for GDL for these uses has not been supported.

Questions/issues that must be addressed.

1. Which uses, if any, for GDL are actually essential?
2. A new annotation must be created to ensure that GDL used in organic production is nonsynthetic and made without genetically engineered enzymes.

Tartaric acid

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

Environmental and health impacts

As listed on the National List, tartaric acid must be made from grape wine. The evaluation of tartaric acid must thus take into consideration the use of pesticides in the non-

[45] Lines 281-287.
[46] Lines 761-763.
[47] Lines 23-24.

organic production of grapes and the availability of organic grape wine for this purpose, as well as the potential availability of the tartaric acid from organic grape wine if the demand existed. The following impacts are derived from the Beyond Pesticides web-based database *Eating with a Conscience*.[48]

Grapes

California Farmworker Poisonings, 1992–2010: 1,234 reported (CA acreage: 796,000). 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 grapes grown with toxic chemicals show low pesticide residues on the finished commodity, there are 124 pesticides with established tolerance for grapes, 38 are acutely toxic creating a hazardous environment for farmworkers, 108 are linked to chronic health problems (such as cancer), 20 contaminate streams or groundwater, and 99 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 34 pesticides used on grapes 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.

Question to investigate

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 (CAS #9004-34-6)

205.605(b) (CAS #9004-34-6)—for use in regenerative casings, powdered cellulose as an anti-caking agent (non-chlorine bleached) and filtering aid. Microcrystalline cellulose is prohibited.

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.[49]

---

[48] http://www.beyondpesticides.org/resources/eating-with-a-conscience/choose-a-crop?foodid=19.

[49] 2016 Cellulose TR, lines 373-391.

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.[50]

Questions to address

1. Is cellulose necessary for use in organic production?
2. Are there alternatives that cause less damage in their production?

Chlorine materials (Calcium hypochlorite, Chlorine dioxide, hypochlorous acid, sodium hypochlorite)

205.605(b) Acidified sodium chlorite—Secondary direct antimicrobial food treatment and indirect food contact surface sanitizing. Acidified with citric acid only.
205.605(b) Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except,* That, residual chlorine levels in the water shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).

In our Spring 2017 comments,[51] we included general remarks about when the use of sanitizers and disinfectants is appropriate. Please review those comments. We began with defining some terms, discussing what we believe to be mistaken translations of NOSB recommendations into regulation, discussing some relevant issues of microbial ecology, looking at chlorine-based chemicals, and finally concluding that the NOSB must undertake a much deeper investigation before allowing the use of chlorine-based materials for another five years.

Often we see the NOSB *assuming* a need for strong chemicals as cleaners or disinfectants when none may be needed. We have seen this in our own investigations with personal care products using the biocide triclosan.[52] Research has shown that washing with ordinary soap and water is as effective as using soap containing triclosan. Furthermore, as pointed out by a 2010 report of EPA's Office of Inspector General (OIG), this problem is widespread—the OIG found that approximately 40% of all antimicrobial products have not been tested for efficacy, and one third of all products tested each year fail, without notification of users.[53] We need research into effective means of cleaning food contact surfaces and food containers with organic and natural cleaning methods, such as hot water or steam or materials more compatible with organic processing, including hydrogen peroxide or organic acids.

We need research on organic systems, including growing, harvesting, storing, and transporting crops in ways that avoid the need for rinsing in highly chlorinated water. However,

---

[50] Lines 429-471.
[51] https://www.beyondpesticides.org/assets/media/documents/BP%20comments%20on%20chlorine%20materials.601-603-605.final.pdf.
[52] http://www.beyondpesticides.org/antibacterial/triclosan.php.
[53] U.S. EPA Office of Inspector General, 2010. EPA Needs to Assure Effectiveness of Antimicrobial Pesticide Products, http://www.epa.gov/oig/reports/2011/20101215-11-P-0029.pdf.

it is very likely that we currently have all the non-chlorine tools we need. We need to do all this because organic, to the extent possible, should become chlorine-free, given the human health and environmental hazards associated with its production, transportation, storage, use, and disposal.

The NOSB and NOP need to clarify whether chlorine is required by other statutes. Some have said that other laws require the use of chlorine in higher concentrations than those listed on the National List. If other laws specifically require the use of chlorine, then it must be allowed under the organic program. If it is required, the use should be included on the National List annotated with specific citations for the requirements.

Since organic practices depend on having a healthy balance of microbes, rather than eliminating all of them, growers, certifiers, the NOSB, and NOP all need to be clear about when sanitizing is necessary and when cleaning is sufficient. Removal of all microbial life leaves surfaces available for colonization by spoilage or pathogenic organisms. If strong residual sanitizers are used, strong selection pressure is applied for the development of resistance to materials that may be needed in emergency medical situations.

Current NOP guidance for handling is inconsistent with both the NOSB recommendation and the regulations at §205.605(b) –because it allows use of chlorine for purposes not allowed by the recommendations and food contact with chlorine above the SDWA limits. Thus, regardless of the improvements we would like to see through a thorough investigation of sanitizers, disinfectants, and cleansers, the current listing should be corrected to:

> **[Handling, corrected] §205.605(b) Chlorine materials—disinfecting and sanitizing food contact surfaces, *Except,* That, residual chlorine levels in the water for wash water in direct crop or food contact and in flush water from cleaning equipment and surfaces that is applied to crops or fields shall not exceed the maximum residual disinfectant limit under the Safe Drinking Water Act (Calcium hypochlorite; Chlorine dioxide; and Sodium hypochlorite).**

Microbial Ecology and Implications for Use of Sanitizers Post-Harvest

The true phyllosphere (plant surface) microbiome associated with a plant is the microbial community present on or in plants growing in the field. However, from the viewpoint of consumer safety, the microbial populations present at the point of sale or consumption are more relevant. Many of these bacteria are likely to be plant symbionts or pathogens, but some are human pathogens.[54] Research looking at the microbiota in the field and post-harvest has found that the post-harvest phyllosphere microbial community shifts in the relative abundance

---

[54] Jackson, C. R., Stone, B. W., & Tyler, H. L. (2015). Emerging perspectives on the natural microbiome of fresh produce vegetables. *Agriculture*, *5*(2), 170-187.

of different species, becoming less diverse and containing species that do well under storage conditions.[55, 56]

Post-harvest handling operations can cause disturbances in the microbiota and select for microbes that survive under storage conditions. Washed post-harvest produce has higher risks than unwashed and pre-harvest organic produce, as measured by indicator organisms. Although adding a sanitizer to rinse water results in produce with no significant difference from pre-harvest samples, it does not decrease indicator microbes.[57] Storage temperature affects the microbial community, selecting for cold tolerant species[58, 59] and reducing the diversity and richness of the phyllosphere community, with larger changes at colder temperatures.[60] Another handling measure that affects the microbial community on post-harvest produce is enclosure in air-tight packages. Commercially pre-bagged, refrigerated lettuce samples showed evidence of the presence of additional bacterial populations, including *Pseudomonas libaniensis*.[61] Herbs packaged in plastic containers sealed with polymer contained a high proportion of anaerobic microbes.[62] Thus, research on microbial communities suggests that we may prevent disease better by preserving or augmenting natural microbial communities. An ecological approach to microbiota in humans and plants calls into question the routine use of antimicrobial soaps, as well as sanitizers in food handling, to attempt to exterminate microbes. (Please see our Spring 2017 comments for more details.)

Chlorine materials are hazardous to humans and the environment during manufacture and use.

Chlorine is a strong oxidizer and hence does not occur naturally in its pure (gaseous) form. The high oxidizing potential of chlorine leads to its use for bleaching, biocides, and as a chemical reagent in manufacturing processes. Because of its reactivity, chlorine and many of its compounds bind with organic matter. When used as a disinfectant, chlorine reacts with microorganisms and other organic matter. Similarly, the toxicity of chlorine to other organisms comes from its power to oxidize cells. Chlorine has toxic effects on beneficial soil organisms.[63]

---

[55] Jackson, C. R., Stone, B. W., & Tyler, H. L. (2015). Emerging perspectives on the natural microbiome of fresh produce vegetables. *Agriculture*, *5*(2), 170-187.
[56] Leff, J. W., & Fierer, N. (2013). Bacterial communities associated with the surfaces of fresh fruits and vegetables. *PLoS One*, *8*(3), e59310.
[57] Xu, A. (2014). Microbiological assessment of organic produce pre-and post-harvest on Maryland farms and impact of growing and handling methods on epiphytic bacteria. MS thesis, University of Maryland, College Park.
[58] Leff, J. W., & Fierer, N. (2013). Bacterial communities associated with the surfaces of fresh fruits and vegetables. *PLoS One*, *8*(3), e59310.
[59] Jackson, C. R., Stone, B. W., & Tyler, H. L. (2015). Emerging perspectives on the natural microbiome of fresh produce vegetables. *Agriculture*, *5*(2), 170-187.
[60] Jackson, C. R., Stone, B. W., & Tyler, H. L. (2015). Emerging perspectives on the natural microbiome of fresh produce vegetables. *Agriculture*, *5*(2), 170-187.
[61] http://www.tgw1916.net/Pseudomonas/libanensis.html.
[62] Jackson, C. R., Stone, B. W., & Tyler, H. L. (2015). Emerging perspectives on the natural microbiome of fresh produce vegetables. *Agriculture*, *5*(2), 170-187.
[63] 2011 Crops TR.

In addition to the purposeful production of toxic chlorine compounds, the manufacture and use of chlorine compounds results in the unintended production of other toxic chemicals. Disinfection with chlorine, hypochlorite, or chloramines results in the formation of carcinogenic trihalomethanes, haloacetic acids, and other toxic byproducts.[64] Disinfection with chlorine dioxide produces undesirable inorganic byproducts, chlorite and chlorate. Industrial production of chlorine compounds, use of chlorine bleach in paper production, and burning of chlorine compounds releases dioxins and other persistent toxic chemicals into the environment.[65]

There are alternatives to chlorine materials.

Again, the uses of chlorine materials allowed under §205.605 are more limited than NOP guidance permits. The technical review of sodium dodecylbenzene sulfonate identifies many alternative substances and practices. Alternative materials include: hydrogen peroxide, ozone, essential oils, grapefruit seed extract, salt (sodium chloride), organic acids (including ascorbic acid, citric acid, lactic acid, lactates, tartaric acid, malic acid and vinegar (acetic acid)), egg white lysozyme, high temperatures, and biocontrols.[66] Most importantly, the TR stresses, "However, it is much easier to prevent contamination of products from the first steps of the food production process than to remove contamination later in the process or at the point of use."[67]

Chlorine materials are not compatible with organic production.

The fact that use of chlorine is so universally associated with the production of persistent toxic chemicals has led some environmental groups to seek a ban on chlorine-based chemicals. We believe that organic production should, for the same reasons, avoid the use of chlorine as much as possible. The allowance of chlorine in the rule reflects the fact that many organic growers–like most of the rest of us–depend on water sources that have been treated with chlorine.

Questions to address

1. Are there any uses of chlorine materials that are required by law?
2. Are there any uses of chlorine materials that are necessary in organic production because they cannot be performed by less toxic substances or practices?
3. How can the need for rinsing with highly chlorinated water be avoided?
4. What happens to the sodium hydroxide created in the production of hypochlorous acid?

Conclusion

We do not believe that organic producers should have to filter chlorine out of the tap water they use for irrigating, cleaning equipment, washing vegetables, or cleaning food-contact

---

[64] Alexander G. Schauss, 1996. Chloride – Chlorine, What's the difference? P. 4. http://www.mineralresourcesint.com/docs/research/chlorine-chloride.pdf

[65] ATSDR, 1998. Toxicological Profile for Chlorinated Dibenzo-p-Dioxins. Pp. 369 ff. http://www.atsdr.cdc.gov/toxprofiles/tp104.pdf.

[66] 2017 TR on Sodium Dodecylbenzene Sulfonate (SDBS). Lines 354-520.

[67] 2017 TR on SDBS. Lines 364-366.

surfaces. But they should not be adding more chlorine. Organic production and handling should be, to the extent possible, chlorine-free.[68]

Potassium hydroxide

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

As listed on 205.605(b) Potassium hydroxide carries the annotation, "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,[69] health effects may be severe: 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 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."[70] "Disposal of KOH can be potentially dangerous. Mercury cells are used to produce most of the KOH in the United States."[71]

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."[72]

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

---

[68] The Organic Foods Production Act, §6518(m), lists three criteria that directly pertain to chlorine: (1) the potential of such substances for detrimental chemical interactions with other materials used in organic farming systems; (2) the toxicity and mode of action of the substance and of its breakdown products or any contaminants, and their persistence and areas of concentration in the environment; (3) the probability of environmental contamination during manufacture, use, misuse or disposal of such substance.

[69] Lines 118-122.

[70] Lines 165-166.

[71] Lines 185-186.

[72] Lines 369-374.

that are not allowed 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,"[73] and this is clearly not allowed by the listing.

The 2016 Technical Review (TR) identifies a number of food processing uses of potassium hydroxide:[74]

- 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)].
- 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.
- Soft soap is manufactured with potassium hydroxide.

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 4 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)."[75] (Emphasis added.) Most home freezing uses hot water treatment,[76] and although heat in a certain range is avoided in commercial preparation using potassium hydroxide, steam treatment is a possibility for peeling peaches commercially.[77] TAP Reviewer #3 said, "Suitable equipment exists to remove the peels and pits by mechanical means."[78]

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."[79]

---

[73] HS notes for January 19, 2016.
[74] Lines 52-61.
[75] TR lines 88-92.
[76] https://extension.purdue.edu/extmedia/HHS/HHS-808-W.pdf.
[77] https://archive.org/stream/commercialfreezi0703josl/commercialfreezi0703josl_djvu.txt.
[78] Lines 557-558.
[79] Lines 239-243.

Conclusion

Potassium hydroxide is a hazardous material, possibly (with sodium hydroxide) one of the most hazardous and toxic on the National List.[80] 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. The NOSB must address the following questions:

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

Potassium lactate and sodium lactate

Potassium lactate—for use as an antimicrobial agent and pH regulator only.
Sodium lactate—for use as an antimicrobial agent and pH regulator only.

Potassium lactate and sodium lactate are synthetic preservatives and are thus not appropriate for use in organic food.

Sodium lactate and potassium lactate are synthetic.

As described in the Lactic Acid and Lactates Technical Review (TR), sodium lactate and potassium lactate are manufactured by a reaction of lactic acid with a synthetic chemical, generally sodium or potassium hydroxide. (TR, lines 519-548) Thus, they would be classified as synthetic according to the NOP draft classification guidance.

As stated in the Technical Review, The USDA Food Standards and Labeling Policy Book says:

> It should be noted that meat products that contain sodium and potassium lactates can no longer be labeled as "natural" without a case-by-case assessment of what function these materials are serving in the product, and at what levels (USDA FSIS 2005). The reason is that the lactates are likely to be used as "chemical preservatives," rather than as flavors.

We agree with comments submitted by PCC Natural Markets:[81]

> Since sodium lactate is not acknowledged by the FSIS for use in meat products labeled "natural" (except potentially on a case-by-case basis at the time of label approval), it seems logical that sodium lactate should not be allowed for use in certified organic products. Consumers expect organic standards to be more rigorous than standards for "natural." It seems incongruous that organic would allow something that "natural" would not allow automatically.

[80] TAP lines 376-378.
[81] Letter from Trudy Bialic, December 7, 2009.

The use of sodium lactate and potassium lactate is not essential for organic production.

The TR details several alternative methods and materials available to organic producers to achieve the most important function of the lactates—preventing growth of *Listeria monocytogenes* in processed meats. These include processes that result in a pH or water activity suppressing or limiting microbial growth. The TR says, "Processing alternatives include cook-in-bag products, frozen products with safe handling instructions for cooking, strict facility sanitation and testing requirements (under the FSIS's Listeria Rule (USDA FSIS 2012)), or post processing applications such as high pressure pasteurization and steam/water pasteurization." It identifies natural materials, "Alternative nonsynthetic additives include vegetable and fruit juice powders that contain natural nitrite, or that modify pH. Other nonsynthetic alternatives include organic acids such as citric and lactic acid, lactic acid starter cultures such as *Staphylococcus carnosus*, vinegar, essential oils and bacteriophages." We do not support the addition of nitrite through use of celery powder, but other natural materials can be used.

The use of sodium lactate and potassium lactate for the petitioned use is prohibited by organic regulations at §205.600(b)(4).

Both chemicals are used as preservatives, to prevent the growth of microorganisms. In addition, they are also considered flavor and color enhancers. They may also be combined with sodium diacetate. (TR, lines 266-326) Since sodium diacetate is not on the National List and is added for its functional effect of reducing pH, certainly any lactate product containing it should not be allowed.

> §205.600(b)(4) of the regulation states:
> (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;

Since the purpose for which the lactates were petitioned is as a preservative, and other uses include flavor and color enhancement, sodium lactate and potassium lactate have no place on the National List.

Conclusion

Potassium lactate and sodium lactate are unnecessary. They are synthetic chemicals used for purposes not allowed in organic processing. Therefore, they should not be relisted.

Silicon dioxide

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

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).[82] According to the 2010 Technical Review (TR), other plant materials may be the basis for biogenic silica products.[83]

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."

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors

[82] "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."
[83] Lines 438-448.