



September 30, 2021

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP

**Docket:** AMS-NOP-21-0038

**RE: Handling Subcommittee – 2023 Sunset Reviews for §205.605**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2023 Sunset Review.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing over 9,500 organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA thanks NOSB for carefully considering each handling input scheduled for review as part of the 2023 Sunset Review cycle. Materials that have been placed onto the National List for use in handling should remain on the National List if: 1) they are still essential to and compatible with organic production and handling practices; 2) there are no commercially available alternative materials (natural, organic) or practices; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517 and 6518] National List). Furthermore, decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at large. It's critical that NOSB hear from certified handlers on whether these inputs are consistent with and essential to organic handling, or whether there are other effective natural or organic alternatives available.

#### **About OTA Sunset Surveys**

OTA is submitting results to our Sunset Surveys created for each input under review as part of the 2023 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input (**Appendix A**). Our surveys do not address information regarding the impacts on human health or the environment.

The surveys are open to any NOP certified organic operation. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) to distribute the survey to all of their clients as well as to targeted clients they know are using the inputs under review.

**Results of OTA Sunset Surveys**

OTA has received **30** total responses on our 2023 Handling Sunset Surveys. Below is a summary of the feedback received via OTA’s Sunset Surveys to date on the § 205.605 materials under review.

**§205.605(a) – Non-synthetic Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).**

<b>Substance</b>	<b>Summary of responses</b>	<b>Average rating of Essentiality</b> (from 1 to 5, with 5 being “critical – would leave organic without it”)
<b>Agar-Agar</b>	<p><b>3 Responses</b> received from certified operations.</p> <p><b>Uses:</b></p> <ul style="list-style-type: none"> <li>- Used routinely in yogurt as a thickener/gelling agent</li> <li>- Used routinely in snack bars as a thickening agent in the binder so that the bar will maintain its shape and provide the chewy texture desired.</li> <li>- Enriched agar growing medium for mushroom cultures</li> </ul> <p><b>If the material were prohibited:</b></p> <ul style="list-style-type: none"> <li>- If agar-agar were to no longer be allowed the quality of our products would be altered.</li> <li>- It would impact product quality. Snack bars would be deformed and break apart more easily, and not have the quality (chewy texture) desired.</li> <li>- Agar-agar is the basis for standardized culturing of fungus. I don't know of another way to propagate and store cultures.</li> </ul>	Rating not provided
<p><b>Animal Enzymes</b></p> <p>(Rennet—animals derived; Catalase—bovine liver;</p>	<p><b>5 Responses</b> received from certified operations.</p> <p><b>Used routinely and/or daily in:</b></p> <ul style="list-style-type: none"> <li>- Cheese – coagulant</li> </ul>	<b>4.8</b>

<p>Animal lipase; Pancreatin; Pepsin; and Trypsin).</p>	<ul style="list-style-type: none"> <li>- Artisan Cheese - The chymosin/pepsin attributes in traditional animal rennet produce positive effects on milk coagulation that are critical to many styles of cheese production that fungi or plant based rennets simply cannot provide.</li> <li>- Used in various cheese ingredients, as a thickener, across multiple items daily to weekly</li> </ul> <p><b>The material is essential because:</b></p> <ul style="list-style-type: none"> <li>- Helps milk coagulate and turn fluid milk into curds and whey for cheesemaking. No suitable alternatives.</li> </ul> <p><b>Alternative are not sufficient because:</b></p> <ul style="list-style-type: none"> <li>- Some styles of cheese (softer) are able to be produced successfully with non-animal based rennets. Longer aged, harder styles of cheese are unable to be successfully coagulated when being produced with these non-animal based rennets. It is necessary for the production of these styles of cheese.</li> <li>- Microbial rennet and thistle rennet are alternatives.</li> <li>- Unaware of any alternatives or management practices that would eliminate its need</li> </ul> <p><b>If the material were prohibited:</b></p> <ul style="list-style-type: none"> <li>- The product quality would be impacted.</li> <li>- It would be catastrophic to the health of our company and our industry. We assume 95%+ of organic cheesemakers across the United States are using animal rennet and would have to stop production if animal rennet was no longer allowed.</li> <li>- It would affect the tradition of cheesemaking as well as product quality.</li> <li>- We would not produce organic cheese anymore.</li> <li>- Fruit Juices as a stabilizer</li> </ul>	
<p><b>Calcium Sulfate-Mined</b></p>	<p><b>1 Response</b> received from a certified operation.</p> <p><b>Uses:</b></p> <ul style="list-style-type: none"> <li>- Used in daily as a coagulant in Tofu products</li> </ul>	<p>5</p>
<p><b>Carrageenan</b></p>	<p><b>1 Response</b> received from a certified operation.</p> <p><b>Uses:</b></p> <ul style="list-style-type: none"> <li>- In Fruit Juices as a stabilizer</li> </ul>	<p>3</p>

	<p><b>Alternative are not sufficient because:</b></p> <ul style="list-style-type: none"> <li>- There are no alternatives available, but have not tried any.</li> </ul> <p><b>If the material were prohibited:</b></p> <ul style="list-style-type: none"> <li>- Separation. Neutral on essentiality, nice to have it but could live without it.</li> </ul>	
<p><b>Glucono-delta-lactone</b> – production by the oxidation of D-glucose with bromine water is prohibited.</p>	<p><b>1 Response</b> received from a certified operation.</p> <p><b>Uses:</b></p> <ul style="list-style-type: none"> <li>- Used in daily in tofu products as a coagulant</li> </ul> <p><b>Alternative are not sufficient because:</b></p> <ul style="list-style-type: none"> <li>- Have not tried alternatives and unaware of any management practices that would eliminate its need</li> </ul>	<p>4</p>
<p><b>Tartaric Acid</b> – made from grape wine</p>	<p><b>3 Responses</b> received from certified operations.</p> <p><b>Used in:</b></p> <ul style="list-style-type: none"> <li>- Wine</li> <li>- Cookies</li> <li>- Fruit snacks, routinely for a sour taste for certain types of fruit snacks</li> </ul> <p><b>The material is essential because:</b></p> <ul style="list-style-type: none"> <li>- Being able to adjust our pH with TA helps us to avoid the use of the synthetic chemical SO2</li> </ul> <p><b>Alternative are not sufficient because:</b></p> <ul style="list-style-type: none"> <li>- There are times when we do not need to adjust the pH</li> </ul> <p><b>If the material were prohibited:</b></p> <ul style="list-style-type: none"> <li>- It would hinder us since we have spent years perfecting a synthetic free wine.</li> <li>- There would be a change in defining character and flavor of the product</li> </ul> <p><b>Is there a sufficient supply of organic grapes to make tartaric acid from organic grapes?</b></p> <ul style="list-style-type: none"> <li>- Yes, but would need to grow it as a new industry. The organic grapes are used for wine, not for tartaric acid.</li> </ul>	<p>4</p>

**§205.605(b) – Synthetic Non-agricultural (non-organic) substances allowed as ingredients in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).**

Substance	Summary of responses	Average rating of Essentiality <small>(from 1 to 5, with 5 being “critical – would leave organic without it”)</small>
<p><b>Cellulose</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.</p>	<p><b>3 Responses</b> received from certified operations.</p> <p><b>Used routinely in:</b></p> <ul style="list-style-type: none"> <li>- Cheese as an anti-caking agent</li> <li>- Pizza, bagels, salad dressing</li> <li>- Cheese as an anti-caking agent</li> </ul> <p><b>The material is essential because:</b></p> <ul style="list-style-type: none"> <li>- There are no other alternatives. Clumped cheese would cause uneven ingredient distribution and can lead to greater manufacturing variability</li> <li>- No other alternatives. Would consider alternative as available</li> </ul> <p><b>If the material were prohibited:</b></p> <ul style="list-style-type: none"> <li>- Clumped cheese would not mix well contributing to inconsistent product quality; increase in production losses (product not meeting weight standards, downtime)</li> <li>- Would result in increased costs and negative impacts to business operations</li> </ul>	<p><b>4.5</b></p>
<p><b>Chlorine Materials</b></p> <p>-Calcium hypochlorite.</p> <p>-Chlorine dioxide.</p> <p>-Hypochlorous acid—generated from electrolyzed water</p>	<p><b>6 Responses</b> received from certified organic operations.</p> <p><i>Please also see OTA’s comments directly below this survey results table.</i></p> <p><b>Used in:</b></p> <ul style="list-style-type: none"> <li>- Lettuces, routine, daily</li> <li>- All of our wash equipment is sanitized with it and leafy greens are dunked in water with a small concentration of Na Hypochlorite in it, daily</li> <li>- Row crops, vegetables, daily</li> <li>- Dairy, eggs – daily</li> <li>- Processed vegetables and baby lettuce items for water sanitation and equipment cleaning; daily</li> </ul>	<p><b>4.8</b></p>

<p>-Sodium hypochlorite</p>	<p><b>The material is essential because:</b></p> <ul style="list-style-type: none"> <li>- Sanitation, prevention of spread of human pathogens – food safety</li> <li>- To bring wash water to potable water standards</li> <li>- Sanitizer, powerful cleaner that is good for milk protein</li> </ul> <p><b>Alternative are not sufficient because:</b></p> <ul style="list-style-type: none"> <li>- I have looked, but not been able to find appropriate products that are readily available</li> <li>- Chemical sanitation is our only option for cleaning our surfaces</li> <li>- We also use peroxyacetic acid and hydrogen peroxide. All are essential.</li> <li>- Alternative sanitizer materials exist with comparable effectiveness. We have tried chlorine dioxide and peracetic acid - preference for chlorine-based materials for effectiveness, availability, training.</li> </ul> <p><b>If the material were prohibited:</b></p> <ul style="list-style-type: none"> <li>- Food safety would be impacted</li> <li>- There would be a significantly increased risk of human pathogen spread.</li> <li>- We would have to find another way to get water to potable standard</li> <li>- This would be a huge loss, especially on dairy farms. For processing and handling is it very common for equipment and food surface cleaning</li> <li>- Impacts to food safety and business operations</li> </ul>	
<p><b>Potassium Hydroxide</b> - prohibited for use in lye peeling of fruits and vegetables.</p>	<p><b>3 Responses</b> received from certified organic operations.</p> <p><b>Used in:</b></p> <ul style="list-style-type: none"> <li>- Yogurt, and use potassium hydroxide as a cleaning agent, daily</li> <li>- Beverages - pH adjuster, routinely</li> <li>- Nutritional Products, routinely in most formulas</li> </ul> <p><b>The material is essential because:</b></p> <ul style="list-style-type: none"> <li>- Chlorinated Alka Plus Foaming Liquid- (Contains Potassium hydroxide &amp; Sodium hypochlorite) this product is used for foam cleaning the exterior of all equipment, then rinsed off with potable water. Foaming products are extremely important to our routine sanitation practices.</li> <li>- There are no management practices that would eliminate the need for this material</li> <li>- Needed to adjust pH and as a source of potassium fortification</li> </ul>	<p>4.7</p>

	<p><b>Alternative are not sufficient because:</b></p> <ul style="list-style-type: none"> <li>- For nutritional products, calcium hydroxide can be used, but it is less soluble than potassium hydroxide and quality (heavy metals) is a concern. We're also not aware of any other management practices that would eliminate the need for potassium hydroxide.</li> </ul> <p><b>If the material were prohibited:</b></p> <ul style="list-style-type: none"> <li>- We would need to identify something else that could play the same role in sanitization of our equipment.</li> <li>- Without potassium hydroxide we would lose the ability to maintain product stability (i.e., product would coagulate, etc.)</li> <li>- Significant impact to products. Without pH adjustment the product may not survive the manufacturing process leading to unacceptable product quality. We would leave organic if we could no longer use this product.</li> </ul>	
<p><b>Silicon Dioxide</b> - Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.</p>	<p><b>4 Responses</b> received from certified organic operations.</p> <p><b>Used in:</b></p> <ul style="list-style-type: none"> <li>- As a defoamer in Beverages (used as needed when certain conditions arise)</li> <li>- As a defoamer in Raw Ingredients (used routinely)</li> <li>- As a defoamer in all products as needed</li> <li>- As routinely as a flow agent (processing aid) used in the cheese drying and the cheese filling and pouching. It keeps the product from clumping in process, packaging and when consumer prepares finished product.</li> </ul> <p><b>Alternative are not sufficient because:</b></p> <ul style="list-style-type: none"> <li>- There are no other alternatives for our purposes</li> <li>- Unknown whether there is a consistent commercial availability of organic rice hulls</li> <li>- Research was conducted on organic rice hulls, but the results did not match in process performance. There are no other management practices that would eliminate the need for this material.</li> </ul> <p><b>If the material were prohibited:</b></p> <ul style="list-style-type: none"> <li>- We would not able to continue to use this material, cheese would not flow through the dryer efficiently. Cheese would not fill into pouches and clog filling system. Cheese would clump or cake in pouch and cheese would not mix well when making sauce.</li> </ul>	<p>4.5</p>

<b>Potassium Lactate</b> - for use as an antimicrobial agent and pH regulator only.	No responses received so far.	
<b>Sodium Lactate</b> - for use as an antimicrobial agent and pH regulator only.	No responses received so far.	

**Additional OTA Comments on Chlorine Materials**

It is critical that organic producers and handlers have a tool kit of antimicrobials that will allow them to fully comply with all food safety requirements, and have the ability to rotate among several materials to reduce the incidence of microbial resistance. It is also critical that the National List continues to represent the best and least-toxic technology our food system has developed. For this reason, the Organic Trade Association continues to be supportive of NOSB’s work to better understand sanitizer (antimicrobial) materials used in organic production and handling systems.

However, as reflected by several of the questions included under the Sunset Review for chlorine materials, we are concerned that NOSB’s “draft framework” document is being prematurely incorporated into the Sunset Process and imposing several questions on the organic community that are outside the scope of the Sunset Review.

We believe that NOSB and organic stakeholders share a common interest in that we prioritize food safety *and* we want to see the least toxic cleaners, sanitizers and disinfectants being used. If this is the goal, and we believe it is, OTA asks NOSB to consider the following:

- For handling operations, cleaners, sanitizers & disinfectants are listed under a National List heading that references “**ingredients**” (§ 205.605). This has been a source of confusion for individuals inside and outside the organic sector for a very long-time. On-going education is necessary.
- For handling operations, any cleaner, sanitizer or disinfectant that is used **in direct contact with an organic** product must be on the National List. Materials that are used on food contact surfaces do not need to appear on the National List, provided they do not come in contact with the organic product (§ 205.272(a)). This is not directly spelled out in the regulations, and although it is well understood by certifiers and experienced organic operations, it continues to be an area where constant education and clarification are needed.
- NOSB does not review the majority of the cleaners, sanitizers or disinfectants used in organic process facilities because they do not come in contact with organic products. They are used on food contact surfaces followed by a rinse or some other intervening event. However, certifiers and inspectors review these materials along with a complete description of how, when and why they are used, and how



contamination prevention requirements are met. This is a requirement of the Organic System Plan and applies to ALL cleaners, sanitizers or disinfectants used in organic handling and processing, direct or indirect use.

- There is a facility pest management practice standard (§ 205.271) that requires an integrated approach to pest management. A stepwise preferential approach is applied to preventive measures and mechanical, physical and biological controls, followed by materials that are on the National List followed by materials that are not on the National List. However, the facility pest management practice standard does not apply to cleaners, sanitizers or disinfectants, or at least it has not historically.
- The Canadian Organic Standards – CAN/CGSB-32.310-2020 (under the Permitted Substances Lists – CAN/CGSB-32.311-2020) include a designated list for cleaners, sanitizers and disinfectants (crops, livestock and handling) that is divided into a section for materials permitted without a mandatory removal event and a section for which a removal event is mandatory prior to an organic production load or run. Further, the Canadian Organic Standards are structured like the NOP facility pest management practice standard at § 205.271. Substances on the list are preferred. When they are not sufficient, materials that are not on the National List may be used with documented justification.

Given the above, OTA asks NOSB to consider the following pathways that could support best use of cleaners and sanitizers:

- Develop research questions and set research priorities about the use and development of cleaners and sanitizers in organic systems, and how to ensure food safety requirements are met in a way that minimizes overall health and environmental risks.
- Restructuring the National List so that cleaners, sanitizers and disinfectants have a designated section. This would generally help certified operations understand the cleaners, sanitizers and disinfectants that that may be used, and it would help organic outreach and education efforts. The list could be designed to accommodate an integrated stepwise approach (such as § 205.271) to using cleaners, sanitizers and disinfectants to minimize overall economic, health and environmental risks. A designated list could also provide further opportunity for Materials Review Organizations that maintain brand name product lists *and* for their clients that are in the business of developing NOP compliant products compatible with organic principles. Overall, a designated list could help NOSB in its review of sanitizers, cleaners and disinfectants and it could support the use of alternative, less toxic materials, when their use can meet strict food safety standards.

On behalf of our members across the supply chain and the country, the Organic Trade Association thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,



Gwendolyn Wyard  
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Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

### **Appendix A – Sample Survey for Handling Inputs**

- 1. Is your operation certified organic? Yes / No**
- 2. Is [SUBSTANCE] included in your organic system plan? Yes / No**
- 3. Which types of organic products do you use this substance in/on? (e.g., yogurt, fruit juices, baked goods, etc.)**
- 4. What function does the substance provide in/on your organic products and why is it essential? (e.g., stabilizer, thickener, flavor, sanitizer, etc.)**
- 5. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)**
- 6. NOSB collects information about the "ancillary substances" (e.g. carriers, preservatives, stabilizers) that may be used to formulate commercial forms of the substance. Please list any ancillary substances that are identified on the ingredient statement on the specification sheet that accompanies the substance you purchase.**

**7. Have you tried using any *other* substances as an alternative to [SUBSTANCE]?** (e.g. other natural substances if the substance in question is synthetic; or organic substances if the substance in question is natural)

If so, please describe your search and sourcing efforts, which substances you've tried and whether the quantity available was sufficient and/or whether the alternative substance had the quality and form necessary to fulfill the required function of the organic product or process.

**8. Are there any other *management practices* that would eliminate the need for [SUBSTANCE]?** If so, please describe the efficacy of the alternative management practices:

**9. How would your organic handling be impacted if [SUBSTANCE] was no longer be allowed?** (describe the effects on product quality, economic effects, environment effects, or human health effects)

**10. On a scale from 1 to 5 stars, rate the overall necessity of [SUBSTANCE] for your organic operation:**

Unnecessary (don't  
need it at all)

Neutral (nice to have  
but could live without it)

Critical (would leave  
organic without it)

