



October 4, 2018

Ms. Michelle Arsenault  
National Organic Standards Board  
USDA-AMS-NOP  
1400 Independence Avenue, SW  
Room 2648-So., Ag Stop 0268  
Washington, DC 20250-0268

**Docket:** AMS-NOP-18-0029

**RE: Handling Subcommittee – 2020 Sunset Reviews for §205.606 (Agricultural)**

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2020 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 2020 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. 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 electronic surveys that were created for each input under review for 2020. The surveys were created and made available to **every NOP certificate holder** and include 7-10 questions addressing the **necessity (farm and livestock) or essentiality (handling)** of the National List input under review. 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) and OMRI to distribute the survey links to all of their clients as well as to targeted clients they know are using the inputs under review. OTA also worked

through its Farmers Advisory Council<sup>1</sup> to help assist in distribution to NOP certified farmers. OTA’s surveys are set up to provide information addressing the use (necessity or essentiality) and the availability of alternatives. They do not however address adverse impacts on humans and on the environment; we defer to the science community to provide such information.

### Results of OTA Sunset Surveys

The Organic Trade Association has received the following total responses to the surveys on handling materials:

- §205.605(a) Nonsynthetic, Non-agricultural: 20 + 14 (new)
- §205.605(b) Synthetic, Non-agricultural: 11 + 6 (new)
- §205.606 Agricultural: 11 + 3 (new)

**Total: 65 (24 new)**

Below is a summary of the feedback received via OTA’s Sunset Surveys to date. New responses received since the spring 2018 meeting are highlighted and marketed as “new”. Because most of the 2020 Sunset materials were recently reviewed under the 2017 Sunset cycle, we have included the comments we received at that time as well.

### §205.606 – Non-organically produced agricultural products allowed as an ingredient in or on processed products labeled as “organic” only when the product is not commercially available in organic form.

Substance	Survey Response & OTA Position
Fructooligosaccharides	<p><b>2020 Sunset Comments</b></p> <ul style="list-style-type: none"> <li>• <b>Certified Handler Comment (NEW):</b> Sold in all the US and various export. Used in infant formula and nutritional products. Certified for 10 plus years. It plays a nutritional role as a source of fiber and prebiotic. Currently there is no FDA approved organic source of FOS that can be used in infant formula. We know of no alternative source at the present time that meets our quality, quantity and form requirements. There are other prebiotics available but none are included on the Nat'l list. Organic GOS is available and is used in some products that contain FOS - the combination provides a synergy prebiotic effect that has been studied infants. Each year we mine industry suppliers to determine if they have an organic form meeting our specification and for which is GRAS approved for use in infant formula. We continue to seek an organic version and would conduct appropriate research when an appropriate organic alternative was available. There are no alternative management practices that would eliminate the need for the specific substance that we are aware of. Customer / Consumer would not get what they wanted in the market place. If removed from the Nat'l List, product would need to be reformulated to remove FOS. Loss of sales due to product discontinuation. Essentiality: 10 critical</li> <li>• <b>Certified Handler Comment:</b> Used as Prebiotic for Kombucha production. Company certified for 20 years. Selling products in all 50 states. There are no organic alternatives. The only option would be to remove it from our product</li> </ul>

<sup>1</sup> OTA’s Farmers Advisory Council was established in 2013 to formalize two-way communication between OTA and member producers as well as regional organic producer organizations across the United States. Through dialog and input, FAC gives organic farmers a voice to directly influence OTA’s policy and provides an avenue for OTA to share information and advocacy work with this stakeholder group.

	<p>formulations. On a scale of 1 to 10 on essentiality, this ingredient is a 5. We would need to reformulate with other probiotics, but they would not be organic.</p> <ul style="list-style-type: none"> <li>• <b>Certified Handler Comment:</b> Used as prebiotic for infant formula. Company certified for over 10 years. Selling products in all 50 states. There are no organic alternatives. We have done research and have not found an alternative. On a scale of 1 to 10 on essentiality, this ingredient is a 10.</li> <li>• <b>Certified Handler Comment:</b> Used as prebiotic in baby formula. Company certified for 15 years. Selling products in 45 states and Canada. FOS functions as a “prebiotic” that can feed and promote healthy bacterial flora in the intestines. FOS is added to enhance the beneficial activity of the probiotic cultures naturally found in dairy products. There are limited products and ingredients that meet the necessary nutritional requirements for infant formula, while also meeting the stringent standards of the USDA's National Organic Program. On a scale of 1 to 10 on essentiality, this ingredient is a 5.</li> </ul>
<p>Gums: Arabic, Carob bean, Guar, Locust bean – water extracted only.</p>	<p><b>2020 Sunset Comments</b></p> <ul style="list-style-type: none"> <li>• <b>Certified Handler Comment (NEW):</b> Used for production of excipients in dietary supplements. Certified for 10 years. Selling to all 50 states + exports. Helps bind powders in excipients for tablets &amp; capsules. The listed gums are critical and no other organic alternatives exist. Yes, R&amp;D was done looking at various gums needed to achieve the desired functionality vs. synthetic alternatives. The functionality without the gums would not be acceptable and organic tablets would be inferior to conventional. Loss of \$1-2 million in sales. Essentiality: 10 critical.</li> <li>• <b>Certified Handler Comment:</b> Used as a stabilizer &amp; thickener in toddler meals, plant based beverages, non-dairy frozen desserts, dairy beverages, fruit preps, yogurt. Company certified for 30 years. Selling products in all 50 states. We have done extensive research and have not found suitable organic alternatives. We would no longer make the products if gums were removed from the National List.</li> <li>• <b>Certified Handler Comment:</b> Used as a thickener in juices, beverages, jams and jellies. Company certified for 20+ years. National sales and exported. We have used gums in our organic products for over 20 years. Every year we fill out commercial availability forms and there are no known alternatives. We have conducted research on the use of allowed organic alternatives. We have also researched alternatives practices but gums have specific uses for specific products. We need all varieties of gums to meet the various products. Loss of gums from the National List would result in poor quality products and there would be a lack of competition with conventional products. This would result in lack of sales due to quality and competition with superior products that use gums. On an essentiality scale of 1 to 10 gums are critical.</li> <li>• <b>Certified Handler Comment:</b> Used to set semi soft structure to our cereal bars. Company certified for 20 years and selling products in all 50 states and Canada. Gelatin can be used as an alternative, but our consumers prefer vegan options. Without the use of this material, the product identity would change because the product would be dense and not as soft. <b>Essentiality on scale of 1-10: 8.</b></li> <li>• <b>Certified Handler Comment: Guar and locust bean:</b> We use organic locust bean gum and organic guar gum in the processing of some of the fruit we use in our yogurt. We have had no trouble sourcing organic versions of these ingredients. However, we also do not have data on the general supply and demand for these ingredients, so it is hard to predict what level of demand increase might occur if the non-organic versions of these ingredients were to be removed from the</li> </ul>

	<p>National List now. We suggest that the NOSB should instead apply commercial availability to these ingredients before removing them from the list entirely.</p> <ul style="list-style-type: none"> <li>• <b>Certified Handler Comment:</b> Used as stabilizer and for viscosity control in our salad dressings. Company certified for 15 years and selling products in 45 states and Canada. We use organic ingredients whenever possible. Although organic gums exist, there is limited commercial availability in terms of quality and quantity. Without the use of this material, products would not have the appropriate viscosity to meet consumer expectations. <b>Essentiality on scale of 1-10: 5.</b></li> </ul> <p><b><u>2017 Sunset Comments</u></b>        Used for organic juice as a thickener and stabilizer. Certified for 13 years. Sold throughout the U.S., Canada, &amp; EU. We purchase gum blends and while some may be available in organic form, they are not sufficient when used alone. When used as individual organic gums, they should not be an issue to source. A variety of gums are used for ideal quality and function. If removed, it would impact the quality of our product; juice blends would separate. This would result in loss in sales. This ingredient is critically essential to our organic products.</p>
Lecithin	<p><b><u>2020 Sunset Comments</u></b></p> <ul style="list-style-type: none"> <li>• <b>Certified Handler Comment (NEW):</b> Company has been certified for 14 years. Selling product in all 50 states and also exported to other countries. We are the original manufacturer first in the world to produce organic lecithin. Deoiled lecithins are typically used as a convenience, easier to measure out, not as sticky and messy as the fluid. Normally used in dry mixes such as spice, taco &amp; chili mixes as example helping with dispersion when used. They can be used to substitute for a fluid lecithin, but more costly in a formulation. They have a higher HLB, so work's best in an Oil in Water emulsion. Both organic soy and sunflower deoiled lecithin are available of superior quality to conventional deoiled lecithins. How much quantity is enough? Only 5% of all lecithin consumed in the world is in deoiled form statistically. Volatile solvent residue from non-organic production is evident in the conventional deoiled lecithin currently allowed which is known to lead to birth defects. Companies can use the organic liquid lecithins that are readily available. Environmental effects if lecithin is removed from the National List are the continued allowance due to the volatile solvents hexane and acetone used in the deoiling process known to lead to birth defects. If conventional lecithin remains on the National List, this will result in loss of sales of Certified Organic Liquid Lecithins. Ancillary substances? Typically unknown to the buyer flow agents are added, primarily synthetic silicon dioxide which now is restricted by the FDA.</li> <li>• <b>Certified Handler Comment:</b> Used as a release agent, lubricant, for drum driers in infant cereals. Company has been certified for 20 years. Selling products in all 50 states and worldwide. The essentiality of this substance is an 8 out of 10. If we were no longer able to use it we would have lower efficiency, yield and product quality and increased prices due to lower production output.</li> <li>• <b>Certified Handler Comment:</b> Used in our cookies, crackers, and gluten-free granola bars. Company certified for 20 years and selling products in all 50 states and Canada. Helps ingredients to mix more easily and remain mixed (emulsifier); used in chocolate chips to prevent "blooming". Our consumers avoid soy, so we primarily use sunflower lecithin. Most is organic, but we have had to use non-organic at times due to supply availability. Without the use of this material, ingredients will fall apart or not remain mixed in; chocolate chips will "bloom"</li> </ul>

	<p>causing consumer complaints. <b>Essentiality on scale of 1-10: 8.</b></p> <ul style="list-style-type: none"> <li>• <b>Certified Handler Comment:</b> Used as an emulsifier in wide variety of products, mostly baked goods. Company has been certified for 15 years. Selling products in over 45 states with exports to Canada. Organic lecithin is available and we use it whenever possible. Many of our products do use organic lecithin. However some products still use non-organic lecithin because we have not secured a consistent supply in the appropriate quality and quantity. The essentiality of this substance is an 8 out of 10.</li> </ul> <p><b><u>2017 Sunset Comments</u></b></p> <p>-Used in many baked goods, frozen desserts, beverages. Certified for over 15 years. Sold in 50 states and many countries. Organic lecithin is available in liquid form. We use it in some products. Other products require a de-oiled lecithin. There is no organic de-oiled lecithin. The so-called dry organic lecithins are just liquid lecithin mixed with a carrier. These do not work in many applications. Alternative and organic emulsifiers do not work in many applications. There are no alternative management practices that would eliminate the need for the specific substance. Loss of this listing would diminish quality and marketability of our products and would lead to loss of sales. Critically essential.</p> <p>-Cake mixes, cookies, crackers, pizza crust, waffles/pancakes, cheese sauces, chewing gum, colors, frostings, granola bars, ice cream, frozen desserts, cones, instantiating, meat sauces, gravies, milk powders, non-dairy creamers. Certified for 11 years.</p> <p>-Cookies and crackers. We source organic.</p> <p>-Used as an emulsifier in cheese: cheese and dairy-based seasonings. There are no alternatives. Company is 15 years' certified. Products are sold in all U.S. states and around the world. Loss of lecithin would result in loss of business due to products not functioning as needed by the customer. Critically essential.</p> <p>-Supplier of Certified Organic Soy Lecithin Powder De-oiled. We currently ship this product to Certified Organic customers in ME, CA, MN, &amp; PA. Other countries we ship this product to are Australia, New Zealand, &amp; Norway. Certified Organic Soy Lecithin Powder De-oiled has superior quality as verified by a leading lecithin expert of 40+ years' experience. We have been providing this product from the manufacturer for over two years in the U.S. organic market with growing usage by our customers. The manufacturer now has two facilities that can produce this product with their majority of sales going to Europe. Since de-oiled lecithin use in the world is less than 5%, these two facilities alone can easily produce enough supply for the demand. 95% of all lecithin used in the world is in liquid form. So there are only a few applications a de-oiled lecithin would be necessary, primarily in baking. It is used primarily as a convenience—using a dry product vs. a viscous liquid in all other applications, being easier to handle. Certified Organic (de-oiled) Soy Lecithin has been available for over two years. If the allowance of non-organic de-oiled lecithin is removed, more companies would produce this ingredient. If de-oiled lecithin were removed through Sunset, there would be economic gain for organic companies supplying Organic De-oiled Lecithin to the U.S. organic market. Non-organic form is <b>not</b> essential.</p>
Tragacanth Gum	<p><b><u>2020 Sunset Comments</u></b></p> <ul style="list-style-type: none"> <li>• No responses received</li> </ul>



In closing, we thank the Board for its time and commitment. OTA is committed to collecting information from our broad membership and beyond in order to assist NOSB in determining whether or not a substance on the National List remains essential to organic handling.

Again, on behalf of our members across the supply chain and the country, OTA thanks NOSB for the opportunity to comment and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard  
Vice President of Regulatory and Technical Affairs  
Organic Trade Association

cc: Laura Batcha  
Executive Director/CEO  
Organic Trade Association

**Appendix A – Survey Questions (Example: Xanthan Gum)**

1. Please describe the types of certified products or processes this substance is used in:

2. How many years has your company been certified organic?

3. Where is your organic production located (state, region, country, etc):

4. How many states are your products sold in? Are they exported to other countries?

5. What is the function of the substance in your products or processes (e.g. stabilizer, thickener, flavor, sanitizer, etc.)?

6. Describe the availability of allowed alternatives (organic or natural) for this substance in terms of quality, quantity and form:



7. If available, have you conducted research (e.g. R & D trials) on the use of allowed natural or organic alternatives?

8. Are there any alternative management practices that would eliminate the need for the specific substance?

9. NOSB is requesting information about the ancillary substances (e.g. carriers, preservatives, stabilizers) that may be used in xanthan gum. Based on the ingredient statement provided in specification sheet that accompanies the xanthan gum you purchase, please list any ingredients that are added and remain in the product you buy. Note: The "ancillary substances" should be listed in the ingredient statement found on the specification sheet.

10. Describe the effects to your operation should you no longer be allowed to use xanthan gum:

Organic product effects (effects to the quality and marketability of the organic product(s) you are marketing):

Environmental effects (effects to environment if the substance was no longer allowed AND effects to environment from potential alternatives):

Economic effects (effects to economic health of your operation):

11. Based on your answers to the questions above, rate the essentiality of this substance (i.e. how necessary is this substance to the continued success of your organic products and operation?):

**1 Less Essential**    2    3    4    **5 More Essential**    6    7    8    9    **10 Critical**

12. Does your company intend on submitting comments directly to NOSB regarding the sunset review of this substance?