



October 1, 2020

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

Docket: AMS-NOP-20-0041

RE: Handling Subcommittee – 2022 Sunset Reviews for §205.606

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on its 2022 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 2022 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 2022 Sunset Review cycle. These electronic surveys include about 10 questions addressing the **necessity (crop and livestock)** or **essentiality (handling)** of each input. See Appendix A for a sample survey. 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.

Organic Ingredients and Commercial Availability

Agricultural ingredients listed on § 205.606 of the National List must be used in organic form when they are commercially available (quality, quantity, form). The process of determining whether an ingredient is available in organic form is an interactive process that takes place between a certifying agent and a certified operation, and it occurs on at least an annual basis. Certified operators must document and demonstrate their efforts to source organic ingredients, and certifying agents must carefully assess and document their approval. For the certified operator, this process includes a description of the frequency that the search is performed and research efforts to evaluate the quantity, quality and form of known organic sources. For the certifier, this process includes evaluating the applicant or certified operator's Organic System Plan and the operator's documented claims that the organic ingredient is commercially available/unavailable in the form, quality, or quantity needed to fulfill the required function of the organic product.

The inclusion of an ingredient on § 205.606 of the National List does not mean wholesale allowance to use a non-organic form. It means an organic alternative does not exist or there is a fragile supply, and therefore certifying agents must make determinations on a case-by-case basis. It also means that there is an opportunity for the development of an organic alternative that is available in the quality, quantity and form that will meet the industry's needs (aka *commercially available*). The organic industry and NOSB must work together to determine when the supply of a particular § 205.606 ingredient is no longer fragile. It is important to recognize that while the Sunset process continues, so does the relationship between the certified operation and certifying agent and the **requirement** to use organic when it is commercially available. Further, the option to petition a material OFF the National List is always open, and we commend the example that has been set with the petition to remove Whey Protein Concentrate.

OTA acknowledges that for some there is frustration with the number of agricultural ingredients that remain on the National List, and there is growing discontent with "commercial availability" and the role it plays in the organic standard. Does it serve its purpose or is it actually an impediment? The challenges we are grappling with mirror the discussions and NOSB recommendations that have occurred with organic seed, and the option to use non-organic seed when an equivalent variety is not commercially available. One notable difference, however, is that NOP issued Guidance on Commercial Availability of Organic Seed and Planting Stock (NOP 5029), whereas the 2006 NOSB recommendation on Commercial Availability for § 205.606 ingredients continues to be unaddressed by NOP. Another notable difference is that NOSB recently passed a recommendation for a rule change that requires organic producers to demonstrate improvement in use of organic seed/planting stock every year. NOSB also more recently passed a recommendation to update the existing Guidance on organic seed/planting stock. Aside from the unaddressed NOSB recommendation on §205.606, the only Guidance we know of that is publicly available on commercial availability for handling materials has been developed by the Organic Trade Association¹ and the Accredited Certifying Association². Both documents describe the process and criteria that is followed by most certifiers in the course of reviewing commercial availability for any § 205.605 or § 205.606 ingredient.

¹ [USDA organic flavors Required When Commercially Available](#) – A practical guide to complying with the new requirements for natural flavors

² [ACA Best Practices for Commercial Availability of Natural Flavors, June 2020](#)

OTA shares concerns about how well the commercial availability provision actually drives market incentive. We recognize the role that industry can take, and we are constantly working on initiatives to advance efforts and resources to support the development of natural and organic alternatives. We have long considered § 205.606 to be the “entrepreneurial list of opportunity,” and we have a record of advocating for the removal of items when there is industry consensus that the organic supply of an ingredient is available and stable. We have also championed petitions and efforts to assign commercial availability to ingredients on § 205.605 (natural flavors, yeast and silicon dioxide), and of course we are leading efforts to develop an organic alternative to celery powder.

OTA is sensitive to the frustrations of the organic community and the ongoing role of commercial availability almost 20 years into the National Organic Program. We are interested in the best approach to drive innovation and incentive within the boundaries of OFPA and NOSB’s authority. The question that we continue to hear is, “What is my role as an NOSB member and how do we know when the time is right to vote an ingredient off the National List?” As one member of NOSB summarized the dilemma in 2008, “I feel like I am stuck in a chicken-and-an-egg thing ... until it is off the list, industry won’t be incented to use it.”

OTA does not support voting a material off the National List to make a point, or to scare or drive incentive. We can appreciate the temptation and even the sentiment, but a decision to vote a material off the National List without sufficient evidence to prove that the ingredient is commercially available in an organic form is not consistent with OFPA criteria or the role of NOSB. We understand that it is often difficult to know when there is sufficient evidence, but at the same time, we *know when there is* sufficient evidence because there is consensus and the industry voice will come through. We also recognize that the Sunset process--as well as the petition process--is a two-stage rulemaking process. Therefore, if NOSB is *uncertain* and votes to remove an ingredient from the National List, there is the NOP rulemaking process to further confirm that decision via another comment period that tends to catch the attention of stakeholders that were not aware of the NOSB process. With this second comment period in mind, if a NOSB member prematurely votes a material off the National List to send a message, unfortunately, this may end up reflecting poorly on USDA and the organic community as a whole, if USDA is not able to accept that recommendation because it doesn’t meet the criteria of OFPA.

OTA is committed to further discussion about the sunset and petition process and the best approach to support the development of organic alternatives. We have invested heavily in this area but clearly there is much more work to be done. We believe there are untapped solutions for incentivizing the development of organic ingredients, supporting organic manufacturers and certifying agents, and setting clear guidelines for improvement that can incentivize the creation of new organic ingredients and enforce the highest standard of “organic preference.” OTA welcomes a discussion document on this topic.

For this round of Sunset on § 205.606, based on the survey results we collected and direct outreach to our members, it appears that there is a stable supply of **Turkish Bay Leaves** and the listing should sunset. It also appears that there is a stable supply of **Whey Protein Concentrate**. Again, we commend the petition that was submitted because it reflects a proactive approach and will allow for a much deeper analysis with more time for consideration if needed. We did not receive any comments on sweet potato starch, but again, we also didn’t receive any information to prove that the organic form is available. For all other § 205.606 ingredients, the organic supply appears to be fragile, meaning that the quality, quantity and/or

form is not available as needed at this time. We look forward to seeing the comments submitted by others that will hopefully fill in some gaps and shed further light.

Finally, please continue to keep in mind that for all of the ingredients listed on § 205.606, the use of an organic form *is required* when it is commercially available despite its listing on § 205.606. We frequently see organic products that contain organic colors, organic corn starch, organic gums, organic carnauba wax and others. The presence of these organic ingredients on the statement of organic products in the marketplace demonstrate success, and it shows that the process is working. It is critical that we recognize the certifier end of the review process and the efforts that are in fact being made by the organic industry. Organic consumers want to see an ingredient statement list all organic ingredients and that demand drives the most powerful form of incentive.

Results of OTA Sunset Surveys

OTA has received 105 total responses (605 and 606 combined) on our 2022 Handling Sunset Surveys. Below is a summary of the feedback received via OTA’s Sunset Surveys to date on § 205.606 only. Please see our separate comments on the § 205.605 substances.

- **§ 205.606 Responses:** 81 responses

§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	# of responses	Summary of responses	Average rating of Essentiality (from 1 to 5, with 5 being “critical – would leave organic without it”)
Carnauba wax	5	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for texture and appearance in gummy bears and fruit snacks; it creates a shiny appearance on gummy snacks and provides an anti-stick coating to keep the products from clumping - Used for gummy dietary supplements - Cereals, snacks, frozen entrees and breakfast foods – functions as a component of an anti-sticking agent. <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Organic carnauba wax is available consistently according to one respondent, but others report that a reliable and stable organic supply has not yet been established. - Encourage that Carnauba Wax remain on 606 until a stable organic supply has been established. - We contact 3 or more suppliers annually to source organic alternatives. There is limited availability and it does not function as intended as determined through research trials. - Limited availability in the organic version; does not function as intended <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Organic supply may not be available if non-organic forms are prohibited. - Without this material, we would need to reformulate and sell non-organic instead of organic products. 	2.5

		- Would require reformulation	
Colors Several new comments were submitted	48 (total)	<p>Survey responses were received for the following:</p> <ul style="list-style-type: none"> • Beet Juice Extract Color (2 responses) • Beta-carotene Extract Color (3 responses) • Black Current Juice Color (2) • Black/Purple Carrot Juice Color (6) • Blueberry Juice Color (3) • Carrot Juice Color (3) • Cherry Juice Color (2) • Chokeberry, Aronia Juice Color (2) • Elderberry Juice Color (3) • Grape Juice Color (2) • Grape Skin Extract Color (1) • Paprika Color (2) • Pumpkin Juice Color (2) • Purple Sweet Potato Juice Color (2) • Red Cabbage Extract (5) • Red Radish Extract Color (3) • Saffron Extract Color (2) • Turmeric Extract Color (3) <p>Colors are essential because:</p> <ul style="list-style-type: none"> - Coloring agents are used in fruit snacks, candy, juices, cereal, plant-based ice cream and yogurt, baby teether crackers, crackers, baked goods, gummy dietary supplements - Used in certified organic flavors - Used in juices containing mango which browns readily (comment for beta carotene). Also a natural source of vitamin A. - Used in cereals and snacks <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Organic forms are beginning to be available and suitable for some products, although it takes considerable amount of resources and time to validate the organic options, and some products need to be reformulated to meet manufacturing processing capabilities. - Annual search done and has been determined there is not an organic source available - Support that Fruit/Veg Colors remain on 606 while the work continues to validate organic options. - They are not commercially available, but we continue to work with our certifier on an annual basis and must demonstrate that we cannot find an organic alternative. We must document a search as well as report R & D efforts. - At least annually we ask approved suppliers for organic sources of beta carotene. We have been unable to find a supplier that could provide sufficient quantities and still meet our own internal food safety, quality and 3rd party audit requirements. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Would have to reformulate, if possible, or convert to conventional - Would have to discontinue products 	4

		<ul style="list-style-type: none"> - Would need to discontinue products and therefore stop sourcing and using rest of the 95% of the organic ingredients - Would not be competitive with conventional products - Organoleptic change to both flavor and CPG product - Loss of sales due to inability to provide expected product - We would lose the ability to keep trying to source and develop organic colors while the market grows because we would need to discontinue organic. - It may not result in the development of organic colors and instead the loss of organic products. 	
Glycerin	8	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used as a solvent, carrier in manufacturer of organic flavors and plant-based ice cream, yogurt, baby food - Use as humectant and moisture stability in making granola bars. It helps lower water activity to prevent mold growth. It helps with moisture control to allow for a chewy texture. - Stabilizes enzyme preparations, protecting them in the event of extreme temperature changes. Enzymes are used in the process of standardizing the amount of pectin in certain fruits, such as grapes, as they are prepared for use as juice and in fruit spreads. Depectinization ensures that the fruit is consistent in these products from batch to batch. Enzymes are essential to processing certain fruits, but are used at extremely low levels and do not have a function in the finished products. <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Some manufacturers are currently using organic glycerin. However, others report that high quality organic forms are not available for some manufacturers. Others have identified suitable organic alternatives, but reliable stable supplies are not established. - The supply of organic glycerin will not support our current annual demand to manufacture and sell organic compliant flavors - Support glycerin to remain on 606 until a stable organic supply has been established. - Organic flavors and organic compliant flavors use organic glycerin, but there is not enough organic glycerin to supply the entire market. It is a developing minor organic ingredient and supply of organic products in general is not high enough to bring up a consistent supply of organic glycerin. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - The supply of organic glycerin will not support our current annual demand to manufacture and sell organic compliant flavors. The cost of using organic glycerin in lieu of natural glycerin would not align with our client's cost-in-use. Loss of business is expected. - The entire line of organic compliant flavors would not be available and that would have a devastating impact on the organic industry. 	5
Inulin-oligofructose – enriched (IOE)	6	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used in making plant-based ice cream and yogurts, fluid milk, dairy yogurt, and infant formula 	5

		<ul style="list-style-type: none"> - Provides fiber - Provides mouthfeel/bulking to help with sweetness perception - Pre-biotic <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - IOE from chicory is not available in organic form - organic inulin + conventional FOS does not provide same functionality - Have searched and not found any alternatives. - Search the USDA database regularly <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Unable to produce organic products without it - Would leave the organic market; stop making organic products 	
<p>Kelp</p> <p>No new comments since spring 2020</p>	2	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for flavor in organic seasoning blends - Use as thickener and supplement in plant-based protein supplements <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Not identified. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Loss of flavor profile 	4
<p>Orange shellac – unbleached</p> <p>No new comment since spring 2020</p>	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Prevents jelly beans from sticking together <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Other alternatives have not provided functional equivalence <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Products would be discontinued 	5
<p>Cornstarch</p>	7	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Thickener in macaroni and cheese, tortillas, baking mixes, and baked goods - Used in cereals, snacks, frozen entrees and breakfasts - Build viscosity to maintain fruit distribution in fruit preparations - Used as a moulding medium for gummy bears and fruit snacks. It is a processing aid in manufacture of confections. - Critical for our production process. <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Some manufacturers are able to find organic forms, although consistency of supply is not reliable (two shortages in past ten years). Other manufactures have not found any organic form that meets their specifications for functionality and quality - We have other types of starch but they are not functional equivalents. - We have not found alternatives that work. 	4.5

		<ul style="list-style-type: none"> - Support cornstarch to remain on 606 until a reliable, stable organic supply has been established. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - Organic supply may not be available if non-organic forms are prohibited. - Would have to reformulate, if possible, or convert to conventional - We would no longer be able to manufacture organic products 	
Sweet potato starch	0	No comments were provided	
Turkish bay leaves No new comments since spring 2020	1	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for flavor in a wide range of canned soups <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - N/A - Respondent states there is full availability of organic forms. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - No impact because organic forms can be used and are available. 	1
Whey protein concentrate (WPC) One new commenter since spring 2020	3	<p>The material is essential because:</p> <ul style="list-style-type: none"> - Used for nutrition in baby food - Used in cereals, baked goods/snacks, frozen breakfasts and frozen meats as a protein source, flavor and thickener <p>Organic alternative are not sufficient because:</p> <ul style="list-style-type: none"> - Some organic processors are not able to find enough organic supply, while others do not have a problem finding this ingredient in organic form. - There is a search done annually and regularly as there is not always organic supply available and/or supply is not consistent. <p>If the material were prohibited:</p> <ul style="list-style-type: none"> - At least one processor reports that they would have to continually change formulas of products to deal with inconsistent supply or organic form. <p>One manufacture said that organic alternatives are available and will meet the requirements needed. However, leaving it on the list would support any interruption in supply continuity.</p> <p>According to another manufacturer of WPC that completed our survey: We produce Whey Protein Concentrate. It is made from cheese whey which yields lactose and whey protein concentrate. Lactose is a very popular offering. Whey protein concentrate is in less demand. We believe this is due to use of non-organic whey protein concentrate. If we utilized all our whey stream (which we are working on) we do not feel organic availability will be an issue.</p>	3



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,

A handwritten signature in black ink, appearing to read "Gwendolyn Wyard".

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

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendix A – Sample Survey for Handling Inputs

1. Please describe the types of organic products produced or handled on your operation:
2. How many states are your products sold in? Are they exported to other countries?
3. How many years has your operation been certified organic?
4. Which organic products do you use this substance on/in? (e.g., yogurt, fruit juices, baked goods, etc.)
5. What function does the substance provide in your organic products and why is it essential? (e.g., stabilizer, thickener, flavor, sanitizer, etc.)
6. With what frequency does your operation use the substance? (e.g., seldom, as needed when a certain condition arises, routinely, etc.)
7. Have you conducted a search for the availability of natural (if the substance in question is synthetic) or organic (if the substance in question is natural) alternatives? (e.g. using yeast instead of chemical leavening agents)
 - If so, please describe what your search entailed:
 - Based on your search, describe the availability of allowed alternatives (organic or natural) in terms of quality, quantity and form:
 - If available, have you conducted research (e.g. R & D trials) on the use of allowed natural or organic alternatives in your organic product(s)? Briefly describe the results. Did they meet your specification requirements?
8. Are there any other management practices that would eliminate the need for the substance? (e.g., delayed harvesting instead of using a chemical growth hormone for ripening). If so, please describe the efficacy of the alternative management practices:
9. Describe the impact to your operation should you no longer be allowed to use the substance:
 - Organic product effects (effects to the quality of the organic product(s) you are marketing):
 - Environmental effects (effects to environment if the substance was no longer allowed; effects to environment from potential alternatives):
 - Economic effects (effects to economic health of your operation):
10. On a scale from 1 to 5 stars, rate the overall essentiality of this 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)
★	★	★
11. 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.