



April 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-17-0057

RE: Handling Subcommittee – 2020 Sunset Summaries for 206.605 (Non-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 to sunset in 2020. It's critical that NOSB hear from certified farmers and handlers on whether these inputs are consistent with and essential to organic production and handling, or whether there are other effective natural or organic alternatives available.

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 (FAC¹) to help assist in distribution to NOP certified farmers. The comments submitted at this time include everything we have received through April 4, 2018. We have received the following total responses:

¹ 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.

- 205.605(a) Nonsynthetic, Non-agricultural: 20
- 205.605(b) Synthetic, Non-agricultural: 11
- 205.606 Agricultural: 11
- **Total:**

Please note that most of the 2020 Sunset materials were recently reviewed under the 2017 Sunset cycle, therefore we have also included the comments we received at that time as well. We believe the recent 2017 Sunset review and the reorganization of sunset review dates has contributed to the lower number of survey results we received on this round of comments. With such a short passing of time, very little if anything has changed since the 2017 review.

National List Criteria

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.

Based on survey results and/or feedback received directly by members, the following materials meet the essentially criteria listed above. We are not aware of any new information regarding adverse impacts on humans and on the environment and defer to the science community to provide such information. Our focus is to provide information addressing the use (necessity or essentiality) and the availability of alternatives.

Non-agricultural non-synthetic (205.605(a)) Non-synthetic (non-agricultural): Allowed as ingredients in or on processed products labeled “organic” or “made with organic (specified ingredients or food group(s)).

Substance	Survey Information
Calcium Carbonate	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> • Certified Handler Comment: Used in chips to modify texture. Company certified for 20 years. Selling throughout the USA & Canada. We are not aware of any organic or viable National List alternatives. If this material were removed from the NL our products would not be able to be manufactured to the same specifications. This would have a detrimental effect on the economic health of our operation. Essentiality on scale of 1-10: 8 • Certified Handler Comment: Used in Cereal, Beverages, Non-Dairy Milks, Baked goods, etc. Company certified for 15 years. Selling products in over 40 states and Canada. We are not aware of any alternatives. We source and prefer organic alternatives whenever possible. However there are not commercially available organic alternatives for calcium carbonate. If this material were removed from the NL we would not be able to make our products. Essentiality on scale of 1-10: 8 • Certified Handler Comment: Used as for nutrient fortification in plant-based beverages. Company certified for over 30 years. Selling products throughout the USA.

	<p>We have yet to find a suitable alternative. Essentiality on scale of 1-10: 10, critical.</p> <ul style="list-style-type: none"> • Certified Handler Comment: Used for fortification in baby and toddler snacks and cereals, toddler formula. Company certified for over 10 years. Selling products in all states. We are not aware of any suitable alternatives. Essentiality on scale of 1-10: 10, critical • Certified Handler Comment: Calcium carbonate is used as a nutrient in our soy beverages and is an important nutrient. There are no alternatives. • Certified Handler Comment: Used as a dough agent in cookies. Company certified for 20 years and selling products in all 50 states and Canada. There are no other alternatives available. Dough will not process well through the forming equipment. Essentiality on scale of 1-10: 8, critical • Certified Handler Comment: Used in our organic soy yogurt. Calcium carbonate provides a critical function in this product as a gelling agent. If we did not include calcium carbonate in our products, the soy yogurt would not set properly. It also provides an important nutritional function, allowing us to deliver 15% of the RDA for calcium in a serving of soy yogurt. To our knowledge there is no other ingredient that would deliver both the functional and nutritional benefits that calcium carbonate does in our soy yogurt, and we support its renewal on the National List. <p>2017 Sunset Comments Handler Comment: Calcium carbonate is used as a calcium source in soy-based cheese alternate. Because the soy-based cheese alternate is a substitute for milk-based cheese, our supplier would like to be able to provide a similar calcium level for nutritional purposes. Alternates are not more natural and may change the flavor of the soy-based cheese alternate.</p>
Flavors	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> • See OTA’s attached comments to USDA-NOP on the proposed rule to revise the annotation on natural flavors. OTA supports retaining Natural Flavors on the National List with the expectation that the annotation will be revised via NOP rulemaking to require the use of organic flavors when they are commercially available. We strongly urge NOSB to revisit guidance on commercial availability for 205.605 and 205.606 materials. NOSB passed a recommendation to NOP several years ago and NOP has not acted on it. • Certified Handler Comment: Flavors are ubiquitous in food products to meet consumer quality expectations and taste profiles. Company certified for 15 years. Selling products in over 40 states and in Canada. Most flavors have specific and unique flavor properties, which are not always available in an organic form for the specific flavor profile. All flavors used in our products meet the FDA Definition of Natural Flavors. We prefer organic flavors and source whenever available in the appropriate form, quality, and quantity. Flavors should not come off the list at this time. We do agree that commercial availability should apply to the listing. If flavors came off the list completely many organic products would be unable to meet consumers’ quality expectations and desired flavor profiles. Essentiality on scale of 1-10 is 9. • Certified Handler Comment: Used for flavoring in baby snacks, dairy, yogurt, plant based beverages and ice cream. Certified for almost 30 years. Selling products in all states. We continually look for organic alternatives in the right quality, quantity and form. We have conducted research (e.g. R & D trials) on the use of organic alternatives. We believe it is appropriate to retain all natural flavors on 205.605(a) of the National List if organic flavors and require organic to be used when commercially available (in quality, quantity or form). Flavors should not come off the National List.

Essential.

- **Certified Handler Comment:** We make natural flavors and organic natural flavors for use in all types of products Certified for 10+ years. Selling products in all states and exporting to the EU and Canada. Alternatives? Solubility, stability, availability, consumer acceptance and TASTE can make each flavor/food application pairing unique. If the pairing is not successful, consumers will not buy the product and the organic market will not grow. The raw materials used in flavors are often by products (relatively small volume) of other food production streams – e.g. citrus oils and juice industry. The flavor industry has little ability to drive market demand. We are at the mercy of the overall organic market demand for food products. We have conducted research on organic flavors but often we cannot get to the same flavor profile with available organic materials. Flavors should not come off the National List. No, there are not enough organic flavors. Further, we recommend that the class of “natural flavors” be kept together. Natural flavors have a regulatory definition under FDA, and distillates, for example do not. This would add little value to the consumer of organic foods and create confusion around terms that are not well defined in the regulations. We agree that commercial availability should be assigned to the listing of Natural Flavors, BUT, quality, quantity and form need to be fully defined to include taste and consumer preference (if available) and can not require extensive sourcing requests to compare. Other flavor companies will spend valuable resources sending samples to the organic food manufacturer that will not taste the same and will never result in business for them. This is unfair at all levels and will drain the energy and resources away from growing the organic market. If flavors come off the National List it would result in substantial business loss especially where organic natural flavors do not have enough downstream supply. We would lose over \$10M in sales. The essentiality of this substance is critical (10 on a scale of 1 to 10).
- **Certified Handler Comment:** Used for flavor in juices, jams, spreads, ice cream toppings. Company certified for 20 years and selling products nationwide and exported. We have ALWAYS used certified organic flavors in ALL of our products. No issues with quality, quantity, form. In our opinion organic flavors are available in all types of the above types listed. Commercial availability should apply to the listing. YAs a company who uses 100% certified organic flavors this would help other products transition to organic. Without commercial availability there is no incentive to switch to organic. If flavors are removed from the National List completely, some organic flavors would not be able to be produced as they use natural flavors as an ingredient in organic flavors. Commercial availability would be best option. Relist and hope that the rule to apply commercial availability goes through. **Essentiality on scale of 1-10:** 10, critical.
- **Certified Handler Comment:** Used for flavor in cookies, fruit snacks and granola bars. Company certified for 20 years and selling products in all 50 states and Canada. We are using some organic flavors and continue to test more as they become available. We support OTA's recommendation to apply commercial availability requirements to natural flavors. Flavors are necessary in cookies, fruit snacks and granola bars in order to meet consumer expectations. **Essentiality on scale of 1-10:** 10, critical.
- **Certified Handler Comment:** In support of relisting. In 2014, we submitted comments in favor of relisting flavors on 205.605(a) with an annotation change to reflect that natural flavors should only be used when organic flavors are not commercially available. NOP has issued a proposed rule to this effect, but the rule has not yet been finalized. We do not recommend that the NOSB pursue further changes to this listing until this rule has been finalized and there is adequate time to observe

	<p>whether it is effective at encouraging the development of more high quality organic flavors. The allowance of flavors on 205.605(a) is of critical importance for the organic industry. Over the past decade we have seen improvement in the availability of organic flavors, and we have worked to utilize organic flavors where possible in our products. But we have found that there is still a great deal of variability in the quality and consistency of organic flavors. In some cases, such as vanilla, we find that we can consistently source high-quality organic vanilla and we do not need to explore non-organic options for this ingredient. However, most other organic flavors are not as well developed and in those cases we find that we cannot consistently create the flavor profile we are looking for without using some non-organic flavors. As we have noted in previous comments, better guidance from NOP on how commercial availability should be evaluated would help to ensure a consistent and more effective approach to compliance across the industry. The NOSB should urge the National Organic Program to prioritize action on the “Recommendation for establishment of Commercial Availability Criteria” issued by the NOSB in May of 2006, and issue proposed commercial availability guidance for public review and comment.</p>
Gellan gum	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> • Certified Handler Comment: Used as a stabilizer in plant based creamers, plant based beverages, dairy beverages. Company certified for over 30 years. Selling products in all states. We have done extensive research and have not found organic alternatives in the quality and quantity needed. If this material were removed from the NL we would no longer be able to make these products. The economic impact would be significant. Essentiality on scale of 1-10 is 10, critical. • Certified Handler Comment: Used as a thickener, emulsifier, and stabilizer in Non-Dairy Soy, Nut, and Coconut Milk. Company certified for 15 years. Selling products in over 40 states and Canada. There are few vegetarian alternatives that have the same properties as gellan gum. If this material were removed from the NL it would impact the product quality and texture would be negatively impacted. The economic impact would be significant. Essentiality on scale of 1-10 is 7. • Certified Handler Comment: In instances where we use additional ingredients with our farmers’ products, we strive to use certified organic ingredients whenever possible, and strictly limit the use of approved non-synthetics or synthetics to meet consumer expectations for the highest quality products. We have several products that include gellan gum; chocolate milk, eggnog, and soy beverages, protein shakes, and ultra-pasteurized heavy cream. Additionally, it could be used as an ingredient in future products. We have removed carrageenan from our products, replacing it with gellan gum for its properties as a stabilizer that suspends particles and acts as a thickening agent. Gellan gum provides a comparable alternative in body and flavor to current consumer expectations of product performance. • Certified Handler Comment: We support the continuance of Gellan Gum on the National List. Used in our YoKids Squeezers. In this product Gellan Gum replaces carrageenan, which we removed from our products in response to consumer concerns. Our R&D team spent a considerable amount of time and effort searching for a replacement for carrageenan, which has a unique functionality. Gellan Gum remains the only possible substitute for carrageenan in our products, and if it were removed from the list it is likely that we would have to discontinue the product we use it in. Gellan gum is an essential ingredient because of its unique properties. Gels formed by high acyl gellan gum are relatively soft and elastic due to the presence of a high number of RCO functional groups, which prevent brittle gel formation due to excessive interaction with divalent cations. Because gels are strong, use in finished

	<p>levels are often lower than those for other gums, giving greater flexibility in formulation to deal with defects occurring during equilibration with the white mass in yogurt. It is important to note that various other properties, including stability to a wide range of pH and Brix levels, texture build and freeze-thaw stability cannot be matched by other ingredients available to us.</p>
Oxygen	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> No responses received
Potassium chloride	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> Certified Handler Comment: Used for fortification of Infant and toddler formula and snacks. Company certified for over 10 years. Selling products in all states. We have done extensive research and have not found organic alternatives in the quality and quantity needed. If this material were removed from the NL we would no longer be able to make these products. The economic impact would be significant. Essentiality on scale of 1-10 is 10, critical. Certified Handler Comment: Used for sodium reduction in soup for health purposes. Company certified for 20 years and selling products in all 50 states and Canada. Sodium reduction in prepared foods is a continued focus by our company, FDA, and other health and consumer advocacy groups. Potassium Chloride (aka Potassium Salt) should be allowed in organic products as a salt substitute. Essentiality on scale of 1-10: 5. <p>2017 Sunset Comments</p> <p>Handler Comments: Company responding has been certified for up to 15 years. Used in Cheese and Cheese and Dairy-Based Powders. Finished products that contain our ingredients are sold in all U.S. states and around the world. This input functions as a salt replacer. The loss of this material would limit our ability to make reduced sodium products and would likely eliminate the line altogether. This input is essential in organic processing due to the lack of an alternative.</p>

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

Substance	Survey Information
Alginates	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> Certified Handler Comment: Used in juices and jams as a thickener. Company certified for 20+ years. Selling productions nationwide and international. There are no other alternatives. We have conducted research both on alternative materials as well as management practices. If we were no longer allowed to use this material it would lower the quality and appeal of the product to the consumer and this would result in the loss of sales. On an essentiality scale of 1 to 10 we rate this material as “8.” Certified Handler Comment: Used as texture agent; allows for a smooth, creamy cheese sauce that melts uniformly. Company certified for 20 years and selling products in all 50 states and Canada. This material is essential. Cheese Sauce texture would not be optimal and unacceptable to our consumers. Essentiality on scale of 1-10: 8.
Calcium hydroxide	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> Certified Handler Comment: Used for fortification in Infant formula. Certified

	<p>for Over 10 years. Selling products in all states. We have yet to find a suitable organic alternative. If this material is removed from the NL we will no longer make the products.</p> <p>2017 Sunset Comments Handler Comments: Calcium hydroxide/lime has been used for centuries to dissolve the pericarp (outer coating) of corn to improve its ability to stick together. This processing allows the manufacture of corn tortillas. Excess calcium hydroxide is removed from the corn in the process, leaving only a small residual of calcium. Calcium hydroxide is also used by a few of our suppliers to assist in removing impurities from solutions. For example, calcium hydroxide can be used in the manufacture of cane juice to coagulate proteins and removed unwanted carbohydrates.</p>
Ethylene	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> • Certified Handler Comment: We purchase ingredients that may use this as a processing aid for fruit ripening. Company certified for over 20 years. Products are sold nationwide and we export. We are not aware of any alternative materials that provide the same function. We purchase the ingredients so we have not conducted research on alternative materials or methods. Inconsistent ripening would result is product loss and quality issues. Increased ingredient costs would result in increased product cost to the consumer. Ethylene is essential, rates 10 on scale of 1 to 10. <p>2017 Sunset Comments Handler Comment: We make organic pineapple juice. Certified for 18 years. Selling nationwide and exporting. Used for the ripening of pineapples. There will not be any organic pineapple juice in the quality and quantity that we need if ethylene is removed from the national list. This material is essential for ripening of citrus. We would not have enough supply to produce organic juice. We would loose sales and go out of business. Handler Comment: Used for ripening bananas, to ripen bananas for processing into puree or for dehydrating. Certified for 19 years. Selling products in most states in USA and is an ingredient in Stonyfield Farm Yogurt. Also sold to Switzerland and European Union. We have ripened naturally. Very time-consuming. We're not aware of any alternatives. It allows efficient ripening. Loss of this material would greatly increase waste and loss, and increase labor costs. It's critical to our business. Handler Comment: Production of organic banana puree. Used to ripen bananas. Certified for two years. Located in Costa Rica and selling products to USA and Europe. Not aware of any alternative materials. Without this material, the quality of our products and business would be highly affected. This operation cannot be done without ethylene. It's critical to our business.</p>
Glycerides (mono & di)	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> • No responses received <p>2017 Sunset Comments Handler Comments: Mono- and diglycerides are used in drum drying of certain ingredients such as potato flakes. It prevents the potatoes from sticking to the drum. Potato flakes have unique water absorption properties due to their surface area. For this reason, drum-dried potato flakes are a preferred source for water-binding function.</p>
Magnesium Stearate	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> • No responses received

Phosphoric acid	<p><u>2020 Sunset Comments</u></p> <ul style="list-style-type: none"> • Certified Handler Comment: Used as a sanitizer on processing lines in manufacturing plants. Company certified for 30 years. Products are sold in all states. Phosphoric acid is critical. There are no other alternatives. Essentiality is a 10 on a scale of 1 to 10. <p><u>2017 Sunset Comments</u></p> <p>Handler Comments: Phosphoric acid is used in sanitation of food contact surfaces and food equipment. This cleaning is critical in our food safety program. No residual remains that could contaminate the food.</p>
Potassium Carbonate	<p><u>2020 Sunset Comments</u></p> <ul style="list-style-type: none"> • Certified Handler Comment: Used as a Sodium reduction agent for chips. Company certified for 20 years. Selling products throughout the USA. We are not aware of any alternatives. If this material were removed from the NL it would increase sodium content of products by approximately 18%. Sodium content reduction is important for our consumers regarding both market appeal and consumer well being. Essentiality on scale of 1-10: 7
Sulfur Dioxide	<p><u>2020 Sunset Comments</u></p> <ul style="list-style-type: none"> • Importer Comment: Used in products labeled as “made with” and used as a stabilizer and preservative to avoid bacterial spoilage and oxidation. We import Wine Made with Organic Grapes from Europe to the US. ALL other countries allow this substance in their Organic Wines. There are no and have been no more natural alternatives. SO2 is a natural product of Sulfur. It is an allowed synthetic only in “made with.” We have conducted research on the use of wines without SO2. Wines are less stable without this, particularly white, sparkling and rose wines. If this material were removed from the NL there would be an immediate lowering of quality and end of sales in US. Total loss of business as it now exists. Essentiality on scale of 1-10: 10 – critical • Distributor Comment: Used in products labeled as “made with.” Sulfites are a preservative that allow wine to age. We distribute Wine Made with Organic Grapes only in CA. We’re not aware of any alternatives. If wines using sulfites under 100ppm no longer qualified for the "made with organic grapes" label it would significantly impact marketability, in that, consumers would have an even harder time identifying wines made with organically farmed grapes, thereby negatively impacting producers who are choosing to farm organically but whom are using sulfites in their winemaking process. Wine grapes are the most treated crops on the planet so we do not want to punish grape growers who are making the commitment to farm organically by giving them less consumer visibility. By allowing organic vintners who choose to use sulfites to benefit from organic labeling we reward them for keeping much more harmful pesticides/herbicides/chemicals out of our environment. We have a hard enough time educating our retailers on the differences between USDA Organic wines, Made with Organic Grape wines, Ingredients: Organic Grapes, Biodynamic, etc., etc. The levels of "organic," when it comes to wine, is confusing enough for consumers to decipher, and this change would add yet another layer, likely negatively impacting sales of our current "made with organic grapes." Essentiality on scale of 1-10: 10 – critical • Comment: Used in wine labeled “made with organic grapes” provided that the total sulfite concentration does not exceed 100 ppm and is used to prevent

	<p>spoilage of wine and to retain color. We represent several certified organic wineries that have had certification for varying timeframes, but we have been in business for 25 years. Our wineries are located throughout California, Oregon and Washington as well as in Europe, Chile, Argentina and Australia. There are limited if any available organic replacements. I believe that this is the most commonly used ingredient for prevention of spoilage of wine. There are varying degrees to which this is used in winemaking but I do not think that it can be eliminated overall. Loss of this material from the National List would give little benefit to wineries that have built their brand and message on being "Made With Organic Grapes." Essentiality on scale of 1-10: 10 – critical</p> <p>2017 Sunset Comments</p> <p>Handler Comments: Used as a stabilizer in wine, though Sulfur Dioxide has a number of important functions in winemaking. Made with Organic Grapes Wines. Certified for 6 years. Our products are sold in all 50 states, and are exported to other countries. There are no alternatives that perform the same functions as Sulfur Dioxide. The stability of wines made with added Sulfur Dioxide (Sulfites) is much greater than those made without Sulfur Dioxide. Those without Sulfur Dioxide have a very short shelf life, which is not desirable in wines. These other wines compare very poorly to wines made with Sulfur Dioxide when compared in blind taste tests. Sulfur Dioxide has been used for hundreds of years because it is effective in maintaining wine quality. This would effectively end our participation in the Organic business. We have certified hundreds of acres as Organic, and have certified three of our winery facilities as organic. Wines made without Sulfur Dioxide would not be commercially acceptable, in our opinion. Essential on scale of 1-10: 10 Critical – to our business and to NOP certified “made with” wine.</p> <p>Handler Comment: Used as an antimicrobial/antioxidant in “made with” certified wine. Certified for 15 years. Products are sold nationwide, and exported globally to many countries including Canada, the EU, and Japan. SO2 is the most effective tool available to organic winemakers to inhibit undesirable microbial growth in wine. It is also an antioxidant, especially in white wine, ensuing it stays fresh. There are no organic or natural sources of SO2. We are not aware of any equivalent organic inputs that can achieve the same result. No, there are no alternative management practices. Barrels are an essential part of our wine making practices, and cannot be managed for spoilage microbes without SO2. If this material were removed from the NL the shelf life of our products would decrease = inability to compete with international organic wines that allow the use of SO2. Devastating to brand quality and longevity. Essentiality on scale of 1-10: 10 Critical – to our business and to NOP certified “made with” wine.</p>
Xanthan gum	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> • Certified Handler Comment: Used as a stabilizer, emulsifier, binder, thickener, and gelling agent in a wide array of products. Certified for 15 years and selling products nationwide & in Canada. There are no alternatives that have the same multi-faceted technical effect as xanthan gum. We source and prefer organic alternatives whenever possible. If the material were removed the quality and texture of our products would be impaired and would result in significant economic effects to our company. 10 for essentiality. Critical – to our business. • Certified Handler Comment: Used as a thickener in juices, jams and jellies. Company certified for 20+ years. National & sales. 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 xanthan gum is specific for its intended use. Other gums do not work. Our spec sheets do not list the use of any ancillary substances. Loss of this material from the National List would result in lower quality resulting in loss of sales. On an essentiality scale of 1 to 10 gums are critical.

- **Certified Handler Comment:** Used as a thickener that helps stabilize the emulsion. Company certified for 20 years and selling products in all 50 states and Canada. We have tried other thickeners, but none have been able to deliver an emulsion that works through shelf life, shipping and distribution. This material is essential. Without it, separation is visible through the bottle so consumers will not purchase it at the stores and customers will reject the products. **Essentiality on scale of 1-10: 10.**

2017 Sunset Comments

Handler Comment: Used as a thickener in organic juice and fruit spreads Certified for 18 years and selling products nationwide. Unaware of an alternative that works. If the material were removed we would not produce some products.

Handler Comment: We utilize xanthan gum in organic dry dip and dressing mixes as a thickener. Certified for over 20 years and selling products across U.S. and Canada. There are no organic alternatives for xanthan gum. Other organic gums are available, but they do not provide the same function as xanthan in our application. There are no alternative management practices that would eliminate the need for the specific substance. If we were no longer allowed to use it, the products that the xanthan gum go into would need to be discontinued as other products are not available that would perform the same function. Sales for the last 12 months of products that utilize xanthan gum are roughly \$585,000. This would be a significant impact to our business. Critical to making our organic products.

Handler Comment: Used in organic frostings and cake mixes, cake and cookie mixes, beverages, soups, and frozen entrees and in juice and fruit spreads. Functions as a thickener and stabilizer. Sold throughout the U.S. Other gums and thickeners do not have comparable function. Alternatives don't work as well. The specification sheets do not list ancillary substances except for organic guar gum. The loss of this input from the National List would result in loss of sales due to decreased quality and marketability. We would cease to exist due to massive recall of products labeled organic. Eliminates our entire value proposition (organic). Would not be able to market as organic. Essential to all companies that responded.

Handler Comment: Used in cake and cooking mixes, beverages, soups and frozen entrees as a thickener and stabilizer. Company has been certified for over 15 years. Sold in 50 states and other countries. Other gums and thickeners do not have comparable function. Researched alternatives but they do not have a comparable function. Loss of this product would lead to decreased quality and marketability of our products.

Handler Comment: Thickening agent in juice and fruit spreads. Certified for 13 years. Products are sold throughout U.S. and Canada. Xanthan has a specific form needed. There are no other alternatives that work. Loss of this product would lead to loss of sales.

Handler Comment: Stabilizer and thickener in creams and lotions. Certified for 9 years. Our products are sold in 50 states and 7 countries. There are no alternatives with the same quality and function. Cellulose can work but it's not as effective.

Handler Comment: Ancillary Substances: None known, none listed on the specification sheet. For mixed blends, organic guar gum is used.

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:



March 19, 2018

Robert Pooler
National Organic Program, Standards Division
USDA-AMS-NOP
1400 Independence Avenue, SW
Room 2642-So., Ag Stop 0268
Washington, DC 20250-0268

Docket: AMS-NOP-14-0079

RE: Proposed Rule; Amendments to the National List of Allowed and Prohibited Substances (Crops, Livestock and Handling) – Natural Flavors

Dear Mr. Pooler:

Thank you for this opportunity to provide comment on several amendments to the National List of Allowed and Prohibited Substances (National List) as recommended to the Secretary of Agriculture (Secretary) by the National Organic Standards Board (NOSB). This comment focuses on the proposed amendment to Natural Flavors. We have submitted a separate set of comments addressing the complete list of proposed changes.

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.

Summary

The Organic Trade Association supports the judicious use of materials that have been added to the National List due to their necessity in a certain organic production system or due to their essential function in an organic processed product or organic handling system. We also strongly support the critical role of NOSB and its responsibility to ensure that materials added to or removed from the National List meet the criteria of the Organic Foods Production Act (OFPA) and USDA's organic regulations (7 CFR 205). Specifically, materials should be added or remain on the National List if: 1) they are necessary 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).

Except for our requested adjustment to the annotation for Natural Flavors, the Organic Trade Association supports the NOSB recommendations that informed this proposed rule. In all instances where this proposed rule will change the use restriction for materials on the National List, we request that a 12-month implementation period be provided from the date the final rule is published. Regardless of the

extensive review and comment period provided prior to and during the NOSB meetings, OTA remains realistic about our ability to reach every single organic certificate holder. Many certified operators may be unaware of the NOSB recommendations and this proposed rule, and they will not become aware of the changes until a final rule is released and they are notified of the change by their certifier.

OTA requests the following changes be made and reflected in the final rule:

- **The requirement to use organic flavors when commercially available applies only to products labeled as “ORGANIC”:** The Organic Trade Association strongly supports applying commercial availability to natural flavors on § 205.605 of the National List. However, the proposed change to require the use of organic flavors when commercial available should only apply to products labeled as “organic.” The Organic Trade Association’s petition to require the use of organic flavors when they are commercially available was explicitly intended to apply to products labeled as “organic” only since commercial availability does not apply to the “made with organic” label category (see **Appendix A and B**). The proposed rule erroneously applies this change to both “organic” and “made with” products.
- **1-Year Implementation Period:** To allow industry adequate time to comply with the changes, we respectfully request a 12-month implementation period be provided from the date the final rule is published to accommodate the changes proposed under this rule.

OTA also requests that NOP issue guidance on Commercial Availability Criteria:

- Given the proposed amendments for natural flavors, glycerin, and carnauba wax that will require the use of organic forms when they are *commercially available*, OTA urges NOP to act on the recommendation that NOSB passed in November 2007 titled “Further Guidance on the Establishment of Commercial Availability Criteria” (**Appendix C**). The recommendation provided broader clarifications to the terms of commercial availability for use by certifying agents and the organic industry at large. To date, NOP has not acted on this important recommendation. In the fall of 2005, NOSB passed a recommendation for guidance on commercial availability of seed. NOP did, in fact, act on this recommendation and final guidance became effective on March 4, 2013. To improve the clarity, quality and consistency of the process for determining and verifying commercial availability in organic processed products, OTA requests that NOP prioritize action on the 2007 recommendation and release proposed guidance for public review and comment.

We offer the following more detailed comments:

The National Organic Program (NOP) is proposing to revise the annotation for flavors listed at §205.605(s) to read as follows (new language underlined):

“Non-synthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.”

The Organic Trade Association has long advocated for the use and further development of organic flavors. Currently, there is no requirement to use organic flavors; all use is voluntary. In response to the

growing number of organic flavors available in the marketplace, we submitted a petition in 2014 to revise the current listing of Flavors on the National List to require organic flavors to be used in products labeled as “organic” when they are commercially available in the necessary quality, quantity or form. We continue to believe this regulatory change is consistent with the intent of the law, and therefore strongly support NOP’s proposal to revise the annotation for the listing of natural flavors at §205.605 of the National List. As an important point of clarification, the Organic Trade Association did not intend for the annotation change to apply to products labeled as “made with organic specified ingredients or food group(s).” As clearly articulated in our petition and in our comments to NOSB (**Appendix A and B**), natural flavors used in the 30% of a “made with” product should continue to be allowed provided they are non-synthetic, non-GMO and made without the use of synthetic solvents, carriers and artificial preservatives. The annotation we suggested in our petition submitted on November 6, 2014, is as follows:

Flavors – Non-synthetic flavors may be used in products labeled as “organic” when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

As explained to us at the time NOSB drafted its recommendation, the Handling Subcommittee removed the phrase “in products labeled as organic” because it would appear that natural flavors, in general, are only *allowed* in “organic” products. We believe NOSB’s revision to our suggested language resulted in the following explanation in this proposed rule, that could unfortunately be read as a requirement to use organic flavors in “made with” products when commercially available:

Pg. 63 (Proposed Rule AMS-NOP-14-0079): “In addition, the NOSB recommended a revision to convey that the listing for flavors applies to products in the “organic” and “made with organic (specified ingredients or food group(s))” categories.”

The Organic Trade Association respectfully requests that the intent of our petition be clearly conveyed in the final rule. This clarification would maintain the regulatory status quo for all non-agricultural and agricultural ingredients allowed in the 30% of the “made with” label category.

With this one important correction in mind, the Organic Trade Association continues to express our strong belief that the organic flavor supply has grown to a size where it is no longer appropriate to allow the use of non-organic natural flavors when organic forms may be commercially available. At the same time, the number of available certified organic flavors is not sufficient to completely meet the current needs of the marketplace, given the numerous and different types and forms used by the organic sector. Natural flavors must remain on the National List, but additional requirements to source organic are warranted. As proposed in this rule, the insertion of a commercial availability clause into the annotation on natural flavors not only strikes the right balance and moves the organic sector in a positive direction, it supports the vision of the early NOSB that originally recommended the allowance of natural flavors in organic products provided organic forms were not available.

Since the first recommendation by NOSB to include the use of natural flavors in organic foods in 1995, there has been the expectation that over time, manufacturers would begin to produce certified organic flavors and efforts would be made to support the use and development of organic flavors. In 2007, NOP recognized that Accredited Certifying Agents (ACAs) were certifying flavors and that over time there

would be more sources. Below are the results of a survey conducted by ACAs in 2011:

3. Indicate the number of natural flavors you certify under the following categories:								
Natural Flavor 11 responses	Extracts 11 responses	Essential Oils 11 responses	Distillates 9 responses	Oleoresin 7 responses	Essence 9 responses	Powders 9 responses	Emulsions 8 responses	Other 7 responses
TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
1,978	964	1,341	125	33	112	177	12	26

The 2011 survey also reported that 157 companies were being certified at the time. A similar survey was conducted in September 2014 with the following results:

3. Indicate the number of natural flavors you certify under the following categories:									
Natural Flavor (Compounded flavor) 5 responses	Natural Flavor (WONF) 7 responses	Extracts 6 responses	Essential Oils 5 responses	Distillates 4 responses	Oleoresin 5 responses	Essence 4 responses	Powders 5 responses	Emulsions 4 responses	Other 2 responses
TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
2,146	405	272	1,645	4	18	33	254	19	0

This survey reported that 189 companies are being certified at this time. However, since there were fewer responses submitted than in the 2011 survey, this number may be significantly higher.

When flavors were initially included on the National List, the number of flavor compounds comprising natural flavors was estimated to number up to 100 or more. There were no known companies making organic flavors at that time. The data from the ACA surveys demonstrate that these numbers have grown substantially, not only for natural flavors in general, but certainly for certified organic flavors.

During the NOSB 2012 Sunset Review, in response to public comments, NOSB acknowledged the evolution of the organic flavor industry and the investment in further developing organic alternatives. At that time, NOSB stated on record that it could envision a time when flavors would not need to be listed. NOSB also communicated its belief in the final Sunset recommendation that *“the full category should not be relisted in five years when next reviewed for sunset.”*

Although we are not at a point where complete removal of natural flavors from the National List is appropriate, a requirement to use organic flavors when they are commercially available will require companies currently using non-organic flavors to start sourcing organic flavors to find out if they are available and if they meet the requirements of their products in the quantity, quality and form needed. This research and sourcing process married with a requirement to use organic flavors when they are commercially available will further stimulate the development of organic flavors, which, in turn, will increase the supply. Flavor manufacturers will be able to enter into the organic arena with confidence that their organic flavors must be used if they meet the necessary quality, quantity and form of the end-user product.

Revising the annotation on natural flavors to require organic forms when commercially available meets the intent of the law. It is time that the organic sector supports continuous improvement by requiring the use of organic flavors in products labeled “organic” when commercially available. As with any change that places additional requirements on certified operators, we acknowledge the inherent challenges and resources that will be involved. We recognize that certified companies, including certified flavor manufacturers, will need to increase the time and resources spent on sourcing organic flavors. We also recognize that certifying agents will need to spend more time and resources verifying the commercial availability claims made by operators unable to find organic flavors. Given the existing and growing supply of organic flavors, the Organic Trade Association does not believe the organic sector can afford to continue its business without including some requirement to use organic flavors. We understand there will be work involved, but we also believe that the organic sector must embrace the supply of organic flavors and determine if they are available in sufficient quantity, quality and form.

The Organic Trade Association is not requesting that natural flavors be removed from the National List. We recognize that organic flavors are not available in sufficient quantity, quality and form to satisfy the current demand for all applications, therefore the allowance to use natural flavors when organic alternatives do not exist must continue. The Organic Trade Association’s requested change, as proposed by this rule, will provide organic food producers and flavor manufacturers with the flexibility and time to source and research the existing supply of organic flavors and decide whether they meet the quantity and functionality needed to meet customer and consumer expectation.

Formal guidance from NOP is needed on commercial availability practices

OTA recognizes the need to improve the quality and consistency of the verification process for determining commercial availability. The ultimate success of this rule change will partly rely on the success of the certification process and certifier due diligence in verifying commercial availability claims. It will also rely on certified operators developing and following a clear plan for sourcing and determining the commercial availability of organic flavors (as submitted and agreed upon in the Organic Systems Plan) and certifiers making sound and sensible decisions accordingly. OTA believes that certifiers and certified operations are doing a good job on this front, but there is significant room for improvement. There is a need for guidance and training that would bring about a better understanding of commercial availability criteria (quantity, quality and form) and the documentation needed to support commercial availability claims. This would result in greater consistency in practice between one certifier to the next and throughout the organic industry as a whole.

In November of 2007, NOSB passed a titled “Further Guidance on the Establishment of Commercial Availability Criteria” (**Appendix C**). The recommendation provided broader clarifications to the terms of commercial availability for use by certifying agents and the organic industry at large. To date, NOP has not acted on this important recommendation. In the fall of 2005, NOSB passed a recommendation for guidance on commercial availability of seed. NOP did, in fact, act on this recommendation and final guidance became effective on March 4, 2013. To improve the clarity, quality and consistency of the process for determining and verifying commercial availability in organic processed products, OTA requests that NOP prioritize action on the 2007 recommendation and release proposed guidance for public review and comment as soon as possible.

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

Respectfully submitted,



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

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendices:

- **Appendix A:** Organic Trade Association's 2014: "Petition to amend the annotation to Natural Flavors on 205.605(a)"
- **Appendix B:** Organic Trade Association's 2015 comment to NOSB Handling Subcommittee on petition to revise the annotation for Natural Flavors
- **Appendix C:** National Organic Standards Board, Handling Committee - Recommendation for the Establishment of Commercial Availability Criteria

November 6, 2014

National List Manager
USDA/AMS/NOP, Standards Division
1400 Independence Ave. SW
Room 2648-So., Ag Stop 0268
Washington, DC 20250-0268

Re: Petition to amend the annotation to Flavors on the National List as a non-agricultural (non-organic) substance allowed in or on processed products labeled as “organic or “made with organic (specified ingredient),” at §205.605(a).

Dear National List Manager:

Please accept the attached petition to revise the current listing of Flavors on the National List to require organic flavors to be used in products labeled as “organic” when they are commercially available in the necessary quality, quantity or form. The proposed change is as follows (changes in red):

Flavors – Non-synthetic flavors may be used in products labeled as “organic” when organic flavors are not commercially available. All flavors must be derived from organic or non-synthetic sources only, and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

Natural flavors appear on the National List as a broad category listing, therefore many different natural forms are allowed. Examples include extracts, oleoresins, essential oils, compounded flavors, and distillates. OTA believes that the number of certified organic flavors currently in the marketplace is substantial. However the number of available certified organic flavors is not sufficient to meet the current needs of the marketplace, given the numerous and different types and forms used by the organic sector. Currently, there is no requirement to use organic flavors; all use is voluntary at this time.

In order to further the use and development of organic flavors, OTA is submitting this petition to revise the current listing of Flavors to require organic flavors in products labeled “organic” when they are commercially available in the necessary quality, quantity or form.

Historically, commercial availability only applied to § 205.606. However, moving Flavors from §205.605 to § 205.606 would cause a significant disruption to the industry. The complexity of such a broad category and the significant number of distinctly different natural flavor makes it impractical to individually list flavors on the National List. This was acknowledged by the NOSB at both Sunset Reviews.

Furthermore, the NOSB on October 28, 2010 applied the concept of commercial availability to yeast, listed on § 205.605(a), when used as a food or fermentation agent in products labeled as “organic.” And on February 11, 2010, a petition was submitted to NOSB to remove silicon dioxide from §205.605(b) because rice hulls can serve as an alternative. The final decision by the board on December 2, 2011 was to add an annotation for Silicon dioxide stating “Permitted as a defoamer. Allowed for other uses when organic rice hulls are not

commercially available.” In both these cases, the NOSB recognized that organic alternatives had been developed and were available for use although not sufficiently available. Through the decisions to extend the concept of commercial availability to non-agricultural nonsynthetic, as well as agricultural, materials, the NOSB has encouraged the organic sector to continuously increase its use of organic ingredients and to invest in the development of organic alternatives to other substances or ingredients used in organic handling operations.

OTA is requesting that the NOSB again encourage and support continuous improvement by mandating the use of organic flavors when commercially available.

Thank you for your assistance in putting this petition before the NOSB. If you need any additional information, please contact me via email or telephone: gwyard@ota.com or (503) 798-3294.

Respectfully submitted,



Gwendolyn Wyard
Regulatory Director of Organic Standards and Food Safety
Organic Trade Association (OTA)

CC: Laura Batcha, Executive Director / CEO, OTA

October 7, 2015

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-15-0037

RE: Handling Subcommittee –Petition to revise the annotation for Natural Flavors on 205.605(a)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board (NOSB) on the petition to require the use of organic flavors when they are commercially available.

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 organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect the growth of organic trade to benefit the environment, farmers, the public and the economy.

Summary

OTA has long advocated for the use and development of organic flavors. In the current listing for "Flavors" on §205.605(a) as a broad category allowance, commercial availability¹ does not apply, and there is no requirement that organic alternatives be used when available. All use of organic flavors is voluntary. We believe the organic flavor supply has grown to a size where it is no longer appropriate to simply allow the use of non-organic natural flavors when organic forms may be commercially available. At the same time, the number of available certified organic flavors is not sufficient to completely meet the current needs of the marketplace, given the numerous and different types and forms used by the organic sector.

In order to further the use and development of organic flavors, OTA submitted a petition to revise the listing of natural flavors on § 205.605 of the National List to require the use of organic flavors in products labeled "organic" when the flavors are commercially available in the necessary quality, quantity or form. We are not requesting that commercial availability be applied to natural flavors used in "made with organic X" products. Natural flavors used in the 30% of a "made with" product would continue to be allowed provided they are non-synthetic, non-GMO and made without the use of synthetic solvents, carriers and artificial preservatives.

¹ *Commercially available.* The ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling, as determined by the certifying agent in the course of reviewing the organic plan.

Since the first recommendation by NOSB to include the use of Natural Flavors in organic foods in 1995, there has been the expectation that over time, manufacturers would begin to produce certified organic flavors, and efforts would be made to support the use and development of organic flavors. In 2007, the National Organic Program (NOP) recognized that Accredited Certifying Agents (ACAs) were certifying flavors and that over time there would be more sources. During the NOSB 2012 Sunset Review, in response to public comments, NOSB acknowledged the evolution of the organic flavor industry and the investment in further developing organic alternatives. At that time, NOSB stated on record that it could envision a time when flavors would not need to be listed. NOSB also communicated its belief in the final Sunset recommendation that *“the full category should not be relisted in five years when next reviewed for sunset.”*

OTA, through the work of its Flavor Task Force formed in 2010 by the request of NOSB, has conducted extensive outreach to organic stakeholders including flavor manufacturers (organic and natural), certifying agents, organic manufacturers using flavors (organic and natural), and suppliers of minor ingredients used in natural and organic flavors. We received widespread support for the submission of our petition, and we continue to receive positive feedback for moving forward.

As with any change that places additional organic requirements on certified operators, we acknowledge the inherent challenges and additional resources that will be involved. We recognize that certified companies, including certified flavor manufacturers will need to increase the time and resources spent on sourcing organic flavors. We also recognize that certifying agents will need to spend more time and resources verifying the commercial availability claims made by operators unable to find organic flavors. Given the growing supply of organic flavors and the roughly **180 certified flavor** companies in business at this time, OTA does not believe the organic sector can afford to continue its business without including some requirement to use organic flavors. We believe that that the organic sector must embrace the growth challenges we’ve mentioned and move forward.

Revising the annotation on natural flavors is the right thing to do. OTA is requesting that NOSB and the organic sector at-large encourage and support continuous improvement by mandating the use of organic flavors in products labeled “organic” when commercially available.

We offer our more detailed comments:

The Supply of Organic Flavors

Natural flavors appear on the National List as a broad category listing. Therefore, many different natural forms are allowed. Examples include extracts, oleoresins, essential oils, compounded flavors, and distillates. The types of flavors allowed must be consistent with the FDA definition of “natural flavors” codified in 21 CFR 101.22².

² **21 CFR 101.22 Foods; labeling of spices, flavorings, colorings and chemical preservatives.**

The term natural flavor or natural flavoring means the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate, or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products, or fermentation products thereof, whose significant function in food is flavoring rather than nutritional.

Even though organic certification of natural flavors is not required, many operators have voluntarily chosen certification because of the great demand by consumers. Below are the results of a survey of ACAs by The Accredited Certifiers Association Inc. in 2011. (See Appendix A for an explanation of the following categories.)

3. Indicate the number of natural flavors you certify under the following categories:								
Natural Flavor 11 responses	Extracts 11 responses	Essential Oils 11 responses	Distillates 9 responses	Oleoresin 7 responses	Essence 9 responses	Powders 9 responses	Emulsions 8 responses	Other 7 responses
TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
1,978	964	1,341	125	33	112	177	12	26

This survey also reported that 157 companies were being certified at the time. The actual number may be even higher. A similar survey was sent in September 2014 with the following results:

3. Indicate the number of natural flavors you certify under the following categories:									
Natural Flavor (Compounded flavor) 5 responses	Natural Flavor (WONF) 7 responses	Extracts 6 responses	Essential Oils 5 responses	Distillates 4 responses	Oleoresin 5 responses	Essence 4 responses	Powders 5 responses	Emulsions 4 responses	Other 2 responses
TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL	TOTAL
2,146	405	272	1,645	4	18	33	254	19	0

This survey reported that 189 companies are being certified at this time. However, since there were fewer responses submitted than in the 2011 survey, this number may be significantly higher.

When flavors were initially included on the National List, the number of flavor compounds comprising natural flavors was estimated number up to 100 or more. There were no known companies making organic flavors at that time. The data from the ACA surveys demonstrate that these numbers have grown substantially, not only for natural flavors in general, but certainly for certified organic flavors.

Commercial Availability of Organic Flavors

Applying commercial availability to flavors is largely consistent with the original 1995 NOSB Recommendation (see Appendix B) to make efforts toward the ultimate production of an organic natural flavor, and it will satisfy NOSB’s 2012 Sunset Review statement that *“the full category should not be relisted in five years when next reviewed for sunset.”*

A review of the ACA survey results as well as a quick run down the aisles at an organic foods grocery store reveals that the number of certified organic flavors currently in the marketplace is substantial. Applying commercial availability to natural flavors would be a **significant step in the right direction** and it would lay the critical foundation to build upon for the next Sunset Review. A requirement to use organic flavors when they are available will require companies currently using non-organic flavors to start sourcing organic flavors to find out if they meet the requirements of their products in the quantity, quality and form needed. This research and sourcing process married with a requirement to use organic flavors when they are commercially available will further stimulate the development of organic flavors, which, in

turn, will increase the supply. Flavor manufacturers will be able to enter into the organic arena with confidence that their organic flavors must be used if they meet the necessary quality, quantity and form of the end-user product.

Take for example peppermint extract. Currently, a certified operator can use **non-organic** peppermint extract without any requirement to explore an organic form let alone use it. Organic peppermint extract is made using organic alcohol and organic peppermint. The product is not complex and organic forms are readily available. The commercial search and documentation process between a certified operator and its certifier in this case would be fairly straight-forward. A complex flavor on the other hand, such as a compounded natural strawberry flavor, would be much more difficult to source, and the documentation process for demonstrating its commercial availability status would be much more involved. None-the-less, organic natural strawberry flavor does exist and it could conceivably work in many different types of products. However, at this time, manufactures of certified organic products are not required to investigate its potential.

OTA is aware of the inherent problems associated with the commercial availability clause in the organic regulations, namely that it is a good effort process operating in a capitalistic supply and demand economy. It is understood, or at least expected, that if there is demand, the supply will come. But, if operators are not mandated to use an organic ingredient and can instead demonstrate that a flavor, for example, does not meet the quality or form they are looking for, then they can use the non-organic form rather than demanding an organic version. Commercial availability doesn't always work as well as it was intended! OTA recognizes the need to improve the rigor of the verification process for determining commercial availability, and we accept that a revision to the annotation won't create a perfect result. However, we strongly believe that it will move us in the right direction along the continuous improvement spectrum, and create enough change to help swing the pendulum more permanently in favor of organic flavors.

Retention of Flavors on 205.605 (a) with a requirement to use organic when available

OTA believes that it is appropriate to retain flavors on § 205.605 of the National List (listing for allowed non-agricultural substances) and apply commercial availability to the entire broad category listing. Certified operators will then work with their certifiers to determine the types of organic flavors available in the required quantity, quality and form. The process of parsing out and sourcing organic flavors is going to be a process best facilitated by ACAs.

Removing individual types of flavors such as simple flavor extracts or attempting to move some or all flavors from §205.605 to §205.606 would cause a significant disruption to the industry, and require resources NOP and NOSB simply do not have. First, the complexity of such a broad category listing makes it impractical to individually list flavors on the National List. This was acknowledged by NOSB at both previous Sunset Reviews. Second, if flavors as a broad category were moved to §205.606, then non-agricultural flavors would no longer be allowed according to the requirements for inclusion on §205.606: Non-organically produced agricultural products allowed as ingredients in or on processed products labeled as "organic."

Flavors are both agricultural and non-agricultural, and it would be extremely difficult to separate out the **literally thousands of flavors** into agricultural and non-agricultural categories. The OTA Flavor Task Force explored this option extensively and concluded that it was not a reasonable or practical approach. Also, some non-agricultural flavors can be produced organically because they are derived from or

produced using agricultural source material. Flavors produced via fermentation are a great example, and are analogous to yeast, which is used as a flavor as well and classified as non-agricultural. Several products of fermentation are classified as non-agricultural, yet they can be produced organically provided the agricultural source material is certified organic and all other ingredients and processing aids meet the NOP product composition requirements for labeling a product “organic.” Additionally, some flavors are derived from agricultural material but the isolated flavor component is classified as non-agricultural according to the current NOP definition of non-agricultural³. Again, similar to yeast, the “non-agricultural” distinction does not preclude the ability for the flavor to be certified organic due to the agricultural source material.

To consider to sunset some flavors but not others, or to move some to § 205.606 would be an arbitrary exercise that would take resources we do not have. NOSB as well as accredited certification agents would have to make thousands of determinations about which flavors were agricultural and allowed. This would be a time-consuming and costly endeavor that, at this time, would be done without final guidance from NOP on how to make agricultural and non-agricultural determinations. At the end of the day, certifiers and certified operators need only search for organic flavors and make determinations between organic and non-organic flavors.

Finally, precedent has been set for applying commercial availability to certain substances on 205.605. NOSB on October 28, 2010, applied the concept of commercial availability to yeast, listed on §205.605a, when used as a food or fermentation agent in products labeled as “organic.” And on February 11, 2010, a petition was submitted to NOSB to remove silicon dioxide from §205.605(b) because rice hulls can serve as an alternative. The final decision by NOSB on December 2, 2011, was to add an annotation for silicon dioxide stating, “Permitted as a defoamer. Allowed for other uses when organic rice hulls are not commercially available.” In both these cases, NOSB recognized that organic alternatives had been developed and were available for use although not sufficiently available. Through the decisions to extend the concept of commercial availability to non-agricultural non-synthetic (205.605(a), NOSB has encouraged the organic sector to continuously increase its use of organic ingredients and to invest in the development of organic alternatives to other substances or ingredients used in organic handling operations.

OTA is requesting that NOSB recognize the complexity of flavors and apply the precedent set with yeast and silicon dioxide, and again encourage and support continuous improvement by mandating the use of organic flavors when commercially available while retaining the broad category listing of flavors on §205.605a.

Formal guidance from NOP is needed on commercial availability practices

As mentioned earlier, OTA recognizes the need to improve the rigor of the verification process for determining commercial availability. If our petition is adopted and a rule change is made to require organic flavors when they are commercially available, the ultimate success of the rule change will partly

³ *Non-agricultural substance.* A substance that is not a product of agriculture, such as a mineral or a bacterial culture, that is used as an ingredient in an agricultural product. For the purposes of this part, a non-agricultural ingredient also includes any substance, such as gums, citric acid, or pectin, that is extracted from, isolated from, or a fraction of an agricultural product so that the identity of the agricultural product is unrecognizable in the extract, isolate, or fraction.

rely on the success of the certification process and certifier's due diligence in verifying commercial availability claims. OTA believes that many certifiers are doing an excellent job on this front, but there is room for improvement along with greater consistency in practice between one certifier to the next.

In May 2006, NOSB passed a "Recommendation for establishment of Commercial Availability Criteria" when making commercial availability decisions regarding the use of materials on 205.606. To date, NOP has not acted on this recommendation. In the fall of 2005, NOSB passed a recommendation for guidance on commercial availability of seed. NOP did, in fact, act on this recommendation and final guidance became effective on March 4, 2013. In favor of making the commercial availability clause function as it was intended in certified organic products, OTA requests that NOSB urge NOP to prioritize action on the 2006 recommendation and release proposed guidance for public review and comment.

Standardized questionnaire to verify compliance

During the spring 2015 NOSB comment period, NOSB asked the public if a standardized questionnaire on natural flavors would be helpful. OTA responded by saying that there **is** a Natural Flavor Questionnaire (Affidavit/Declaration) in use by several accredited certifiers. This questionnaire was developed by a group of certifiers with technical assistance from flavor manufactures and flavor chemists. It appears to be one of the most thorough affidavits in circulation. However, it may not be in use by all ACAs. **See Appendix C.** Although the use of this questionnaire is outside the scope of our petition, we believe its use is important for verifying the compliance of natural flavors used in organic products. It could also be revised to include questions about the commercial availability of organic flavors. Therefore, OTA requests that NOSB make a recommendation to NOP requesting that the flavor questionnaire be formally recognized and offered to ACAs in guidance as the standardized questionnaire to use.

In closing, we thank the Board for its time and commitment and for considering this timely and very important petition.

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

Respectfully submitted,



Gwendolyn Wyard
Senior Director of Regulatory and Technical Affairs
Organic Trade Association

cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Appendix A: Flavor Nomenclature – "Types of Flavors"

Appendix B

NATIONAL ORGANIC STANDARDS BOARD - FINAL RECOMMENDATION ADDENDUM NUMBER 14 THE USE OF NATURAL FLAVORS IN ORGANIC FOODS - Date adopted: October 31, 1995

Additionally, manufacturers shall provide written documentation in their Organic Handling Plan showing efforts made toward the ultimate production of an organic natural flavor as listed in the stepwise progression below:

Natural flavor constituents and non-synthetic carrier base and preservative agents (ex. grain ethanol, non-synthetic glycerin and non-synthetic acetic acid.).

Organic flavor constituents, organic carrier base, and organic preservative agents.

Organic flavor constituents extracted using organically produced solvents, organic carrier base, and organic preservative agents.

Appendix C: Natural Flavor Questionnaire

Note: Appendices are not attached

**FORMAL RECOMMENDATION BY THE
NATIONAL ORGANIC STANDARDS BOARD (NOSB)
TO THE NATIONAL ORGANIC PROGRAM (NOP)**

Date: November 30, 2007

Subject: Further Guidance on the Establishment of Commercial Availability Criteria

Chair: Andrea Caroe

(sign)

Recommendation

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement: XXXXXX

Other: _____

Statement of the Recommendation (including Recount of Vote):

The recommendation, as amended, proposes further standardized criteria to be used by NOSB, ACA's, and the organic industry when making commercial availability determinations for agricultural ingredients.

NOSB Vote:

Motion: Bea James

Second: Julie Weisman

Board Vote: Yes – 15

No – 0

Abstain – 0

Absent - 0

Rationale Supporting Recommendation (including consistency with OFPA and NOP):

§ 205.2 Commercial availability [defined] – the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling as determined by the certifying agent in the course of reviewing the organic plan.

§ 205.201(a) (2) “The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food groups (s))” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

* * * *

(2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of **commercial availability**, as applicable.”

Statutory Background

7 U.S.C. 6518:

Sec. 2119. **NATIONAL ORGANIC STANDARD BOARD.**

(k) Responsibilities of the Board.

(2) National List. The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 2118.

Response by the NOP:

In general agreement

**National Organic Standards Board
Certification and Accreditation Committee
Further Guidance on the Establishment of Commercial Availability Criteria**

November 30th, 2007

Introduction

In light of the June 9, 2005 court final order and judgment arising from *Harvey v. Johanns*, the NOSB was asked to review petition procedures for adding materials to § 205.606 of the National List. On September 12, 2006 the Handling Committee submitted a recommendation to the NOP for the establishment of commercial availability criteria. Although the recommendation establishes the process for establishing commercial availability in the petitioning process, the NOSB is proposing broader clarifications to the terms of commercial availability for use by certifying agents, and the organic industry at large.

Background

The ability for any person to petition to amend the National List is authorized by the OFPA (7 U.S.C. 6518(n)) and the NOP regulations, in § 205.607 *Amending the National List*. This authorization provides that any person may petition the NOSB for the purpose of handling a substance evaluated by the NOSB recommendation to the Secretary for inclusion on, or removal from, the National List. The NOSB is authorized to review petitions under specified evaluation criteria in OFPA (7U.S.C. 6518(m)), and forward recommendations for amending the National List to the Secretary. Since the NOP regulation became effective in October 2002, several petitions to include synthetic or non-synthetic substances in their respective sections of the National List have been reviewed by the NOSB.

§ 205.606 states “*Only the following nonorganically produced agricultural products may be used as ingredients in or on processed products labeled as “organic,” only in accordance with any restrictions specified in this section, and only when the product is not commercially available in organic form.*”

However, some producers, handlers, and certifiers may have misinterpreted § 205.606 to mean that any non-organic agricultural product which was determined by an accredited certifying agent to be not commercially available in organic form could be used in organic products, without being individually listed pursuant to the National List procedures.

In January 2005, the First Circuit decision in *Harvey v. Johanns* held that such a misinterpretation is contrary to the plain meaning of the OFPA and ordered that 7 CFR § 205.606 shall not be interpreted to create a blanket exemption to the National List requirements specified in §§6517 and 6518 of the OFPA (7 U.S.C. 6517-6518).

Consistent with the district court’s final judgment and order, dated June 9, 2005, on July 1, 2005, the NOP published a notice regarding §205.606 (70 FR 38090), and on June 7, 2006, the NOP published a Final Rule revising § 205.606 to clarify that the section shall be interpreted to permit the use of a non-organically produced agricultural product only when the product has been listed in § 205.606 pursuant to National List procedures, and when an accredited certifying agent has determined that the organic form of the agricultural product is not commercially available (71 FR 32803).

USDA was ordered to notice the content of this Declaratory Judgment and Order within 30 days in the published Federal Register and on the NOP web site, and remove all conflicting references and notify its certifying agents of the same. USDA-NOP complied with a Federal Register notice published on July 1, 2005 and on its web site.

On January 18, 2007 the NOP released 7 CFR Part 205 (Docket No. AMS-TM-06-0223; TM-06-12) *Notice of Guidelines on Procedures for Submitting National List Petitions*. This Federal Register Notice provides guidance on who may submit petitions, what substances may be petitioned and the information that is required to be included within a submitted petition. Additionally, this notice establishes some new commercial availability evaluation criteria that will be applied

during the petition review of non-organic agricultural substances for inclusion onto or removal from § 205.606 of the National List.

The Federal Register Notice was developed in collaboration with the NOP and based on the October 2006 NOSB recommendation on commercial availability which modified the information to be included in a petition to provide for the review of non-organic agricultural substances to be included onto § 205.606. Although the notice helped to clarify the information to be included for all types of petitions submitted to amend the National List, additional clarification on commercial availability is recommended for use by ACA's for the review of ingredients in specific organic system plans.

Regulatory Citations Background

§ 205.2 Commercial availability [defined] – the ability to obtain a production input in an appropriate form, quality, or quantity to fulfill an essential function in a system of organic production or handling as determined by the certifying agent in the course of reviewing the organic plan.

§ 205.201(a) (2) “The producer or handler of a production or handling operation, except as exempt or excluded under § 205.101, intending to sell, label, or represent agricultural products as “100 percent organic,” “organic,” or “made with organic (specified ingredients or food groups (s))” must develop an organic production or handling system plan that is agreed to by the producer or handler and an accredited certifying agent. An organic system plan must meet the requirements set forth in this section for organic production or handling. An organic production or handling system plan must include:

* * * *

(2) A list of each substance to be used as a production or handling input, indicating its composition, source, location(s) where it will be used, and documentation of **commercial availability**, as applicable.”

Statutory Background

7 U.S.C. 6518:

Sec. 2119. **NATIONAL ORGANIC STANDARD BOARD.**

(k) Responsibilities of the Board.

(2) **National List.** The Board shall develop the proposed National List or proposed amendments to the National List for submission to the Secretary in accordance with section 2118.

Discussion

The current petition procedures as required under § 205.606 and § 205.607 (b) for placing nonorganic agricultural substances or materials on the National List specifically as it relates to commercial availability are not adequate. As noted in the background portion of this document on January 18, 2007 the NOP released 7 CFR Part 205 (Docket No. AMS-TM-06-0223; TM-06-12) *Notice of Guidelines on Procedures for Submitting National List Petitions*. Although the Federal Register Notice gives further clarification on submitting information in a petition, further clarification is still needed for the industry at large. Evidence of this was revealed in the March 2007 NOSB meeting in which many petitions submitted for inclusion onto the National List were received by the NOP, but not all of these petitions were eligible for consideration. There were various reasons why many of the petitions did not contain sufficient information; including insufficient documentation of commercial availability.

The NOSB is recommending that the following additional guidance on commercial availability for use by the NOP to educate about and enforce the 606 review requirements of accredited certifying agents.

Additional consideration specifically on commercial availability of organic seed was considered in this guidance document. On March 21, 2001 the NOSB submitted response to questions on commercial availability of organic seed,

then on August 17, 2005 the NOSB submitted a formal recommendation to the NOP on commercial availability of organic seed, and finally during the October 2006 NOSB meeting the Crops Committee submitted a formal response to the public comment concerning the recommendation from the August 2005 commercial availability recommendation of organic seed. Public commenters have submitted serious concerns about the inconsistent efforts to source and organic seed by certified organic farmers and that the verification efforts of accredited certifying agents are inconsistently applied. One commenter reported that only 10% of the seed used on certified organic farms is organic. Organic seed has poses a particular issue regarding the determination of commercial availability primarily because petition procedure for 606 are for agricultural ingredients used in handling and not for petitioning for the use of non-organic seed. There is no requirement that farmers petition the NOSB to review and recommend the listing of varieties of seeds as commercially unavailable as organic. Therefore, the NOSB recommends evaluation of the above listed documents in order to improve the ability to enforce 205.204 as well as collaboration between the certification and accreditation, crops and livestock committees to review the above documents on seed and determine the process for enforcement of commercial availability of organic seed with a goal to present a recommendation at the spring 2008 NOSB meeting

The following recommendation below proposes further standardized criteria to be used by NOSB, ACA's, and the organic industry when making commercial availability determinations for agricultural ingredients..

Recommendation

A. NOSB and NOP role in review of commercial availability

In support of an ACA's role for determining commercial availability of a material the NOSB recommends that the NOP:

Implement training procedures and process to ACA's for protocol on determining commercial availability. Training should include a review of NOP's current and any new courses of action for determining commercial availability, as well as review of procedures for proactive steps that the applicant or certified operator takes to generate the organic form of commercially unavailable organic ingredients and materials.

B. ACA's role in determining commercial availability.

The ACA, in determining that an agricultural ingredient or material listed on § 205.606 is not commercially available in organic form, shall:

1. Evaluate the applicant or certified operator's documented claim that no organic substitutes of the ingredients or materials are commercially available in the form, quality, or quantity needed by the operation to fulfill the required function as appropriate to the operation. Documented claims should be accompanied by supporting evidence demonstrating that the organic forms of the ingredients or materials do not meet the functional requirements for the form, quality, quantity or equivalent variety necessary to the operation. Examples of such evidence include but are not limited to test data, market reports, third party research, reports on local growing season, and letters from suppliers. [Note: The global market is the universe of supply for agricultural ingredients – local market conditions are not sufficient criteria – aside from as described above.]
2. Validate that the applicant or operator has credible documentation that the ingredient or material is not commercially available in an organic form by reviewing available information that includes a list of all known sources of organic ingredients or materials. Documentation could include various detailed results (commensurate with known supply) of the applicants' efforts to contact credible sources of ingredients or materials and should also show the applicants effort to do such research with proper lead time. Examples of documentation would include dated letters stating ingredient or material, needed and the form, quantity and quality specifications required to fulfill availability, as well as follow up documentation from the addressee explaining the response to the request.

3. ACA's will maintain and keep accessible sources of information which list available organic ingredients or materials if the certifying agent finds that such sources exist..
4. ACA's will keep an up-to-date listing of certified organic 205.606 ingredients. This list will be maintained and submitted to the NOP annually by the ACA for the NOP to collate into a master list of materials and ingredients that are available in organic form. It is recommended that the data base of all organic materials and ingredients will be maintained by the NOP, or other NOP appointed organization.
5. Require certified operators to update commercial availability information in each organic system plan update. The NOSB would like to recommend that the NOP consider requiring a plan to include detailed documentation of proactive steps that the applicant or certified operator is taking to generate the organic form of commercially unavailable organic ingredients or materials. Examples of proactive steps could be, but are not limited to, the following: documentation of research, funding of research, funding or sourcing of development, promotion to develop the organic source of material, incentive or bonus to crops in transition to organic status, hiring of consultants to help promote and source organic material, or grower contracting.

All documentation of the above will be incorporated as part of the ACA's annual audit process of the certified parties to validate authentic and established processes for commercial availability determinations as part of the Organic System Plan.

Conclusion

The NOSB recommends the above additional adaptations be adopted to establish acceptable criteria and procedures to determine commercial availability.

CAC vote:

Moved: *Bea James* ***Second:*** *Joe Smillie*

Yes: 6 *No-* 0 *Abstain:* 0 *Absent:* 0