



October 4, 2018

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

Docket: AMS-NOP-18-0029

RE: Handling Subcommittee – 2020 Sunset Reviews for §205.605 (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 for review as part of the 2020 Sunset Review cycle. Materials that have been placed onto the National List for use in handling should remain on the National List if: 1) they are still essential to and compatible with organic production and handling practices; 2) there are no commercially available alternative materials (natural, organic) or practices; and 3) no new information has been submitted demonstrating adverse impacts on humans or the environment (OFPA SEC. 2118 [7 U.S.C. 6517 and 6518] National List). Furthermore decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at-large. Furthermore decisions must be transparent, non-arbitrary, and based on the best current information and in the interest of the organic sector and public at-large. It's critical that NOSB hear from certified handlers on whether these inputs are consistent with and essential to organic handling, or whether there are other effective natural or organic alternatives available.

About OTA Sunset Surveys

OTA is submitting results to our electronic surveys that were created for each input under review for 2020. The surveys were created and made available to **every NOP certificate holder** and include 7-10 questions addressing the **necessity (farm and livestock) or essentiality (handling)** of the National List input under review. The names of the companies submitting the information are confidential (not disclosed to OTA). To ensure wide distribution of the surveys beyond OTA membership, OTA worked with Accredited Certifying Agencies (ACAs) and OMRI to distribute the survey links to all of their clients as well as to targeted clients they know are using the inputs under review. OTA also worked

through its Farmers Advisory Council¹ to help assist in distribution to NOP certified farmers. OTA's surveys are set up to provide information addressing the use (necessity or essentiality) and the availability of alternatives. They do not however address adverse impacts on humans and on the environment; we defer to the science community to provide such information.

Results of OTA Sunset Surveys

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

- 205.605(a) Nonsynthetic, Non-agricultural: 20 + 14 (new)
- 205.605(b) Synthetic, Non-agricultural: 11 + 6 (new)
- 205.606 Agricultural: 11 + 3 (new)
- **Total: 65 (24 new)**

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

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

Substance	Survey Information
Calcium Carbonate	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> • Certified Handler Comment (NEW): Used in extruded snack items. Certified for 13 years. Selling products in 50 states plus worldwide. Used as a textural modifier. No alternatives are available. We would not be able to manufacture our organic product if we were no longer allowed to use this material. It would be detrimental to our business. Essentiality: 9 critical • Certified Handler Comment (NEW): Used in our organic soy yogurt. Selling to 48 states. Certified since 2007. 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. We would stop making this product if we could not use calcium carbonate. Essentiality: 10 (critical). • 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

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.

	<ul style="list-style-type: none"> • 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. We have yet to find a suitable alternative. Essentiality on scale of 1-10: 10, critical. • 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"> • 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. As the petitioner to revise the annotation to require the use of organic flavors when commercially available, the Organic Trade Association is in strong support of the use and development of organic flavors and we believe they should be used when commercially available (quality, quantity and form). 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 on § 205.606 and NOP has not acted on it. • Certified Handler Comment (NEW): Flavored teas and tea blends. Certified for 10 years. 20 states. Exported only once to Singapore. We currently use allowed natural alternatives. There are no alternatives to many natural flavors. And we already use essential oils when and where possible. No, let's keep going with the 95% + category, as organic flavorings can be prohibitively expensive and if we are forced to use them, our customers will most likely not purchase due to the price. It would be appropriate to retain all natural flavors on the list, along with organic flavors. I do not have examples,

	<p>but I am aware that organic flavors can be exceedingly expensive. We would lose several blends, as 100% organic alternatives do not exist or are dramatically more expensive.</p> <ul style="list-style-type: none"> • Certified Handler Comment (NEW): Tea. Certified for 10 years. National sales. Extremely Limited Options for organic alternatives. The availability of organic is not sufficient. Doing away with the 95% allowance will cause deleterious harm to our business, a large portion of which consists of Certified Organic (using NOP-compliant flavors) Flavored options. This is the most popular category of tea for our customers. Disastrous. The company is marketed as Certified Organic & Certified Kosher. The Organic Flavored Tea category makes up the majority of our offerings. This is the most popular category for our loyal customer base. Essentiality: 9 (critical). • Certified Handler Comment (NEW): Custom Tea Blends. Certified for 9 years. Selling in USA and other Countries. Mostly using natural (organic compliant) flavors in our organic tea blends. Organic alternatives are limited has very low potency and high priced. It is not viable to use the organic flavors in many instances. Organic flavors have less potency and require high usage in the products. Organic flavors are considerably expensive than the natural flavors. If we are to use only organic flavors, we will not be able to give the customers a product with good quality at an acceptable price. An organic flavor with less potency will lead to lower quality. Organic flavors are not really functionally or practically available. We would lose the majority of our organic products if the flavoring rules changed. I think it would also unfortunately encourage tea manufacturers like us to "give up" and use non-organic compliant flavors if it cant get certified organic anyway, which is worse for the environment and consumers overall as it removes another level of regulation/accountability. We would drop the organic status on 80% of our 300+ products if natural flavors come off the National List. Essentiality – 10 (critical). • Certified Handler Comment (NEW): Tea (black, green, oolong, etc.) herbal blends (mint, chamomile, etc.). Certified for 30 years. Selling products in all USA states. Also Canada, EU, Japan, China. Organic flavors are available. Organic flavors typically carry prohibitively higher cost and less intensity in taste, requiring higher % use in a flavored tea blend. Of our roughly two dozen flavored teas, we have 2-3 that use organic flavors; the rest are not readily available/identical/affordable. We require the current options of natural flavors to achieve the taste profile we have already established. Limiting to Organic flavors could mean converting the entire tea base to conventional to maintain the taste profile - thus having fewer Organics in our line in the long run. Without the use of natural flavors, taste profiles would change, and costs would increase. We may choose to go to conventional products if we couldn't continue the flavor profiles by going to organic flavors. Cost increases of 10-30% TBD would be a challenge to our business, and growing Organics in general. Essentiality: 9 (critical). • Certified Handler Comment (NEW): Tea (<i>camellia sinensis</i>) and herbal tea blends. Certified for 4 years. Selling to 50 states. A few retail packages to other countries. There are practically no alternatives with the same qualities as "flavors" for our industry. They don't exist. Yes, we have conducted research on organic alternatives. They are phenomenally lower in quality and contribution to blend then the presently allowed "flavors" that fall under the 95% rule. All the organic alternatives do not contribute to the quality and desirability of our products sufficiently. De-listing "natural flavors" will dramatically hurt our business and our industry. We have tried practically every "organic" flavor available and they are all lacking in quality, besides being phenomenally more expensive-so much so that they become impractical. If
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natural flavors come off the list, we would probably have to reduce the number of our organic offerings and raise the price of our remaining organic offerings. We would lose customers and business overall. We would have to reduce the number of organics we carry, at the same time raise their prices, and lower the quality of organics we carry. Our customers would walk away with a noticeably lesser quality product when they buy organic tea blends, if the 95% flavor rule is discontinued. Essentiality: 10 Critical

- **Certified Handler Comment (NEW):** Used in yogurts. Certified for 11 years. Selling in 49 states. Our experience is that there is still wide variability in the quality of organic flavors, and they are often not available in the specific quality we need for our products. We are using organic where we can (e.g. vanilla). We have conducted research on organic. In some cases. Often the specific flavor profile we are looking for is not available in organic. We support applying commercial availability to organic flavors. Vanilla is a volatile crop and very subject to weather incidents. The availability of natural flavors on the list is very useful in the event an extreme weather event decimated the availability of organic vanilla. Loss of natural flavors on the national list would result in diminished product quality. Essentiality – 8.
- **Certified Handler Comment (NEW):** Used in Dry tea blends. Certified for 10 years. Selling in 40 states. Not currently exporting. There are no organic options available for many natural flavorings. For example there is no alternative to natural peach flavoring that can be used on dry tea leaves. Dried peaches impart no flavor in tea and peach essential oil does not exist. In many cases natural/organic alternatives simply do not exist. So we cannot do R&D on products that do not exist. With the exception of essential oils, most of the organic flavors cannot be applied to loose dry tea leaves because they are water-based or because they are in a powder format that will not blend with loose tea. Loss of natural flavors from the NL would require us to either discontinue half of our products, or we would have to forfeit out organic certification. Essentiality – 10 critical.
- **Certified Handler Comment (NEW):** Used in Many organic food products including but not limited to snacks, teas, spreads and baked goods. Certified for 13 years. Selling in 50 states plus worldwide. Commercial availability of organic flavors remains limited given the unique nature of flavor combinations. While organic flavoring options have increased and it may appeal to consumers, the overall supply of organic flavors pales in comparison against the overall supply of natural (organic compliant) flavors. So long as natural flavors are organic compliant, they should all remain on the National List. Again, the unique nature of flavors and distinct flavor profiles of the finished products necessitate the inclusion of all organic compliant natural flavors on the National List. Loss of natural flavors from the NL would limit the variety of organic product offerings with unique flavor profiles. Essentiality 10 Critical.
- **Certified Handler Comment (NEW):** Used in custom tea blends. Certified for 9 years. Selling in the USA and other countries. Mostly using natural (organic compliant) flavors in our organic tea blends. Organic alternatives are limited as the have very low potency and they are high priced. It is not viable to use the organic flavors in many instances. We have done trials with Organic certified flavors. Organic flavors have less potency and require high usage in the products. Organic flavors are considerably more expensive than the natural flavors. If we are to use only organic flavors, we will not be able to give the customers a product with good quality at an acceptable price. When the flavor is less potency, we need to use more flavor to get the required quality and since organic flavors are more expensive than natural flavors, it is not viable. Essentiality: 10 critical

- **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

	<p>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.</p> <ul style="list-style-type: none"> • 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 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.
Gellan gum	<p>2020 Sunset Comments</p> <ul style="list-style-type: none"> • Certified Handler Comment (NEW): Used in yogurt tubes. Certified for 11+ years. Selling to 48 states. 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. We believe that 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 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>We are not aware of any other alternative, this was an alternative to carrageenan and we had to work hard to find it. If gellan gum is removed from the National List we would probably discontinue product.</p> <ul style="list-style-type: none"> • Certified Handler Comment (NEW): Used in grain based snack bars. Certified for 20 years. Manufacturing in the mid-west and selling in all 50 states. Used as thickener/texturizer as a replacement for gelatin. Alternatives: Gelatin is available on 205.606, but not suitable for a vegetarian product. No other gums provide similar properties. We also tested Agar Agar, Xanthan, Pectin (only amidated showed promise which is not allowed) and a few salt setting gums. The gellan gum produced the effect we were interested in. If removed from the NL, we would have to discontinue the product. Vegetarian is important to our product differentiation. Without gellan gum the product will not exhibit the "marshmallow" properties that are needed. <i>Economic impact on your company if removed?</i> While not devastating, this product is growing distribution and consumer acceptance, so we would lose those product sales. Essentiality: 10 critical. • 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 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
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	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.
Oxygen	<u>2020 Sunset Comments</u> <ul style="list-style-type: none"> No responses received
Potassium chloride	<u>2020 Sunset Comments</u> <ul style="list-style-type: none"> Certified Handler Comment (NEW): Used in organic snack items. Certified for 13 years. Selling to 50 states plus worldwide. Used as a Sodium Reduction Agent. Sodium Chloride is the only alternative we know of and we have researched using it, however its exclusion could result in close to 20% higher sodium content in finished products. While this ingredient is not organic, its inclusion is necessary to provide product offerings that are not only organic but also offer lower sodium alternatives. If this material comes off the NL we would need to use the alternative and that would result in products with a higher sodium content. The impact would be detrimental as it reduces consumer market appeal of the products. Essentiality: 9, critical. 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. <u>2017 Sunset Comments</u> 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.

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

Substance	Survey Information
Alginates	<p><u>2020 Sunset Comments</u></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><u>2020 Sunset Comments</u></p> <ul style="list-style-type: none"> • Certified Handler Comment (NEW): Used as a pH adjustor to achieve maximum extraction of fat, protein and carbohydrates. Company certified for 10 + years. Selling products in 50 states + Exports. We are not aware of any alternatives. We moved to this product 10 years ago when we became organic. Previously used Sodium Hydroxide. This was the only choice on the national list. We would lose about \$2-3 million in sales if this material is removed from the National List. Our sales would be reduced by 50%. We rate this material as 10 (critical) for essentiality. • Certified Handler Comment: Used for fortification in infant formula. Certified 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><u>2017 Sunset Comments</u> 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><u>2020 Sunset Comments</u></p> <ul style="list-style-type: none"> • Certified Handler Comment (NEW) (8/16): Company has been certified for 30 years. Products are sold in all states except AZ, CA and exported to Canada. Ethylene is used as a post harvest aid for all citrus types along with other fruits to insure complete color and consistent maturing of the produce. It is a post harvesting aid. To my knowledge there is no other organic or natural product available that can provide the necessary functions of ethylene. I would if I could find an alternative. Citrus matures internally faster than it does externally. Thus the fruit has surpassed maturity requirements established for selling the fruit

	<p>based upon juice quantity, quality and brix levels (sugars) but the fruit has not colored enough (mostly green) to pass the market requirements established for the sale of fruit. Ethylene as a post harvest aid assists the fruit to reach the necessary color requirements to be packed and sold. Eliminating the use of ethylene as an aid in the maturing process would require the fruit to reach full color prior to harvesting. This would be a loss of 2-3 months of market access during the holiday season when demand for citrus is at its peak. It would reduce our market season from 6 months down to 4, without ethylene. Ethylene provides access to the market when fruit is unavailable from any other citrus production area. This gives us an opportunity to put product in the shelves we demand is high. We operate in a supply and demand economy. Our best returns are during this part of the market season, without the use of ethylene this opportunity would be lost and devastating to the economic health of our company. Essentiality? 10 Critical</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 in 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 lose 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"> • Certified Handler Comment (NEW) (9/12): Used in Dietary supplements, tablets mainly & capsules. Certified for 10 + years. Selling in 50 states & 20+

	<p>countries. Used as a lubricant - reduces the sticking of tablets in the die, allows the tablets to be released after pressing and allows capsules to close properly. Organic "rice extract blend" has been used effectively in many applications in the US, Canada, EU and Australia. We have conducted research trials and commercial implementation on several products. Magnesium stearate acts like a lubricant so high speeds and efficiency can be achieved. Organic alternatives are available; however, the "Made With" distinction seems proper for the allowance of this material. Alternatives are available and the cost difference is about 1 penny / bottle. Essentiality? 2</p>
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 (NEW): Used in alkalized cocoa powders. Certified for 24 years. Producing in Peru, Netherlands, & France. Selling to all states and Canada. Used as an alkalizing agent. There are no alternatives. Loss of this material would result in a large financial loss and our customers. Essential – 10 critical. • 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 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**

2017 Sunset Comments

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.

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, ensuring 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.**

Xanthan gum	<p><u>2020 Sunset Comments</u></p> <ul style="list-style-type: none"> • Certified Handler Comment (NEW): Used in our organic beverages, sauces and baked goods. Certified for 13 years. Selling products to 50 states plus worldwide. Used as a binder. While other gums are available that share similar characteristics, none provide the same functionality. Usage of other gums on the National List have been researched but do not function as well as Xanthan Gum. Essentiality: 10, critical. • Certified Handler Comment (NEW): Used in our Organic Flavor Emulsions. We have been certified organic since 1999. We sell across the United States and to other countries as well. Xanthan Gum is used as a binder for oil and water flavor emulsions. It is essential to keep emulsions uniform so they do not separate. There isn't an alternative that would work as well. We're not aware of any practices that could be used instead. Our Ingredient Statement lists Xanthan Gum It is essential 100% to quality and marketability of the organic product(s) we are marketing). If removed from the National List we would more than likely have to discontinue any products using Xanthan Gum. We would lose annual revenue by having to discontinue Essentiality? 10 Critical • 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. <p><u>2017 Sunset Comments</u></p> <p>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.</p> <p>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</p>
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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.

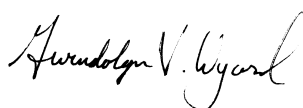
Handler Comment: Stabilizer and thickener in creams and lotions. Certified for 9 years. Our products are sold in 50 states and 7 countries. There are no alternatives with the same quality and function. Cellulose can work but it's not as effective.

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:

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

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

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

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

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

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

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

Appendices are not included in this packet to NOSB.