



April 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-15-0002

RE: Handling Subcommittee – 2017 Sunset Summary: Natural Flavors

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment to the National Organic Standards Board on its 2017 Sunset Review of Natural Flavors.

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.

OTA appreciates the opportunity to respond to the subcommittee's questions regarding the listing of natural flavors at 205.605(a) as an allowed non-synthetic (non-agricultural) ingredient. 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 the 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 flavors when organic forms may be commercially available.

In order to further the use and development of organic flavors, OTA has submitted a petition to revise the current listing of natural flavors (on 205.605 of the National List) to require organic flavors in products labeled "organic" when they are commercially available. The petition was accepted by NOP on February 3, 2015 and forwarded to NOSB at that time. We look forward to working with you on this topic, and to a favorable recommendation at the fall 2015 meeting.

Consistent with the information we submitted in our petition, we offer the following information as requested by the Handling Subcommittee:

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.

1. Supply: Organic flavors of various types are available in the marketplace (extracts, essential oils, compounded natural flavors, essences, distillates, etc.). Is the supply of some specific organic flavors sufficient to warrant the sunset of some specific natural (non-organic) flavors on 205.605 of the National List? If so which ones?

OTA: 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. 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 and the fact that to-date, there has been no requirement to use organic flavors.

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

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.

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.

2. Commercial Availability: Given the availability of some organic flavors, do you think that commercial availability should apply to the use of natural flavors in organic products (i.e., use organic when commercially available in quantity, quality and form)?

OTA: Yes. As explained above, OTA believes 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. This will further stimulate the development of organic flavors, which, in turn, will increase the quality, quantity and forms available.

Applying commercial availability to flavors would also be consistent with the original 1995 NOSB Recommendation to list flavors on the National List. **See Appendix B.**

3. Would it be appropriate to retain all natural flavors on the National List if organic flavors were required to be used when available? Please explain your reasoning and provide specific examples.

OTA: Yes. OTA believes the best approach is to retain flavors on § 205.605 of the National List 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 that are 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 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 we 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 convened in 2010 by request of NOSB explored this option 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.

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.

4. Essentiality: Are flavors essential to the continued success of the organic sector? Describe the effects to your operation should you no longer be allowed to use non-organic flavors. Specify which flavors you use.

Yes, flavors are essential to the continued success of the organic sector. OTA defers to comments submitted by individual organic handlers.

5. Would certifiers and Material Review Organizations (MROs) find a standardized industry questionnaire to verify compliance a helpful document?

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.

To the best of our knowledge, 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**. OTA recommends that the flavor questionnaire be formally recognized by NOP, and offered to ACAs in guidance as the standardized questionnaire to use.

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. In the case of flavors, we urge NOSB to retain natural flavors on 205.605(a) of the National List provided a separate recommendation is made to revise the annotation to require the use of organic flavors when commercially available.

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



NATURAL FLAVOR PRODUCT QUESTIONNAIRE - NATIONAL ORGANIC PROGRAM USE

The **USDA National Organic Program (NOP)** allows the use of certain natural (non-synthetic) substances, including flavors, in products labeled as “Organic” or “Made with Organic...(specified ingredients or food groups)” providing they comply with provisions established in the USDA NOP (*7 CFR Part 205*).

The NOP defines **Non-synthetic** (natural) in 7 CFR 205.2: a substance that is derived from mineral, plant or animal matter and does not undergo a synthetic process as defined in section 6502 (21) of the Act (*7 U.S.C. 6502(21)*). Under the terms of the Act, "**synthetic**" means a substance that is formulated or manufactured by a chemical process or by a process that chemically changes a substance extracted from naturally occurring plant, animal or mineral sources, except that such term shall not apply to substances created by naturally occurring biological processes.

Non-synthetic Flavors authorized under the NOP, Section 205.605 (a)(9) must be from non-synthetic sources only and must not be produced using synthetic solvents, carrier systems or any artificial preservative. In addition, **Sections 205.105 (e)(f)(g)** respectively prohibit so-called “excluded” methods (GMOs), ionizing radiation or sewage sludge, defined in 205.2, from being applied to any ingredients or products under the NOP.

FDA Definition of Natural Flavors *FDA 21 CFR Part 101.22(a)(3)*: “... **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. Natural flavors include [*but not exclusively*] the natural essences or extractives obtained from plants listed in §§182.10, 182.20, 182.40, and 182.50 and part 184 of this chapter, and the substances listed in §172.510 of this chapter.”

The use of this questionnaire is to determine compliance of a natural flavor for use in an “organic” or “made with organic...” product under the terms of the NOP. **Oregon Tilth may request additional information as needed.**

Identification of Natural Flavor Product (code/Name): _____

Supplier Name, Address: _____

Type of flavor (select one or more as necessary):

<input type="checkbox"/>	Compounded flavor	<input type="checkbox"/>	Extracts	<input type="checkbox"/>	Isolate
<input type="checkbox"/>	Compounded WONF	<input type="checkbox"/>	Essential oil	<input type="checkbox"/>	Oleoresin
<input type="checkbox"/>	Distillate	<input type="checkbox"/>	Essential oil Isolate	<input type="checkbox"/>	Other (please specify):

Natural Flavor Product

A. Flavor constituents

- Do all of the flavor constituents in the natural flavor product named above meet the FDA definition of a natural flavor (see above)?
 Yes No
- Natural flavors** authorized for use in NOP “organic” or “made with organic” products, in addition, must not be produced using **synthetic extraction solvents**. Extraction may only use **nonsynthetic, non-petroleum based solvents (see below)***.
 - Is/are the natural flavor constituent(s) made using NOP-suitable extraction solvents*?
 Yes No
 - If the solvent used to extract the natural flavors is not listed as an example of one of the NOP-suitable extraction solvents* please disclose: _____

***Allowed natural extraction solvents include water, natural ethanol, super-critical carbon dioxide, authentic essential oil, and natural vegetable oils.** No hydrocarbon solvents, or chlorinated, or halogenated solvents may be used. Propane, hexane, and freon are examples of solvents that are prohibited.



B. Non-flavor constituents and other ingredients

1. **Natural flavors** authorized for use in NOP “organic” or “made with organic” products must not contain any **synthetic carrier systems** or any **artificial preservatives**. This extends to synthetic processing aids, emulsifiers or antioxidants; i.e. prohibited substances include but are not limited to, e.g., propylene glycol, polyglycerol esters of fatty acids, mono- and di-glycerides, benzoic acid, polysorbate 80, medium chain triglycerides, BHT, BHA, triacetin, etc. **Acceptable carriers, preservatives or other additives or foodstuffs MUST BE either organic, nonsynthetic, or on the National List at 205.605(b).**

➤ Please list any carrier system(s) used in this Natural Flavor Product or attach an Ingredient Statement: N/A

Carrier: _____ Source Material: _____

➤ Please list any preservative(s), or other additives or foodstuff ingredients used in this Natural Flavor Product or attach an Ingredient Statement: N/A

Preservative/Additive/Foodstuff: _____ Source Material: _____

2. **If any of the above are synthetic, are they listed on the NOP National List at § 205.605(b)?** Yes No N/A

C. Genetically Modified Organism (GMO) products may not be used at any stage in the process of making natural flavor products for NOP goods. **Excluded methods** (= GMO use) – a variety of methods used to genetically modify organisms or influence their growth and development by means that are not possible under natural conditions or processes and are not considered compatible with organic production. Such methods include but are not limited to recombinant DNA technology (including gene deletion, gene doubling, introduction of a foreign gene, and changing the positions of genes when achieved by recombinant DNA technology); therefore, GMO-plant extracts may not be used nor may natural flavors be the product of GMO-yeast fermentation, for example.

➤ *This natural flavor product, including any solvents, carriers, preservatives or other or processing aids used or contained therein, was produced or handled using excluded (GMO) methods?*
 Yes No

D. Ionizing Radiation is prohibited for all uses involving food preservation, pest control and pathogen control in NOP products. Other radiation uses, including food inspection, are permitted providing such use meets applicable FDA regulations, which establish limitations applicable to all (organic and non-organic) food products.

➤ *Ionizing radiation as described in 21 CFR 179.26 was used in the processing of this natural flavor product?*
 Yes No

E. Sewage Sludge (as a crop fertilizer) is solid, semisolid, or liquid residue generated during the treatment of domestic sewage in a treatment works. Sewage sludge includes but is not limited to: domestic septage; scum or solids removed in primary, secondary, or advanced wastewater treatment processes; and a material derived from sewage sludge. It is not permitted in the manufacture of any ingredients used in NOP products.

➤ *This natural flavor product was derived from products using sewage sludge in their agricultural production:*
 Yes No

This questionnaire is only to be signed by a qualified technical person¹:

Pursuant to 7CFR §205.605(a)(9) and §205.105(e)(f)(g), I, on behalf of the supplier, hereby attest that the information provided in this form is accurate and truthful to the best of my knowledge.

Identification of Natural Flavor Product (code/Name): _____

Company Name: _____ **Phone/e-mail:** _____

Printed Name: _____ **Title¹:** _____

Signature: _____ **Date:** _____

¹ *Falsifying statements to ACA’s or the Secretary under the NOP will be subject to possible fines.*