



April 5, 2023

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

Docket: AMS-NOP-22-0071

RE: Handling Subcommittee Discussion – Sunset Flavors

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee’s Sunset Review of Natural Flavors. The Handling Subcommittee is reviewing the listing of Natural Flavors on § 205.605(a)(12) of the National List:

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

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 organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA supports the retention of Natural Flavors on the National List as listed. The success of growing the availability of organic flavors relies heavily on robust and well documented search efforts by industry and rigorous and consistent commercial availability review and oversight by ACAs and NOP. OTA encourages NOSB and NOP to focus on strategy and tactics that improve both.

NOSB Questions to Stakeholders

- 1. Do you produce or certify organic flavors that include ingredients listed on § 205.605? If so, what ingredients?*

No, OTA does not produce or certify organic flavors. However, our membership consists of many businesses that produce, manufacture, handle, buy, sell, distribute and certify organic flavors. A significant portion of our membership are users of both organic and non-organic flavors.

OTA was the petitioner for the historical annotation change published in December 2018 that requires organic operations to use organic flavors when they are commercially available. OTA submitted the petition to help grow the availability and use of organic flavors. In consideration of filing the petition, we recognized that the number of available certified organic flavors was not sufficient to meet the current needs of the organic marketplace. We also recognized that the

growing organic flavor sector deserved more support than it was receiving. At that time, there was **no requirement to use organic flavors**; all use was voluntary despite the significant number of organic flavors available in the marketplace.

OTA’s petition was a proactive step to push the needle in the direction of continuous improvement and require the use of organic flavors when they are available in the quality, quantity and form needed. We remain committed to this effort.

2. *How would removal of flavors from § 205.605 impact the commercial availability of organic flavors?*

The removal of flavors would be premature and negatively impact the commercial availability of organic flavors. The current listing requires organic operations to use organic flavors when they are commercially available. This status is still needed for most types of flavors and is particularly important for natural compounded flavors and the flavor isolates compounded flavors rely on.

OTA’s data demonstrates 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 and specificity of the marketplace, given the numerous and different types and forms used by the organic product formulators and the fact that until recently (2018), there has been no requirement to use organic flavors.

To inform OTA’s petition, submitted in 2014, we worked with the Accredited Certifiers Association (ACA) to conduct a survey to determine how many organic flavors are available on the market.

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
2146	405	272	1645	4	18	33	254	19	0

The survey reported that 189 companies were certified in 2014. When flavors were initially included on the National List, the number of flavor compounds comprising natural flavors was estimated up to 100 or more. The data from the ACA survey demonstrates that this number has grown substantially, not only for natural flavors in general, but for certified organic flavors. **A new survey with updated numbers should be conducted for the Fall 2023 meeting.** While we expect to see growth in the number and types of organic flavors, we do not expect to see numbers that would justify the complete removal of natural flavors from the National List.

The challenge is that Natural Flavors appear on the National List as a broad category listing, therefore many different natural forms (agricultural and non-agricultural) are allowed. Examples include extracts, oleoresins, essential oils, compounded flavors, and distillates. **See Appendix A for the list of flavor types and a description of each one.**

There are literally thousands of distinctly different natural and organic flavors, making it impractical to individually list every single flavor on the National List. This was acknowledged by NOSB at both previous Sunset Reviews and informed the decision to revise the § 205.605 broad category listing with an annotation requiring the use of organic flavors when they are commercially available.

OTA continues to support the retention of flavors on § 205.605 of the National List with commercial availability assigned to the entire broad category listing. We remain committed to the growth of the organic flavor sector and believe this approach continues to make the most sense. Our ability to succeed, in terms of growing the organic flavor sector, comes with a responsibility that relies heavily on robust and well documented commercial search efforts by industry and rigorous and consistent review and oversight by accredited certifying agencies and the NOP.

To help with this effort, OTA and the ACA have developed guidance on best practices for sourcing and reviewing flavors for compliance with the organic regulations. OTA developed guidance for organic operations and the ACA developed best practices for certifiers. **See Appendix B and C.** The two documents are excellent and complementary and would be furthered if NOSB and/or NOP could elevate their visibility through formal adoption. A rigorous and consistent approach to commercial availability is needed for the regulation to work as it was intended. OTA believes that many operations and certifiers are doing an excellent job on this front, but there continues to be room for improvement and greater consistency in practice between one operation and certifier to the next.

3. *Are there flavors currently used in organic products that cannot be produced organically (including any of the examples listed in the TR such as castoreum derived from beavers, Tonquin musk oil from musk deer, wood chips from nonorganic forest products, distilled liquid smoke, fish flavors)?*

These are all good examples, especially the beaver example. It is important to keep in mind that natural flavors on § 205.605(a) is a broad category listing of agricultural and nonagricultural flavors. Any flavor where the **source** is non-agricultural (liquid smoke, wood chips) or outside of the scope of NOP certification (e.g., aquaculture) cannot be produced organically. All flavors that are derived from an agricultural source could potentially be certified, provided all processing aids solvents, carriers, stabilizers, etc. are organic and available in sufficient supply (e.g., organic glycerin) and/or on the National List.

Aside from non-agricultural flavors that cannot be organic, the type of flavor with the lowest organic availability is likely the **flavor isolates**, also known or referred to as the flavor “keys” or “aroma chemicals.” This type of flavor is very important to the organic sector because the “isolates” are the critical (packed with flavor) component of compounded natural flavors. The examples below should help explain what a flavor isolate is and how it is used in a compounded flavor.

Example flavor isolates used in organic compounded flavors:

Natural Ethyl Butyrate - the starting materials are alcohol (fermentation and distillation) and butyric acid (from cane sugar via fermentation, extraction and then purified via distillation). The products are combined and then undergo an esterification process (either cooking under controlled conditions or an enzymatic process). The final product is then purified via distillation.

Natural Acetic Acid – the starting material is cane sugar, which is then fermented, extracted and then purified via distillation.

Natural cis-3-Hexenol – manufacturing of mint essential oil results in mint terpenes, which is then purified via distillation.

Natural Benzaldehyde – derived from Cassia oil via extraction to obtain cinnamic aldehyde. It’s then cooked under controlled conditions and purified via distillation.

Example of a Natural Compounded Flavor:


Organic composition category: 95% - Organic

Actual organic percentage: 95.3% = 95% rounding down

Ingredient	% Organic	% used in the formulation
OG Ethyl Alcohol	100.00	30.00
OG “Sugar” Syrup	100.00	30.00
Water (excluded)	0.00	25.00
OG Strawberry Juice Concentrate	100.00	10.00
Natural Isolate (aroma chemical) – often can be a mix of several to a hundred isolates	0.00	02.00
Natural Citric Acid	0.00	01.50
Organic Hibiscus Extract	100.00	01.50

In closing, and behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture and organic flavors!

Respectfully submitted,



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

cc: Tom Chapman, CEO
Organic Trade Association

Appendix A: Types of Flavor or ‘Flavor Nomenclature’

Appendix B: OTA’s Practical Guide to Complying with NOP Flavor Requirements

Appendix C: ACA Best Practices for Commercial Availability of Natural Flavors

Appendix A: Type of Flavor or ‘Flavor Nomenclature’

The search for organic flavors can be broken down and communicated to your certifier by ‘type of flavor.’ The general manufacturing process is implied by the nomenclature of the product, and helps determine the likelihood of an organic form due to the agricultural nature of the product and the complexity of processing.

Compounded Flavor: A mixture of ingredients such as extracts, essential oils and natural isolates. In most cases, it’s usually dissolved in a solvent or it would be too concentrated.

Compounded WONF: Combination of a compounded flavor and a natural flavor WONF (with other natural flavor).

Distillate: A clear, flavorful liquid produced from fruits, herbs, roots, etc., by distillation; also the condensed product separated by distillation.

Extracts: Extracts are products that use solvents (typically alcohol or alcohol-water mixture) to pull out certain volatile and non-volatile fractions from raw materials such as spices and herbs, cocoa and vanilla, or flowers. Extracts found on the grocer’s shelf, such as orange, almond, lemon, etc. are essential oils dissolved in an alcohol-water mixture.

Essential Oil: A volatile oil. An essential oil is what gives a botanical its aroma and can be the aromatic essence of a spice, flower, root, leaf or peel. It’s made by steam distillation or cold pressing.

Essential Oil Isolate: Isolate of an essential oil – see above.

Isolate: A chemical or fraction obtained from a natural substance. For example, citral can be isolated from lemon oil or lemongrass.

Oleoresin: Solvent extracts of spices where the solvent has been completely removed. An oleoresin will contain the essential oil plus other important non-volatile components that characterize the flavor, color and other aspects of the starting raw material. For example, the oleoresin of pepper will contain its aroma as well as its taste sensations of heat and spice.

Single flavor chemical: A single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity.

Others – could include:

Add-Back Flavor - Adds back flavor lost during processing. For instance, orange juice can lose much of its flavor during the concentration process but flavorists can add orange oil during the formulation to increase the flavor. Add-back flavors imply that all ingredients of the flavors are derived from the named fruit.

Essence: Concentrated fragrance or flavorant. In some countries, essence is used to designate volatile oils, but in the U.S. this term is commonly applied to alcoholic solutions of volatile oils.

Natural Flavor WONF – A natural flavor that contains both a characterizing flavor from the named material and other natural flavor, which simulates, resembles or reinforces the characterizing flavor.

Single-fold Oil: The oil as it is produced from the plant (distillation or expression), without concentration.

References

George A. Burdock. Fenaroli's Handbook of Flavor Ingredients, 5th ed. Washington D.C. CRC Press.

Primo Bader and Steve Phelps. January-March 2007. The Flavor Factor: Exploring Today's Taste-Improving Technology. *Organic Processing Magazine*.

USDA Organic Flavors Required When Commercially Available!



A practical guide to
complying with the
new requirements
for natural flavors



I. INTRODUCTION

The National Organic Program (NOP) has published a final rule that amends the National List of Allowed and Prohibited Substances (National List). The new ruling was implemented on December 27, 2019 and requires the use of certified organic flavors whenever they are commercially available.

The new listing of flavors reads as follows:

Flavors—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.

This change is brought to you by the Organic Trade Association (OTA) as a result of a petition we submitted on November 6, 2014, to help grow the availability and use of organic flavors. In consideration of filing the petition, we recognized that the number of available certified organic flavors was not sufficient to meet the current needs of the organic marketplace. However, we also recognized that the growing organic flavor sector deserved more support than it was receiving. Prior to the rule change, there was no requirement to use organic flavors; all use was voluntary despite the significant number of organic flavors available in the marketplace. The petition was a proactive step to push the needle in the direction of continuous improvement, and require the use of organic flavors when they are available in the quality, quantity and form needed.

The Organic Trade Association's position is 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.

II. BACKGROUND

For almost two decades, Natural Flavors have been allowed for use in NOP certified products labeled as "organic (95%+)" and "made with (70%+)," provided they are produced without synthetic solvents, synthetic carriers and artificial preservatives. As a general prohibition, they must also be produced without the use of genetic engineering and ionizing radiation. Natural flavors appear on the National List as a broad category listing, therefore many different types of natural forms are allowed. Examples include extracts, oleoresins, essential oils, compounded flavors, and distillates. **See "Types of Flavors" on Page 4.**

Flavors were not added to the National List as a result of a petition. Instead, they were included among natural substances initially placed on the list when NOP promulgated regulations pursuant to the Organic Foods Production Act of 1990. Since the first recommendation by the National Organic Standards Board (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 fact, the 1995 NOSB Recommendation required certified operators to demonstrate efforts toward the ultimate production of an organic natural flavor. To a large degree, the expectation has become a reality. Over a decade later, we have over 3,000 flavors available in organic form. Now it is time for the regulations to catch up with the marketplace and level the playing field by requiring everyone to use organic flavors when available.



On October 29, 2015, in response to the Organic Trade Association's petition and wide industry support, NOSB unanimously passed a recommendation to revise the annotation for flavors to require organic **when commercially available**. On December 27, 2018, after approving the NOSB recommendation and considering comments from the public during the proposed rule stage, NOP issued a final rule amending the National List. The final ruling on flavors was implemented on **December 27, 2019**.

III. QUESTIONS AND ANSWERS

What is a natural flavor?

Natural Flavors are defined by the U.S. Food and Drug Administration (FDA) as 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. (21 CFR 101.22). They are typically used in very small amounts in products that, due to functional attributes, contain less than optimal amount of flavor necessary to give the finished product the desired flavor profile. The purpose of a flavor as described by FDA is not to provide any nutritional or caloric purpose in the final product (21 CFR Part 101.22).

Are natural flavors allowed in USDA NOP certified products and what are the new requirements?

Yes, with restrictions. NOP regulations allow the use of natural flavors provided they meet the FDA definition of a flavor, are from non-synthetic sources, and are not produced using synthetic solvents and carrier systems or any artificial preservatives. They must also be produced without the use of excluded methods (GMOs) and ionizing radiation. Since flavors are added to food to impart, modify or enhance flavor, the following are not considered flavors: 1) flavor enhancers; and 2) substances that have an exclusively sweet, sour, or salty taste (e.g. sugar, nutritive sweeteners, vinegar, and table salt). These requirements have not changed. Certifiers commonly use a document referred to as a 'Natural Flavor Questionnaire' to help verify compliance. The **new requirement** is that natural flavors **may only** be used when organic flavors are not commercially available.

What is an organic flavor?

An organic flavor is a flavor product that complies with the requirements of USDA's organic regulations. Specifically, the flavor must meet the 95/5 composition requirements (§205.301), the organic processing requirements (§ 205.270 – § 205.272), and the organic labeling requirements (§205.300 - § 205.311). Organic flavors can range from simple flavors such as extracts, essential oils and distillates to more complex or compounded flavors (commonly referred to as an 'organic natural flavor') that include organic concentrates, organic solvents, organic carriers and organic and/or natural isolates. In all cases, the flavor must be comprised of at least 95% organically produced ingredients and the 5% allowance may only include substances that are on the National List AND they must be organic if they are commercially available. This includes flavors.



How is commercial availability defined?

Commercial availability is defined as 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 (7 CFR 205.2). Price cannot be a consideration for determination of commercial availability.

Does the rule change apply to the "made with" label category?

No. Commercial availability only applies only to the 5% of certified organic (95%+) products (§ 205.301(b)). The "made with" labeling category allows for the use of up to 30% non-organic agricultural ingredients and/or non-agricultural ingredients listed on § 205.605 of the National List. Consistent with the organic regulations, the petition that the Organic Trade Association submitted was for certified organic (95%+) products only. This includes organic products utilizing natural flavors as an ingredient, and/or organic flavors utilizing natural flavors as an ingredient.

Will I be out of compliance on 12/27/2019 if I am still using non-organic flavors?

No, you will not be out of compliance if you are using non-organic flavors on 12/27/2019. That is the date when search and documentation efforts begin; the process is ongoing. Compliance will be met through documented activity to source and obtain organic flavors that are commercially available. Compliance will be evaluated on an ongoing basis (continuous improvement) and determined through communication with the operation's certifier and the plan agreed to in the certified operation's Organic System Plan. The frequency and extent of the search and the specifications used to determine appropriate form, quality and quantity should all be detailed in the Organic Handling System Plan.

See "Guidance" on Page 5.

I am a flavor house making certified organic flavors. Am I required to use organic flavor isolates?

Yes, when commercially available. It is understood that some compounded organic flavors may contain natural flavor compounds (e.g. isolates, distillates, aroma chemicals, flavor keys) in the 5% allowed non-organic portion. This is possible because of the allowance of 'natural flavors' on the National List and NOP organic product composition standards. However, the new requirement to use organic flavors when commercially available applies to all certified organic products, including flavors. **IMPORTANT! As a reminder, the term "organic" must not be used in a product name to modify a non-organic ingredient in the product (§ 205.300(a)).** For example, a strawberry flavor may not be labeled as "Organic Strawberry Flavor" unless the strawberry flavor is "organic." Flavors that meet the organic composition requirements (95%+ organic) but contain natural flavor isolates in the 5% must be labeled as "Organic Natural Flavor."

What does the search process involve, and how can I meet the requirements of this new regulation?

First and foremost, don't panic. The intent is continuous improvement and to increase the growth and use of organic flavors over time. The intent is not to hand down non-compliances to companies that are unable to secure organic flavors when they do not meet the specifications needed to make an awesome product that organic shoppers will buy and love. The intent is to: 1) start the process; 2) make a search and evaluation plan; and 3) work with your certifier on an annual basis.

Is there any guidance or commercial search criteria that can be used to help the process? There is no formal guidance from the National Organic Program on commercial search and use of natural and organic flavors in NOP certified products. However, the Organic Trade Association has developed guidance for its members that reflect NOSB recommendations that were passed on commercial availability search for ingredients on § 205.605 and § 205.606, and related instruction from NOP on filing a petition. Additional resources on commercial availability are included below.

IV. TYPE OF FLAVOR OR 'FLAVOR NOMENCLATURE'

The search for organic flavors can be broken down and communicated to your certifier by 'type of flavor.' The general manufacturing process is implied by the nomenclature of the product, and helps determine the likelihood of an organic form due to the agricultural nature of the product and the complexity of processing.

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Oleo-resin: Solvent extracts of spices where the solvent has been completely removed. An oleo-resin will contain the essential oil plus other important non-volatile components that characterize the flavor, color and other aspects of the starting raw material. For example, the oleo-resin of pepper will contain its aroma as well as its taste sensations of heat and spice.



Single flavor chemical: A single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity.

Add-Back Flavor: Adds back flavor lost during processing. For instance, orange juice can lose much of its flavor during the concentration process but flavorists can add orange oil during the formulation to increase the flavor. Add-back flavors imply that all ingredients of the flavors are derived from the named fruit.

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Natural Flavor WONF: A natural flavor that contains both a characterizing flavor from the named material and other natural flavor, which simulates, resembles or reinforces the characterizing flavor.

Single-fold Oil: The oil as it is produced from the plant (distillation or expression), without concentration.

V. GUIDANCE ON DETERMINING COMMERCIAL AVAILABILITY OF ORGANIC FLAVORS

The aim of the following information is to help certified operators: 1) develop a sound and sensible organic flavor search plan that can be submitted to and agreed upon by the certifier; and 2) collect and maintain auditable documentation to support the plan and search findings.

Commercial Availability is defined as 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** (7 CFR 205.2 – Terms Defined).



The requirements of the **Organic Handling System Plan**, are described in § 205.201(a)(2) of the regulations:

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

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

In addition to documentation of commercial availability, the Organic Handling System Plan also requires the following:

- A description of practices and procedures to be performed and maintained, including the frequency with which they will be performed;
- A description of the monitoring practices and procedures to be performed and maintained, including the frequency with which they will be performed, to verify that the plan is effectively implemented;
- A description of the recordkeeping system implemented to comply with organic requirements.

The Organic Handling System Plan is the foundation and primary document that should be used to demonstrate compliance with the requirement to use organic flavors when they are commercially available.

Role of the accredited certifying agency in determining commercial availability

An accredited certifier, in determining that a non-organic flavor is not commercially available in organic form, will:

- Evaluate the applicant or certified operator's Organic Handling System Plan and the operator's process for sourcing organic flavors. This includes a description of the frequency that the search is performed and research efforts to evaluate the quantity, quality and form of known organic sources.
- Evaluate the applicant or certified operator's Organic Handling System Plan and the operator's documented claims that an organic flavor is commercially available/unavailable in the form, quality, or quantity needed to fulfill the required function of the organic product.
- Validate that the applicant or certified operator has auditable documentation that the flavor is not commercially available in an organic form by reviewing the list of known sources carrying organic flavors alongside documentation to support an unavailability claim.
- Require certified operators to update commercial availability information in each organic system plan update, as needed or annually.

It is also recommended that certifiers maintain and submit to NOP an up-to-date listing of its certified organic operations and their certified organic flavors.

Role of the applicant or certified operator in demonstrating commercial availability

To adequately demonstrate that an organic flavor is not available, the following should be provided:

- Complete or update the Organic Handling System Plan with detailed information on the process that will be used to conduct and document a commercial availability evaluation for organic flavors. Include the search and procurement methods used to identify organic sources that meet the quantity, quality and form requirements and the frequency of your search. Also describe the process or method used to determine whether the organic flavor fulfills the specification requirements of the organic product(s) the flavor is used in. Submit the plan to your certifier for approval, and then follow the plan.
- Search, sourcing and development efforts should be documented and include the identification of the organic flavor along with the date, source and contact information of the company contacted. Contacting a minimum of three to five sources that are known to offer organic flavors is recommended. The number of companies contacted should be relative to the potential number of suppliers. A great place to start is with your current flavor houses. They may be best situated to provide or develop the organic flavor you need! Certifiers may ask that additional sources be contacted, depending on the availability of the flavor type and knowledge of other companies/sources that may carry the ingredient.
- If the flavor is not available in organic form, please include a statement to this effect from the company contacted (letter, e-mail, phone log.). Alternatively, if search engines or databases are used, please describe the source, web link, and any other helpful information such as a screenshot or search report.
- If the flavor is available, but not in the quantity, quality or form needed, the following documentation may be submitted to support the non-availability claim:



Quantity – Report on the number of suppliers and amount produced. Specify the projected production and quantity of the flavor needed for a given amount of time and contrast that amount with the amount available. Describe other issues that may present a challenge to a consistent supply (e.g. stable supply chain, able to meet order quantities, not restricted by exclusivity agreements). A statement from the company contacted (or similar documentation) regarding the amount available must be submitted.

Quality – Specify how this determination was made, i.e. R & D testing, visual of the product upon arrival (e.g. physical, microbial, organoleptic, analytical, etc.) Clearly describe to your certifier why the quality of the flavor is not acceptable and how this conclusion was made (e.g. acceptable usage rate, acceptable performance in the finished product). A statement or documentation from R & D supported by test results should be submitted if the ingredient was tested.

Form – The inappropriateness of the form available should be clearly described with supporting proof. Examples of form characteristics: 1) acceptable physical form (e.g. liquid, powder, extract, emulsion); 2) acceptable ingredient labeling (e.g. carrier system); 3) acceptable solubility, 4) meets desired shelf life. A specification sheet (or similar document or method) for the desired flavor along with a specification sheet (or similar document) of the flavor found could support your description.

Note: Price cannot be a consideration for determination of commercial availability.

- Operators are required to at least update commercial availability information in each annual Organic Handling Plan Update.

HELPFUL RESOURCES FOR SOURCING ORGANIC FLAVORS

1. National Organic Program Organic Integrity Database: <https://organic.ams.usda.gov/integrity/>
2. Find.Organic Business Directory: <https://find.organic/>

REFERENCES

1. George A. Burdock. Fenaroli's Handbook of Flavor Ingredients, 5th ed. Washington D.C. CRC Press.
2. NOP 3011: National List Petition Guidelines
3. NOSB Fall 2006 Recommendation: Commercial Availability Criteria for National List Materials (unanimously passed)
4. NOSB Fall 2007 Recommendation: Guidance on the Establishment of Commercial Availability Criteria
5. NOSB Fall 2015 Recommendation: Petition to revise the annotation for Flavors listed at § 205.605(a)
6. Primo Bader and Steve Phelps. January-March 2007. The Flavor Factor: Exploring Today's Taste-Improving Technology. Organic Processing Magazine.



ACA Best Practices for Commercial Availability of Natural Flavors

June 2020

Purpose

ACA Best Practices describe actions certifiers should take to verify operator compliance, as well as producer activities that can easily be approved by certifiers. The ACA strives to ensure that all Best Practices are consistent with the Organic Foods Production Act (OFPA) and the USDA Organic Regulations. These Best Practices are not legally binding, but if a producer presents plans that fall outside of these Best Practices, then the Organic System Plan (OSP) should provide a rationale for alternative methods and an explanation for how their system fulfills the applicable portion(s) of the related regulations. Certifiers will evaluate whether the differences can be justified. Similarly, if certifiers take an approach that is different from what is presented here, they should be able to articulate how the differing approach is justified according to the OFPA and the USDA Organic Regulations.

Background

This ACA Guidance document describes background, policy, and procedural steps that certifiers should take to ensure compliance with §205.605(a):

Flavors—nonsynthetic flavors may be used when organic flavors are not commercially available. All flavors must be derived from organic or nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.

In 1995, the National Organic Standards Board (NOSB) recommended the use of Natural Flavors in organic foods with the requirement that certified operators demonstrate efforts towards production of organic natural flavors. In 2011, the National Organic Program (NOP) published [Policy Memo 11-1](#), which clarified that current requirements for flavors permitted in organic production and handling. The Organic Trade Association submitted a [petition](#) on November 6, 2014 to require the use of organic flavors when they are available in the quality, quantity and form needed. On October 29, 2015, the NOSB unanimously passed a recommendation to revise the annotation for flavors to require organic when commercially available. On December 27, 2018, the NOP issued a final rule amending the National List with the implementation date of December 27, 2019.

Historically, commercial availability has applied to seeds, materials listed at §205.606, yeast and silicon-dioxide at §205.605. The application of commercial availability to natural flavors led to many questions among certifiers:

- How do certifiers assess commercial availability of natural flavors?
- How do certifiers assess commercial availability of flavoring components?
- What type of documentation is required for processors to demonstrate lack of commercial availability?
- How does quantity, quality, and form specifically apply to flavors?

The working group identified two groups of operations to consider for the commercial availability of natural flavors: operators sourcing flavors as an ingredient in an organic processed product and operators creating certified organic flavors. Operators sourcing flavors as an ingredient in an organic processed product may only use non-organic natural flavors that meet the requirements at §205.605(a) if they have demonstrated that an organic version of that flavor is not commercially available. Operators creating organic natural flavors may only use non-organic flavoring components that meet the requirements at §205.605(a) if they have demonstrated that an organic version of that flavoring component is not commercially available.

Definitions

Natural flavor: 21 CFR 101.22. Foods; labeling of spices, flavorings, colorings and chemical preservatives. (a) (3) 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. Natural flavors include the natural essence 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.

Flavoring Substances: Substances added to impart or help impart a taste or aroma in food. FDA regulations refer to these as Flavoring agents and adjuvants.

Commercial Availability

According to 7 CFR 205.2, commercial availability is 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. The working group agreed to the following when determining commercial availability of organic natural flavors and flavoring substances:

- Operators must contact at least three valid suppliers, with exceptions considered on a case-by-case basis.
 - An operator sourcing natural flavors products or flavoring components to be used in an organic flavor must contact flavor houses that may have an organic version of the flavor/ flavoring substance or the ability to create an organic version.
 - Operators should check with different suppliers of flavors year-to-year.

- Having a contract in place with a flavor manufacturer is not sufficient justification to contact fewer than three valid suppliers. Additional documentation must be submitted and may be considered on a case-by-case basis.
 - A contract in place with a non-organic flavor manufacturer working towards certification or with a certified organic flavor manufacturer working to develop an organic version may be sufficient justification for contacting fewer than three valid suppliers, provided that documentation is submitted to verify the anticipated date of certification and/or organic system plan.
- Claiming that a flavoring substance cannot be certified organic is not sufficient justification for contacting fewer than three valid suppliers. Additional documentation must be submitted justifying the lack of ability to certify the ingredient, which may be considered on a case-by-case basis, or three valid suppliers must be contacted.
- Operators must verify and document commercial availability annually for each non-organic flavor or flavoring substance used, with exceptions considered on a case-by-case basis.
 - An ordering or manufacturing schedule can be considered if part of the company's Standard Operating Procedure (SOP).
- The use of otherwise compliant non-organic flavors in made-with-organic products does not invoke a commercial availability search (as long as it meets the requirements of made with organic products).
- Using the flavor name alone may not be sufficient evidence to verify lack of commercial availability of an organic flavor.
- Price cannot be a consideration for determination of the commercial availability.

Quantity, Quality, and Form

The working group clarified quantity, quality, and form as it relates to Natural Flavors:

Quantity relates to the appropriate amount needed for production. Factors to consider regarding quantity:

1. Insufficient amounts for production requirements
2. Excessive minimum purchase requirement

The working group agreed that the operation should submit documentation on the number of suppliers and the amount produced. This report should specify the projected production and quantity of the flavor needed for a given amount of time and contrast the amount with the amount available.

Quality relates to performance attributes most often accompanied by research and development (R & D). Examples of quality for commercial availability:

1. Unreliable manufacturer - providing product with inconsistent quality
2. Shelf life
3. Analytical test results from or that support R & D (microbial testing)
4. Results from a table top comparison (comparing the flavor to other flavors by diluting it to the level used and tasting them side by side)
5. Results from a taste panel (often done after a tabletop comparison)
6. Grade
7. Flavor profiles
8. Effect on the quality of the finished product

The working group agreed that the operation must submit appropriate documentation justifying that an organic version is not of the appropriate quality, which may include but is not limited to R & D testing, visual of the product upon arrival, microbial testing, organoleptic, etc. Operations must provide a clear description as to why the quality of the organic flavor is not acceptable and how this conclusion was made.

Form relates to the physical attributes of a flavor or flavoring substance such as its specifications. Examples of form for commercial availability:

1. Whether the product is powder or liquid

The working group agreed that information should be submitted as to why the form of the ingredient cannot be used in the product or why the product cannot be modified within reason. For example, why can't the product be modified to include a powder instead of a liquid? If the final product is in powder form then it is not within reason to request product modification. Documentation may include specification sheets for the desired flavor and similar flavors found.

Use Up

When an organic version of a natural flavor or flavor substance is commercially available, the working group agreed to the following use up parameters:

- Operators must develop a plan for using up non-organic natural flavors or flavoring substances when organic versions become commercially available. Operators may use up existing stock on a case-by-case basis, but generally no longer than 12 months.
 - Factors to consider for an extended use up include existing production schedules, amount the producer has on-hand, and whether or not the product can be diverted (used in a conventional product),
 - A client cannot use a contract with a non-certified manufacturer to indefinitely stall using an organic flavor or flavoring component.

Documentation

Operators must have annual documentation of their commercial availability search looking at three sources for each flavor or flavoring component, or justification for fewer sources. The organic system plan should include a commercial availability plan which details the operations overall usage of natural flavors. Documentation must include justification of a lack of commercial availability when an organic version of a natural flavor or flavoring component is identified.

The working group created sample forms to use for documentation of commercial availability. Usage of these forms is not mandatory; however, the information in these forms should be documented by the client. Documentation should be verified as part of the Organic System plan by either being submitted to certifiers, verified at inspection, or a combination of both.

The [ACA Commercial Availability Form Organic Search](#) is completed by the certified operator intending to use a non-organic flavor or flavor substance. The form is used to indicate the three valid sources that were checked for an organic version of the flavor or flavor substance.

The [ACA Commercial Availability Plan](#) is completed by the certified operator using or intending to use non-organic flavors or flavor substances as ingredients in or on processed products labeled as “organic.” The plan details the operations overall usage of natural flavors and flavor substances.

The [ACA Commercial Availability Manufacturer Affidavit](#) is completed by a flavor manufacturer contacted during a commercial availability search. This form is not to be used solely to determine commercial availability but can be used as a supplement to document commercial availability.

Examples

The working group discussed the following scenarios and considerations for commercial availability of organic natural flavors:

Scenario	Considerations
An organic processor of organic ice cream, “Ice, Ice, Baby,” would like to make a label claim about the origin of a specific flavor. Their “Tahitian Vanilla” ice cream product is labeled as such, so they must use Tahitian flavor. They are unable to find organic Tahitian Vanilla flavor.	Claiming lack of commercial availability of an organic flavor because it is not available from a particular geographical origin with a “kosher” label claim is not sufficient. More information must be submitted to justify a difference in form, quality, or quantity, such as differing flavor profiles. An operation should not source a specific flavor name but

	instead should source the flavor components and ingredients
An organic processor of organic candy, “Santa’s Sweet Shop,” is producing a chocolate bar with candy cane flavor for the holidays. They are unable to find “candy cane” flavor as organic.	Using the flavor name alone is not sufficient evidence to verify lack of commercial availability. The producer must look at three valid suppliers for equivalent flavor profiles such as mint.
An organic processor is sourcing a non-organic flavor from a flavor house, and the flavor house is certified and has the ability to make the flavor organic.	The processor must submit justification for why the flavor house cannot make a version in suitable quantity, quality, or form, and the client is responsible for checking three valid sources for an organic version of the flavor.
An organic processor has a contract with a flavor house that is not certified organic and is not necessarily familiar with organic flavors.	The processor is responsible for checking three valid sources for an organic version of the flavor. If an organic version is commercially available, the processor will have to develop a certifier-approved use-up plan.
An organic processor has located an organic version of a flavor, but the flavor is not available consistently, which will affect the production schedule of the processor.	This may be an acceptable reason for lack of commercial availability due to quantity. A statement from the company contacted (or similar documentation) regarding the amount available must be submitted. The processor must still check with two other valid sources.
An organic processor contacts a supplier of organic natural flavor but there is only so much organic flavor in inventory.	This may be an acceptable reason for lack of commercial availability due to quantity. A statement from the company contacted (or similar documentation) regarding the amount available must be submitted. The processor must still check with two other valid sources.
An organic processor needs a quantity of flavor and the flavor house can create it organically but not by the time needed for production.	This may be an acceptable reason for lack of commercial availability due to quantity. A statement from the company contacted (or similar documentation) regarding the amount available must be submitted. The processor must still check with two other valid sources.
The required minimum order is too large for an organic processor’s needs.	This may be an acceptable reason for lack of commercial availability due to quantity. A

	statement from the company contacted (or similar documentation) regarding the amount available must be submitted. The processor must still check with two other valid sources.
An organic processor has an agreement with the flavor house that it will be the sole supplier of flavor products for 2 years.	The processor must still check three valid sources for an organic version of the flavor. If an organic version is identified, the certifier should ask for a plan moving forward.
A flavor house designed the whole product, not just the flavor, then the organic processor brought it to market.	The processor must still check three valid sources for an organic version of the flavor. If an organic version is identified, the certifier should ask for a plan moving forward.
An organic processor uses a non-organic flavor in a processed product. They document the lack of commercial availability of an organic version every 18 months, which coincides with ordering and production schedules.	This may be an acceptable reason to verify commercial availability every 18 months instead of every year.
The organic processor is using a natural flavor in powder form and there is an organic version available in liquid form.	This may be an acceptable reason for lack of commercial availability due to form. Documentation of the flavor's form and why it is not an appropriate form for the product must be submitted. The processor must still check with two other valid sources.
An organic processor wants to use food grade lavender flavor in their cookies but checked three sources and could only find aromatherapy grade organic lavender flavor, not food grade.	This may be an acceptable reason for lack of commercial availability due to quality.
The organic processor needs (or is using) a 2% concentration of a flavor but a supplier only has an organic 5% concentration available.	This may not be an acceptable reason for a form or quality exemption since the processor or supplier may be able to make adjustments to the product in order to make it usable. However, this may be an acceptable reason for lack of commercial availability if the changes made to use the different concentration affects the finished product. Documentation of the flavor's concentration and why it is not an appropriate form or

	<p>quality for the product must be submitted. The processor must still check with two other valid sources.</p>
<p>The organic processor “Jamrock Hasidic Foods” only manufactures foods that are kosher and from Jamaica. It uses a kosher-certified natural rum flavor in products it wishes to certify as Organic. Equivalent organic kosher flavors are commercially available; and equivalent organic Jamaican rum flavors are commercially available, but there are no equivalent organic rum flavors on the market that are both Jamaican and kosher. The company claims that the Jamaican rum flavor is allowed since organic flavors are not available in the quality, form, or quantity required.</p>	<p>Claiming lack of commercial availability of an organic flavor because it is not available from a particular geographical origin with a “kosher” label claim is not sufficient. More information must be submitted to justify a difference in form, quality, or quantity, such as differing flavor profiles. An operation should not source a specific flavor name but instead should source the flavor components and ingredients</p>

Conclusion

The ACA recommends all accredited certifiers adopt ACA Guidance for consistent implementation of the USDA Organic Regulations. ACA Guidance Documents are reviewed periodically to ensure they are accurate and up to date. Concerns with this or any ACA Best Practice or guidance document should be submitted to the ACA Coordinator.

Resources

Definitions of types of flavors - [OTA petition](#), page 13/81

OTA’s [guide](#) to commercial availability of flavors

[NOP Policy Memo 11-1](#)

[PART 170 -- FOOD ADDITIVES](#)

[ACA Commercial Availability Form Organic Search](#)

[ACA Commercial Availability Plan](#)

[ACA Commercial Availability Manufacturer Affidavit](#)