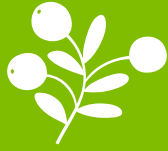


# USDA Organic Flavors Required When Commercially Available!



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.

**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.



**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.

**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.

## 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

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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.



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