

# USE OF NATURAL FLAVORS IN ORGANIC PRODUCTS



## WHAT IS A NATURAL FLAVOR?

Flavors are materials added to food to help impart a taste in food. Flavors do not include materials that qualify exclusively as flavor enhancers, substances with an exclusively sweet, sour, or salty taste (e.g. sugar, non-nutritive and nutritive sweeteners, vinegar, and table salt), or flavor maskers.

The use of certain natural (non-synthetic) materials, including flavors, in products labeled as “Organic” or “Made with Organic”/”70-95% Organic” is allowed provided they comply with provisions established in the organic regulations and other relevant regulatory requirements.

The material must legally be able to be identified as a natural flavor on the ingredient panel of a final product; the only exceptions being:

- Where the flavor is a single-ingredient material, such as bergamot oil. In such cases, the flavor should be labeled by its common name, e.g., “bergamot oil”; and
- Where the flavor is a natural smoke flavor. In such cases, it must either be listed as “natural smoke flavoring” on the ingredient panel or the product name/description must identify the product, or ingredient therein, as “smoked”, “smoky”, or similar description.
- There may be other regulatory reasons why a flavor ingredient may need to be identified by its common name on the finished product label. QAI will assess these situations on a case-by-case basis to determine compliance.

Additionally, the material may only be used for flavoring purposes (no nutritional use or other function is permitted).

QAI’s guide discusses the requirements for seeking approval to use natural flavors in compliance with the following organic regulations:

- USDA National Organic Program (NOP) 7 CFR Part 205.605
- Canadian Organic Regime (COR) CAN/CGSB 32.311-2015, Section 6.4
- European Commission (EC) No 889/2008 Organic Regulations (EU) Article 27 (c)
- Mexico Organic Standard Guidelines for the Organic Operation (LPO) Annex I

The Organic Trade Association has developed a [Practical Guide](#) to understanding flavors and requirements for NOP processed products that we recommend reading as a primer.

## Required Documentation for Flavor Ingredient Approval

A manufacturer seeking certification with QAI is required to submit a **QAI Natural Flavor Questionnaire** for each non-organic natural flavor used in organic products. The flavor supplier who has technical knowledge about how the flavor is created should complete the form.

Under the USDA NOP, flavors are required to be organic. Non-organic natural flavors can only be used in products represented as “Organic” (>95%) when an organic equivalent flavor is commercially unavailable. Commercial Availability is the ability to obtain an input, in this case a natural flavor product, in an appropriate form, quality, or quantity to fulfill an essential function. Price is not a valid consideration.

When non-organic natural flavors are used, manufacturers seeking NOP certification must demonstrate ongoing effort to source and formulate with certified organic flavors by submitting the **QAI Organic Flavor Commercial Availability Plan** on an annual basis.

- This Organic Flavor Commercial Availability Plan (OFCAP) is the document from which QAI staff and inspectors will evaluate ongoing compliance with organic flavor commercial availability requirements.
- Individual Natural Flavor Questionnaires (NFQs) also include a section for flavor suppliers to provide organic commercial availability information specific to the natural flavor in question. However, that only addresses one supplier’s ability to provide an organic flavor. QAI relies primarily on the information in the OFCAP document to evaluate what steps are being taken to source organic flavors including reformulation of existing natural flavors.

Additionally, the organic standards place restrictions on ingredients allowed in organic and natural flavors. It may become necessary to evaluate ingredients or their constituent parts, such as flavor carriers, to determine their agricultural, non-agricultural or synthetic status. For this review QAI utilizes our **Nonorganic Material Compliance Questionnaire**.

Let’s take a closer look at the purpose for these forms and some of their questions...

### QAI Natural Flavor Questionnaire

A completed Natural Flavor Questionnaire (NFQ) provides QAI with necessary information to determine if a material qualifies as a non-organic “natural flavor” and is compliant for use in products certified organic to specific standards. **Please reference Annex A of this document for regulatory definitions of a natural flavor.**

The NFQ asks which regulatory body or regulation the natural flavor complies with such, as the FDA (USA), CFIA (Canada), European Commission (EU), or Codex Alimentarius (Mexico). The answer will determine how QAI further evaluates the material to be in compliance with the relevant organic standard(s).

The name and type of flavor (extract, essential oil, WONF, etc) is required along with attestations of compliance to confirm the non-gmo non-ionizing radiation, and non-nanotechnology status of the flavor, all of which are prohibited practices under most organic standards.

QAI must also evaluate how the flavor is formulated to ensure it contains only natural flavors and is produced with allowed solvents, carriers and preservatives.

- Non-flavoring constituents must be disclosed on the form. Requirements vary by standard so read each question carefully.
- Glycerin is a tricky material that must be certified organic or agricultural if used in a natural flavor approved for NOP products. If not organic, we require the QAI Nonorganic Material Compliance Questionnaire to be completed to determine its agricultural status. That form is discussed later in this guide.

A material can only qualify as a natural flavor if it is formulated for flavoring purposes (no nutritional, sweetening or other use). Therefore, we've included a question that asks if the flavor could serve as a flavor enhancer/modifier or in a nutritional, sweetening, or similar function if used at specific rates. This is common for flavors that use ingredients such as Luo Han Guo (Monk Fruit), Steviol, Thaumatin, etc.

- When this is the case, QAI needs to know what the ingredient is and the usage rate when we review the formulation for the finished organic product containing the natural flavor in order to ensure it used as a flavor and not for other purposes.
- Any flavor supplier concerned about disclosing this information may work directly with QAI under a confidentiality agreement as needed.

The Natural Flavor Questionnaire also includes a section for flavor suppliers to provide organic commercial availability information specific to the natural flavor listed on the form. Although the supplier may not be able to determine if an alternative certified organic flavor would be suitable for their customer, disclosing its availability will indicate to the customer if there is an opportunity to pursue and evaluate an organic flavor replacement.

## QAI Organic Flavor Commercial Availability Plan

Organic products certified to the USDA NOP must use organic flavors unless commercially unavailable. The QAI Organic Flavor Commercial Availability Plan (OFCAP) is only applicable for companies seeking NOP certification.

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

For QAI to approve the use of non-organic natural flavors, we must approve the plan for attempting to find alternative organic flavors and assessing their overall commercial availability. The QAI Organic Flavor Commercial Availability Plan is a required part of the organic system plan. Its purpose is to describe the practices and procedures you implement to source and use organic flavors in products requested for certification.

Organic flavor search, sourcing, and development efforts must be documented. The QAI Organic Flavor Commercial Availability Plan requests information regarding what types of records are maintained to document these efforts.

QAI understands flavors have unique attributes. A great place to start is with your current flavor house(s). They may be best positioned to provide or develop the organic flavor you need. In completing the QAI Organic Flavor Commercial Availability Plan, consider the following:

- Detail if your plan for flavor types such as extracts, essential oils, oleoresins, essences, and distillates, which may be more readily available in organic form, is different than how you will approach sourcing more complex mixtures such as compounded flavors.
- Use your plan to help us understand what R&D is required after you find a potential organic flavor replacement.
- Be descriptive when detailing why form, quality, or quantity is the reason an available organic flavor is not suitable and maintain evidence to support the claim.

The QAI Organic Flavor Commercial Availability Plan does not provide a location to list our all your natural flavors currently in use. QAI is assessing your plan and approach for all flavors. We recommend using the comments field on the Profile Workbook Supplier List if you would like to document sourcing information on an ingredient by ingredient basis in addition to completing the plan.

## QAI Nonorganic Material Compliance Questionnaire

The QAI Nonorganic Material Compliance Questionnaire needs to be submitted upon request when a non-organic material, such a glycerin, can be produced in a variety of ways that result in either an agricultural, non-synthetic, or synthetic form of the material.

The USDA National Organic Program (NOP) published a Classification of Materials guidance document<sup>1</sup> and decision trees to assist in assessing whether a material is agricultural, non-agricultural, synthetic, or non-synthetic. QAI receives Natural Flavor Questionnaires and statements of “natural” status for materials that may actually be synthetic and out of compliance. This is because there is a slight difference in interpretation of “natural” or “non-synthetic” between the FDA and NOP.

The Food and Drug Administration (FDA) defines the term natural on whether the flavoring substance is derived from a natural source (e.g., spice, fruit, etc.). The FDA definition does not consider whether it has been chemically transformed during the manufacturing process. According to the FDA, a flavor from a naturally occurring source is always “natural”, regardless of a chemical transformation process occurring further along the manufacturing process.

According to NOP definitions, however, the source of a non-synthetic substance must be natural, but certain chemical transformations occurring during the manufacturing process can switch the classification of the substance from non-synthetic to synthetic.

This results in materials that may be considered “natural” by FDA and the Flavors Extract Manufacturers Association (FEMA), but “synthetic” by NOP.

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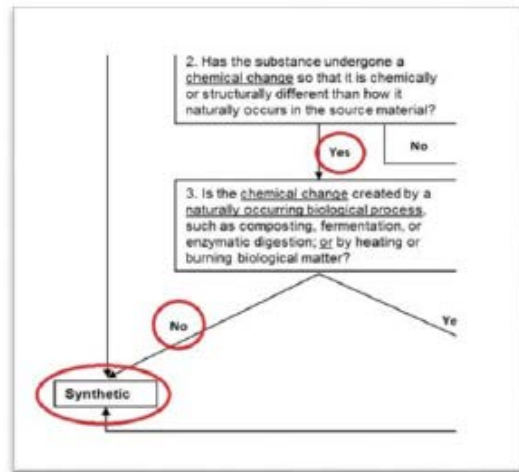
<sup>1</sup> <https://www.ams.usda.gov/sites/default/files/media/NOP-5033.pdf>

**For flavors, QAI accepts those that qualify as natural flavors under the FDA.**

**For carriers, preservatives and solvents, QAI applies the NOP Classification of Materials guidance/decision tree to determine the synthetic or non-synthetic status of the material.** In accordance with the annotation for natural flavors on the NOP National list, only those carriers, preservatives and solvents deemed to be non-synthetic according to the NOP guidance/decision trees are permitted in natural flavors used in organic products.

To illustrate, triethyl citrate is determined by FDA and FEMA to be natural because it is produced using ethyl alcohol derived from fermented grain and citric acid produced via fermentation of carbohydrates. The ethyl alcohol and the citric acid are heated together, which results in the conversion of these two materials into a new material, triethyl citrate. This activity results in a chemical reaction of two chemicals. The chemical change is not caused by biological or mechanical methods.

If we run triethyl citrate's manufacturing process through the NOP Classification of Materials Decision Tree for determining if a material is synthetic or non-synthetic, we see that the process step above (i.e. "ethyl alcohol and the citric acid are heated together, which results in the conversion of these two materials into a new material, triethyl citrate") results in a synthetic material.



*NOP Classification of Materials Decision Tree*

Since the process combines the citric acid (even though it is natural) and the alcohol (even though it is natural) and heats them to create a new substance, and that heating step is not a biological or mechanical process, it is a synthetic material under the NOP. It is a chemical process that involves creating a new substance from the combination of two materials under heat. (Please note the reference in the decision tree to the heating of biological matter applies to crop inputs not processed products.)

If triethyl citrate is used as a carrier, then its classification would be synthetic and it would not be allowed. **If it is used to impart flavor, however, it is assessed according to the FDA natural flavor definition and would be permitted.**

The QAI Nonorganic Material Compliance Questionnaire provides information on the step-by-step processes used, including raw materials, to manufacture a material so that QAI may evaluate its classification as agricultural, non-agricultural, synthetic, or non-synthetic.

## Certified Organic Flavors

If your operation is a flavor manufacturer and you wish to make a certified organic flavor, the same organic requirements apply as they would to any other certified organic product. In order for a flavor to make an organic claim, the product must consist of at least 95 percent organic ingredients and no more than 5 percent non-organic ingredients allowed by the organic standard.

- Some ingredients allowed in the creation of a natural flavor are not always permitted to be added directly to an organic flavor. For example, an amino acid cannot be added directly as an ingredient in the formula. The reason is that amino acids are not listed on the approved Material List in the standard. However, an amino acid can be used in the production of a non-organic natural flavor. That non-organic natural flavor can then be added as an ingredient in the formula of an organic flavor as part of the 5 percent or less non-organic ingredient allowance.

For certification to the NOP, the same commercial availability requirements previously discussed also apply to natural flavors used to make organic flavors.

- Flavor manufacturers are often in the unique position of making their own non-organic natural flavors. Those natural flavors are also subject to commercial availability requirements. QAI will be evaluating how flavor manufacturers are reviewing their natural flavors made in-house or sourced externally to find a suitable organic replacement.
- Additionally, we hope to see certified organic flavor manufacturers encouraging their customers to increase the organic content of currently certified organic flavors as more natural flavor ingredients become available in organic form.

Organic flavors may be labeled in compliance with the same regulatory requirement as non-organic natural flavors with a few additional requirements.

- The organic flavor must be affixed with a lot # when sold in non-retail bulk packaging.
- If the flavor formula contains “organic natural flavor” and non-organic “natural flavor”, both must be disclosed separately on the flavor label and/or technical data sheet.
- The word “organic” in the product name may not modify a non-organic ingredient in the product.
  - For example, a strawberry flavor that does not contain any organic strawberries in the formula may not be labeled “Organic Strawberry Flavor”. It may, however, be labeled “Organic Flavor Strawberry Type”, or something similar.
- Flavors that only qualify for the “Made with Organic” claim cannot be labeled as “Organic”, but they can be labeled as follows: “Strawberry Flavor, Made with Organic alcohol” or “Strawberry Flavor, 70% Organic”, or similar.

## Annex A

In addition to the organic regulations allowing a natural flavor in organic products, the following regulations define natural flavors:

The **United States FDA** Definition of Natural Flavors per FDA 21 CFR Part 101.22(a)(3) is: ... 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 **Canadian Food Inspection Agency (CFIA)** Definition of Natural Flavours and Flavour Descriptors is: Substances which impart flavours which have been derived from a plant or animal source, may be claimed to be "natural". As well, any additive, such as preservatives and solvents added to a flavour preparation to have a technological effect solely on the flavour, does not modify the "natural" status of the flavouring material itself. Furthermore, SFCR Part 11, Division 2, Subdivision D, Section 224(1) expands the list from which natural flavours may be derived to include natural substances such as meat, fish, poultry, vegetables, edible yeast, herbs, spices, bark, buds, roots, leaves, or other plant material. Additional details regarding flavouring preparation requirements are detailed in the Canadian Food and Drug Regulations Part B Division 10.

The **European Union (EU)** definition of natural flavors, as described in Council Directive 88/388/EEC (14) is: The word 'natural', or any other word having substantially the same meaning, may be used only for flavourings in which the flavouring component contains exclusively flavouring substances as defined in Article 1(2)(b)(i) and/or flavouring preparations as defined in Article 1(2)(c). If the sales description of the flavourings contains a reference to a foodstuff or a flavouring source, the word 'natural' or any other word having substantially the same meaning, may not be used unless the flavouring component has been isolated by appropriate physical processes, enzymatic or microbiological processes or traditional food-preparation processes solely or almost solely from the foodstuff or the flavouring source concerned.

The **Mexico** LPO definition of natural flavors relies on that of the Codex Alimentarius Commission: Natural flavourings are products used to impart flavor to a food or beverage – with the exception of only salty, sweet or acid tastes. Their aromatic part consists exclusively of “natural flavours” and/or “natural flavouring substances” and they may or may not contain adjuncts. They are not intended to be consumed as such. Natural flavours and natural flavouring substances are preparations and single substances respectively, acceptable for human consumption, obtained exclusively by physical, microbiological or enzymatic processes from material of vegetable or animal origin either in the raw state or after processing for human consumption by traditional food preparation processes (including drying, roasting and fermentation).



## Frequently Asked Questions

### **QAI has updated its Natural Flavor Questionnaire. Do I need to submit an updated version for all my previously approved natural flavors?**

- No. It is not necessary to submit an updated Natural Flavor Questionnaire for previously approved flavors unless QAI requests it in order to close the gap on missing compliance information.
- The updated Natural Flavor Questionnaire should be used to submit all new non-organic flavors to QAI for review.

### **Are my products out of compliance as of December 27, 2019, if I am still using non-organic natural flavors?**

- No. That is the date when the requirement to start searching for organic flavors begins. Compliance will be evaluated on an on-going basis through the annual submission of your updated Organic Flavor Commercial Availability Plan.
- Once you source an organic flavor to replace a non-organic natural flavor, work with QAI to submit updated formulas and labels.

### **Am I required to update my Organic Flavor Commercial Availability Plan during every midyear product addition when I submit new ingredients?**

- No. Product additions may occur without updating the commercial availability plan midyear. The plan is part of your organic system to be updated during renewal and verified annually during the inspection.

### **If I source an organic flavor but still have the non-organic natural flavor in inventory, can I use-up the non-organic natural flavor in my products?**

- Yes, QAI will consider inventory use-up on a case-by-case basis. Submit the request including quantity and timeline to QAI for review and approval.

### **If my labels need to change after sourcing an organic flavor, can I use up my old labels in inventory?**

- Yes, QAI will consider label use-up for a reasonable amount of time. Submit the request including quantity and timeline to QAI for review and approval.