USE OF NATURAL FLAVORS
IN ORGANIC PRODUCTS
WHAT IS A NATURAL FLAVOR?

Flavors are materials added to products to impart or help impart taste, though substances with an exclusively sweet, sour, or salty taste do not qualify as flavors (i.e. sugar, non-nutritive and nutritive sweeteners, vinegar, and table salt). The definition of a natural flavor varies from country to country, and applicable regulatory references should be consulted for exact definitions. In the USA, the FDA defines natural flavors at 21 CFR Part 101.22(a)(3).

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.

In the USA, the material must legally be able to be identified as a natural flavor in the ingredient panel of a final retail 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 32.311-2020, Section 6.4
- European Commission (EC) No 889/2008 Organic Regulations (EU) Article 27 (c)

The Organic Trade Association has developed a Practical Guide to understanding flavors and requirements for NOP processed products that QAI recommends reading as a primer.
Required Documentation for Flavor 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 efforts 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 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 as available specific to the natural flavor in question. However, this 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, non-synthetic status. QAI utilizes the Nonorganic Material Compliance Questionnaire to review this information.

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.

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 should correspond to the region the flavor will be used in and will determine how QAI further evaluates the material under 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.
A material can only qualify as a natural flavor if it is formulated for flavoring purposes (no nutritional, sweetening or other use). The NFQ requires attestation to this requirement. QAI has also included a question that asks if the flavoring agent(s) used only consist of substances that do not impart a specific characteristic flavor, such as flavorings with modifying properties (FMPs). This is common for flavors that use ingredients such as Luo Han Guo (Monk Fruit), Steviol, Thaumatin, etc.

- When this is the case, QAI requires documentation detailing the maximum usage rate for the overall flavor to qualify as a natural flavor. This is needed when QAI reviews 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.

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

- Non-flavor ingredients/adjuvants 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 use in NOP products. If not organic, QAI requires completion of the QAI Nonorganic Material Compliance Questionnaire to verify its agricultural status. This form is discussed later in this guide.

The Natural Flavor Questionnaire also includes a section for flavor suppliers to provide organic commercial availability information as available 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 does not require submission of specification sheets for flavors if the current QAI NFQ is completed. If an obsolete version is submitted, a specification sheet may be requested. Additionally, an updated QAI NFQ may be requested for previously approved flavors when it appears FMPs might be the only flavoring agent(s) present in the flavor, or if additional information is required based on regulatory changes.

**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.

To approve the use of non-organic natural flavors, QAI 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 an organic operation implements 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 searching for an organic flavor is with your current flavor house(s). They may be best positioned to provide or develop the organic flavor needed. 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 QAI 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 all your natural flavors currently in use. QAI assesses 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 non-organic, non-flavor ingredients/adjuvants like glycerin can be produced in a variety of ways that could impact the agricultural, non-agricultural, non-synthetic, or synthetic classification of the material.

The USDA National Organic Program (NOP) published a Classification of Materials guidance document and decision trees to assist in assessing whether a material is agricultural, non-agricultural, synthetic, or non-synthetic. QAI receives statements of “natural” status for non-flavor ingredients/adjuvants that may actually be synthetic under the NOP 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) assess the natural status of a flavor based on whether the flavoring substance is derived from a natural source (e.g., spice, fruit, etc.). The FDA definition does not consider whether the substance has been chemically transformed during 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 the FDA and the Flavors Extract Manufacturers Association (FEMA), but “synthetic” by the NOP.

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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 may be determined by the FDA 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, resulting in an esterification reaction that produces a new material, triethyl citrate. This is a chemical reaction, and the chemical change is not caused by biological or mechanical methods.

If triethyl citrate’s manufacturing process is run through the NOP Classification of Materials Decision Tree for determining if a material is synthetic or non-synthetic, the process step above (i.e. esterification of citric acid with ethyl alcohol) results in a synthetic material.

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 may 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.

- **Reaction Flavors** - some ingredients allowed in the creation of a natural flavor may not always be permitted for addition directly to an organic flavor. For example, an amino acid cannot be added as an ingredient directly to a NOP organic flavor formula. This is because amino acids are not included on the National List of Allowed Substances. However, amino acids could be used in the production of a non-organic reaction flavor via the Maillard reaction. The resultant non-organic 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 so long as it meets all requirements for a natural flavor. When reporting the use of a reaction natural flavor produced using non-National List ingredient to QAI:
  
  - List the overall reaction natural flavor on the Profile Workbook Supplier List rather than listing the ingredients used to produce the reaction natural flavor and submit an NFQ that covers the entire flavor.
  
  - Alternatively, if the individual ingredients used to produce the reaction natural flavor are listed on the Profile Workbook Supplier List, an NFQ that covers the resultant flavor and a description of the reaction type utilized to produce the reaction natural flavor is required. Ultimately, QAI needs to know what ingredients listed in the Profile Workbook are covered by the applicable NFQ.

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 evaluates how flavor manufacturers review their natural flavors made in-house or sourced externally to find a suitable organic replacement.

- Additionally, QAI hopes 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.
- The word “organic” may not modify a non-organic ingredient in the product name or ingredients statement.
  
  - 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.
- Favors 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.
Formulation Disclosure - all ingredients used in organic flavors requested for certification must be disclosed to QAI. However, QAI allows a single “non-organic flavors” entry to be added to the Profile Workbook Supplier List and Recipe Sheets to represent all non-organic natural flavors used in products requested for certification.

- All non-organic natural flavors in use must still be individually listed in the Supplier List.
- This generic “non-organic flavors” recipe sheet entry only applies to non-organic natural flavors. All other non-organic ingredients and organic ingredients must still be individually disclosed in Recipe Sheets.
- Disclosure of the specific natural flavors used in each recipe may still be requested or required by QAI to verify specific compliance issues.

Non-Organic Flavors Entry Supplier List Example

<table>
<thead>
<tr>
<th>Name</th>
<th>OG Supplier</th>
<th>OG Certificate</th>
<th>NOG Supplier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vanilla extract</td>
<td>N/A</td>
<td>N/A</td>
<td>Flavorhouse XYZ</td>
</tr>
<tr>
<td>Lemon oil</td>
<td>N/A</td>
<td>N/A</td>
<td>Flavorhouse XYZ</td>
</tr>
<tr>
<td>Amel Butyrate</td>
<td>N/A</td>
<td>N/A</td>
<td>Flavorhouse XYZ</td>
</tr>
<tr>
<td>Anise Oil</td>
<td>N/A</td>
<td>N/A</td>
<td>Flavorhouse XYZ</td>
</tr>
<tr>
<td>Delta Decadron</td>
<td>N/A</td>
<td>N/A</td>
<td>Flavorhouse XYZ</td>
</tr>
<tr>
<td>Mint Oil</td>
<td>N/A</td>
<td>N/A</td>
<td>Flavorhouse XYZ</td>
</tr>
<tr>
<td>Non-Organic Flavors</td>
<td>N/A</td>
<td>N/A</td>
<td>In House</td>
</tr>
<tr>
<td>Organic Ethanol</td>
<td>Ethanol ‘n’ U’s</td>
<td>ETS</td>
<td></td>
</tr>
<tr>
<td>Silicon Dioxide</td>
<td>N/A</td>
<td>N/A</td>
<td>Sand’s Our Specialty Group</td>
</tr>
</tbody>
</table>

- New “Non-Organic Flavors” Supplier List entry. All non-organic natural flavors, other non-organic ingredients, and organic ingredients must still be individually listed.

Non-Organic Flavors Entry Recipe Sheet Example

<table>
<thead>
<tr>
<th>Ingredient (no water or salt)</th>
<th>Recipe Quantity</th>
<th>OG%</th>
<th>OG Qty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Organic Flavors</td>
<td>32.0000</td>
<td>0.00%</td>
<td>0.0000</td>
</tr>
<tr>
<td>Organic Ethanol</td>
<td>884.0000</td>
<td>100.00%</td>
<td>884.0000</td>
</tr>
</tbody>
</table>

- New “Non-Organic Flavors” Recipe Sheet Entry. All other non-organic ingredients and organic ingredients must still be individually listed, but all non-organic natural flavors used in this recipe are covered by the “Non-Organic Flavors” entry.

Recipe Sheet Example:

- “Label Claim Calculation”, product composition and standards of the destination market, together determine the eligible label claim. All labels must be submitted to QAI for approval.
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. Compliance is 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 if significant changes are made that could impact compliance. It is 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.