



USE OF NATURAL FLAVORS IN ORGANIC PRODUCTS

WHAT DOES NATURAL FLAVOR MEAN?

Flavors are products that are added to food to help impart a taste in food. Flavors do not include flavor enhancers¹; substances with an exclusively sweet, sour, or salty taste (e.g. sugar, non-nutritive and nutritive sweeteners, vinegar, and table salt); flavor maskers.²

The flavoring constituents in a natural flavor product must comply with the following criteria:

1. The material must meet FDA (NOP-certified clients), CFIA (COR-certified clients), or Council Directive 88/388/EEC (14) (EU-certified clients) definition of natural flavor.
2. The material must legally be able to be identified as a "natural flavor" per FDA/CFIA/EEC on the ingredient panel of a final product; the only exceptions being:
 - a. 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
 - b. 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.
 - c. 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.
3. The material may only be used for flavoring purposes (no nutritional use or other functions is permitted).
4. The material must be listed as a natural flavor on the finished product labels, except per the exception stated in Section 2 above.

THE ORGANIC REQUIREMENT

1. Natural flavors authorized for use in NOP, COR, EU "organic" or "made with organic" (70-95%) products must not be produced using synthetic extraction solvents and must not contain any synthetic carrier systems or any artificial preservatives.
2. Natural flavors, including any solvents, carriers, preservatives or other processing aids used or contained therein, must not be produced and handled with the use of excluded (GMO) methods.
3. Ionizing radiation as described in 21 CFR 179.26(US) and Canadian Food and Drug Regulations, Division 26, must not be used in the production or handling of the flavor.

¹ Defined in 21 CFR 170.3 O (11) as *Substances added to supplement, enhance, or modify the original taste and/or aroma of a food, without imparting a characteristic taste or aroma of its own.*

² On occasion, at certain levels used in a product, the material that is a flavor enhancer, sweetener, or flavor masker, may also qualify as a natural flavor in its own right. See below for the example of Luo Han Fruit (Monkfruit) that illustrates this. The flavor material cannot be used if it ONLY meets the enhancer or adjuvant definitions.

4. If the natural flavor contains organic ingredients which are counted toward a finished product's organic content, the manufacturer of that flavor must be certified organic, and the flavor in question must be certified or verified by an accredited certifying agent.

NOP VS. FDA DEFINITIONS

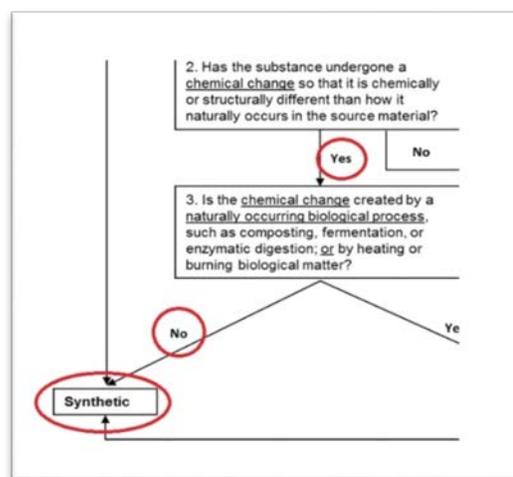
The USDA National Organic Program (NOP) has published a Classification of Materials guidance document³ and decision trees to assist in assessing whether a material is agricultural, non-agricultural, synthetic, or non-synthetic. QAI receives Natural Flavor Questionnaires and statements of “natural” status for materials that may still 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.

Meanwhile, according to the NOP definitions, the source of a *non-synthetic* substance has to be natural, but certain chemical transformations occurring during the manufacturing process can switch the classification of the substance from non-synthetic to synthetic.

Therefore, there are materials that may be considered “natural” (by FDA and FEMA) but “synthetic” by NOP. Essentially, for flavor chemicals (the ingredients that impart flavor), QAI accepts those that qualify as *natural flavors* under FDA. **But, for carriers, preservatives, solvents, QAI applies the NOP Classification of Materials guidance/decision tree to determine the synthetic or non-synthetic status of the material. Only those carriers, preservatives, 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. Therefore, 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.



NOP Classification of Materials Decision Tree

³ <https://www.ams.usda.gov/sites/default/files/media/NOP-5033.pdf>

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.

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. 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.

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 final product 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. Those 5 percent non-organic ingredients must be listed on the NOP National List, 205.605 (a) and/or (b) or 205.606.

Please note that an amino acid cannot be added directly as an ingredient in the formula when creating a certified organic flavor. The reason is that amino acids are not listed on the NOP National List. Natural flavors are listed on the National List, however, so 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.

Most flavors are sold in bulk to other food manufacturers. Organic flavors may be labeled in compliance with FDA or USDA labeling requirements. The only addition is that the organic flavor must be affixed with a lot #. Also note that the word “organic” in the product name may not modify a non-organic ingredient in the product. So, a strawberry flavor that does not contain any organic strawberries in the product may not be labeled “Organic Strawberry Flavor”. It may, however, be labeled “Organic Flavor Strawberry Type”, or something similar. For flavors that only qualify for the “Made with Organic” claim, they 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.

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