

Formal Recommendation
From: National Organic Standards Board (NOSB)
To: the National Organic Program (NOP)

Date: October 29, 2015

Subject: Petition to revise the annotation for Flavors listed at §205.605(a)

NOSB Chair: Jean Richardson

The NOSB hereby recommends to the NOP the following:

Rulemaking Action: X

Guidance Statement:

Other:

Rationale Supporting Recommendation:

Organic flavors have become more available over time and when available in an appropriate organic form are no longer necessary in non-organic forms. However all flavors in all types are not available in organic form and are still necessary when not available in organic form. This change will require the use of organic flavors when commercially available but continue to allow non-organic flavors when organic versions are not available. This is consistent with OFPA criteria for inclusion of the additional list §6517(c)(1)(A)(ii).

NOSB Vote:

Motion to revise the Flavors annotation at §205.605(a) to read: Non-synthetic 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.

Motion by: Tom Chapman

Seconded by: Jean Richardson

Yes: 14 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Outcome: Motion Passed

**National Organic Standards Board
Handling Subcommittee
Petitioned Material Proposal
Flavors, Nonsynthetic
August 25, 2015**

Summary of Proposed Action: Flavors are currently listed on §205.605(a) of the National List as an allowed nonsynthetic under the following listing: *Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.* A petition was received from the Organic Trade Association on November 6, 2014 to revise the flavors annotation to read: *Flavors – Non-synthetic flavors may be used in products labeled as “organic” 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.* The NOSB Handling Subcommittee is recommending the listing to be revised to read as: *“Flavors – Non-synthetic 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.”*

History

Flavors were not added to the National List as the result of a petition. Instead, they were included among substances initially placed on the National List when USDA promulgated regulations pursuant to the Organic Food Production Act of 1990. The NOSB has debated the issue of using natural flavors as ingredients in organic foods. On October 31, 1995 the NOSB recommended the addition of Natural Flavors and stated the following:

The Committee has debated the issue of the use of natural flavors as ingredients in organic foods. The focus of the debate has been whether natural flavors, with certain constraints, are appropriate for use in "organic foods" (95%-100% organic ingredients) or whether natural flavors should be restricted to use in foods "made with organic ingredients" (50%-95% organic ingredients) only...

Recommendation:

Upon implementation, all manufacturers will be required to have certification from the producers of the natural flavors that,

For "organic foods" (95%-100% organic ingredients):

- 1) All of the flavor constituents used in the natural flavor are from natural sources and have not been chemically modified in a way which makes them different than their natural chemical state.
- 2) The natural flavor has not been produced using any synthetic solvent and carrier systems or any artificial preservatives.

For "foods made with organic ingredients" (50%-95% organic ingredients):

- 1) All of the flavor constituents used in the natural flavor are from natural sources and have not been chemically modified in a way which makes them different than their natural chemical state.
- 2) The natural flavor does not contain propylene glycol, any artificial preservatives, and is not extracted with hexane.

Additionally, manufacturers shall provide written documentation in their Organic Handling Plan showing efforts made toward the ultimate production of an organic natural flavor as listed in the stepwise progression below:

Natural flavor constituents and non-synthetic carrier base and preservative agents (ex. Grain ethanol, non-synthetic glycerin and non-synthetic acetic acid).

Organic flavor constituents, organic carrier base, and organic preservative agents.

Organic flavor constituents extracted using organically produced solvents, organic carrier base, and organic preservative agents.

The rule was published with the annotation: *Flavors, nonsynthetic sources only and must not be produced using synthetic solvents and carrier systems or any artificial preservative.* This annotation is applicable to both “organic” and “made with organic” products. On April 20 2006 the NOSB stated the following in their Sunset Review:

There were many comments recommending the continued allowance of non-synthetic flavors in organic handling. The federal register notice regarding Sunset Review asked the public to provide evidence and address concerns for any substance they believed should be discontinued. There was a comment addressing the concern that colors and flavors were added to the National List without a technical review by the NOSB. The Handling Committee requested and received a technical overview of flavors on October 14, 2005. This technical review offered no information that would suggest that either non-synthetic flavors are inconsistent with organic practices. The use of flavoring substances is regulated by the FDA. All flavoring substances, non-synthetic, fall into one of two categories. They are either GRAS (Generally Recognized as Safe) a designation granted by a panel of technical experts whose authority is accepted by the FDA, or they are food additives that have been reviewed and approved by the FDA directly. To obtain approval from the FDA for a flavor as a food additive, the manufacturer must submit a petition demonstrating safety of the substance with information including manufacturing process, stability data, safety studies and toxicity data. Consequently, all non-synthetic flavoring substances are subject to pre-market approval requirements. There were numerous comments specifically opposing the renewal of non-synthetic flavors on 205.605a. Of these, all but one requested that non-synthetic flavors be listed instead on 205.606, an action which cannot be taken as part of Sunset.

On February 16, 2007 the NOP issued “Guidance for Certifiers on Flavors.” This guidance includes the following:

Flavors do not need to be petitioned to be placed on 205.606 as long as they meet the definition of a flavor, according to FDA, and they are from nonsynthetic sources and are not produced using synthetic solvents and carrier systems or any artificial preservatives. We realize that there are some ACAs certifying flavors, which contradicts the National List...if we have flavors listed as non-agricultural, non-synthetic, how can we at the same time be stating that there are flavors out there able to meet NOP standards, eligible for certification?...

The NOSB completed Sunset Review of Flavors for re-listing and on September 3, 2010 and stated:

The Handling Committee recognizes that the category of flavors is broad, including everything from simple herbal extracts to complex compound flavors...The complexity of the category and proprietary nature of most flavor formulas and processes was such that the board did not feel that it was

practical to individually list flavors on the National List, so chose to relist the category as a single listing...In order to avoid unnecessary disruption to industry, we are recommending relisting of Flavors on §205.605(a), but we are also communicating our belief that the full category Sunset should not be relisted in five years when next reviewed for sunset. Instead, we are recommending that the NOSB, in consultation with the National Organic Program, establish a Flavors Task Force. The Flavors Task Force would be asked to develop a recommendation to appropriately divide flavors into rational subparts, or classes, composed of flavors which shared similar sources and processes. The recommendation would include whether the class was compatible with organic production, how the sub-part should be classified on the National List, and would petition for listing

of the class, if necessary, on the National List. We expect that this work could be done prior to the next sunset review for flavors.

On January 21, 2011 the NOP issued a Policy Memorandum on Use of Natural Flavors, this states in part:

In 1995 the NOSB reviewed the use of natural flavors and recognized that natural flavors are complex; they are derived from natural sources and are compound substances derived from plants, herbs, spices and botanicals....The NOP recognizes that some accredited certifying agents are certifying flavors that meet the NOP requirements for handling organic products, and that this organic market will continue to grow and develop...

The 2017 Sunset review is being considered at the fall 2015 meeting concurrently with this proposal.

Manufacture: Flavors can be derived via several different methods. Distillates are a clear, flavorful liquid produced from fruits, herbs, roots, etc., produced and condensed by distillation. 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 oils are volatile oils that give 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 is an isolate of an essential oil. Isolates are chemicals or fractions obtained from a natural substance by further distillation. For example, citral can be isolated from lemon oil or lemongrass. Oleoresin are 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. A single flavor chemical is a single molecule that provides flavor. These can be naturally or artificially derived, but they are specified to have a greater than 95% purity. Mixtures of these substances can also be considered natural flavors. A Compounded Flavor is a mixture of ingredients such as extracts, essential oils and natural isolates.¹ Processed flavors, also known as reaction flavors, are ones which are generated as a result of some form of processing upon a mixture of ingredients. A process flavor is a unique mixture of starting materials, like carbohydrates, proteins and fat, which must then be heated for a length of time to yield the desired profile.²

Flavoring components (i.e., those ingredients that impart the flavor) as listed here can typically make up 5-100% of the formulation of a flavor. The remaining components are preservatives, carriers and/or solvents that can make up 0-95% of a typical flavor formulation. Nonsynthetic flavors are also subject to the general requirement that they are not produced using sewage sludge, irradiation or GMOs.

Flavors can be further divided into "Natural" or containing only flavoring constituents from the named flavor; "WONF" (with other natural flavors) - containing flavoring constituents from the named product as well as other natural flavors derived from other sources that enhance or support the named flavor; or "type" which contain non-flavoring constituents from the named product but still impart the characteristic named flavor.

Discussion:

As this proposal is focused on revising the annotation, a review of OFPA criteria is not included here.

¹ <http://www.ams.usda.gov/sites/default/files/media/Flavors%20nonsynthetic%201%20Petition.pdf>

² http://www.fona.com/sites/default/files/WhitePaper_DevelopmentResources.pdf

The goal this proposal is to further the usage of organic flavors while not negatively disrupting business. The Subcommittee agrees with the petitioner that subdividing the flavors into “unavailable categories” or “allowable and unallowable” components would cause unnecessary disruption. Individually listing distinctly different natural flavors would be impractical due to the larger number in usage. Additionally, the petition and rule making process is too long in duration to meet the needs of new product development both in terms of availability of organic flavors and development of formulated organic products.

There are concerns from the Handling Subcommittee that this proposal does not go far enough and that certifiers will be unable to effectively apply commercial availability to flavors. It is the subcommittee’s opinion that this is just a first step and that future NOSB’s should continue to push industry in the development and adoption of organic flavors along the lines original envisioned in 1995:

Current - Natural flavor constituents and non-synthetic carrier base and preservative agents

Proposed, when commercially available: Organic flavor constituents, organic carrier base, and organic preservative agents

Future: Organic flavor constituents, organic carrier base, and organic preservative agents and then Organic flavor constituents extracted using organically produced solvent, organic carrier base, and organic preservative agents.

Comments were received during the 2017 sunset review of flavors (at the spring 2015 meeting) in support of the OTA’s petition from trade associations, ACAs and industry. Additional comments were received about labeling of organic flavors. Concerns were raised about the labeling of organic flavors of a named ingredient when the formulation of the flavor was 95% organic carriers and solvents but all flavoring constituents are non-organic. This proposal while not fully addressing this issue would require commercial availability to be applied by the certifier of the flavor manufacturer, which may serve to crack down on this practice indirectly. The proposal does not directly address this concern and this may be better addressed through certifier guidance from the NOP.

The handling subcommittee revised the original petition by remove the following crossed out words: Flavors – Non-synthetic flavors may be used in ~~products labeled as “organic”~~ 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. The line “in products labeled as ‘organic’” was removed to make it clear that both flavors and this annotation are applicable to both “organic” and “Made with organic” products.

Subcommittee Action & Vote:

Proposed Annotation Motion: Move to revise the Flavors annotation to read: *Non-synthetic 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.*

Motion by: Tom Chapman

Seconded by: Jean Richardson

Yes: 7 No: 0 Abstain: 0 Absent: 0 Recuse: 0

Approved by Tom Chapman, Subcommittee Chair, to transmit to NOSB August 25, 2015