



April 5, 2023

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-22-0071

Comments to the National Organic Standards Board Spring 2023

National Organic Standards Board:

Thank you for this opportunity to provide comment on multiple topics. The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Our members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others.

One of OTA's strongest assets as an organization is the diversity and breadth of its membership. Unlike many trade associations, OTA is uniquely structured to include the full value chain for the organic industry, ensuring that all segments, from farm to marketplace, have a strong voice within the organization. It also creates a platform for a diverse group of stakeholders to work together to catalyze solutions, form coalitions and collaborate on matters critical to the organic sector.

Addressing critical issues and growing the organic industry are all part of our work together. It all fits in with OTA's Mission, to **grow and protect organic** with a unifying voice that serves and engages its diverse members from farm to marketplace.

WHAT IS OTA'S COMMENT PROCESS?

OTA submits comments on behalf of its membership. Our positions and policies are primarily shaped through our member task forces. In all cases, OTA's regulatory and legislative staff carry out an extensive process of membership engagement to capture how current issues and activities such as proposed rules or NOSB recommendations will impact certified farmers and handlers. Prior to submission of final comments, draft comments are distributed to membership at least a week in advance. Members are provided an opportunity to weigh in and shape any changes that may be needed prior to final submission. To carry out a meaningful comment process under OTA's governance structure, a comment period needs to be at least 30 days.

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April 05, 2023

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-22-0071

RE: CAC Subcommittee – Proposal: Organic Is Climate-Smart Agriculture

Dear Ms. Arsenault:

Thank you for this opportunity to comment on the National Organic Standards Board (NOSB) Compliance, Accreditation & Certification Subcommittee's (CACS) proposal, Organic Is Climate-Smart Agriculture.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. We are the leading voice for the organic trade in the United States, representing more than 10,000 organic businesses across 50 states. OTA's mission is to grow and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

The CACS proposes certified organic producers should be automatically considered climate-smart and made eligible for all climate-smart funding, buying, and other programmatic opportunities administered by the USDA. OTA supported and [offered many supplements](#) to the Fall 2022 [climate-smart discussion document](#). The proposal for the Spring 2023 meeting appears to be unchanged without any discussion around the stakeholder comments received and why they were not incorporated.

OTA believes the CACS proposal would have been stronger with the incorporation and/or discussion of stakeholder feedback. However, the proposal is still a substantial piece of work, and we celebrate the subcommittee's continued advocacy to recognize organic as climate smart. Organic is the original climate-smart commercial agriculture in the United States. Fossil fuel-based and most synthetic fertilizers and pesticides are prohibited in organic agriculture, and their manufacture and application constitute more than 10% of direct global agricultural GHG emissions.ⁱ Across all food groups, organic production uses around 50% less new reactive nitrogen in comparison with conventional production.ⁱⁱ NRCS recognized climate-smart techniques such as cover cropping, organic soil amendments, and crop rotations are required in organic production.ⁱⁱⁱ In a 2017 study, organic growers who adopted best practices increased their soil organic carbon by 26%.^{iv}

Organic farmers are dedicated to practices that have the power to reverse the effects of climate change, while increasing farm resilience in the face of droughts and floods. We look forward to the memorialization and codification of organic's climate change mitigation and soil regeneration. We are optimistic that USDA will increase their support and encouragement of organic farming systems as the climate, economic, and health benefits of those systems are continuously revealed. The CACS proposal, as written, supports this end goal and should signal to the greater USDA that certified organic production should be automatically considered "climate-smart" agriculture.



On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

Gwendolyn Wyard
Vice President, Regulatory, OTA

cc: Tom Chapman
Chief Executive Officer, OTA

ⁱ Walling, Eric, and Celine Vaneeckhaute. “Nitrogen Fertilizers and the Environment.” In Nitrate Handbook. CRC Press, 2022.

ⁱⁱ Shade, Jessica et al. 2020. “Decreasing Reactive Nitrogen Losses in Organic Agricultural Systems.” Organic Agriculture. <https://doi.org/10.1007/s13165-020-00297-0> (July 14, 2020)

ⁱⁱⁱ 7 C.F.R. §§ 205.205-206

^{iv} Elham A. Ghabbour et al., “National Comparison of the Total and Sequestered Organic Matter Contents of Conventional and Organic Farm Soils,” in Advances in Agronomy, vol.

April 5, 2023

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-22-0071

RE: Handling Subcommittee Proposal – Ion Exchange Filtration (Resins)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee's Proposal on Ion Exchange Resins. The Subcommittee, in response to a request from the National Organic Program (NOP), is making a recommendation on whether ion exchange resins and membranes, associated with ion exchange filtration, should be added to the National List.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

- OTA supports the Handling Subcommittee's proposal (Option 1) that ion exchange resins do not need to be on the National List because they do not meet the Organic Foods Production Act (OFPA) criteria for listing.
- OTA also agrees with the Handling Subcommittee's position that ion exchange and all associated media/materials should be reviewed and approved, by certifying agents, as part of an organic operation's Organic Systems Plan (OSP). To ensure proper and consistent review we fully support the subcommittee's request that NOP issue instruction to certifiers. We support the request as written.

Background

OTA has submitted extensive comments to NOSB in response to the Spring 2020 Discussion Document, the Fall 2020 Proposal, the Spring 2021 Proposal, and the most recent Discussion Document and Proposal from the Fall 2022. See our most recent comments for helpful background on the use, function, and regulatory status of ion exchange filtration in organic processing (**Appendix A**).

Handling Subcommittee Recommendation on Ion Exchange Recharge Resins

OTA supports the Handling Subcommittee's recommendation because ion exchange **resins** are not 'ingredients' or 'processing aids' (See **Attachment B** for a more detailed explanation). Consistent with other food contact substances such as tubing, tank coatings, packaging adhesives, wire mesh, etc., **ion exchange resins** should be reviewed and approved on a case-by-case basis by the accredited certifying agent as part of the certified operation's OSP.

To the best of our knowledge, most certifiers are already reviewing ion exchange filtration as part of the OSP if it is being used. The review of the process and associated materials are required to be disclosed in the operation's OSP and it is reviewed annually as part of the inspection and certification process. The focus of the review is to ensure that the recharge materials are on the National List, the resins are classified as food contact substances and the ion exchange equipment is well maintained to prevent degradation and incidental contamination events.

To further ensure adequate and consistent review by all inspectors and certifiers, we strongly support the Subcommittee's request that NOP issue instruction that includes the following requirements:

1. Verification of the ion exchange system through review of an operation's OSP including the requirements at § 205.201 (management practices, procedures, frequency, media, sanitation, contamination & commingling prevention, records, etc.), along with evaluation of adherence to the OSP at the on-site inspection.
2. Verification that the recharge materials are on the National List.
3. Verification that the exchange resins have been reviewed and approved by the FDA as food contact substances through inclusion on either the Inventory of Effective Food Contact Substance Notification Database or Inventory of Food Contact Substances Listed in 21 CFR.

Issues around ion exchange resin degradation and subsequent contamination

The Handling Subcommittee is requesting information on current monitoring strategies or testing being used to ensure there is not leaching and that ion exchange systems are functioning properly.

The term "degradation" when applied to ion exchange resins, refers to conditions that can alter the resin's molecular structure and compromise the effectiveness of the resin. In other words, the resin is no longer able to bind with the functional groups of ions that are key to the reaction – it hinders the exchange process.

Extremely high or low temperatures, fouling (typically from poor-quality regenerant), and oxidation can all lead to resin degradation. Appropriate use, inspection, cleaning, storage, testing, analysis, and regeneration measures are all instrumental in avoiding such problems. At some point, ion exchange resins need replacing, but they can last for years if they are properly maintained. From an economic perspective (bottom line) and a food safety perspective, operators want their systems to be as effective as possible, so proper maintenance is essential.

The maintenance of an ion exchange system is important and subject to basic food safety and GMP requirements. The appropriate use of such equipment falls under the purview of federal, state, and local food safety inspections and such requirements supersede the organic regulations. Food safety

requirements are outside the purview of NOSB and the National List, but well within the review of the certified operation as part of its food safety inspections (**Attachment C: Current Good Manufacturing Practices**, 21 CFR Chapter 1 Subpart B § [117.40 Equipment and Utensils](#)). Further, verifying an operation is current and in good standing on required food safety inspections is part of an organic inspection and a common mechanism used to review and verify contamination prevention methods as required by the organic regulations (§ 205.272).

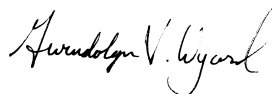
Conclusion

The topic of ion exchange filtration in organic processing is complex from both a technical and regulatory perspective, and there is a long history of its use and allowance. Throughout time, NOP has consistently clarified that ion exchange is allowed under NOP regulations as a processing technology. The moving target has been the status of the ion exchange media and whether all materials/inputs need to be on the National List.

To the best of our knowledge, the use of ion exchange and all associated media and practices must be described and approved in the certified operator's OSP, inspected at least annually, and approved as part of the annual certification cycle. We support the Handling Subcommittee's recommendation to ensure practices and procedures are formally documented and publicly communicated to all organic stakeholders and consistently carried out by all certifying agents.

In closing, and behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture. We support the critical role of NOSB in this decision-making process, and above all, we support transparency and consistency.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gwendolyn V. Wyard".

Gwendolyn Wyard
Vice President of Regulatory and Technical Affairs
Organic Trade Association

cc: Tom Chapman, CEO
Organic Trade Association

Attachment A: OTA's comments from the Fall 2022 meeting

Attachment B: Background on Resins vs. Recharge Materials

Attachment C: 21 CFR Chapter 1, Subpart B § 117.40 Equipment and utensils.

Attachment B

Ion exchange filtration media: resins vs. recharge materials

At the Fall 2022 meeting, NOSB voted that ion exchange **recharge materials** must be on the National List to be used in organic processing. For this meeting, NOSB is voting on whether ion exchange **resins** need to be on the National List. It is therefore important to clearly understand the difference between the two, and how each one interacts with the product being processed and how it is regulated.

Ion exchange filtration is a technique that involves a column, like a large pipe, packed with **ion exchange resins** that selectively remove unwanted ions from the liquid. The **resin** is an insoluble matrix (or support structure) normally in the form of small microbeads, on which a fixed ion has been permanently attached. The ion cannot be removed or displaced; it is part of the resin structure. The ion exchange resin microbead also holds charged molecules that are mobile and available for exchange with mobile molecules in a fluid that is passed through the column. The resin is charged with a chemical solution that is periodically regenerated with a **recharging material** when the resins become exhausted.

The table below summarizes the function of the ion exchange resin vs. the recharge materials and provides examples. The resins (the microbeads themselves) are *not added* to the organic product, they are not intended to have *any technical effect in the finished food*, and they are *not present in the finished food*. They simply facilitate the ion exchange process. **It is the ions in the recharging solution (recharge materials) that are mobile and interact via ion exchange with the organic product being filtered.**

Table 1

| <i>Term</i> | <i>Definition</i> |
|--|---|
| Ion Exchange Resin: The ions are covalently bonded to the ion exchange resin and do not interact with the product. Initially classified as secondary additives but now considered and reviewed as food contact substances ¹ by FDA. Historically have not needed to be on the National List, per 2002 NOP policy. See Appendix A | An adsorbent material in an ion exchange column. Holds charged molecules available for exchange with mobile molecules in a fluid. <i>Examples: Polymeric resin beads, Zeolite minerals, Activated carbon, Polystyrene resins, Acrylic resins</i> |
| Recharging Material: Ions that interact with organic because they are mobile. Certifiers currently require these materials to be on the National List. | Chemical solution used for flushing or regenerating the ion-exchange resin. Returns the resin to its original ion-exchange capacity after it becomes saturated with unwanted ions from repeated use. <i>Examples: Sodium chloride (allowed), Potassium chloride (allowed), Hydrochloric acid (prohibited), Hydrogen peroxide (allowed)</i> |

As explained above, the recharge materials are compounds used to recharge the exchange resins, not the exchange resins themselves. The **resins are plastic-type polymers coated with fixed ions** that are permanently bound within the polymer matrix of the resin. In this regard, when the resin acts as an inert

¹ Section 409 of the FD&C Act defines a Food Contact Substance as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food. The Food Contact Substance Notifications (FCS), FCS 45, FCS 52 and FCS 74, are examples of the specific ion exchange resins listed at 21 CFR 173.25.

delivery or holding system, it is functioning in the same manner as any traditional food contact substance that is used in a food processing facility (e.g., tubing, tank coatings, etc.). They are not removed, and like any piece of equipment, they do not become a part of the processed product if properly maintained. Just like all equipment in contact with organic product, the maintenance of ion exchange systems (to prevent degradation/contamination) is subject to local, state and federal food safety and GMP requirements. Unlike ion exchange resins, certifiers currently require recharging materials to be on the National List because they function as a **'processing aid'** and are therefore subject to National List review.

Ion exchange **resins** on the other hand do not meet the definition of an **ingredient** or a **processing aid** because they are not "still present," and they are not "added to a food." The resins (substrate) themselves are not intended to become a part of or have any technical effect on the finished food. They are simply there to facilitate the exchange of molecules but do not have a continuing effect on nor are they intended to transfer to the food or product being processed. There is no need to filter out the ion exchange resin because it is **not added to the food**.

For organic handling, OFPA states that a certified handling operation "shall not...add any synthetic **ingredient** not appearing on the National List during the processing or post-harvest handling of the product..." (7 USC 6510(a)(1)). The *Harvey v. Johanns* court interpreted "ingredient" for the purposes of the OFPA to include "**processing aids**." A definition of "ingredient" and "processing aid" is provided in the organic regulations at 7 CFR 205.2. Neither term is defined in the statute.

Attachment C: 21 CFR Chapter 1, Subpart B § 117.40 Equipment and utensils.

§ 117.40 Equipment and utensils.

(a)

(1) All plant equipment and utensils used in manufacturing, processing, packing, or holding food must be so designed and of such material and workmanship as to be adequately cleanable, and must be adequately maintained to protect against allergen cross-contact and contamination.

(2) Equipment and utensils must be designed, constructed, and used appropriately to avoid the adulteration of food with lubricants, fuel, metal fragments, contaminated water, or any other contaminants.

(3) Equipment must be installed so as to facilitate the cleaning and maintenance of the equipment and of adjacent spaces.

(4) Food-contact surfaces must be corrosion-resistant when in contact with food.

(5) Food-contact surfaces must be made of nontoxic materials and designed to withstand the environment of their intended use and the action of food, and, if applicable, cleaning compounds, sanitizing agents, and cleaning procedures.

(6) Food-contact surfaces must be maintained to protect food from allergen cross-contact and from being contaminated by any source, including unlawful indirect food additives.

September 29, 2022

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-20-0042

RE: Handling Subcommittee – Ion Exchange Filtration (Recharge Materials – Proposal) & (Resins Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee's Proposal and Discussion on Ion Exchange. The Subcommittee, in response to a request from the National Organic Program (NOP), is making a recommendation on whether recharge materials, associated with ion exchange filtration, should be added to the National List.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

Summary

- OTA supports the continued allowance of ion exchange filtration as an organic processing method.
- OTA supports the Handling Subcommittee's proposal that ion exchange **recharge materials must be on the National List** to be approved for use in organic processing. Unlike the resins, the recharge materials function as a 'processing aid,' as defined at 7 CFR 205.2 and are therefore subject to National List review.
- Ion exchange **resins** do not function as a 'processing aid' and certainly not as an 'ingredient' as defined at § 205.2, and therefore **do not need to appear on the National List**. As a food contact substance, they are however **subject to review and approval as part of a certified operator's Organic System Plan (OSP)** and the overall organic certification process.
- **OTA recommends NOSB adopt Option 1 with a recommendation to NOP to issue Instruction to certifying agents** to review the use of ion exchange and all associated media as part of the operation's OSP. This shall include requirements for: 1) verification of the ion exchange system in the context of OSP requirements at § 205.201 (management practices, procedures, frequency, media, sanitation, contamination & commingling prevention, records, etc.); 2) verification that the recharge materials are on the National List; and 3) verification that the exchange resins have been reviewed and approved by FDA as food contact substances.

Background

OTA has submitted extensive comments to NOSB in response to the Spring 2020 Discussion Document, the Fall 2020 Proposal, and the Spring 2021 Proposal. For this meeting, and primarily for the new NOSB members, we are bringing forth important background information from our previous comments.

Ion exchange filtration and its allowance in organic processing

Ion exchange is a processing technology used for filtration and purification. It is the most effective technology available for removing heavy metals (such as arsenic) and other inadvertent deleterious compounds from organic products. It is used in the processing of products such as starch sweeteners, sugar, fruit juice, rice syrup, soy sauce, wine, beer, whey, coffee, and milk, and is also commonly used in potable water treatment systems.

Ion exchange has been allowed in USDA-NOP certified organic processing since the organic regulations were first established. The intent of the technology is not to chemically change¹ a product, but to eliminate unwanted contaminants or impurities through removal of their associated ions. The process does however rely on a reversible interchange of one kind of ion present in an insoluble solid, with another of like charge present in a solution surrounding the solid. Thus, the name ion exchange.

There are several allowed NOP processing technologies that may chemically alter a processed product but do not render the final product “synthetic.” Examples range from cooking/baking and heating to the use of activated carbon for filtration, an allowed organic processing technology that relies on chemical absorption and separation. Similar to activated carbon filtration, ion exchange depends on a chemical process (exchange of ions of the same charge). In the context of the organic processing regulations, it can be identified as a processing technology or method that is allowed under filtration or “separating,” as described in § 205.270(a) - Organic Handling Requirements:

Mechanical or biological methods, including but not limited to cooking, baking, curing, heating, drying, mixing, grinding, churning, separating, distilling, extracting, slaughtering, cutting, fermenting, eviscerating, preserving, dehydrating, freezing, chilling, or otherwise manufacturing, and the packaging, canning, jarring, or otherwise enclosing food in a container may be used to process an organically produced agricultural product for the purpose of retarding spoilage or otherwise preparing the agricultural product for market.

The **ion exchange media (recharge materials and resins)** are non-agricultural substances used in ion exchange that contact the organic product. For processed NOP certified products labeled as “organic” and “made with organic (specified ingredients/food group(s)),” non-organic, nonagricultural substances (ingredients and processing aids) must appear on the National List, whether they are ‘synthetic’ or ‘non-synthetic.’ The question is whether the recharge materials and/or the ion exchange resins are subject to National List review.

¹ It should be noted that it is neither the ion exchange resins nor the recharge materials that facilitate or bring about a chemical change. It is the water used in the process. This is a moot point, however, because the question of a “chemical change” is not relevant to the discussion of whether the ion exchange media are subject to National List review. It is the ion exchange materials (resins and recharge materials) that are under evaluation and not the processing technology itself.

Ion exchange filtration media: resins vs. recharge materials

The ion exchange filtration process is a technique that involves a column, like a large pipe, packed with **ion exchange resins** that selectively remove unwanted ions from the liquid. The **resin** is an insoluble matrix (or support structure) normally in the form of small microbeads, on which a fixed ion has been permanently attached. This ion cannot be removed or displaced; it is part of the resin structure. The ion exchange resin microbead also holds charged molecules that are mobile and available for exchange with mobile molecules in a fluid that is passed through the column. The resin is charged with a chemical solution that is periodically regenerated with a **recharging material** when the resins become exhausted.

The table below summarizes the function of the ion exchange resin vs. the recharge materials and provides examples. The resins (the microbeads themselves) are *not added* to the organic product, they are not intended to have *any technical effect in the finished food*, and they are *not present in the finished food*. They simply facilitate the ion exchange. **It is the ions in the recharging solution (recharge materials) that are mobile and interact via ion exchange with the organic product being filtered.**

Table 1

| <i>Term</i> | <i>Definition</i> |
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| Ion Exchange Resin: The ions are covalently bonded to the ion exchange resin and do not interact with the product. Initially classified as secondary additives but now considered and reviewed as food contact substances ² by FDA. Historically have not needed to be on the National List, per 2002 NOP policy. See Appendix A | An adsorbent material in an ion exchange column. Holds charged molecules available for exchange with mobile molecules in a fluid. <i>Examples: Polymeric resin beads, Zeolite minerals, Activated carbon, Polystyrene resins, Acrylic resins</i> |
| Recharging Material: Ions that interact with organic because they are mobile. Certifiers currently require these materials to be on the National List. | Chemical solution used for flushing or regenerating the ion-exchange resin. Returns the resin to its original ion-exchange capacity after it becomes saturated with unwanted ions from repeated use. <i>Examples: Sodium chloride (allowed), Potassium chloride (allowed), Hydrochloric acid (prohibited), Hydrogen peroxide (allowed)</i> |

As explained above, the recharge materials are compounds used to recharge the exchange resins, not the exchange resins themselves. The resins are plastic-type polymers coated with fixed ions that are permanently bound within the polymer matrix of the resin. They are not removed, and like any piece of equipment, they do not become a part of the processed product if properly maintained. **The maintenance of ion exchange systems is subject to local, state and federal food safety and GMP requirements.**

² Section 409 of the FD&C Act defines a Food Contact Substance as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food. The Food Contact Substance Notifications (FCS), FCS 45, FCS 52 and FCS 74, are examples of the specific ion exchange resins listed at 21 CFR 173.25.

Handling Subcommittee Recommendation on Ion Exchange Recharge Materials

OTA agrees with the Handling Subcommittee recommendation that the **recharge materials** must be on the National List to be allowed in organic processing. This is consistent with current practice and with the training NOP provided to certifiers in 2010. Most importantly, they are subject to National List review because unlike the resins, the recharge materials function as a ‘processing aid,’ as defined at 7 CFR 205.2.

DISCUSSION: Do Ion Exchange Resins Need to be Added to the National List?

The more challenging and controversial question is whether ion exchange **resins** are subject to National List Review. The Handling Subcommittee is presenting three options for discussion followed by a series of questions to stakeholders. We offer the following comments on each option and answers to the questions below.

- **Option 1: Resins do not need to be listed**

OTA supports this option because ion exchange **resins** are not ‘ingredients’ or ‘processing aids.’ They do however function as a ‘food contact substance’ and should be reviewed and verified as such as part of the certified operation’s OSP.

For Handling, OFPA states that a certified handling operation “shall not...add any synthetic **ingredient** not appearing on the National List during the processing or post-harvest handling of the product...” (7 USC 6510(a)(1)). The *Harvey v. Johanns* court interpreted “ingredient” for the purposes of the OFPA to include “**processing aids.**” A definition of “ingredient” and “processing aid” is provided in the organic regulations at 7 CFR 205.2. Neither term is defined in the statute.

- *Ingredient* (7 CFR 205.2) Any substance used in the preparation of an agricultural product that is still present in the final commercial product as consumed.
- *Processing aid* (7 CFR 205.2). (1) Substance that **is added to a food** during the processing of such food but is removed in some manner from the food before it is packaged in its finished form; (2) a substance that **is added to a food during processing**, is converted into constituents normally present in the food, and does not significantly increase the amount of the constituents naturally found in the food; and (3) a substance that **is added to a food** for its technical or functional effect in the processing, but is present in the finished food at insignificant levels and does not have any technical or functional effect in that food.
- *Food Contact Substance*: Section 409 of the FD&C Act defines an FCS as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food.

The resin is designed to be inert and stationary. It provides a delivery or holding system from which ion exchange can happen from the liquid or recharge solution. In this regard, when the resin acts as an inert delivery or holding system, it is functioning in the same manner as any traditional food contact substance that is used in a food processing facility (e.g., tubing, tank coatings, etc.).

The ion exchange resin also holds charged molecules that are mobile and available for exchange with mobile molecules in a fluid that is passed through the column. The resin is charged with a chemical solution that is periodically regenerated with a **recharging material** when the resins become exhausted. It is the ions in the recharging solution (recharge materials) that are mobile and interact via ion exchange with the organic product being filtered. The ions in the recharge solution have a technical effect on the food; the resin does not. Unlike the resins, certifiers currently require the recharging materials to be on the National List because they function as a **processing aid** and are therefore subject to National List review.

Ion exchange **resins** on the other hand do not meet the definition of an **ingredient** or a **processing aid** because they are not “still present,” and they are not “added to a food.” The resins (substrate) themselves are not intended to become a part of or have any technical effect on the finished food. They are simply there to facilitate the exchange of molecules but do not have a continuing effect on nor are they intended to transfer to the food. There is no need to filter out the ion exchange resin because it is **not added to the food**.

OTA does not believe ion exchange resins are subject to National List review, because they are a Food Contact Substance exerting no technical effect on the food. If NOSB decides the resins must appear on the National List, we are concerned about the precedent that would be set for reviewing food contact substances in general (*e.g.*, tubing, tank coatings, packaging adhesives, wire mesh, etc.) and the horrendous implications this would have on the organic sector.

Ion exchange resins should however be carefully reviewed and approved on a case-by-case (OSP-by-OSP) basis by the accredited certifying agent. OTA is not suggesting that anything FDA defines as a ‘food contact substance’ should be carte blanche allowed. **OTA supports careful consideration of all materials that come in contact with organic product during processing and we need clear parameters and guidance for whether the material must appear on the National List.** For the latter, NOP’s scope of authority in regulating food contact substances still must be addressed.

For our analysis and conclusion, we focused on the requirements set by OFPA and the definitions within the USDA organic regulations. We urge NOSB to recommend the following to NOP:

- ⇒ **Option 1 + Instruction.** To formalize current practice, OTA urges NOSB to recommend Option 1 and ask NOP to issue Instruction to certifying agents and inspectors to review the use of ion exchange as part of the operation’s OSP. The review and approval should include:
- 1) A description of ion exchange (management practices, procedures, frequency, media, sanitation, contamination & commingling prevention, records, etc.) as specified in § 205.201
 - 2) Verification that the recharge materials are on the National List
 - 3) Verification that the exchange resins have been reviewed and approved by FDA as food contact substances
 - 4) Verification that ion exchange systems are well maintained, and adequate contamination prevention measures are in place

- **Option 2: Require listing of Resins – Categorically**

OTA does not favor this option for the reasons described above. Under this option, we assume a petition would still need to be submitted. If added, the Sunset process would prompt a periodic review for stakeholders to respond to, and the overall process would signify that inert physical delivery systems are subject to National List review. Our preference is Option 1, with an emphasis on NOP Instruction as we have described. Should NOSB and NOP decide that ion exchange resins must be listed, we would support a categorical listing over an individual listing (Option 3). This option would also require adequate time for a petition, rulemaking, and implementation.

- **Option 3: Require listing of Resins – Individually**

OTA is not in favor of this option. If this option is chosen, a long and appropriate phase-in period would be needed. Adequate time for petitions and rulemaking would be necessary along with a reasonable implementation period.

Questions for stakeholders:

1. *Has there been new information since the NOP policy statement from December 2002, that would indicate a change in policy position about what types of substances are required to be listed on the National List in accordance with OFPA?*

Several clarifications have been made related to the NOP policy statement from 2002, but we are unaware of anything “new” that has not already been raised in comments. OTA provided a complete timeline in our spring 2020 comments (See appendix B). The information in its totality does not indicate a policy change, just a need for clarification. The historical information we believe is the most important comes from the *Harvey v. Johanns* holding, clarifying that “ingredients” **and** “processing aids” must appear on the National List.

2. *Does the fact that resins are listed by FDA as a food contact substance exempt these materials from needing to be reviewed by the NOSB and placed on the National List? If so, why?*

The classification as a food contact substance helps identify whether the resin beads function as ‘processing aids’ as defined under the USDA organic regulations.

OTA believes that ion exchange resins (beads/substrate) do not meet the definition of a processing aid because resins are not added to the food, and they are not intended to become a part of or have any technical effect on the finished food. They are simply there to facilitate the exchange of molecules, but do not have a continuing effect on nor are they intended to transfer to the food. There is no need to filter out the ion exchange resin because it is **not added to the food**. The resins, however, do meet the definition of a **food contact substance** as they contact food, but do not have a technical effect on the food.

As stated in the NOP Memo to NOSB (August 10, 2021), “.... resins used for ion exchange purposes may be the subject of existing regulations (e.g., 21 CFR 173.25) or are evaluated through the food contact substance notification (FCN) process, which includes a safety review to identify any potential impacts on human health.”

IMPORTANT: Since the FDA Modernization Act of 1997, the FCN process has been the primary method by which FDA regulated food additives that are food contact substances. Meeting memoranda from the Regulatory and Science Policy Board (RASPB) noted that “ion exchange resins should qualify as **food contact substances**, because they are used to *treat* food, but do not become components of the food” (emphasis added).

FDA since has directed all new approvals of ion exchange resins through its FCN program and has cleared 11 new ion exchange resins through this process, but they have not amended 21 CFR 173.25 to add any new resins. It is even unlikely that FDA would accept a food additive petition to add an ion exchange resin to Section 173.25 rather it would likely require these materials be cleared as FCNs.

Clearance for ion exchange resins and similar such additives granted via the FCN program indicate that FDA has determined that these substances meet the food contact substance definition. For FDA to be permitted to grant a clearance under the FCN program, the substance must be considered a food contact substance by definition and statutory obligation.

If NOSB wants to make a recommendation to NOP to follow its 2002 FCS Policy Statement (archived in the NOP Handbook, but never officially rescinded), then FDA’s classification as a *food contact substance* becomes more significant (as policy) and would further support a decision that the resins do not need to be on the list. However, consistent with the second implication³ noted in NOP’s memo to NOSB (8/10/2021), OTA prefers a decision that is made using OFPA and the 7 CFR definitions.

3. *Does the fact that since resins are listed as a secondary food additive, regardless of their listing as a food contact substance place them under the purview of OFPA and therefore need to appear on the National List. If so, why?*

No, we do not believe so. The resins were historically listed as secondary food additives at Section 173.25. However, FDA has acknowledged that some secondary direct food additives meet the definition of a food contact substance, and since 1997, the review and all new approvals of ion exchange resins have been cleared through the FCN program because FDA has determined that they meet the *food contact substance* definition.

OTA recommends we focus on the terms, definitions and requirements found in OFPA and 7 CFR 205 and then look to FDA’s definitions and decisions to further support our conclusion. Ion exchange resins themselves do not clearly meet the definition of a “processing aid” as defined in 7 CFR 205.2, and FDA’s determination that the resins meet the food contact substance definition further supports our conclusion.

³ NOP Memo to NOSB, pg. 3, 2nd bullet under implications: “If the NOSB refers to FDA’s definitions, it could result in substances that are *not* currently on the National List necessitating addition to the List (e.g., wire meshes and certain filters), or substances that *are* currently on the National List not needing to be on the List (e.g., antimicrobial agents used in contact with poultry carcasses).”

4. *How and to what extent do resins degrade? Does the degradation occur during the recharge process or during the food filtration process?*

A better understanding of what is meant by “degradation” and “column leakage” is needed. The resins are plastic-type polymers (porous) coated with fixed ions that are permanently bound within the polymer matrix of the resin. As explained, they are not removed, and like any piece of equipment, they do not (and should not) become a part of the processed product if properly maintained. Further, at no point would the resin themselves be viewed or approved as incidental additives. They are not designed to become part of the food product, even at incidental levels.

The term “degradation” when applied to ion exchange resins, refers to conditions that can alter the resin’s molecular structure and compromise the effectiveness of the resin. In other words, the resin is no longer able to bind with the functional groups of ions that are key to the reaction – it hinders the exchange process. The term is not intended to mean that the resin is breaking or falling apart and altering the organic product, that would be a contamination event.

Extremely high or low temperatures, fouling (typically from poor-quality regenerant), and oxidation can all lead to resin degradation. Appropriate use, inspection, cleaning, storage, testing, analysis, and regeneration measures are all instrumental in avoiding such problems. At some point, ion exchange resins need replacing, but they can last for years if they are properly maintained. From an economic perspective (bottom line) and a food safety perspective, operators want their systems to be as effective as possible, so proper maintenance is essential.

We have also read comments about ion exchange resins leaking from columns and thus becoming incidental additives. This is not inaccurate. Ion exchange leakage typically refers to the endpoint of “demineralization.” At the end of the process, the resin beads have loaded all cations and anions from the water and released H⁺ and H⁻ ions. When the resin beads are exhausted, ions from the feed solution “escape” from the resin column into the treated solution. This can occur right when the operation is stopped and is called ion leakage. This refers to the mobile ions, not the resin beads or the fixed ion on the resin bead.

The maintenance of an ion exchange system is important and subject to basic food safety and GMP requirements. The appropriate use of such equipment falls under the purview of federal, state, and local food safety inspections. Food safety requirements are outside the purview of NOSB and the National List, but well within the review of the certified operation as part of its food safety inspections. Further, verifying an operation is current and in good standing on required food safety inspections is part of an organic inspection and a common mechanism used to review and verify contamination prevention methods.

Conclusion

The topic of ion exchange filtration in organic processing is complex from both a technical and regulatory perspective, and there is a long history of its use and allowance. Throughout time, NOP has consistently clarified that ion exchange is allowed under NOP regulations as a processing technology. The moving target has been the status of the ion exchange media and whether all materials/inputs need to be on the National List.

The best of our knowledge, the use of ion exchange and all associated media and practices must be described and approved in the certified operator's OSP, inspected at least annually, and approved as part of the annual certification cycle. Recharge materials must be on the National List and ion exchange resins must be approved as food contact substances in the OSP. We support a recommendation from NOSB that will support this existing practice (Option 1) and result in NOP Instruction that will help ensure practices and procedures are formally documented and publicly communicated to all organic stakeholders and consistently carried out by all certifying agents.

In closing, OTA thanks NOSB for the opportunity to share background, both technical and policy information, to support NOSB's recommendations. We support the critical role of NOSB in this decision-making process, and above all, we support transparency and consistency.

On behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture.

Respectfully submitted,

A handwritten signature in black ink, reading "Gwendolyn V. Wyard".

Gwendolyn Wyard
Vice President of Regulatory and Technical Affairs
Organic Trade Association

cc: Tom Chapman, CEO
Organic Trade Association

Attachment A: NOP 2002 Policy – Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances are Used as Ingredients in Processed Food Products.

Attachment B: NOP Policy References and Timeline

- **2008:** The NOP Q&A dated May 14, 2008, included the question, "Is ion exchange allowed for processing organic products?" with the answer, "Yes, ion exchange is allowed under the NOP regulations as a processing technology. Any synthetic associated with the use of such technology would still need to be on the National List as an allowed synthetic."
- **2010:** NOP addressed the topic of ion exchange in its annual training to certifiers in 2010. In the training slides (Dated August 8, 2010), NOP reiterated its existing policy that ion exchange technology is allowed, provided the materials used are on the National List. According to the training slides, ion exchange technology is allowed. NOP also gave examples of what materials may be used to charge the ion exchange columns based on this policy. Sodium hydroxide and sodium chlorite are examples of "National Listed" items that are allowed. Hydrochloric acid is an example of a "Not Listed" item.

- **2012:** This topic was added to the NOSB work agenda at the beginning of 2012. From the NOSB Materials Subcommittee notes, they were waiting for more information on ion exchange resins from NOP before they could do any work on it. Eventually, the topic was removed from the work plan by NOP.
- **2019:** In 2018, the topic of ion exchange reappeared on NOP's radar because of a conflicting materials review decision among certifiers. NOP published a policy notice to certifiers on May 7, 2019, to resolve the issue, but the notice was an abrupt departure from its long-standing policy. The notice stated that "all non-agricultural substances used in the ion-exchange process must be on the National List. This includes but is not limited to resins, membranes, and recharging materials." In response to the policy notice, several stakeholders and certifiers submitted requests for NOP to clarify the rationale, extend the timeframe for implementation, and/or provide opportunities for input from stakeholders.
- **2019:** On August 19, NOP requested NOSB provide recommendations to address inconsistencies between certifiers and to ensure that organic stakeholders have an opportunity to provide input. NOP specifically asked for information "about the various ways ion exchange filtration is used by organic operations, the substances used in these processes, potential alternatives to ion exchange technology, and recommendation(s) on whether it is appropriate to include these substances on the National List."
- **2021:** On August 10, 2021, NOP reported on research conducted on FDA's classification of ion exchange resin. The research was conducted in response to a request from the April 2021 NOSB to provide information about FDA's classification of resins used in the ion exchange process. Given the information provided, NOP requested NOSB to make a recommendation on whether resins should be listed on the National List.

Synthetic Substances Subject to Review and Recommendation by the National Organic Standards Board When Such Substances Are Used as Ingredients in Processed Food Products

Accredited certifying agents, food processors, and food manufacturers have contacted the National Organic Program (NOP) regarding under what conditions synthetic substances used as ingredients in processed food products are subject to review and recommendation by the National Organic Standards Board (NOSB).

7 CFR 205.2 defines ingredient as “any substance used in the preparation of an agricultural product that is “still present” (quotations added) in the final commercial product as consumed.” This definition arose from an April 25, 1995, NOSB recommendation on good manufacturing practices in certified organic handling operations.

The NOP defines “still present” as those ingredients regulated by the Food and Drug Administration (FDA) as food additives permitted for direct addition to food for human consumption under:

1. 21 CFR Part 172, Food additives permitted for direct addition to food for human consumption.
2. 21 CFR Part 173, Secondary direct food additives permitted in food for human consumption: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
3. 21 CFR Part 180, Food additives permitted in food or in contact with food on an interim basis pending additional study: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
4. 21 CFR Part 181, Prior-sanctioned food ingredients: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
5. 21 CFR Part 182, Substances generally recognized as safe.
6. 21 CFR Part 184, Direct food substances affirmed as generally recognized as safe.

The NOP also defines “still present” as those materials approved by the Bureau of Alcohol, Tobacco and Firearms (ATF) as being acceptable for use by proprietors in the production of alcohol beverages under:

1. 27 CFR Part 24, Section 24.246, Materials authorized for the treatment of wine and juice: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
2. 27 CFR Part 24, Section 24.247, Materials authorized for the treatment of distilling material: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.
3. The Brewers Adjunct Reference Manual: *Except*, That, substances classified by the FDA as food contact substances are not subject to this definition.

Accordingly, substances listed in 21 CFR Parts 172, 173, 180, 181, 182, and 184; 27 CFR Part 24; and the Brewers Adjunct Reference Manual, except those substances classified by the FDA as food contact substances, must be on the National List of Allowed and Prohibited Substances to be used in the production of an “organic” or “made with organic (specified ingredients or food group(s))” processed product.

Handlers must include in their organic systems plan a list of all synthetic substances to be used in the production of processed products. Each synthetic substance must be identified as an ingredient or a contact substance. Any substance identified as a contact substance must be accompanied by documentation that substantiates the claim.

December 12, 2002



April 5, 2023

Ms. Michelle Arsenault
National Organic Standards Board
USDA-AMS-NOP

Docket: AMS-NOP-22-0071

RE: Handling Subcommittee Discussion – Sunset Flavors

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee's Sunset Review of Natural Flavors. The Handling Subcommittee is reviewing the listing of Natural Flavors on § 205.605(a)(12) of the National List:

Flavors - nonsynthetic 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.

The Organic Trade Association (OTA) is the membership-based business association for organic agriculture and products in North America. OTA is the leading voice for the organic trade in the United States, representing organic businesses across 50 states. Its members include growers, shippers, processors, certifiers, farmers' associations, distributors, importers, exporters, consultants, retailers and others. OTA's Board of Directors is democratically elected by its members. OTA's mission is to promote and protect organic with a unifying voice that serves and engages its diverse members from farm to marketplace.

OTA supports the retention of Natural Flavors on the National List as listed. The success of growing the availability of organic flavors relies heavily on robust and well documented search efforts by industry and rigorous and consistent commercial availability review and oversight by ACAs and NOP. OTA encourages NOSB and NOP to focus on strategy and tactics that improve both.

NOSB Questions to Stakeholders

1. *Do you produce or certify organic flavors that include ingredients listed on § 205.605? If so, what ingredients?*

No, OTA does not produce or certify organic flavors. However, our membership consists of many businesses that produce, manufacture, handle, buy, sell, distribute and certify organic flavors. A significant portion of our membership are users of both organic and non-organic flavors.

OTA was the petitioner for the historical annotation change published in December 2018 that requires organic operations to use organic flavors when they are commercially available. OTA submitted the petition 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. We also recognized that the

growing organic flavor sector deserved more support than it was receiving. At that time, there was **no requirement to use organic flavors**; all use was voluntary despite the significant number of organic flavors available in the marketplace.

OTA's 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. We remain committed to this effort.

2. *How would removal of flavors from § 205.605 impact the commercial availability of organic flavors?*

The removal of flavors would be premature and negatively impact the commercial availability of organic flavors. The current listing requires organic operations to use organic flavors when they are commercially available. This status is still needed for most types of flavors and is particularly important for natural compounded flavors and the flavor isolates compounded flavors rely on.

OTA's data demonstrates that the number of certified organic flavors currently in the marketplace is substantial. However, the number of available certified organic flavors is not sufficient to meet the current needs and specificity of the marketplace, given the numerous and different types and forms used by the organic product formulators and the fact that until recently (2018), there has been no requirement to use organic flavors.

To inform OTA's petition, submitted in 2014, we worked with the Accredited Certifiers Association (ACA) to conduct a survey to determine how many organic flavors are available on the market.

| Indicate the number of natural flavors you certify under the following categories: | | | | | | | | | |
|--|---|-------------------------|-------------------------------|----------------------------|--------------------------|------------------------|------------------------|--------------------------|----------------------|
| Natural Flavor (Compounded flavor) 5 responses | Natural Flavor (WONF) 7 responses | Extracts 6 responses | Essential Oils 5 responses | Distillates 4 responses | Oleoresin 5 responses | Essence 4 responses | Powders 5 responses | Emulsions 4 responses | Other 2 responses |
| TOTAL | TOTAL | TOTAL | TOTAL | TOTAL | TOTAL | TOTAL | TOTAL | TOTAL | TOTAL |
| 2146 | 405 | 272 | 1645 | 4 | 18 | 33 | 254 | 19 | 0 |

The survey reported that 189 companies were certified in 2014. When flavors were initially included on the National List, the number of flavor compounds comprising natural flavors was estimated up to 100 or more. The data from the ACA survey demonstrates that this number has grown substantially, not only for natural flavors in general, but for certified organic flavors. **A new survey with updated numbers should be conducted for the Fall 2023 meeting.** While we expect to see growth in the number and types of organic flavors, we do not expect to see numbers that would justify the complete removal of natural flavors from the National List.

The challenge is that Natural Flavors appear on the National List as a broad category listing, therefore many different natural forms (agricultural and non-agricultural) are allowed. Examples include extracts, oleoresins, essential oils, compounded flavors, and distillates. **See Appendix A for the list of flavor types and a description of each one.**

There are literally thousands of distinctly different natural and organic flavors, making it impractical to individually list every single flavor on the National List. This was acknowledged by NOSB at both previous Sunset Reviews and informed the decision to revise the § 205.605 broad category listing with an annotation requiring the use of organic flavors when they are commercially available.

OTA continues to support the retention of flavors on § 205.605 of the National List with commercial availability assigned to the entire broad category listing. We remain committed to the growth of the organic flavor sector and believe this approach continues to make the most sense. Our ability to succeed, in terms of growing the organic flavor sector, comes with a responsibility that relies heavily on robust and well documented commercial search efforts by industry and rigorous and consistent review and oversight by accredited certifying agencies and the NOP.

To help with this effort, OTA and the ACA have developed guidance on best practices for sourcing and reviewing flavors for compliance with the organic regulations. OTA developed guidance for organic operations and the ACA developed best practices for certifiers. **See Appendix B and C.** The two documents are excellent and complementary and would be furthered if NOSB and/or NOP could elevate their visibility through formal adoption. A rigorous and consistent approach to commercial availability is needed for the regulation to work as it was intended. OTA believes that many operations and certifiers are doing an excellent job on this front, but there continues to be room for improvement and greater consistency in practice between one operation and certifier to the next.

3. *Are there flavors currently used in organic products that cannot be produced organically (including any of the examples listed in the TR such as castoreum derived from beavers, Tonquin musk oil from musk deer, wood chips from nonorganic forest products, distilled liquid smoke, fish flavors)?*

These are all good examples, especially the beaver example. It is important to keep in mind that natural flavors on § 205.605(a) is a broad category listing of agricultural and nonagricultural flavors. Any flavor where the **source** is non-agricultural (liquid smoke, wood chips) or outside of the scope of NOP certification (e.g., aquaculture) cannot be produced organically. All flavors that are derived from an agricultural source could potentially be certified, provided all processing aids solvents, carriers, stabilizers, etc. are organic and available in sufficient supply (e.g., organic glycerin) and/or on the National List.

Aside from non-agricultural flavors that cannot be organic, the type of flavor with the lowest organic availability is likely the **flavor isolates**, also known or referred to as the flavor “keys” or “aroma chemicals.” This type of flavor is very important to the organic sector because the “isolates” are the critical (packed with flavor) component of compounded natural flavors. The examples below should help explain what a flavor isolate is and how it is used in a compounded flavor.

Example flavor isolates used in organic compounded flavors:

Natural Ethyl Butyrate - the starting materials are alcohol (fermentation and distillation) and butyric acid (from cane sugar via fermentation, extraction and then purified via distillation). The products are combined and then undergo an esterification process (either cooking under controlled conditions or an enzymatic process). The final product is then purified via distillation.

Natural Acetic Acid – the starting material is cane sugar, which is then fermented, extracted and then purified via distillation.

Natural cis-3-Hexenol – manufacturing of mint essential oil results in mint terpenes, which is then purified via distillation.

Natural Benzaldehyde – derived from Cassia oil via extraction to obtain cinnamic aldehyde. It's then cooked under controlled conditions and purified via distillation.

Example of a Natural Compounded Flavor:

Organic composition category: 95% - Organic

Actual organic percentage: 95.3% = 95% rounding down

| Ingredient | % Organic | % used in the formulation |
|--|------------------|--------------------------------------|
| OG Ethyl Alcohol | 100.00 | 30.00 |
| OG "Sugar" Syrup | 100.00 | 30.00 |
| Water (excluded) | 0.00 | 25.00 |
| OG Strawberry Juice Concentrate | 100.00 | 10.00 |
| Natural Isolate (aroma chemical) – often can be a mix of several to a hundred isolates | 0.00 | 02.00 |
| Natural Citric Acid | 0.00 | 01.50 |
| Organic Hibiscus Extract | 100.00 | 01.50 |

In closing, and behalf of our members across the supply chain and the country, OTA thanks the National Organic Standards Board for the opportunity to comment, and for your commitment to furthering organic agriculture and organic flavors!



Respectfully submitted,

Gwendolyn Wyard
Vice President of Regulatory and Technical Affairs
Organic Trade Association

cc: Tom Chapman, CEO
Organic Trade Association

Appendix A: Types of Flavor or 'Flavor Nomenclature'

Appendix B: OTA's Practical Guide to Complying with NOP Flavor Requirements

Appendix C: ACA Best Practices for Commercial Availability of Natural Flavors

Appendix A: 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.

Oleoresin: 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.

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.

Others – could include:

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.

References

George A. Burdock. Fenaroli's Handbook of Flavor Ingredients, 5th ed. Washington D.C. CRC Press.

Primo Bader and Steve Phelps. January-March 2007. The Flavor Factor: Exploring Today's Taste-Improving Technology. *Organic Processing Magazine*.

USDA Organic Flavors Required When Commercially Available!



A practical guide to
complying with the
new requirements
for natural flavors

SINCE 1985
Organic
trade association

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.



Oleoresin: 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.



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

1. George A. Burdock. Fenaroli's Handbook of Flavor Ingredients, 5th ed. Washington D.C. CRC Press.
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.

ACA Best Practices for Commercial Availability of Natural Flavors

June 2020

Purpose

ACA Best Practices describe actions certifiers should take to verify operator compliance, as well as producer activities that can easily be approved by certifiers. The ACA strives to ensure that all Best Practices are consistent with the Organic Foods Production Act (OFPA) and the USDA Organic Regulations. These Best Practices are not legally binding, but if a producer presents plans that fall outside of these Best Practices, then the Organic System Plan (OSP) should provide a rationale for alternative methods and an explanation for how their system fulfills the applicable portion(s) of the related regulations. Certifiers will evaluate whether the differences can be justified. Similarly, if certifiers take an approach that is different from what is presented here, they should be able to articulate how the differing approach is justified according to the OFPA and the USDA Organic Regulations.

Background

This ACA Guidance document describes background, policy, and procedural steps that certifiers should take to ensure compliance with §205.605(a):

Flavors—nonsynthetic 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.

In 1995, the National Organic Standards Board (NOSB) recommended the use of Natural Flavors in organic foods with the requirement that certified operators demonstrate efforts towards production of organic natural flavors. In 2011, the National Organic Program (NOP) published [Policy Memo 11-1](#), which clarified that current requirements for flavors permitted in organic production and handling. The Organic Trade Association submitted a [petition](#) on November 6, 2014 to require the use of organic flavors when they are available in the quality, quantity and form needed. On October 29, 2015, the NOSB unanimously passed a recommendation to revise the annotation for flavors to require organic when commercially available. On December 27, 2018, the NOP issued a final rule amending the National List with the implementation date of December 27, 2019.

Historically, commercial availability has applied to seeds, materials listed at §205.606, yeast and silicon-dioxide at §205.605. The application of commercial availability to natural flavors led to many questions among certifiers:

- How do certifiers assess commercial availability of natural flavors?
- How do certifiers assess commercial availability of flavoring components?
- What type of documentation is required for processors to demonstrate lack of commercial availability?
- How does quantity, quality, and form specifically apply to flavors?

The working group identified two groups of operations to consider for the commercial availability of natural flavors: operators sourcing flavors as an ingredient in an organic processed product and operators creating certified organic flavors. Operators sourcing flavors as an ingredient in an organic processed product may only use non-organic natural flavors that meet the requirements at §205.605(a) if they have demonstrated that an organic version of that flavor is not commercially available. Operators creating organic natural flavors may only use non-organic flavoring components that meet the requirements at §205.605(a) if they have demonstrated that an organic version of that flavoring component is not commercially available.

Definitions

Natural flavor: 21 CFR 101.22. Foods; labeling of spices, flavorings, colorings and chemical preservatives. (a) (3) the term 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 the natural essence 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.

Flavoring Substances: Substances added to impart or help impart a taste or aroma in food. FDA regulations refer to these as Flavoring agents and adjuvants.

Commercial Availability

According to 7 CFR 205.2, commercial availability is 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. The working group agreed to the following when determining commercial availability of organic natural flavors and flavoring substances:

- Operators must contact at least three valid suppliers, with exceptions considered on a case-by-case basis.
 - An operator sourcing natural flavors products or flavoring components to be used in an organic flavor must contact flavor houses that may have an organic version of the flavor/ flavoring substance or the ability to create an organic version.
 - Operators should check with different suppliers of flavors year-to-year.

- Having a contract in place with a flavor manufacturer is not sufficient justification to contact fewer than three valid suppliers. Additional documentation must be submitted and may be considered on a case-by-case basis.
 - A contract in place with a non-organic flavor manufacturer working towards certification or with a certified organic flavor manufacturer working to develop an organic version may be sufficient justification for contacting fewer than three valid suppliers, provided that documentation is submitted to verify the anticipated date of certification and/or organic system plan.
- Claiming that a flavoring substance cannot be certified organic is not sufficient justification for contacting fewer than three valid suppliers. Additional documentation must be submitted justifying the lack of ability to certify the ingredient, which may be considered on a case-by-case basis, or three valid suppliers must be contacted.
- Operators must verify and document commercial availability annually for each non-organic flavor or flavoring substance used, with exceptions considered on a case-by-case basis.
 - An ordering or manufacturing schedule can be considered if part of the company's Standard Operating Procedure (SOP).
- The use of otherwise compliant non-organic flavors in made-with-organic products does not invoke a commercial availability search (as long as it meets the requirements of made with organic products).
- Using the flavor name alone may not be sufficient evidence to verify lack of commercial availability of an organic flavor.
- Price cannot be a consideration for determination of the commercial availability.

Quantity, Quality, and Form

The working group clarified quantity, quality, and form as it relates to Natural Flavors:

Quantity relates to the appropriate amount needed for production. Factors to consider regarding quantity:

1. Insufficient amounts for production requirements
2. Excessive minimum purchase requirement

The working group agreed that the operation should submit documentation on the number of suppliers and the amount produced. This report should specify the projected production and quantity of the flavor needed for a given amount of time and contrast the amount with the amount available.

Quality relates to performance attributes most often accompanied by research and development (R & D). Examples of quality for commercial availability:

1. Unreliable manufacturer - providing product with inconsistent quality
2. Shelf life
3. Analytical test results from or that support R & D (microbial testing)
4. Results from a table top comparison (comparing the flavor to other flavors by diluting it to the level used and tasting them side by side)
5. Results from a taste panel (often done after a tabletop comparison)
6. Grade
7. Flavor profiles
8. Effect on the quality of the finished product

The working group agreed that the operation must submit appropriate documentation justifying that an organic version is not of the appropriate quality, which may include but is not limited to R & D testing, visual of the product upon arrival, microbial testing, organoleptic, etc. Operations must provide a clear description as to why the quality of the organic flavor is not acceptable and how this conclusion was made.

Form relates to the physical attributes of a flavor or flavoring substance such as its specifications. Examples of form for commercial availability:

1. Whether the product is powder or liquid

The working group agreed that information should be submitted as to why the form of the ingredient cannot be used in the product or why the product cannot be modified within reason. For example, why can't the product be modified to include a powder instead of a liquid? If the final product is in powder form then it is not within reason to request product modification. Documentation may include specification sheets for the desired flavor and similar flavors found.

Use Up

When an organic version of a natural flavor or flavor substance is commercially available, the working group agreed to the following use up parameters:

- Operators must develop a plan for using up non-organic natural flavors or flavoring substances when organic versions become commercially available. Operators may use up existing stock on a case-by-case basis, but generally no longer than 12 months.
 - Factors to consider for an extended use up include existing production schedules, amount the producer has on-hand, and whether or not the product can be diverted (used in a conventional product),
 - A client cannot use a contract with a non-certified manufacturer to indefinitely stall using an organic flavor or flavoring component.

Documentation

Operators must have annual documentation of their commercial availability search looking at three sources for each flavor or flavoring component, or justification for fewer sources. The organic system plan should include a commercial availability plan which details the operations overall usage of natural flavors. Documentation must include justification of a lack of commercial availability when an organic version of a natural flavor or flavoring component is identified.

The working group created sample forms to use for documentation of commercial availability. Usage of these forms is not mandatory; however, the information in these forms should be documented by the client. Documentation should be verified as part of the Organic System plan by either being submitted to certifiers, verified at inspection, or a combination of both.

The [ACA Commercial Availability Form Organic Search](#) is completed by the certified operator intending to use a non-organic flavor or flavor substance. The form is used to indicate the three valid sources that were checked for an organic version of the flavor or flavor substance.

The [ACA Commercial Availability Plan](#) is completed by the certified operator using or intending to use non-organic flavors or flavor substances as ingredients in or on processed products labeled as “organic.” The plan details the operations overall usage of natural flavors and flavor substances.

The [ACA Commercial Availability Manufacturer Affidavit](#) is completed by a flavor manufacturer contacted during a commercial availability search. This form is not to be used solely to determine commercial availability but can be used as a supplement to document commercial availability.

Examples

The working group discussed the following scenarios and considerations for commercial availability of organic natural flavors:

| Scenario | Considerations |
|--|---|
| An organic processor of organic ice cream, “Ice, Ice, Baby,” would like to make a label claim about the origin of a specific flavor. Their “Tahitian Vanilla” ice cream product is labeled as such, so they must use Tahitian flavor. They are unable to find organic Tahitian Vanilla flavor. | Claiming lack of commercial availability of an organic flavor because it is not available from a particular geographical origin with a “kosher” label claim is not sufficient. More information must be submitted to justify a difference in form, quality, or quantity, such as differing flavor profiles. An operation should not source a specific flavor name but |

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|--|--|
| | instead should source the flavor components and ingredients |
| An organic processor of organic candy, “Santa’s Sweet Shop,” is producing a chocolate bar with candy cane flavor for the holidays. They are unable to find “candy cane” flavor as organic. | Using the flavor name alone is not sufficient evidence to verify lack of commercial availability. The producer must look at three valid suppliers for equivalent flavor profiles such as mint. |
| An organic processor is sourcing a non-organic flavor from a flavor house, and the flavor house is certified and has the ability to make the flavor organic. | The processor must submit justification for why the flavor house cannot make a version in suitable quantity, quality, or form, and the client is responsible for checking three valid sources for an organic version of the flavor. |
| An organic processor has a contract with a flavor house that is not certified organic and is not necessarily familiar with organic flavors. | The processor is responsible for checking three valid sources for an organic version of the flavor. If an organic version is commercially available, the processor will have to develop a certifier-approved use-up plan. |
| An organic processor has located an organic version of a flavor, but the flavor is not available consistently, which will affect the production schedule of the processor. | This may be an acceptable reason for lack of commercial availability due to quantity. A statement from the company contacted (or similar documentation) regarding the amount available must be submitted. The processor must still check with two other valid sources. |
| An organic processor contacts a supplier of organic natural flavor but there is only so much organic flavor in inventory. | This may be an acceptable reason for lack of commercial availability due to quantity. A statement from the company contacted (or similar documentation) regarding the amount available must be submitted. The processor must still check with two other valid sources. |
| An organic processor needs a quantity of flavor and the flavor house can create it organically but not by the time needed for production. | This may be an acceptable reason for lack of commercial availability due to quantity. A statement from the company contacted (or similar documentation) regarding the amount available must be submitted. The processor must still check with two other valid sources. |
| The required minimum order is too large for an organic processor’s needs. | This may be an acceptable reason for lack of commercial availability due to quantity. A |

| | |
|---|---|
| | statement from the company contacted (or similar documentation) regarding the amount available must be submitted. The processor must still check with two other valid sources. |
| An organic processor has an agreement with the flavor house that it will be the sole supplier of flavor products for 2 years. | The processor must still check three valid sources for an organic version of the flavor. If an organic version is identified, the certifier should ask for a plan moving forward. |
| A flavor house designed the whole product, not just the flavor, then the organic processor brought it to market. | The processor must still check three valid sources for an organic version of the flavor. If an organic version is identified, the certifier should ask for a plan moving forward. |
| An organic processor uses a non-organic flavor in a processed product. They document the lack of commercial availability of an organic version every 18 months, which coincides with ordering and production schedules. | This may be an acceptable reason to verify commercial availability every 18 months instead of every year. |
| The organic processor is using a natural flavor in powder form and there is an organic version available in liquid form. | This may be an acceptable reason for lack of commercial availability due to form. Documentation of the flavor's form and why it is not an appropriate form for the product must be submitted. The processor must still check with two other valid sources. |
| An organic processor wants to use food grade lavender flavor in their cookies but checked three sources and could only find aromatherapy grade organic lavender flavor, not food grade. | This may be an acceptable reason for lack of commercial availability due to quality. |
| The organic processor needs (or is using) a 2% concentration of a flavor but a supplier only has an organic 5% concentration available. | This may not be an acceptable reason for a form or quality exemption since the processor or supplier may be able to make adjustments to the product in order to make it usable. However, this may be an acceptable reason for lack of commercial availability if the changes made to use the different concentration affects the finished product. Documentation of the flavor's concentration and why it is not an appropriate form or |

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| | quality for the product must be submitted. The processor must still check with two other valid sources. |
| The organic processor “Jamrock Hasidic Foods” only manufactures foods that are kosher and from Jamaica. It uses a kosher-certified natural rum flavor in products it wishes to certify as Organic. Equivalent organic kosher flavors are commercially available; and equivalent organic Jamaican rum flavors are commercially available, but there are no equivalent organic rum flavors on the market that are both Jamaican and kosher. The company claims that the Jamaican rum flavor is allowed since organic flavors are not available in the quality, form, or quantity required. | Claiming lack of commercial availability of an organic flavor because it is not available from a particular geographical origin with a “kosher” label claim is not sufficient. More information must be submitted to justify a difference in form, quality, or quantity, such as differing flavor profiles. An operation should not source a specific flavor name but instead should source the flavor components and ingredients |

Conclusion

The ACA recommends all accredited certifiers adopt ACA Guidance for consistent implementation of the USDA Organic Regulations. ACA Guidance Documents are reviewed periodically to ensure they are accurate and up to date. Concerns with this or any ACA Best Practice or guidance document should be submitted to the ACA Coordinator.

Resources

Definitions of types of flavors - [OTA petition](#), page 13/81

OTA's [guide](#) to commercial availability of flavors

[NOP Policy Memo 11-1](#)

[PART 170 -- FOOD ADDITIVES](#)

[ACA Commercial Availability Form Organic Search](#)

[ACA Commercial Availability Plan](#)

[ACA Commercial Availability Manufacturer Affidavit](#)