



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,



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>
<p>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 substances¹ by FDA. Historically have not needed to be on the National List, per 2002 NOP policy. See Appendix A</p>	<p>An adsorbent material in an ion exchange column. Holds charged molecules available for exchange with mobile molecules in a fluid.</p> <p><i>Examples: Polymeric resin beads, Zeolite minerals, Activated carbon, Polystyrene resins, Acrylic resins</i></p>
<p>Recharging Material: Ions that interact with organic because they are mobile. Certifiers currently require these materials to be on the National List.</p>	<p>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.</p> <p><i>Examples: Sodium chloride (allowed), Potassium chloride (allowed), Hydrochloric acid (prohibited), Hydrogen peroxide (allowed)</i></p>

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>
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 (RASP) 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

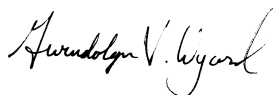
The topic of ion exchange filtration in organic processing is complex from both a technical and regulatory perspective, and there is a long history of its use and allowance. Throughout time, NOP has consistently clarified that ion exchange is allowed under NOP regulations as a processing technology. 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,



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