April 3, 2020

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

Docket: AMS-NOP-19-0095

RE: Handling Subcommittee – Ion Exchange Filtration (Discussion Document)

Dear Ms. Arsenault:

Thank you for this opportunity to provide comment on the National Organic Standards Board (NOSB) Handling Subcommittee's Discussion Document on Ion Exchange Filtration. The Subcommittee, in response to a request from the National Organic Program (NOP), is seeking information about the various ways ion exchange filtration is used by organic operations, the substances used to facilitate the process, potential alternatives to ion exchange technology, and recommendation(s) on whether it is appropriate to include the substances associated with ion exchange on 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.

Introduction

NOSB is asking four questions to help inform its discussion and future proposal. Before answering the questions, OTA would like to provide NOSB with a simple overview of ion exchange technology, followed by very important background information not included in the Subcommittee's Discussion Document. The topic of ion exchange is complex both from a technical and a regulatory perspective. OTA's focus at this time is on the presentation of background information to help ensure that all considerations are on the table to inform future actions.

Ion Exchange Filtration

Ion exchange filtration is a food processing (purification) technique used to facilitate removal of unwanted salts, proteins, colors, flavors, odor compounds, acids, heavy metals, and other impurities using a chemical exchange process. The process 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 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.

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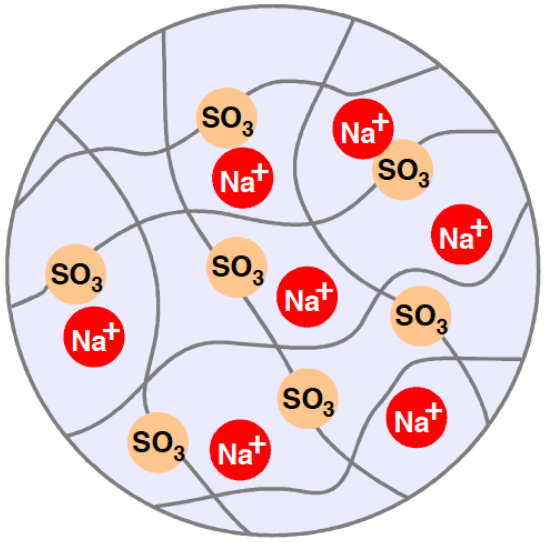
The table below summarizes the function of the ion exchange resin vs. the recharge materials and provides examples. FDA currently regulates ion exchange resins as 'food contact substances.[1]' The resins are not added to the organic product and they are not intended to have any technical effect. It is the ions in the recharging solution (recharge materials) that are mobile and interact via ion exchange with the organic product being filtered. See also Figure 1.

Table 1

Term	***Definition***
Ion Exchange Resin: Considered **food contact substances** by FDA. Historically have not needed to be on the National List, per 2002 NOP policy.	An adsorbent material in an ion exchange column. Holds charged molecules available for exchange with mobile molecules in a fluid. *Examples: Polymeric resin beads, Zeolite minerals, Activated carbon, Polystyrene resins, Acrylic resins*
Recharging Material: Ions that interact with organic product and could become part of the finished processed product. Certifiers 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. *Examples: Sodium chloride (allowed), Potassium chloride (allowed), Hydrochloric acid (prohibited), Hydrogen peroxide (allowed)*

Figure 1 – Schematic cation exchange resin bead



To preserve the electrical neutrality of the resin (SO3-), each fixed ion must be neutralized with a counter ion (Na+). The counter ion is mobile and can get into and out of the resin bead. In this schematic on the left (cation exchange), the dark lines represent the polymeric skeleton of the resin bead: it is porous and contains water. The fixed ions of the cation exchange resins are sulphonates (SO3-) that are attached to the skeleton. In this picture, the mobile ions are sodium cations (Na+) that come from the chemical solution or recharge material. Each ion going into the bead has to be replaced by an ion getting out of the bead to preserve electrical neutrality. This is what is called **ion exchange**. **NOTE:** This is for illustrative purposes only. The functional group (sulfonates) would likely need to be recharged with a strong acid such as HCL or sulfuric acid, which are not on the National List. Therefore this resin would not be acceptable for use in organic.

[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.

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Background: Ion Exchange Used in Organic Processing

Ion exchange filtration has been allowed in USDA-certified organic processing since the organic regulations were first established.

⇒ Based on USDA National Organic Program (NOP) policy information presented in 2002, 2008, and 2010, ion exchange filtration is allowed provided that **recharging materials** are on the National List.

⇒ The **ion exchange resin** itself is allowed provided it is FDA approved as a **food contact substance (see FDA references below)**.

NOP Policy References and Timeline:

- **2002:** In a policy statement issued on December 12, 2002, after consultation with FDA, NOP clarified which substances are subject to review and recommendation by NOSB for inclusion on the National List. According to the policy, **substances that are listed in 21 CFR Part 173 as *secondary direct food additives* are subject to review, unless the substances are classified by the FDA as a *food contact substance.*** In 2002, FDA clarified that ion exchange resins were food contact substances, therefore ion exchange resins under the 2002 policy were not subject to the National List process. The 2002 food contact substance policy was archived when the NOP Handbook was created, however it has never been formally rescinded and remains in use by some certifiers. **See Attachment A**

  FDA references are as follows:
  - Ion exchange resins and membrane are listed in 21 CFR Part 173 as s*econdary direct food additives*, which are substances that have a technical effect in food during processing but not in the finished food.
  - According to FDA guidance, some secondary direct food additives also meet the definition of a *food contact substance,* which is any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.
  - Prior to 1997, FDA regulated ion exchange resins under 21 CFR 173.25. Once Congress established the term "food contact substance" in the Federal Food, Drug, and Cosmetic Act and initiated the Food Contact Notification Program (FCN) in 1999, all ion exchange petitions were converted to this approval method. There was no need to alter or change prior approvals under § 173.25, so they were left as is. Since that time, FDA has directed all new approvals of ion exchange resins through its FCN program. This clearly reflects FDA's stance that they are food contact substances.
  - FDA maintains a database of approved Food Contact Substances, which include ion exchange resins that have been classified and approved by FDA as food contact substances. Any new ion exchange resin is subject to and directed through the Food Contact Notification Program.

- **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**."

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- **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, as long as materials used are on the National List. According to the training slides, **ion exchange technology is allowed, as long as materials used are on the National List.** 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. **See Attachment B**

  (***Note**: As explained above, the recharge materials are compounds used to recharge the exchange resins, not the exchange resins themselves. It is the exchange resins that FDA considers food contact substances. There is an important distinction between the function of the resin and the function of the recharge material. 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 they do not become a part of the processed product.)*

- **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:** Last year, the topic of ion exchange reappeared on NOP's radar as a result 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.

  Concerns NOP received from certifiers regarding the 2019 NOP Policy Notice:
  - The 2019 NOP Policy Notice states that FDA does *not* consider ion-exchange resins or ion-exchange membranes to be food contact substances, which is a departure from FDA references (see above) and the information NOP received in 2002.
  - The 2019 NOP Policy Notice states that ion-exchange resins must be on the National List, which is a departure from the 2002, 2008, and 2010 NOP policy statements (see above).
  - If ion-exchange resins were to be prohibited without suitable alternatives, many certified operations would not be able to produce certified organic product. This would have a significant impact on the industry at large. The prohibition could also affect the classification of many non-synthetic materials that are processed using ion exchange (e.g. citric acid, pullulan).

- **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

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technology, and recommendation(s) on whether it is appropriate to include these substances on the National List."

NOSB Questions

1. **What organic products are currently produced through the ion exchange process?** First, the most common use of ion exchange is for water softening and water purification that is used in many organic processing facilities. The organic products we have identified that are currently produced using ion exchange include:
   - Agave Syrup
   - Beer
   - Cane Sugar
   - Juice Concentrates
   - Infant formula
   - Milk Powders, including Skim Milk Protein Concentrates
   - Pullulan (research quantities scaling up to commercial production)
   - Rice Syrup
   - Starch sweeteners
   - Stevia
   - Vegetable Oils
   - Wine

   This list is not an exhaustive list and it only includes the primary ingredients that rely on ion exchange. It does not include all of the products that utilize these ingredients and would be impacted by a change of policy.

2. **Are there other processing methods used to produce these products?**
   Not for all products listed and not to the purification level needed. We understand that activated carbon filtration is often used in combination with ion exchange, but activated carbon alone will not result in the desired purification to meet many specifications and desired outcomes. Any contaminant that is not ionized cannot be removed by ion exchange, therefore activated carbon can be ideal when used in combination. Ion exchange is a very powerful technology that can result in an extremely pure product. For example, we understand it is the only filtration technology that will remove heavy metals, such as arsenic, from organic rice products to meet both consumer expectation and FDA requirements.

   Another similar technology is electrodialysis, a process for transporting ionic species across an ion exchange membrane. Ions and a solution in a desalting cell are transferred to a concentrating cell across a cation- and anion-exchange membrane under applied current. The process does not use recharge materials like the ion exchange process described thus far, but it still relies on ion exchange and use of ion exchange membranes.

   Finally, another similar and effective filtration method is **Nanofiltration**. This process is a membrane filtration-based method that uses nanometer sized through-pores that pass through the membrane. Nanofiltration membranes have pore sizes from 1-10 nanometers, smaller than that used in microfiltration and ultrafiltration, but just larger than that in reverse osmosis. The

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performance of this process however, while good and inexpensive, is much less effective than ion exchange and will not remove impurities to the levels desired if not required.

3. **What materials are being used in the ion exchange process for current organic products? Please include resins, recharge materials, membranes and any other substances.**
As explained earlier, ion exchange materials include resins and recharge materials. Ion-exchange resins are also produced as membranes. These ion-exchange membranes, which are made of highly cross-linked ion-exchange resins that allow passage of ions, but not of water, are used for electrodialysis. The focus here will remain on resins and recharge materials used for ion exchange.

   - **Resins:** The exchange **resins** can include polymeric resin beads, zeolite minerals, activated carbon, polystyrene resins and acrylic resins. Most typical ion-exchange resins are polymers that act as the medium for ion exchange. They are normally in the form of small porous beads providing a large surface area on and inside them. Most commercial resins are made of cross-linked polystyrene (polystyrene sulfonate). The structure of the resin is a polymer (like all plastics) on which a fixed ion has been permanently attached. This ion cannot be removed or displaced; it is part of the structure. There are two types of ion exchange resins. As the name suggests, cation exchange resins are used to remove positively charged contaminants, while anion exchange resins are used to remove negatively charged contaminants.

   - **Recharge Materials:** When the resins are exhausted, you bring them back to the fresh state and start over again using recharge or regeneration materials. This happens when contaminant ions have bound to nearly all available active sites on the resin matrix. Examples of the common recharge materials include sodium chloride, potassium chloride, hydrochloric acid and hydrogen peroxide. Hydrochloric acid is not allowed. **See Table 1.**

4. **If you do not agree that there is chemical change to the products run through the ion exchange process, please provide rationale for this belief.**

   OTA does not believe the question of "chemical change," when applied to the organic product being processed, is relevant to the clarification NOP is seeking because it doesn't impact the question of whether the ion exchange media (resins, membranes and recharge materials) need to appear on the National List. Under consideration is the ion exchange technology itself, which is not categorically prohibited under the NOP standards, and the regulatory status of the ion exchange media/materials. The question at hand is whether the ion exchange media (nonagricultural inputs) must appear on the National List.

   The reference to a "chemical change" is found in the italicized section on page 2 of the Handling Subcommittee's Ion Exchange Discussion Document (Page 44 of the NOSB packet). This is an excerpt from an unpublished background memo that the Organic Materials Review Institute (OMRI) sent to NOSB in October 2002. The excerpt includes the sentence, "The process chemically changes the resulting fluid." The consideration of a chemical change *would be relevant* to a Materials Review Organization, such as OMRI, or to the National Organic Standards Board, when making a classification decision (synthetic vs. nonsynthetic) on an input such as citric acid

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or pullulan. Both of these examples, as a point of interest, are produced using ion exchange and are classified as nonsynthetic.

As a processing technology, ion exchange is used for filtration and purification; the intent is not to chemically change a product, but to eliminate unwanted contaminants or impurities through removal of their associated ions. There are several allowed NOP processing technologies that will chemically change a processed product. Examples range from cooking/baking and heating to the use of activated carbon for filtration, an allowed processing technology that relies on a chemical absorption and separation. Ion exchange does in fact depend on a chemical process (exchange of ions of the same charge), but as a technology in the context of organic processing (under § 205.270 - Organic Handling Requirements), it can be identified as filtration or "separating."

The ion exchange media on the other hand, are nonagricultural substances, that either should or should not be subject to the National List review process depending on how they are regulated (secondary additive vs. processing aid vs. food contact substance).

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 around 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 in organic processing must be documented and approved in the certified operator's Organic System Plan, including a description of the materials used in the ion exchange process and a description of the sanitation and recharge procedures. Based on the 2010 NOP clarification, most certifiers are currently requiring the recharge materials to be on the National List, but not the resins.

OTA appreciates the opportunity to share background technical and policy information to support NOSB's effort to respond to NOP's request to develop a recommendation on whether the ion exchange resins and membranes need to appear on the National List. 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
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cc: Laura Batcha
Executive Director/CEO
Organic Trade Association

Attachment A: 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 Certifier Training 8-20-2010 (slides 25 & 26)

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Attachment A

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

Ion Exchange

Situation: Certifiers are asking if ion exchange is allowed in organic handling. Specific questions are what materials may be used to charge the ion exchange columns.

Ion Exchange

NOP Guidance:

- NOP has posted policy that ion exchange technology is allowed, as long as materials used are on the National List.
- For example-
  - Listed items:
    - Sodium hydroxide
    - Sodium chloride
  - Not listed:
    - Hydrochloric acid