



1400 Independence Avenue, SW.
Room 2642-South, STOP 0268
Washington, DC 20250-0268

August 27, 2019

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

FROM: Jennifer Tucker, Ph.D.
Deputy Administrator
National Organic Program

SUBJECT: Request to Review Ion Exchange Filtration

The National Organic Program (NOP) requests that the National Organic Standards Board (NOSB) provide recommendations related to ion exchange filtration for handling organic products.

The NOP has received questions about whether USDA organic regulations require that nonagricultural substances used in ion exchange filtration (*e.g.*, resins, membranes, and recharging/regenerating solutions) be included on the National List (§ 205.605). The NOP has learned that certifiers have different policies on this topic. Some certifiers require that only the solutions used to recharge ion exchange membranes/resins be on the National List. Other certifiers require all materials, including ion exchange membranes/resins, be on the National List.

We are requesting the Board's recommendation(s) to help us address inconsistencies between certifiers and to ensure that organic handling operations, certifiers, and other interested parties have an opportunity to provide input. The NOP seeks 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.

The NOP is providing the following supplemental information as attachments to support your review:

- Notice from NOP to Certifiers, May 7, 2019
- Notice from NOP to Certifiers, July 3, 2019
- Letter from Quality Assurance International to NOP, June 5, 2019
- Letter from Oregon Tilth to NOP, August 7, 2019
- Letter from CCOF to NOP, August 9, 2019

We thank you in advance for your work on this topic, and we look forward to your recommendations.

[sent via email by NOP on May 7, 2019]

Subject: Notice to Certifying Agents – Ion Exchange

Notice to Certifying Agents

Dear USDA-accredited Certifying Agent:

The National Organic Program (NOP) was notified of a discrepancy between certifying agents in the review of ion-exchange for processing organic products.

Decision

This notice clarifies that ion-exchange filtration is allowed in organic processing. However, **nonagricultural** substances used in the ion-exchange process must be on the National List of Allowed and Prohibited Substances (National List). This includes, but is not limited to, resins, membranes, and recharging materials. Certifiers that have previously approved use of ion-exchange filtration as part of an organic system plan need to review the ion-exchange process, including resins, membranes, and recharging solutions, to determine if the filtration practices are compliant. If the filtration practices are determined not to be compliant, the affected operations need to be notified. Previously approved filtration practices that are not in compliance must be removed from organic system plans by **May 1, 2020**.

Additional information on this decision is provided below:

Background

Ion-exchange may be used to clarify, decolor, or otherwise filter liquids using a chemical exchange process. The process uses a chemically charged material to selectively remove unwanted molecules from the liquid upon contact. For the purpose of this notice, the term 'ion-exchange resin' is defined as a membrane, resin, or solid material with charged molecules available for exchange with mobile molecules in a fluid. Because repeated use saturates ion-exchange resins with unwanted molecules, recharging (*i.e.*, flushing or regenerating) with chemical solutions is required for continued use. Filtration processes using ion-exchange technology may use a range of ion-exchange resins (*e.g.*, polymeric resin beads, zeolite minerals, activated carbon) and recharging solutions (*e.g.*, sodium chloride, potassium chloride, hydrochloric acid) that may be synthetic or natural.

Justification

USDA organic regulations prohibit use of **nonagricultural** substances "in or on processed products" that are "100 % organic," "organic," or "made with organic ..." except as provided in § 205.605" (§ 205.105(c)). Section 205.605 allows several nonagricultural (nonsynthetic and synthetic) filtering aids. For example, bentonite, diatomaceous earth, and perlite are included at § 205.605(a). Activated charcoal and cellulose are listed at § 205.605(b). These substances were added to the National List following a technical review process to ensure compliance with the Organic Foods Production Act (7 U.S.C. 6501 *et seq.*) criteria *before* allowing for use in or on organic food. If not included on the National

List for use in organic processing, nonagricultural substances used in ion-exchange filtration are considered non-compliant.

Some have argued that ion-exchange resins are food-contact substances that do not chemically affect the finished product. We disagree, because the ion-exchange process is a chemical process intended to have an effect in the food. During ion-exchange filtration, chemical molecules in the liquid being processed are exchanged with chemical molecules on the ion-exchange resin. This results in a different chemical composition of the processed product. Unlike physical filtration methods that selectively remove larger unwanted particles from the liquid passing through the filter, ion-exchange filtration replaces unwanted molecules with different chemical molecules in the liquid being processed.

The U.S. Food and Drug Administration (FDA) considers ion-exchange membranes and ion-exchange resins to be secondary direct food additives (see 21 CFR 173.20 and 173.25). The FDA does not consider ion-exchange resins or ion-exchange membranes to be food contact substances. These substances are defined 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 is not intended to have any technical effect in such food” (21 CFR 170.3(e)(3)). Because ion-exchange resins do provide an effect in foods, they are not considered food-contact substances. As such, to ensure the organic integrity of foods processed using ion-exchange filtration, **any nonagricultural materials used in the ion-exchange process must be on the National List for use in organic processing**

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[sent via email by NOP on July 3, 2019]

Subject: Notice of Delayed implementation of Ion-Exchange

Dear USDA-accredited Certifying Agent:

On May 7, 2019, the National Organic Program (NOP) notified certifying agents that all nonagricultural substances used in the ion-exchange process must be on the National List of Allowed and Prohibited Substances (National List). We noted that previously approved noncompliant filtration practices must be removed from organic system plans by May 1, 2020.

Following the notification to certifiers, we received requests to clarify our rationale, extend the timeframe for implementation, and/or provide opportunities for input from stakeholders and certifiers. This feedback provided additional information to be considered in resolving the current conflict related to ion-exchange technology for use in organic handling. Additional information also came from NOP discussion about the classification of ion-exchange materials with the U.S. Food and Drug Administration, to evaluate how such materials interact with the organic product. **After reviewing this new information, we are delaying the May 1, 2020 implementation date while we gather more information and seek advice from the National Organic Standards Board (NOSB) given the complexity of the issue.**

More broadly, material conflicts between certifiers are rare, but when they occur, they are often complex, and the initial information is not always the complete picture. **The NOP recognizes that we need to enhance our processes to allow for earlier information gathering and increased organic stakeholder engagement when these complex conflicts occur.**

We are drafting new procedures to address this need. These procedures will include more broadly assessing certifier decisions and practices beyond those certifiers involved in the conflict raised to NOP. This will help clarify: (1) whether the conflict is a simple one, where certifier(s) have made errors in materials decision-making that simply need to be corrected OR (2) whether the conflict is a more complex and nuanced one that would benefit from public feedback. Complex conflicts may then lead to new work agenda items for the National Organic Standards Board for subsequent NOP decision-making.

Jennifer Tucker, Ph.D.
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June 5, 2019

Ms. Jennifer Tucker, Ph.D
Deputy Administrator
USDA Agricultural Marketing Service
National Organic Program

Dear Jenny,

Please find more information below regarding QAI's justification for allowing ion exchange in organic handling. QAI is not the only certifier who has allowed ion exchange for several decades. Ion exchange has been discussed at the certifier and NOP level, with differing opinions and guidance provided at different times. However, we believe that ion exchange is compatible with organic processing principles, so long as recharge materials are on the National list or do not have any contact with organic ingredients/products. This is also consistent with the most recent NOP training provided to certifiers in 2010. Our justification is as follows:

- 1. Food Contact Substances:** The recent clarification from the NOP regarding ion exchange claims that the resins and membrane materials are secondary direct food additives rather than food contact substances. Ion exchange resins/membranes are classified by FDA as food contact substances, which supersedes the CFR references cited in the clarification. Food contact substances can be used in organic handling unless expressly prohibited or restricted by the NOP Regulation. Other examples of food contact substances permitted in organic handling include packaging materials and food handling equipment.
- 2. Resins and membranes do not exchange molecules with the organic product:** Resins are plastic-type polymers coated with fixed ions that are permanently bound within the polymer matrix of the resin. The fixed ions are only there to facilitate removal of the salts, color, flavor, odor compounds, acids and other impurities present in the organic product solution. They can also remove harmful heavy metals. These coatings are not removed from the resin and do not interact or change the organic product in any way. These resins are very commonly used for ion exchange in the food & beverage industries. In this capacity, the permanent nature of the resin is similar to a stainless steel surface or a rubber belt on a food contact processing line.
- 3. Recharge Materials can "exchange" ions with the organic product and can also be flushed from the resin matrix prior to organic handling:** The materials used to recharge the resin matrix are materials that *could* interact with the organic product and "exchange" a molecule. For example, hydrogen could exchange with an undesirable molecule in the organic product such as salt. Certifiers have been requiring that these recharge materials are on the National List or flushed out of the resin matrix with water prior to organic handling.



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The 2010 NOP Training slides (slides 25 and 26) refer to materials used for recharging, not resins or membranes. According to the slides, “ion exchange technology is allowed, as long as materials used are on the National List.” The materials listed in the example, e.g., sodium hydroxide and sodium chloride, are compounds used to recharge the exchange resins, not the exchange resins themselves. It is the exchange resins that FDA considers to be food contact substances. The compounds in the recharging solutions are Generally Recognized to be Safe (GRAS) and not subject to FDA regulation as either food contact substances or as food additives.

The recharge materials are used in order to return the resins to their factory initial state and so they can be used again to adsorb impurities from the organic material. When the resin beds are saturated with ions, the resin is unable to adsorb impurities and so has to be cleaned of the ions before it can adsorb more. It is first rinsed with water to remove all traces of syrup and then the resin bed is regenerated (recharged) with hydrochloric acid (HCl - cation resin) and sodium hydroxide (NaOH - anion bed) to remove any salts or contaminants from the previous batch of syrup. The resin is then washed with low flow then a high flow of deionized water until the conductivity of the rinse water indicates all traces of HCl (or sodium hydroxide) are removed. It can also be flushed with a national list material like citric acid, as an additional intervening event, and then flushed again with water. The ion exchange bed is then placed in recirculation to ensure pH is near neutral. The resin bed is then in the same state it was in upon receipt from its manufacturer and ready for organic production. In other words, recharge materials (HCl and NaOH), one of which is on the National List (NaOH) and one that isn't (HCl), can be removed from the resin before its reuse for organic production. This is a similar situation where non-NL materials are used for cleaning and sanitation of food contact surfaces as long as there is an intervening event with a NL material (water wash as the most common example) prior to renewed contact with organic food.

If hydrogen is needed for the cation exchange, hydrogen from the water rinse has become part of the resin during the recharge rinse process. If a hydroxide is needed for exchange during the anion process, then sodium hydroxide, which is on the national list, does not need to be removed from the resin bed prior to use. See #4 for more information.

4. **No Chemical Change occurs as a result of Ion Exchange:** See below for a simple flow chart illustrating the process. The finished product is chemically unchanged from the initial organic ingredient. The only changes are the removal of ions that are considered undesirable impurities that can have adverse effects on finished products that use the organic product as an ingredient.



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Organic product (eg, organic rice syrup)

Salt ↓ ↑ hydrogen ions

Ion exchange resin bed

Organic product (eg, organic rice syrup)

Acids/impurities ↓ ↑ hydroxide ions

Ion exchange resin bed

The first stage is the **Cation Process** where the ion exchange filter takes salt (Na^+) from syrup and replaces it with hydrogen ions (H^+) from water. Other impurities like organic acids, chlorides, heavy metals remain in the organic product until the next step.

The second stage is the **Anion Process** where the ion exchange filter takes hydrogen that was added in the first stage as well as organic acids and other impurities from syrup and replaces them with hydroxide ions (OH^-) from sodium hydroxide, which is on the National List, 205.605.

What remains is the Organic syrup in water with no salts and minimal amount of organic acid and other impurities. The original product remains unchanged aside from a removal of impurities. This is the same result of any filtration system.

Please let me know if you have any follow-up questions and thank you for your time and consideration.

Sincerely,
QUALITY ASSURANCE INTERNATIONAL (QAI)

Jessica Walden

Jessica Walden
Senior Technical Reviewer



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August 7, 2019

Devon Pattillo, Materials Specialist
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Re: May 7, 2019 Notice to Certifiers - Ion Exchange

Oregon Tilth is requesting further clarification regarding the National Organic Program's (NOP) May 7, 2019 Notice to Certifying Agents regarding the use of ion exchange. Specifically regarding the new requirement for 'ion exchange resins', as defined in the notice, to be on the National List for continued use in organic production. The information provided contradicts previous trainings provided by the NOP, and the Food and Drug Administrations (FDA) classification of these substances as 'Secondary Direct Food Additives' at [21 CFR 173](#).

Oregon Tilth has historically required the recharging and sanitizing materials used in ion exchange to be on the National List at §205.605, but considers the resins and membranes to be food contact equipment, per NOP trainings and Frequently Asked Questions (FAQ). The recharging and sanitizing materials are the substances of concern and may be added or incorporated into food. The resins are insoluble and designed to be sanitized, recharged and reused repeatedly to remove contaminants that build up during food processing or are naturally present in food or water. The insoluble ion exchange resins and membranes are never incorporated into food products. This review process ensures that anything exchanged or added to an organic product is an approved substance at §205.605 (e.g., sodium hydroxide, sodium chloride). Please see the attached slides from the 2010 NOP Certifier Training, which includes examples of allowed substances for recharging ion exchange resins when used in organic production. If this change is implemented, please allow adequate time for the petition process for ion exchange resins as part of the implementation timeline.

Please note the following FDA references for ion exchange resins as Food Contact Substances:

- [FDA's Food Ingredient & Packaging Terms with regard to 'Secondary Direct Food Additives'](#), which states: *"This term is in the title of 21 CFR 173, which was "created during recodification of the food additive regulations in 1977. A secondary direct food additive has a technical effect in food during processing but not in the finished food (e.g., processing aid). Some secondary direct food additives also meet the definition of a food contact substance. For more on food contact substances, consult the Food Contact Substance Notification Program".*

- **FDA approved ion exchange resins for use as Food Contact Substances:** Search FDA Inventory of [Effective Food Contact Substance Notifications for 'ion exchange resin'](#). These are used to selectively remove contaminants from liquid water based food materials, such as milk, whey, fruit juice, beer and wine, as well as for demineralizing sugar, softening water for food and beverage production, extracting individual proteins or substances present in liquid water based food materials, and food enzyme solutions. 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](#) and used in food production. None of the synthetic resins listed in section A are currently on the National List. Section B of this part details the types of materials that are used to exchange or replace the less desirable ions found in foods. Some of these materials are listed at §205.605 as allowed ingredients in organic production.

The Notice from NOP states that ion exchange resins and membranes are not food contact substances and requires them to be added to the National List for their continued use in organic production. This change will have a significant impact on our clients and the industry at large. Many organic products currently on the market cannot be produced without this technology. It is unlikely that the NOP or certifiers fully comprehend the extent of the impact without the opportunity for public comment or stakeholder input.

A public comment period for such changes assures adequate participation and feedback from stakeholders and ensures understanding of the technology involved and potential impact on the industry. It also provides adequate time to prepare for and adapt to these changes. This process was not followed and the implementation requirements are not reasonable for the industry to adjust to such a drastic change. We urge the NOP to reconsider their new stance on ion exchange and consider existing technical reviews of other substances that use ion exchange already in section §205.605(a) of the National List.

Thank you for your time and attention to this important matter.

Sincerely,

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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



CCOF

Advancing organic agriculture through certification, education, advocacy, and promotion.

Paul Lewis, Ph.D.
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August 9, 2019

RE: CCOF Comments on the May 7th notification on the ion exchange process

Dear Dr. Lewis:

Thank you for the opportunity to comment on the May 7th notification from the National Organic Program (NOP) to USDA accredited certifying agents clarifying that all nonagricultural substances used in the ion exchange process must be on the National List of Allowed and Prohibited Substances (National List).

California Certified Organic Farmers (CCOF) supports NOP's decision to delay implementation of the May 7th notification. Seeking National Organic Standards Board (NOSB) input and gathering stakeholder feedback through a public comment process is critical to ensuring a transparent and well-grounded outcome.

CCOF remains concerned with NOP's decision outlined in the May 7th notification and recommends NOP reconsider the requirement that all nonagricultural substances used in the ion exchange process be on the National List. CCOF developed an approach to resin filtration and ion exchange review after thoughtful consideration of the process and discussion with other accredited certification agents. The ion exchange process involves a combination of equipment (resin and membrane) and recharge materials. When reviewing an ion exchange process for compliance, CCOF requires the recharge materials to be on the National List and the resin to be FDA approved as a food contact substance. CCOF does not require the resin or membrane to be on the National List as they are analogous to other types of equipment used to process products.

The full impact of the May 7th notification is uncertain. CCOF reviewed an application for certification from a sugar cane processor using ion exchange with sodium hydroxide as the recharge material. The operation's ion filtration system would be noncompliant under the new notification as there are no ion exchange resins on the National List. It is unclear whether the operation could transition to an alternate filtration system.

In addition, there may be implications for other filtration systems that involve resins. We are uncertain how many CCOF certified operations could be affected by NOP's May 7th notification since we have reviewed each ion exchange resin, membrane and recharge material as part of the operation's Organic System Plan, but only recorded recharge materials in our database.

CCOF appreciates the opportunity to comment and urges NOP to address our concerns.

Sincerely,

Sarah Reed

Sarah Reed
Handler Certification Director
CCOF Certification Services, LLC

CC: April Crittenden, Chief Certification Officer, CCOF Certification Services, LLC
Rebekah Weber, Policy Director, CCOF, Inc.