

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

Date: April 27, 2023

Subject: Ion Exchange Filtration Process - Resins

NOSB Chair: Nate Powell-Palm

The NOSB hereby recommends to the NOP the following:

Rulemaking Action:

Guidance Statement: X

Other:

Statement of the Recommendation:

The NOSB vote on the proposal on Ion Exchange Filtration Process – Resins passed. This proposal recommends that ion exchange resins used in the ion exchange filtration process are not required to be on the National List. Additionally, this recommendation requests the NOP provide instruction to certifiers to ensure a consistent review process of ion exchange filtration systems (including resins and recharge materials).

Rationale Supporting Recommendation:

In 2019 the National Organic Program (NOP) asked the National Organic Standards Board (NOSB) to review ion exchange filtration because of conflicting interpretations among certifiers and within the NOP itself. In response, the Board put forth several discussion documents and proposals.

At the Spring 2023 meeting, the NOSB determined that resins are not required to appear on the National List when used in ion exchange filtration systems as they do not meet the definition of an ingredient or processing aid (7 CFR §205.2 Definitions). The Organic Foods Production Act of 1990 (OFPA) requires that “ingredients” be listed on the National List (Section 6510(a)(4)). The *Harvey v. Johanns* court interpreted “ingredient” for the purposes of the OFPA to include “processing aids.”

However, it is vitally important for certifiers to review both the resins and recharge materials in a consistent manner. To that end, the NOSB recommends that NOP provide instruction to certifiers to ensure a consistent review process of ion exchange filtration systems that includes the following requirements:

1. Verification of the ion exchange system through review of an operation’s Organic System Plan (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; and

3. Verification that the exchange resins have been reviewed and approved by 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.

NOSB Vote:

Motion:

Motion to approve the proposal that the ion exchange resins used in the ion exchange filtration process are not required to be on the National List and that NOP provide instruction to certifiers as outlined in this recommendation.

Motion by: Kyla Smith

Seconded by: Wood Turner

Yes: 12 No: 1 Abstain: 1 Recuse: 0 Absent: 1

Motion Passed

**National Organic Standards Board
Handling Subcommittee Proposal
Ion Exchange Filtration Process – Resins
February 7, 2023**

Background:

In an [August 27, 2019 memo](#), the National Organic Program (NOP) requested the National Organic Standards Board (NOSB) provide recommendations related to the process of ion exchange filtration in the handling of organic products. During the NOSB's review, it has become clear that there is inconsistency between certifiers in how they approve or disapprove this type of process. Some certifiers require only the solutions that are used to recharge the ion exchange membranes be on the National List in 7 CFR 205.605. Other certifiers require that all materials, including ion exchange membranes and resins be listed in § 205.605.

The NOP provided clarification to certifying agents in an email sent on May 7, 2019, that nonagricultural substances used in the ion-exchange process must be present on the National List. This would include, but is not limited to, resins, membranes, and recharge materials. Originally, the NOP asked all operations to come into compliance with the statement above by May 1, 2020. However, in response to requests for clarification of NOP's rationale, as well as requests to extend the timeline for implementation, the NOP delayed the implementation date to gather more information and requested that NOSB review the issue.

The NOP determined, and some Materials Review Organizations (MROs) have agreed, that the ion exchange process is a chemical one, and does affect the food in a way that chemically changes it. This process is different from physical filtration. In the ion exchange process, the liquid run through the process exchanges molecules with the those being held on the surface of the resin. The U.S. Food & Drug Administration (FDA) considers ion-exchange membranes and resins to be secondary direct food additives, since there is an effect on the liquid that is run through this process.

Manufacturers and certifiers who wish to continue allowance of the ion exchange process disagree with some of the findings of the NOP on this complex issue. The different opinions on the need for resins, recharge materials, and membranes to be present on the National List, as well as how they interact with each other and the liquid filtered through the ion exchange process, is complicated and the NOP therefore asked the NOSB to assess this issue.

A simplified summary of ion exchange, provided in the past from the Organic Materials Review Institute (OMRI) is as follows:

Ion exchange is based on the principle that a solid mass with immobilized charges can attract the mobile ions of the opposite charge in a fluid media. In practice, this involves a column that is like a large pipe packed with an exchanger, which may be in the form of beads, crystals, gels, or granules. The fluid can pass through, but the ions in solution will be pulled out and held to the exchanger. The process chemically changes the resulting fluid.

Techniques used to produce various sweeteners offer a good example of how the process works. Minerals, salts, proteins and color bodies occur naturally in grape juice, cane juice, beet juice, and corn syrup. The refinement process seeks to remove these "impurities". They are also naturally present or—in case of color bodies—are formed between naturally present components during heating. These can be removed by a

number of techniques. Some are physical, some are chemical, and some use both. However, the use of synthetic cross-linked polymeric resins—such as styrene-divinylbenzene (S-DVB)—to remove certain constituents of liquids based on their chemical properties is a chemical process. The liquified sweetener stream chemically reacts with the ions present on the ion exchange resin to purify and concentrate the desired sugar (Cantor and Spitz, 1956).

Other processing aids that are considered secondary food additives required petitions in order to be considered. In addition to the filtering / clarifying / fining agents mentioned above, these also included the boiler water additives, antifoaming agents, and certain enzymes. Other additives that are considered ‘de minimis’ in conventional processing—such as disinfectants and atmospheric gases—also required petitions, reviews, and recommendations to be added to the National List. Ion exchange resins are known to leak from columns and thus become incidental additives in the food.

The Handling Subcommittee presented a discussion document at the Spring 2020 meeting and presented and voted on a proposal at the Fall 2020 meeting, which recommended that the recharge materials be listed, and the resins not be listed. This vote failed (9 yes, 6 no), and the NOSB requested to keep this as a work agenda item.

The Handling Subcommittee then presented a proposal at the Spring 2021 meeting that outlined the complexity of this material but didn't take a stance on whether recharge materials and/or resins should be listed. The Spring 2021 proposal passed with the inclusion of a request on the cover letter for the NOP to engage with FDA on this topic about how FDA categorizes resins – as secondary food additives or food contact substances.

The NOP sent a memorandum to the Board in August 2021 with a summary of the discussions. The findings from this meeting were inconclusive as the FDA expressed that ion exchange resins can be both secondary food additives and food contact substances (determined on a case-by-case basis). A clear result of the meeting between NOP and FDA is that it is dangerous territory for the NOSB to rely on the FDA definitions of secondary food additives and food contact substances to determine whether substances should be listed on the National List, as this would result in substances not on the National List needing to be petitioned and substances that are listed that would not need to be listed.

At the Fall 2022 meeting, the NOSB unanimously passed a proposal, recommending that recharge materials used in ion exchange filtration must be listed on the National List. The NOSB also discussed the discussion document on ion exchange resins that presented three options for stakeholders to comment on. For the upcoming April 2023 meeting, the Handling Subcommittee now presents this ion exchange resin proposal.

Subcommittee Review and Discussion:

The 2020 technical report (TR) provides a thorough review of ion exchange filtration and should be referred to for details on this process. It is clear that there is widespread use of ion exchange filtration in organic processing whether it be for removal of off-tastes, heavy metals, or clarification of the final product, among others. The TR indicates [880-882], there are no organic agricultural products that serve as an adequate alternative to ion exchange filtration...”

Also noted in the 2020 TR, ion exchange filtration differs from a physical filtration process. Ion exchange filtration induces a chemical change in the ensuing product due to the recharge materials used.

Leakage/Degradation:

The 2020 TR states that there are studies that demonstrate that the resins do degrade over time, however that degradation is generally in terms of their loss of resin activity or efficiency or capacity (2020 TR, lines 784-797). In other words, the resins are simply not as good at holding ions to be exchanged and thus need to be recharged sooner than they would when they were new. In some cases, this loss of efficacy may be because of a loss of functional groups that were originally present, however the citations referenced in the TR note that this loss seems to occur primarily during the recharge process. Thus, the loss of those functional groups would not be into an organic product, but rather into the recharge material. The 2020 TR further states that the TR writers found no published studies on the human health effects of the degradation of the resins (2020 TR, lines 796-797).

During the Fall 2022 meeting, the NOSB received several public comments that support the TR findings. Including the following:

- When ion exchange resin systems are in good working order, they are analogous to a plastic container, mechanical filter or a conveyer belt, a set of materials that are held to the requirements at §205.272.
- When degradation occurs over time, the result is loss of ion exchange activity, either due to strong adsorption of compounds from purified food products or additional crosslinking between existing functional groups on the polymer or with adsorbed materials, not that the resin materials are leaching into foods or materials being filtered.
- The term “leaking” is used when the resins are not capturing the ions they are intending to capture because the resin is full.

Organic Foods Production Act (OFPA)/National List:

Based on past NOP guidance, substances categorized as food contact substances may be used unless explicitly prohibited; whereas if categorized as secondary food additives, then they must appear on the National List. This position comes from a policy statement issued on December 12, 2002. This memo was archived when the NOP Program Handbook was created, however it has never been formally rescinded and remains in use by some certifiers.

To aid in our evaluation, the NOSB requested that the NOP meet with FDA to inform how resins should be categorized: as secondary food additives or food contact substances. Because food additives are listed on the National List and due to the precedent set by the December 2002 policy memo, we believed this distinction would help us to determine if the resins should be listed or not. This meeting took place on June 7, 2021. Unfortunately, the conclusion was that ion exchange resins can be classified both as food contact substances and secondary food additives and are evaluated on a case-by-case basis, and therefore did not provide information to guide the NOSB in either direction.

On a less technical level, there is procedural context. Since some physical filtration materials are listed and resins are not, there are arguments that there is a disparity in the review of materials. There is also some disparity as to the level of scrutiny certifiers apply to reviews of food contact substances. Some certifiers require listing all the food contact substances and others may not.

Given the above information, the below options were presented and discussed at the Fall 2022 meeting.

Option 1: Resins do not need to be listed

In previous public comment periods, stakeholders expressed concern that a de facto statement, that resins do not need to be on the National List, leaves a wide-open playing field for any resin to be used. While resins currently being used might be acceptable, the lack of a required review for resins could cause issues in the future with resins that would be less acceptable for use in organic production

systems. Allowing resin use without review could provide an unintentional loophole to the requirements of OFPA.

However, since resins are currently being used in organic production Option 1 is the least impactful option.

During the Fall 2022 meeting, several stakeholders were in support of Option 1, noting that OFPA requires the listing of ingredients (and processing aids – clarified through the Harvey lawsuit) on the National List. Ion exchange resins do not meet the definition of ingredient or processing aid and therefore should not be listed per OFPA. There was an acknowledgement that the National List does currently list other substances that may also not meet the definition of ingredient or processing aid.

Stakeholders in support of Option 1 also noted that it is part of the certifier's review process to:

- Review a description of ion exchange in an operation's Organic System Plan (OSP)
- Verify that the recharge substance is on National List
- Verify that resin was reviewed and approved by FDA as a Food Contact Substance

Stakeholders in support of this Option 1 stated that the above points should be provided by the NOP in an instruction to certifiers.

Option 2: Require listing of Resins – Categorically

An alternative to allowing all resins without review would be to create a listing on the National List that includes all resins used in ion exchange filtration (similar to other broad categories on the National List). Petitions to the NOSB could be used to annotate this broad listing to exclude problematic resins. This process, however, puts the onus on stakeholders to recognize which resins are being used and to act to exclude particular resins. A petition to remove a resin by annotation takes considerable time and forces the petitioner to provide documentation as to how the resin does not comply with OFPA. While this process is in action the resin would continue to be used. This is opposite the more normal procedures of the NOSB whereby the burden is put on the petitioner to document why something should be added to the List and that substance is not allowed to be used until it is added. In the past, removal of substances already being used from the National List becomes difficult due to economic impacts of that removal.

The NOSB received one comment in support of Option 2, with a slight modification. The commenter proposed that instead of annotating to prohibit problematic resins, the annotation could include certain characteristics or use parameters considered to be consistent with organic principles. The end result is the same as Option 1, as this would also be a blanket listing and the use parameters are already being reviewed by certifiers during the OSP review and inspection process.

Some stakeholders were concerned with the precedent Option 2 may set in listing other Food Contact Substances on the National List that do not meet the definition of ingredient or processing aid.

Option 3: Require listing of Resins – Individually

The final option identified by the Handling Subcommittee is to require each resin to be added to the National List. This would require a petition for each specific resin, technical reports to be commissioned and reviewed, and for the NOSB to approve the addition of each resin. This could cause significant disruption to the processing industry since these ion exchange filtration practices are already in use and have been for some time. Without a long phase in period, the requirement of listing currently used resins would cause significant economic harm. There could also be potential health consequences since some of these filtration processes remove heavy metals and other deleterious compounds from organic foods.

Requiring the listing of these resins could cause significant economic impact and disruption of current organic supply chains.

The NOSB received some comments from stakeholders in support of Option 3, noting the NOSB's prior vote on the proposal that recommended resins not be listed failed, which in their view eliminated Option 1. They also saw concerns with a categorical listing (Option 2). Additionally, while they also may not categorize resins as ingredients or processing aids, they concluded that they are also functionally different than some other food contact substances like a table. Due to this difference, stakeholders support the additional scrutiny through review by the NOSB for individually listing resins on the National List. Based on all these reasons they are in support Option 3. However, they did recognize the disruption to the market that would be caused if resins were to be prohibited during the petition and review process and so were in support of continuing to allow until the petition and review process is complete.

The Handling Subcommittee evaluated whether resins used in ion exchange must be included on the National List through analysis of comments received on the above three options presented in the Fall 2022 discussion document, the 2020 technical report, and the earlier record including discussion documents, proposals and written and oral comments.

Based on this evaluation the Handling Subcommittee is recommending **Option 1 – Resins do not need to be listed on the National List**. The Handling Subcommittee supports Option 1 as it most aligns with the requirements outlined in OFPA, as they will not add any non-organic substances to organic products.

Additionally, the Handling Subcommittee fully supports the review of the ion exchange process and oversight that is currently being conducted by certifiers. To further ensure proper and consistent review by certifiers the Handling Subcommittee requests that the NOP issue instruction to certifiers 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.

Based on the public comments provided during the Fall 2022 meeting related to leaking and degradation, the Handling Subcommittee is comfortable with the review and oversight by certifiers and during the inspection process as the means of evaluating compliance with 7 CFR 205.272. However, the Handling Subcommittee acknowledges the concern expressed by some stakeholders around the concept of leaking or leaching. Therefore, the Handling Subcommittee requests information on current monitoring strategies or testing being used to ensure there is not leaching and that ion exchange systems are functioning properly.

Questions to Stakeholders

1. Are there tests or other ways to monitor final products for contamination?
2. What are the industry recognized practices to ensure your ion exchange system is in "good working order"?

Subcommittee Vote

Motion to approve the recommendation that the ion exchange resins used in the ion exchange filtration process are not required to be on the National List and that NOP provide instruction to certifiers as outlined in this recommendation.

Motion by: Kyla Smith

Seconded by: Wood Turner

Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2