

**National Organic Standards Board  
Handling Subcommittee Proposal  
Review of the Ion Exchange Filtration Process and Materials Used  
August 4, 2020**

**Background:**

In an [August 27, 2019, memo](#) the National Organic Program requested the NOSB provide recommendations related to the process of ion exchange filtration in the handling of organic products. 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 at § 205.605. Others require that all materials, including ion exchange membranes and resins be on the National List.

The National Organic Program 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 in order to gather more information and requested that NOSB review the issue.

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 of 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 run through the process, is complicated and the NOP therefore asked the NOSB to take on this issue.

A simplified summary of ion exchange, provided in the past from 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.

#### **Subcommittee Review:**

The question before the Handling Subcommittee essentially boils down to whether only the recharge materials for the resins must be on the National List or whether both the resins and recharge material must be reviewed and added to the List.

The 2020 Technical Review (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. Alternatives to ion exchange filtration are not generally available.

As noted in the 2020 TR, ion exchange filtration differs from physical filtration processes in that there is an actual chemical change in the ensuing product – ions (either cations or anions depending on the resin and desired outcome) that were present on the resin have been substituted in the final product while ions that were initially found in the product are left attached to the resin. This is not just a physical removal of material or a reaction whereby another material is used to help process the initial substance and then removed after that process. The 2020 TR cites various research articles and states:

...ion exchange filtration requires the replacement of bound ions (ions initially present in the filtration material) by others with the same charge and requires electroneutrality...

...ion exchange filtration is based on the principle that if an ion is removed from the treated substance by the filtration material, it is replaced by an ion of the same charge that began in the filtration material (e.g., removal of positive ion from treated substance is replaced by a different positive ion from the filtration material). The ion exchange process is a result of electrostatic attractions between the ion of interest (ion to be removed from the treated substance) and the charged functional groups incorporated into the filtration material.

The final product, by passing through the ion exchange filter, does have a different ionic makeup than the initial product. In the case of removing “hardness” from water, the substitution of sodium for the original calcium in the water does not change that it is still water, per se, but it can change how that interacts with other materials. Thus, it seems difficult to argue that ion exchange filtration does not cause a chemical change in the final product, even though the chemical change may be beneficial. There is a different ionic makeup in the final product as compared to the initial product and the final product may behave slightly differently than the initial product.

The next question is whether the ion exchange membranes and resins are secondary food additives or food contact surfaces. If they are food contact surfaces, then, based on past NOP guidance, they may be used unless explicitly prohibited. If they are secondary food additives, then they must appear on the National List. It is beyond the capacity of NOSB members to investigate the nuances of FDA rules and regulations. The NOSB received a number of public comments from our Spring 2020 discussion document with a number of viewpoints, however the comments from the Organic Trade Association gave the most details of FDA rule history on this topic:

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.

FDA references are as follows:

- Ion exchange resins and membranes are listed in 21 CFR Part 173 as secondary 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.

Additionally, Ingredient submitted comments that echoed the comments from the Organic Trade Association:

The regulatory classification for ion exchange resins is both a food contact substance AND a secondary direct food additive. <https://www.fda.gov/food/food-ingredients-packaging/food-ingredient-packaging-terms>:

- Food Contact Substance (FCS) - 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.
- Secondary Direct Food Additive (SDFA) - 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.

There were no other comments received that contradicted that materials could be listed as both a secondary direct food additive and food contact surface. It would seem that, even though a material might be listed both ways, the fact that they are listed by FDA as a food contact surface, exempts those materials from needing to be reviewed by the NOSB and placed on the National List.

Finally, there is the question of whether the resins or membranes themselves contribute to a change in the final organic product or whether, as food contact substances, they are simply a structure that holds

the ions to be exchanged. 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. 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 primarily occur 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 there were no published studies on the human health effects of the degradation of the resins found by the TR writers. Based on the findings of the TR and no public comments that provided scientific evidence that the resins degrade and cause changes in the final product it would seem that the resins act in the capacity of food contact surfaces and not primarily as direct food additives.

**Subcommittee Recommendation:**

The inherent nature of ion exchange leads us to the conclusion that recharge materials used to recharge ion exchange resins must be on the National List if they are used in the processing of organic product. These recharge materials leave ions on the resins and those ions will ultimately end up in the final organic product. The public comments received at the Spring 2020 NOSB meeting support this recommendation.

There is less consensus on the question of whether the resins or membranes themselves must be reviewed and included on the National List. From comments received, the resins and membranes appear to be classified as food contact substances. There was no compelling evidence in the 2020 TR or public comments that the resins or membranes degrade and alter the final organic product. Based on this review, it is the recommendation of the NOSB that the recharge materials, but not the resins or membranes themselves, must be reviewed and included on the National List.

**Subcommittee vote:**

Motion to approve the recommendation on ion exchange materials

Motion by: Steve Ela

Seconded by: Scott Rice

Yes: 6 No: 0 Absent: 1 Abstain: 0 Recuse: 0

**Approved by Asa Bradman, Handling Subcommittee Chair, to transmit to NOP August 13, 2020**