National Organic Standards Board
Handling Subcommittee Proposal
Review of the Ion Exchange Filtration Process and Materials Used
February 17, 2021

Background:
In an August 27, 2019 memo, the National Organic Program (NOP) requested the NOSB provide a recommendation 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 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.

The NOP has determined, and some Materials Review Organizations 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 used in the process exchanges molecules with those being held on the surface of the resin. The FDA considers ion-exchange membranes and resins to be secondary direct food additives, since there is an effect on the liquid used in 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 about 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 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.
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> 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 the 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 is whether only the recharge materials for the resins must be on the National List or whether both the resins and recharge materials 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.

Next, there is the question of whether the resins 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 found on the human health effects of the degradation of the resins. 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 substances and not primarily as direct food additives. However, these same resins can be included under secondary food additives.

There is a question of whether the ion exchange membranes and resins are secondary food additives or food contact substances. If they are food contact substances, 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. The NOSB received many public comments on both its Spring 2020 discussion document and Fall 2020 proposal with a number of viewpoints, however the comments from the Organic Trade Association provided 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, Ingredion 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/foodjfood-ingredientspackaging/food-ingredient-packaging-terms:
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> - 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.

The NOSB received no other comments that contradicted that materials could be listed as both a secondary direct food additive and food contact substance. 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 substance, exempts those materials from needing to be reviewed by the NOSB and placed on the National List. The argument can also be made that if a substance is listed as a secondary food additive, regardless of its listing as a food contact substance, that it is under the purview of OFPA and the resins would therefore need to appear on the National List. It is beyond the capacity of NOSB members to investigate the nuances of FDA rules and regulations and how they legally relate to OFPA. The legal ramifications of these decisions should be left to legal counsel for the National Organic Program.

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.

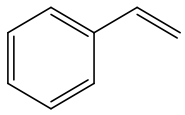
There is less consensus on the question of whether the resins themselves must be reviewed and included on the National List. From comments received, the resins appear to be classified as both secondary food additives and food contact substances, however there are countervailing arguments that should be noted. There are legal arguments and interpretations about how OFPA might apply to FDA regulations defining secondary food additives and food contact substances. A proposal advising the NOP that the resins should not have to appear on the National List was voted down by the full Board at the Fall 2020 NOSB meeting.

Further complicating this issue is that for a material to be classified by FDA as a food contact substance, the manufacturer need only submit an application to FDA requesting the classification. If FDA does not respond to the application (either denying it or asking for further clarification), the material is

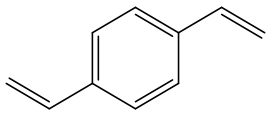
automatically added to the food contact substance list. There is no required review by FDA, no public comment and, with regard to organic classification, no review of how the material relates to OFPA. Once again, this process comes down to a legal opinion as to the interactions of OFPA and FDA regulations that is beyond the scope of the NOSB.

While there was no conclusive evidence in the 2020 TR or public comments that the resins degrade and alter the final organic product, this does not mean that there is no evidence. The quote from OMRI at the beginning of this document refers to ion exchange resins leaking from columns and thus becoming incidental additives. Further research into how and to what extent these resins degrade and whether the degradation occurs during the recharge process or during the food filtration process could help shed light as to whether these resins are strictly in contact with the organic product or are incidental food additives.

There is also the question of how these resins are manufactured. From the TR, the resins are polymeric materials that are synthetic. They are commonly produced as beads, resins, or membranes. Most are produced with the polymerization of styrene and divinyl benzene. While the evidence about the breakdown of the final resin is not conclusive, styrene itself is listed as a Proposition 65 carcinogen. The resins are very similar to plastics. Acidic or basic functional groups are incorporated into the polymeric backbone to make the ion exchange resin.



styrene



divinyl benzene

On a less technical level, there is a procedural context as well. 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. Regardless of the legal issues, these disparities should be noted and clarified.

There is also concern from some stakeholders 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.

An alternative to allowing all resins without review would be to create a section on the National List that includes all resins used in ion exchange filtration (similar to other broad categories on the 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 could take considerable time and forces the petitioner to provide documentation as to how the resin does not comply with OFPA. While this review was underway, the resin would continue to be used. This is opposite the normal procedures of the NOSB whereby the burden is put on the petitioner to document why something should be added to the

National List, and that substance is not allowed to be used until it is added. In the past, removal of substances already in use can be difficult due to economic impacts of that removal.

The final option 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 Board to approve the addition of each resin. This would 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.

While the NOSB would like to give a clear sense of direction on this topic to the National Organic Program, the legal issues are beyond the capability of the Board. The allowance of the use of ion exchange filtration for many years, without requiring the listing of the resins used, also creates a difficult situation. Requiring the listing of these resins could cause significant economic impact and disruption of current organic supply chains; however, not requiring listing could leave an unintentional loophole that would subvert the requirements of OFPA. These technical and procedural issues are best left to legal interpretations and procedural interpretations that are beyond the capabilities of the NOSB.

Subcommittee vote:
Motion to accept the proposal on ion exchange materials
Motion by: Steve Ela
Seconded by: Jerry D'Amore
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 1

Approved by Jerry D'Amore, Handling Subcommittee Chair, to transmit to NOP February 17, 2021.