National Organic Standards Board
Handling Subcommittee Proposal
Review of Ion Exchange Filtration Process – Recharge Materials
July 26, 2022

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 of 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.

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 run through the process exchanges molecules with the 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 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 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.
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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 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.

Th Board presented a discussion document at the Spring 2020 meeting, 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). The board requested to be able to keep this as a work agenda item and presented a proposal at the Spring 2021 meeting. This proposal basically outlined the complexity of this material but didn't take a stance on whether recharge materials and/or resins should be listed. The proposal passed with the inclusion of a request on the cover letter for the NOP to exchange with FDA on this topic and how they categorize resins – as secondary food additives or food contact substances. The NOP held this meeting and sent a memo to the board with a summary of the discussions. The findings from this meeting were inconclusive on a specific path forward for ion exchange resins 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). This is further discussed in the discussion document on ion exchange resins, as this is where the inconsistency lies.

However, there has been a unified approach to the recharge materials used in the ion exchange filtration process. When reviewing ion exchange filtration as a substance, certifiers are aligned in their review of the recharge materials and are presently requiring these materials to be listed on the National List. Examples of substances on the National List that may be used as an ion exchange recharge material include, but are not limited to, sodium chloride, potassium chloride, and hydrogen perioxide.

Subcommittee Review:
Since there is consensus on the listing of the recharge materials used in the ion exchange filtration process on the National List (based on the public comments, discussions of previous proposals and current review practices by certifiers), the Handling Subcommittee decided to decouple the review and recommendation of recharge materials from the resins.

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.

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 on previous discussion documents and proposals, as well as current review practices by certifiers, support this recommendation.

Subcommittee vote
Motion to approve the recommendation that recharge materials used in the ion exchange filtration process must be listed on the National List.
Motion by: Kyla Smith
Seconded by: Kim Huseman
Yes: 6 No: 0 Abstain: 0 Recuse: 0 Absent: 2