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National Organic Standards Board
USDA-AMS-NOP
1400 Independence Ave. SW
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

Docket ID # AMS-NOP-20-0089

Re. HS: Ion exchange resins

These comments to the National Organic Standards Board (NOSB) on its Spring 2021 agenda are submitted on behalf of Beyond Pesticides. Founded in 1981 as a national, grassroots, membership organization that represents community-based organizations and a range of people seeking to bridge the interests of consumers, farmers and farmworkers, Beyond Pesticides advances improved protections from pesticides and alternative pest management strategies that reduce or eliminate a reliance on pesticides. Our membership and network span the 50 states and the world.

We agree with the National Organic Program (NOP) that it is time to clarify the role that ion exchange resins should play in organic food processing. The NOSB should recommend that only resins and their associated recharge materials approved for this use are allowed in organic food processing. Chemicals added during the ion exchange process must be listed on the label. Foods and ingredients treated with ion exchange should be classified as synthetic.

The Handling Subcommittee (HS) has done a good job of describing options—up to a point. We do not believe that the final outcome should be left to NOP because these are substances that should be reviewed by the NOSB.

Ion exchange is chemical change.

As the HS states in its proposal, "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."

Ion exchange is a reaction in which an element from the treated substance is removed and replaced by a different element. The most familiar example is water softening. Hard water contains calcium and magnesium in solution, which are considered undesirable because they can precipitate onto pipes and they destroy the surfactant properties of soap. A water softener replaces calcium and magnesium cations and with sodium ions. The water coming out now contains sodium, which is more soluble, but may pose a health risk for some people.[1]

Ion exchange has many uses in food processing. In sugar production alone, it is used to soften sugar beet juice, demineralize sugar beet juice, remove color from cane juice, increase the yield of sugar from molasses, and convert sucrose into other sugars. It is also used to remove unwanted minerals, metals, acids, colors, tastes, and smells from other liquids like whey, juice, and beverages. It is used in purification of some products of fermentation (e.g., citric acid and amino acids).[2]

Ion exchange may introduce chemicals into food.

The HS states, "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."

First of all, the chemicals exchanged for unwanted chemicals are introduced into the product. There are common problems that arise in the ion exchange process that can introduce other chemicals:

- Resin fouling, which requires the use of caustics or surfactants that may leave residues;
- Resin loss, resulting in leakage of resins—polymers that are not intended to be in food;[3]
- Increased corrosivity, leaching metals (iron, copper, chromium, etc.) from pipes, as well as contaminants (e.g., lead and arsenic) deposited on pipe walls;
- Leaching of components of resins (such as dichloroethene, sulfonated aromatic compounds; solvents, and oxidative byproducts); and
- Growth of organisms in the resin bed.[4]

Secondly, in removing the targeted ions, the process may also remove desirable ions.

Ion exchange is not filtration.

Filtration is a physical process that removes <u>insoluble</u> components in a liquid. Ion exchange is a chemical process that removes <u>soluble</u> components.[5]

Ion exchange is a processing aid, not a food contact substance.

As explained above, ion exchange introduces new chemicals, and the resins and membranes are considered by FDA to be secondary direct food additives. Even if, as stated in the HS proposal, a secondary direct food additive may also be a food contact substance, the

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[1] Stephen Lower, 2007. "Hard water and water softening."

[2] François de Dardel, 2019. Ion exchange resins applications: A general overview. http://dardel.info/IX/applications.html.

[3] https://www.samcotech.com/common-ion-exchange-system-problems-how-to-fix/.

[4] Peter Meyers, 2018. Unintended consequences. https://www.wqpmag.com/resins-ion-exchange/unintended-consequences.

[5] Rohm and Haas, 2008. Ion exchange for dummies. https://www.lenntech.com/Data-sheets/Ion-Exchange-for-Dummies-RH.pdf.

more stringent requirements—that is, for secondary direct food additives—must be applied. The comments from OMRI quoted in the HS discussion document are worth repeating:

> 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.

Options

The HS lays out some options, on which we offer some comments. All agree that recharge materials must be on the National List (NL).

Option 1: Resins do not need to be on the National List.

This option was voted down by the NOSB at the Fall 2020 meeting. We agree with reasons summarized by the HS—poor oversight practices by FDA, the possibility of resins degrading and entering food, the composition and manufacture of the resins, the disparity that would exist with true filtration materials, and the possibility of creating a loophole for allowing non-NL substances.

Option 2: List ion exchange resins as a category.

We have enough experience with categorical NL listings (e.g., List 4 "inerts") to reject this option out of hand. If this option was adopted, then a petition would be needed to remove a specific resin that turns out to be a problem. The HS notes, "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." We agree.

Option 3: Require each resin to be on the National List.

As with other cases in which the NOSB has unwittingly assented to allowing materials without subjecting them to the petition process, the one option that is consistent with the Organic Foods Production Act appears to be an unsolvable problem. As the HS says, "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."

It is not true, however, that "These technical and procedural issues are best left to legal interpretations and procedural interpretations that are beyond the capabilities of the NOSB." They only seem to be such if one believes it essential to resolve questions such as when resins are food contact substance and when they are secondary food additives. But this is not necessary, or even consistent with OFPA, which requires that any synthetic substance added to organic food be on the NL, and only after having been recommended by the NOSB. The HS has established that use of ion exchange resins can result in resins or their breakdown products being added to foods. Therefore, the NOSB must, based on OFPA, decide which resins may be used, and for what purposes. The NOSB may not contravene other laws, but it may (and must) take a precautionary approach based on the strictest interpretations of those laws.

Back to basics: Why isn't food processed with ion exchange classified as synthetic?

So far, our comments have accepted the framing offered by the HS --do the resins themselves need to be on the National List, and how? But here is a question the HS did not, but should, ask: Why shouldn't food that has been processed using ion exchange be classified as synthetic? The HS includes this quote from OMRI:

> 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).
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> 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.

If, as OMRI states, ion exchange "filtration" is chemical change and the substance undergoing the chemical change is the processed food, why isn't that processed food synthetic?

If the processed food is—as in the sugar example above—an ingredient in processed products, then the limitations of no more than 5% in organic food and 30% in food made with organic ingredients must apply, and those synthetic processed ingredients must be listed on §605(b) for the use.

Is ion exchange needed in organic processing?

Situations such as this are probably inevitable, given the exponential growth of organic markets and the influx of technologies from nonorganic production. However, it is crucial to the maintenance of organic integrity that the NOSB bite the bullet and construct a recommendation that is consistent with OFPA. In doing so, the NOSB must ask whether ion exchange is really necessary in organic processing.

Conclusions

The NOSB should find that food processed by ion exchange is synthetic. Ingredients processed with ion exchange must not be used in organic or made with organic food unless they appear on the NL for the purpose. The corollary is that foods processed using ion exchange should not be labeled organic.

In addition, the NOSB should recommend that only resins and their associated recharge materials approved for this use should be allowed in organic food processing, and only when approved for listing on §205.605(b). Chemicals added during the ion exchange process must be listed on the label.

Thank you for your consideration of these comments.

Sincerely,

Terry Shistar, Ph.D.
Board of Directors