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USDA-AMS-NOP
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Docket ID # AMS-NOP-22-0071

Re. HS: Ion exchange resins

These comments to the National Organic Standards Board (NOSB) on its Fall 2022 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 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. It is an important role of the NOSB to recognize inconsistencies in the ways that organic regulations are applied by certifiers and recommend changes to eliminate them. The NOSB must also rectify discrepancies between the law and widespread practice.

While options put forward by the Handling Subcommittee (HS) address the inconsistencies in applying the rule, they fail to address the discrepancy between the law and widespread practice. The NOSB must deal with the fact that major ingredients in organic food are synthetic.

Ion exchange is chemical change.

Ion exchange is not filtration. 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 and the classification of materials guidance

The classification of materials used in organic production is guided by NOP 5033, NOP 5033-1, and NOP 5033-2.

NOP-5033 says:

> 4.5 Materials Derived from Agricultural Products
> Materials derived from agricultural products may be agricultural or nonagricultural, depending on the manufacturing and processing methods used.
>
> The decision tree, NOP 5033-1, includes questions to differentiate between chemical reactions caused by naturally occurring biological processes, such as composting, fermentation, use of enzymes, and by heating or burning biological matter (e.g., cooking, baking, etc.).
>
> Agricultural materials which are chemically changed due to allowed agricultural processing methods (e.g., cooking, baking, etc.) do not result in classification of the processed agricultural product as synthetic.
>
> 4.6 Extraction of Nonorganic Materials
> Some materials are produced using manufacturing processes that involve separation techniques, such as the steam distillation of oil from plant leaves. Separation and extraction methods may include, but are not limited to, distillation, solvent extraction, acid-base extraction, and physical or mechanical methods (e.g., filtration, crushing, centrifugation, or gravity separation).
>
> For purposes of classification of a material as synthetic or nonsynthetic, a material may be classified as nonsynthetic (natural) if the extraction or separation technique results in a material that meets all of the following criteria:

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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.

• At the end of the extraction process, the material has not been transformed into a different substance via chemical change;
• The material has not been altered into a form that does not occur in nature; and
• Any synthetic materials used to separate, isolate, or extract the substance have been removed from the final substance (e.g., via evaporation, distillation, precipitation, or other means) such that they have no technical or functional effect in the final product.

4.7 Products of Naturally Occurring Biological Processes
Products of naturally occurring biological processes, such as fermentation and composting, are statutorily considered natural and nonsynthetic. Examples of nonsynthetic materials produced from naturally occurring biological processes include vinegar, citric acid, compost, gibberellic acid, and 3pinosad. Additional examples are provided in Table 1 of NOP 5033-1.

4.8 Burning or Combustion
Heating or burning of biological matter (e.g., plant or animal material) is considered a natural process that does not result in classification of ash as synthetic. For example, ash from manure burning is classified as a prohibited nonsynthetic substance at section 205.602 of the National List. The use of other types of ash must comply with the soil fertility and crop nutrient management practice standard at section 205.203 of the USDA organic regulations.

Heating or burning of non-biological matter (e.g., minerals) to cause a chemical reaction has resulted in classification of the substance as synthetic. For example, limestone (calcium carbonate, $CaCO3$) heated to release carbon dioxide and produce quicklime (calcium oxide, CaO) is classified as a synthetic process.

For purposes of classification of materials, pyrolysis (i.e., high temperature decomposition of substances in the absence of oxygen) may be treated as equivalent to burning or combustion.

The flowchart for ag/non-ag substances (NOP 5033-1), says that an agricultural material that is chemically changed by a process that is NOT "a result of naturally occurring biological processes such as fermentation or the use of enzymes; or a result of mechanical/physical/biological process described under section 205.270(a)" is nonagricultural.

According to this guidance and flowchart, the chemical change created by ion exchange results in a nonagricultural substance.

Other examples of materials with an agricultural origin used in organic processing that have been found by the NOSB to be synthetic (and hence listed on §205.605(b) are activated charcoal,[3] cellulose,[4] and glycerin.[5]

The flowchart in NOP 5033-2 then classifies such a material as synthetic.

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;[6]
- Increased corrosivity, leaching metals (iron, copper, chromium, etc.) from pipes, as well as contaminants (e.g., lead and arsenic) deposited on pipe walls; [7]
- Leaching of components of resins (such as dichloroethene, sulfonated aromatic compounds; solvents, and oxidative byproducts); [8] and
- Growth of organisms in the resin bed.[9]

In addition, in removing the targeted ions, the process may also remove desirable ions. [10]

As explained above, ion exchange introduces new chemicals, and the resins and membranes may be 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 more stringent requirements—that is, for secondary direct food additives—must be applied. The comments from OMRI quoted in the HS materials 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

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[3] 2002 TAP review: https://www.ams.usda.gov/sites/default/files/media/Activated%20Charcoal%20Processing%20TR.pdf.
[4] 2016 TR: https://www.ams.usda.gov/sites/default/files/media/Cellulose_TR%202_11_2016.pdf.
[5] 2013 TR: https://www.ams.usda.gov/sites/default/files/media/Glycerin%20Petition%20to%20remove%20TR%202013.pdf.
[6] https://www.samcotech.com/common-ion-exchange-system-problems-how-to-fix/.
[7] Peter Meyers, 2018. When do Ion Compositions Shift? https://www.wqpmag.com/filtration/resins-ion-exchange/article/10956280/when-do-ion-compositions-shift.
[8] Peter Meyers, 2018. When do Ion Compositions Shift? https://www.wqpmag.com/filtration/resins-ion-exchange/article/10956280/when-do-ion-compositions-shift.
[9] Peter Meyers, 2018. When do Ion Compositions Shift? https://www.wqpmag.com/filtration/resins-ion-exchange/article/10956280/when-do-ion-compositions-shift.
[10] Peter Meyers, 2018. When do Ion Compositions Shift? https://www.wqpmag.com/filtration/resins-ion-exchange/article/10956280/when-do-ion-compositions-shift.

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.

Ion exchange is not filtration.

Filtration is a physical process that removes insoluble components in a liquid. Ion exchange is a chemical process that removes soluble components and replaces them with others.[11]

Ion exchange transforms major ingredients into synthetic substances.

The question that HS did not ask is most crucial--why shouldn't food that has been processed using ion exchange be classified as synthetic? (We raised this issue in comments last Fall, but the HS review did not acknowledge it in its review.) 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.

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).

If, as OMRI states, ion exchange "filtration" is chemical change and the substance undergoing the chemical change is the processed food, why is that processed food not 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.**

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

To repeat, ingredients like organic grape juice, cane juice, and sugar that are listed on ingredient labels without modification appear to be organic agricultural ingredients. But if they are the result of treatment with ion exchange, they are synthetic ingredients. They should be subject to the restrictions in the law that require food labeled “organic” to be not less than 95 percent organically produced raw or processed agricultural products and those labeled "made with organic [specified ingredients]” to be at least 70 percent organically produced ingredients. In other words, the **processed ingredients** resulting from ion exchange need to be on the National List and limited to no more than a cumulative 5% of processed products labeled “organic” and 30% of processed products labeled "made with organic.”

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), but none addresses the conclusion reached by the TR and the HS, that ion exchange results in chemical change of the treated ingredients, which must therefore be classified as synthetic.

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, but now it is the HS proposal. We agree with reasons previously given—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. We adamantly oppose Option 1.

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 present an unsolvable problem. As the HS said in the Spring 2021, “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.”

Option 4: All additions must be on the National List.

As we have argued above, the issue is even more fundamental. In allowing organic processing to chase the goal of close resemblance to "conventional" foods, we have to be careful not to allow the widening use of synthetic ingredients masquerading as "organic." In compliance with the statute, the integrity of the USDA organic label is directly tied to National List review by the NOSB for substances subject to chemical change.

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 make a real recommendation that is consistent with OFPA. In doing so, the NOSB going forward must evaluate whether ion exchange and the resulting substance(s) is really essential to 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 intended purpose and must be limited to a cumulative 5% of organic products and 30% of made with organic products.

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 they and the treated ingredients are 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