National Organic Standards Board Handling Subcommittee Discussion Document Review of the Ion Exchange Filtration Process January 7, 2020

Summary of Memorandum from the National Organic Program to the National Organic Standards Board, dated August 27, 2019

The National Organic Program has 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 used to recharge the ion exchange membranes be on the National List. 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 processes 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, but have delayed implementation in order to gather more information and give the NOSB a chance to review the issue.

The NOP noted in the 2019 email, and other 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 a physical filtration. In the ion exchange process, the liquid used in the process exchanges molecules with the chemicals used as recharge or resins. The FDA considers ion-exchange membranes and resins to be secondary direct food additives, since there is an effect on the food 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. The different interpretations 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 organic product produced through the process, is complicated and the NOP therefore asked the NOSB to take on this issue.

The NOSB has begun its initial review of this issue, including the NOP email of May 7, 2019, the NOP memorandum to the NOSB of August 27, 2019, the applicable FDA definitions, previous NOSB discussions on this matter from 2002, as well as our current National List and OFPA criteria. The NOSB Handling Subcommittee will be discussing this issue in the coming year and seeks to clarify several issues: Whether or not there is a chemical change; if the various items are food contact substances or processing aids; and if this process is fundamentally different from other filtration processes, in which case the definition in the organic regulation may have to be modified. It is understood that while polymers are used in packaging that do not affect chemical change on the products in that package, the polymers used in ion exchange appear to be functionally different.

The Handling Subcommittee has begun its review of this process by learning about the process and the various materials used. A simplified summary of ion exchange, previously provided by 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.

The Handling Subcommittee has requested a technical review of the ion exchange process. The following questions and issues were added to the standard questions typically included in the TR request template:

- Listing of the uses of ion exchange filtration by organic operations or nonorganic operations, as available, including a description of the products where ion exchange filtration may be used, including processed products, crop, and livestock products;
- Function/purpose of ion exchange filtration, including a description of any chemical changes that occur during the process;
- Uses of ion exchange for water treatment, including domestic and agricultural water treatment and treatment of produced water
- Substances or materials used in ion exchange filtration, including resins, membranes and recharging solutions;
- Alternatives to ion exchange filtration, including practices and substances on the National List;
- Regulations related to ion exchange filtration, especially by U.S. FDA, including categorization/characterization of the substances/materials employed in ion exchange filtration and any associated regulatory terms used to describe substances/materials in ion exchange filtration (i.e., definition of food additive, food contact substance, processing aid, etc.);
- Regulatory terms in USDA organic regulations (<u>7 CFR Part 205</u>) or the Organic Foods Production Act (<u>7 U.S.C. 6501 et seq.</u>) that relate to ion exchange filtration substances/materials;
- Residues/chemicals that may be transferred from ion exchange materials (e.g., resins, beads, membranes, etc.) to food products;
- Regulatory status or approach to ion exchange filtration under international organic standards.

Questions for Public Comment:

The NOSB would like to hear from the public on the topic of ion exchange, and is seeking answers to the following questions to help inform its discussion and future proposal.

- 1. What organic products are currently produced through the ion exchange process?
- 2. Are there other processing methods used to produce these products?
- 3. What materials are being used in the ion exchange process for current organic products? Please include resins, recharge materials, membranes and any other substances.
- 4. If you do not agree that there is chemical change to the products run through the ion exchange process, please provide rationale for this belief.

Vote in Subcommittee

Motion to accept the Ion Exchange Filtration Process and Materials Used discussion document

Motion by: Harriet Behar Seconded by: Lisa de Lima

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

Approved by Asa Bradman, Handling Subcommittee Chair, to transmit to NOSB January 7, 2020

