

National Organic Program 1400 Independence Avenue, SW Room 2642-South, STOP 0268 Washington, DC 20250-0268

July 6, 2023

TO:	USDA-Accredited Certifying Agents
FROM:	Jennifer Tucker, Ph.D. Deputy Administrator National Organic Program (NOP)
SUBJECT:	Ion Exchange Filtration in Organic Production

This memo addresses the National Organic Program's (NOP) May 7, 2019, and July 3, 2019, letters to certifying agents (certifiers) and the October 2022 and April 2023 National Organic Standards Board (NOSB) recommendations on ion exchange filtration. The ion exchange filtration process has two main components: ion exchange resins and the exchange ions (added through a recharge solution).

This memo clarifies that exchange ions/recharge solutions need to be listed on the National List of Allowed and Prohibited Substances (National List), while the ion exchange resins do not need to be on the National List.

Background

Ion exchange filtration is a process used to purify or separate liquids. It is used in processing various products, including organic juices and sugar. In the ion exchange process, a liquid solution is passed through an ion exchange column. This column typically contains resin beads that are used to exchange undesirable ions in the liquid with those on the surface of the resin.

On May 7, 2019, the NOP sent a letter to certifiers stating that all nonagricultural substances used in the ion exchange process needed to be on the National List. This letter was sent in response to a certifier discrepancy and was intended to resolve that discrepancy. In response, several certifiers replied with concerns and provided additional information for the NOP to consider.

On July 3, 2019, the NOP sent another letter to certifiers acknowledging the feedback and concerns about its initial decision. This letter delayed the implementation of the May 7, 2019 decision while the NOP referred the issue to the NOSB, allowing more input from stakeholders and the opportunity to gather more information.

The NOP sent a <u>memo to the NOSB</u> on August 27, 2019 asking it to work on this issue. Specifically, the memo requested information about how ion exchange is used by organic operations, the substances used in these processes, potential alternatives, and recommendations on whether these substances need to be on the National List.

The NOSB discussed ion exchange at its April 2020, October 2020, and April 2021 meetings. At its April 2021 meeting, the NOSB <u>passed a proposal</u> asking the NOP for additional information. The NOSB wanted the U.S. Food and Drug Administration's (FDA) opinion on whether ion exchange resins are secondary direct food additives or food contact substances. This is because past precedent suggests that secondary food additives need to be on the National List while food contact substances do not. The NOSB determined that this information was critical in determining whether or not these resins need to be on the National List.

In an August 10, 2021 <u>memo to the NOSB</u>, the NOP summarized its conversations with the FDA. As requested by the NOSB, this memo discussed the implications of using FDA's definitions for "secondary direct food additive" and "food contact substance". Relying on these definitions may result in substances not on the National List needing to be added (e.g., wire meshes) or substances that are on the National List no longer needing to be on the List (e.g., antimicrobial agents used on poultry carcasses).

The NOSB used this information to continue its review of ion exchange filtration. The NOSB discussed ion exchange again at its October 2022 and April 2023 meetings, resulting in recommendations. The October 2022 recommendation stated that the recharge substances need to be on the National List. The April 2023 recommendation stated that the resins used in ion exchange do not need to be on the National List.

Conclusion

Ion exchange filtration is allowed in organic production. When used, the recharge substances must be on the National List. These substances donate ions to the resins and exchange with target ions in the processed product. Since these ions/substances ultimately end up in the product, they must be on the National List. The resins, however, do not need to be on the National List. Under operating conditions, these resins do not end up in the final product and serve as a structural part of the filter, holding the ions.

When ion exchange filtration is used, the process and substances involved need to be reported in the operation's Organic System Plan and approved by their certifier. Additionally, processes need to be in place to ensure operations follow the contamination prevention practices outlined in 7 CFR 205.272. These processes may include ensuring the resins are approved by the FDA (through a regulatory allowance or Food Contact Notification) and ensuring that proper cleaning, recharging, and operating procedures are followed to prevent premature degradation of the resins.

The NOP thanks the NOSB for its thoughtful work on this complex technical project!