USDA Agricultural Marketing Service
U.S. DEPARTMENT OF AGRICULTURE

1400 Independence Avenue, S.W.
Room 2646-S, Ag Stop 0268
Washington, D.C. 20250-0268

August 10, 2021

MEMORANDUM TO THE NATIONAL ORGANIC STANDARDS BOARD

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Date: 2021.08.10 16:27:05 -04'00'

SUBJECT: Research conducted on FDA's classification of ion exchange resin

Purpose

The purpose of this memorandum is to respond to the National Organic Standard Board's (NOSB) request from the April 2021 meeting to provide information about the U.S. Food and Drug Administration's (FDA) classification of resins used in the ion exchange process. The NOSB is reviewing ion exchange technology and its compatibility with organic production at the request of the National Organic Program (NOP) to address an inconsistency among certifiers.

Definition

Ion exchange is a process used to purify or separate liquids. It is widely used in organic handling of various products, including organic juices. In the ion exchange process, a liquid solution is subjected to solid ion exchanger, typically a polymeric resin, that is used to exchange ions in the solution with those being held on the surface of the resin. The process is used to remove undesirable ions from solutions, such as decolorization, demineralization, and removal of contaminants.

Background

Consistent with NOP 3012, "Interim Instruction Material Review," certifiers originally notified the National Organic Program (NOP) of discrepancies in how ion exchange materials are evaluated. Some certifiers only required the solutions used to recharge the ion exchange membranes to be on the National List at § 205.605, while others required all materials, including ion exchange membranes *and* resins, to be on the National List.

NOP provided an initial clarification to certifying agents on May 7, 2019, instructing that nonagricultural substances (including but not limited to resins, membranes, and recharge materials) used in the ion-exchange process must be present on the National List. Originally, the NOP asked all operations to come into compliance with the above statement by May 1, 2020; however, based on feedback from certifiers, the NOP delayed the implementation date in order to

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gather more information. As part of this process, the NOP requested that NOSB review the issue on August 27, 2019[1].

At the Spring 2021 meeting, the NOSB asked NOP to speak with the Food and Drug Administration (FDA), to learn how FDA classifies resins used in ion exchange. This request was made to help the NOSB reach a final proposal and/or recommendation on which exact components of the ion exchange process should be included on the National List. Specifically, the NOSB was interested to know if the resins used in ion exchange were considered 'food contact substances' or 'secondary direct food additives'. Because food additives are listed on the National List, the NOSB believed this distinction would help determine if the resins should be listed or not.

FDA Definitions

On June 7, 2021, NOP staff met with scientists at the Center for Food Safety and Applied Nutrition within the FDA: Rachel Morissette, Ph.D., Regulatory Review Scientist, and Jeremy Mihalov, M.S., Chemist, both in the Division of Food Ingredients, Office of Food Additive Safety; and Elizabeth Petro, Ph.D., Lead Consumer Safety Officer, Office of Food Additive Safety, Division of Food Contact Substances. FDA scientists explained that ion exchange resins can be classified both as food contact substances and secondary direct food additives and that resins are evaluated on a case-by-case basis.

Dr. Morissette defined 'food additives' as being present in the final product according to Section 201(s) of the Federal Food, Drug, and Cosmetic (FD&C) Act (codified in 21 U.S.C. Sec 321). As noted in FDA's Guidance for Industry: Preparation of Food Contact Notifications (Administrative), in the past, FDA has informally characterized a food additive as being a 'direct additive' if it was intended to have a technical effect in food, a 'secondary direct additive' if it was intended to have a technical effect on food during food processing but not in the finished food as consumed, or an 'indirect additive' if it was intended to have a technical effect in a food contact material. Even though each of these types of food additives is listed in a separate section of 21 CFR (i.e., direct food additives are listed in 21 CFR Part 172, secondary direct food additives are listed in 21 CFR Part 173, and indirect food additives are listed in 21 CFR Parts 175-178), no definitions for direct, secondary direct, or indirect food additive exist in the codified regulations or the statute. Examples of 'secondary direct additives' include: wire meshes, filters, defoamers, clarifying agents, and antimicrobial agents used on poultry carcasses. She explained that resins used for ion exchange purposes may be the subject of existing regulations (e.g., 21 CFR 173.25) or are evaluated through the food contact substance notification (FCN) process, which includes a safety review to identify any potential impacts on human health.

[1] https://www.ams.usda.gov/sites/default/files/media/NOPNOSBIonExchangeJT.pdf

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Dr. Petro noted that the term 'food contact substance' is defined in section 409(h)(6) of the FD&C Act (21 U.S.C. 348(h)(6)) as 'any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.' Food contact substances may also be food additives if, as a result of the intended use, they may reasonably be expected to become a component of food. Since the FDA Modernization Act of 1997, the FCN process has been the primary method by which FDA regulates food additives that are food contact substances. FDA has reviewed several FCNs for uses of ion exchange resins, including effective FCNs 531, 528, 443, 325, 290, 157, 156, 74, 55, 52, and 45. Other examples of food contact substances include components of food packaging, wire meshes, filters, antimicrobial agents used in contact with poultry carcasses, and lubricants for food processing machinery.

Implications

Based on the conversations with FDA, NOP would like the NOSB to note the following implications of using FDA's definitions for "secondary direct food additives" and "food contact substances":

- There is no clear nor consistent distinction between the two terms;
- If the NOSB refers to FDA's definitions, it could result in substances that are *not* currently on the National List necessitating addition to the List (e.g. wire meshes and certain filters), or substances that *are* currently on the National List not needing to be on the List (e.g. antimicrobial agents used in contact with poultry carcasses).

Given the information received from FDA, it appears that caution is needed when considering FDA's classification given the nuances of the criteria described above.

Request

Given the information above, the NOP requests the NOSB's recommendation(s) on whether resins should be listed on the National List. We appreciate the Board's work in considering this topic, as we all work towards increased consistency between certifiers on complex technical areas.

The allowance for current certifier practices remains in effect while the Board considers this topic.