

Notice to Certifying Agents

Dear USDA-accredited Certifying Agent:

The National Organic Program (NOP) was notified of a discrepancy between certifying agents in the review of ion-exchange for processing organic products.

Decision

This notice clarifies that ion-exchange filtration is allowed in organic processing. However, **nonagricultural** substances used in the ion-exchange process must be on the National List of Allowed and Prohibited Substances (National List). This includes, but is not limited to, resins, membranes, and recharging materials. Certifiers that have previously approved use of ion-exchange filtration as part of an organic system plan need to review the ion-exchange process, including resins, membranes, and recharging solutions, to determine if the filtration practices are compliant. If the filtration practices are determined not to be compliant, the affected operations need to be notified. Previously approved filtration practices that are not in compliance must be removed from organic system plans by **May 1, 2020**.

Additional information on this decision is provided below:

Background

Ion-exchange may be used to clarify, decolor, or otherwise filter liquids using a chemical exchange process. The process uses a chemically charged material to selectively remove unwanted molecules from the liquid upon contact. For the purpose of this notice, the term 'ion-exchange resin' is defined as a membrane, resin, or solid material with charged molecules available for exchange with mobile molecules in a fluid. Because repeated use saturates ion-exchange resins with unwanted molecules, recharging (*i.e.*, flushing or regenerating) with chemical solutions is required for continued use. Filtration processes using ion-exchange technology may use a range of ion-exchange resins (*e.g.*, polymeric resin beads, zeolite minerals, activated carbon) and recharging solutions (*e.g.*, sodium chloride, potassium chloride, hydrochloric acid) that may be synthetic or natural.

Justification

USDA organic regulations prohibit use of **nonagricultural** substances "in or on processed products" that are "100 % organic," "organic," or "made with organic ..." except as provided in § 205.605" (§ 205.105(c)). Section 205.605 allows several nonagricultural (nonsynthetic and synthetic) filtering aids. For example, bentonite, diatomaceous earth, and perlite are included at § 205.605(a). Activated charcoal and cellulose are listed at § 205.605(b). These substances were added to the National List following a technical review process to ensure compliance with the Organic Foods Production Act (7 U.S.C. 6501 *et seq.*) criteria *before* allowing for use in or on organic food. If not included on the National List for use in organic processing, nonagricultural substances used in ion-exchange filtration are considered non-compliant.

Some have argued that ion-exchange resins are food-contact substances that do not chemically affect the finished product. We disagree, because the ion-exchange process is a chemical process intended to have an effect in the food. During ion-exchange filtration, chemical molecules in the liquid being processed are exchanged with chemical molecules on the ion-exchange resin. This results in a different chemical composition of the processed product.

Unlike physical filtration methods that selectively remove larger unwanted particles from the liquid passing through the filter, ion-exchange filtration replaces unwanted molecules with different chemical molecules in the liquid being processed.

The U.S. Food and Drug Administration (FDA) considers ion-exchange membranes and ion-exchange resins to be secondary direct food additives (see 21 CFR 173.20 and 173.25). The FDA does not consider ion-exchange resins or ion-exchange membranes to be food contact substances. These substances are defined as “any substance that is 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” (21 CFR 170.3(e)(3)). Because ion-exchange resins do provide an effect in foods, they are not considered food-contact substances. As such, to ensure the organic integrity of foods processed using ion-exchange filtration, **any nonagricultural materials used in the ion-exchange process must be on the National List for use in organic processing**