

HOW DOES THE FDA REGARD ION EXCHANGE RESINS?

FDA has formally reviewed ion exchange technology and has concluded that some ion exchange resins may be safely used in the treatment of food. 21 CFR § 173.25. These resins have been formally classified as “Secondary Direct Food Additives Permitted in Food for Human Consumption” and are regulated in 21 CFR Part 173.

However, under the FDA Modernization Act (FDAMA), ion exchange resins are no longer considered secondary direct additives and a manufacturer or supplier of an ion exchange resin is not required to file a Food Additive Petition with the FDA under 21 CFR Part 171 or have FDA issue a regulation before the resin may be legally used in food processing.

Under FDAMA, ion exchange resins are deemed to be “food contact substances,” defined 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.” Federal Food, Drug, and Cosmetic Act, Section 409(h)(6), 21 U.S. Code § 348 (h)(6).

This puts ion exchange resins in the same category with all other substances used in food processing which come in contact with food but whose use is “not intended to have any technical effect in such food.” These other substances would include materials used in food packaging.

If a substance is a “food contact substance,” a Food Additive Petition (FAP) is not usually required.¹ Instead the manufacturer submits a Food Contact Notification (FCN) of its intent to market the product. FDA has 120 days to object to the marketing of a food contact substance. If the FDA does not object, the substance may be marketed legally on the 121st day without issuance of a regulation.

The FDA published its final rule, “Food Additives: Food Contact Substance Notification System,” in the Federal Register on May 21, 2002 (67 Fed. Reg. 35724-31).

This regulation does not name ion exchange resins or any other specific materials as “food contact substances.” However, on October 15, 2002, the FDA held a workshop on the Notification Process for Food Contact Substances. At this workshop an official of the Office of Food Additive Safety, Dr. Anna Shanklin, stated that ion exchange resins were materials that met the definition of “food contact substance” and that manufacturers and suppliers should submit FCNs for them rather than FAPs.

¹ An FAP may be required in limited circumstances, such as when the Food Contact Substance contains a carcinogenic impurity or is a pesticidal product with a cumulative daily intake greater than 37.5 µg/day.