Report to Congress

Fees Assessed and Collected

FY 2023

Report in Response to Section 743 of the Federal Food, Drug, and Cosmetic Act, as Amended by Section 107(f) of the FDA Food Safety Modernization Act (Public Law 111-353)

Executive Summary

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) was signed into law. Section 107 of FSMA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 743 (21 U.S.C. 379j-31), giving authority to the Food and Drug Administration (FDA) to collect fees from (1) the responsible party for each domestic and foreign food facility subject to a reinspection, (2) importers subject to a reinspection, (3) domestic facilities or importers who do not comply with a recall order, and (4) importers participating in the Voluntary Qualified Importer Program (VQIP). Section 743(f) of the FD&C Act requires the Department of Health and Human Services to submit a report to Congress each fiscal year in which fees are assessed by FDA, including a description of the fees that were assessed and collected, as well as a summary of both the entities that paid these fees and the types of businesses in which these entities engaged.

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I. Introduction

On January 4, 2011, the FDA Food Safety Modernization Act (FSMA) (Public Law 111-353) was signed into law. Section 107 of FSMA amends the Federal Food, Drug, and Cosmetic Act (FD&C Act) to add section 743 (21 U.S.C. 379j-31), giving authority to the Food and Drug Administration (FDA) to collect fees from (1) the responsible party for each domestic and foreign food facility that is subject to a reinspection, (2) importers that are subject to a reinspection, (3) domestic facilities or importers who do not comply with a recall order, and (4) importers participating in Voluntary Qualified Importer Program (VQIP).

Section 743(f) of the FD&C Act requires the Department of Health and Human Services (HHS) to submit a report to Congress each fiscal year in which fees are assessed by FDA. Specifically, section 743(f) states:

> *Annual Report to Congress. – Not later than 120 days after each fiscal year for which fees are assessed under this section, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, to include a description of fees assessed and collected for each such year and a summary description of the entities paying such fees and the types of business in which such entities engage.*

FDA assessed fees under section 743 of the FD&C Act for the first time in Fiscal Year (FY) 2020, triggering the requirement in section 743(f) for HHS to submit a report on the fees collected by FDA and the entities paying these fees. This is the third annual report submitted in response to this mandate, and the report covers FY 2023.

II. Background

FSMA made changes to the FD&C Act that enable FDA to better protect public health by strengthening its food safety measures. FDA now has several additional tools to protect the food supply and to provide better oversight of imported food. These tools include the authority to collect fees for reinspection activities, recall orders, and participation in VQIP.

In particular, section 743(a)(1)(A) and (D) of the FD&C Act provides authority to FDA to collect fees from the responsible party for each domestic food facility that is subject to a reinspection, U.S. agents for each foreign food facility that is subject to a reinspection, and importers who are subject to a reinspection. FDA is authorized to collect fees to cover the costs of the reinspection, which include all expenses, including administrative expenses incurred in connection with (1) arranging, conducting, and evaluating the results of the reinspection and (2) assessing and collecting reinspection fees.

In addition, section 743(a)(1)(B) of the FD&C Act gives FDA the authority to collect fees from the responsible party for each domestic food facility and from importers who do not comply with a recall order under section 423 or section 412(f) of the FD&C Act. FDA is authorized to collect fees to cover food recall activities associated with such orders, including technical assistance, follow-up effectiveness checks, and public notifications.

And finally, section 743(a)(1)(C) of the FD&C Act gives FDA the authority to collect fees from each importer participating in VQIP under section 806 of the FD&C Act to cover the administrative costs of the program. For participating importers who achieve and maintain a high level of control over the safety and security of their supply chains, VQIP provides expedited review and import entry of human and animal foods into the United States.[1]

FDA is required to establish fees to be collected each fiscal year and publish these requirements in the *Federal Register* not later than 60 days before the start of each year. Fee notices for each fiscal year are available on FDA's "Fees under the FSMA" webpage.[2] The fees are based on an estimate of 100 percent of the costs of conducting reinspections, recalls, and VQIP activities, as allowed under section 743 of the FD&C Act and as described above.

Section 743(c)(1) of the FD&C Act requires that fees must be refunded unless the amount of total appropriations for food safety activities at FDA for such fiscal year (excluding the amount of fees appropriated for such fiscal year) is equal to or greater than the adjusted amount of appropriations for the food safety activities at FDA for FY 2009 (excluding the amount of fees appropriated for such fiscal year). In FY 2023, the total appropriations for food safety activities at FDA exceeded the total adjusted appropriations for food safety activities in FY 2009.

III. Fees Collected in FY 2023

A. Reinspection Fees

Although FDA did conduct reinspections in FY 2023, FDA has committed to issuing guidance documents for small businesses on the process for requesting a reduction in FSMA reinspection fees before any fee assessments are issued or before any collections are undertaken. In FY 2023, FDA did not collect any fees for the reinspection of domestic food facilities, foreign food facilities, or importers. In their Operational Evaluation of the FDA Human Foods Program,[3] the Reagan-Udall

[1] See generally https://www.fda.gov/food/importing-food-products-united-states/voluntary-qualified-importer-program-vqip.

[2] See http://www.fda.gov/food/food-safety-modernization-act-fsma/fees-under-fsma.

[3] See http://reaganudall.org/operational-evaluation-fdas-human-foods-programs.

Foundation recommended that FDA strengthen its implementation and use of existing FSMA authority to collect fees. FDA's FY 25 budget includes a legislative proposal to amend the statute to enable FDA to collect a fixed fee for reinspection activities which would reduce the administrative challenges with implementing the fee program.

B. Recall Fees

In FY 2023, no mandatory recall orders were issued and therefore FDA did not collect any fees related to a recall order under section 423 or section 412(f) of the FD&C Act. As explained above, the Reagan-Udall Foundation has recommended that FDA strengthen its implementation and use of existing FSMA authority to collect fees. FDA's FY 25 budget includes a legislative proposal to amend the statute to enable FDA to collect a fixed fee for mandatory recall activities which would reduce the administrative challenges with implementing the fee program.

C. VQIP Fees

In FY 2023, the fee rate for participation in VQIP was $12,962. This amount was invoiced to and collected from six VQIP importers, totaling $77,772 invoiced and collected. The importers who were approved to participate in VQIP in FY 2023 include a retailer of human and animal food, a vertically integrated seafood processing and distribution company, a distributor of consumer products such as olive oil, vegetable oils, and table olives, an importer of spices, a company that oversees the harvesting, milling, processing, and distribution of rice, and a distributor of wheat/corn-based pellets for use in the manufacturing of snack food items.

This report was prepared by FDA's Office of Food Policy and Response.
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This report is available on FDA's home page at https://www.fda.gov/.