November 2019

IMPORTED SEAFOOD SAFETY

Actions Needed to Improve FDA Oversight of Import Alert Removal Decisions

GAO Highlights

Highlights of GAO-20-62, a report to congressional requesters

Why GAO Did This Study

Imports account for over 90 percent of U.S. seafood consumption. FDA and the Department of Homeland Security (DHS) both play a role in overseeing imported seafood. FDA is responsible for ensuring the safety of most imported seafood. DHS provides FDA with import data on FDA-regulated products, including seafood. If FDA finds that imported seafood products appear to violate U.S. laws, FDA may place the products, firms, or countries on an import alert.

GAO was asked to review FDA's efforts to use import alerts to ensure the safety of imported seafood. This report, among other things, (1) describes FDA's import alert process for seafood products, (2) examines FDA oversight of key activities to support import alert removal decisions, and (3) examines the extent to which FDA has assessed the effectiveness of its seafood import alerts. GAO reviewed FDA procedures and data, including data on 274 removal decisions, for a non-generalizable sample of seven import alerts selected for a range of violations of federal law. GAO also interviewed FDA officials.

What GAO Recommends

GAO recommends that FDA (1) establish a process to monitor whether the agency is meeting its audit goals and expectations for sampling and inspections, (2) establish a time frame for developing goals and measures for its imported food safety program, and (3) develop goals and measures for seafood import alerts. FDA agreed with GAO's recommendations.

View GAO-20-62. For more information, contact Steve D. Morris at (202) 512-3841 or morriss@gao.gov.

What GAO Found

The Food and Drug Administration's (FDA) import alert process for seafood products includes three key components: (1) establishing new import alerts, which inform FDA field staff and the public that the agency has enough evidence that products appear to violate a federal food safety law to detain those products at U.S. ports of entry without physically examining them; (2) placing firms and products on existing import alerts; and (3) removing firms and products from those import alerts when violations are resolved. As of July 3, 2018—the most recent data at the time of GAO's analysis—FDA had 52 active import alerts affecting imported seafood that addressed a wide range of violations of federal law, including the presence of foodborne pathogens, such as *Salmonella*, or unapproved animal drug residues.

FDA has established audit goals, requirements, and expectations related to sampling and inspections—key activities to support import alert removal decisions—but does not monitor the extent to which it is meeting them. GAO's review of 274 removal decisions from October 1, 2011, through July 3, 2018, found that FDA had supported only a small percentage of its removal decisions by conducting sampling and inspections. For example, FDA has a goal to audit samples from at least one of the shipments used to support each removal decision to ensure the validity of the analysis that a private laboratory performed. However, GAO found that within a year prior to the 274 removal decisions, FDA did not conduct any audits for 260 (95 percent) of the 274 removal decisions. FDA officials said they conducted limited sampling because many import alert removal decisions can be supported by documentary evidence provided by firms. Additionally, for certain violations that indicate a firm failed to meet regulatory or administrative requirements and may pose a public health hazard, an FDA directive establishes a goal for FDA staff to conduct a follow-up inspection within 6 months. However, GAO's review of removal decisions found that for 31of the 32 firms that received such a finding, FDA did not conduct a follow-up inspection before removing them from an import alert. FDA officials said they did not know whether they were meeting their audit goals because the agency does not have a process to monitor the extent to which it is conducting its sampling and inspections. Establishing such a process would provide greater assurance that FDA is conducting its expected level of sampling and inspections to support its removal decisions and has confidence in continued compliance.

FDA has not established performance goals and measures for seafood import alerts—key elements for assessing the effectiveness of programs. Goals explain the outcomes a program seeks to achieve, and measures track progress towards those goals. In February 2019, FDA published a broad plan for the safety of imported food. The plan states that FDA intends to develop performance goals and measures related to imported food safety, but FDA has not established a time frame for doing so. By establishing a time frame and developing such goals and measures, FDA would be better positioned to assess how well its seafood import alert activities are supporting the agency in achieving its food safety mission.