GAO@100 Highlights

Highlights of GAO-21-231, a report to congressional requesters

March 2021

IMPORTED SEAFOOD SAFETY

FDA Should Improve Monitoring of Its Warning Letter Process and Better Assess Its Effectiveness

Why GAO Did This Study

FDA is responsible for ensuring the safety of most imported seafood. FDA relies, in part, on inspections of importers' facilities and of processors' foreign facilities to ensure compliance with federal law. If FDA identifies significant violations, such as firms not identifying food safety hazards likely to occur during processing, the agency can issue the firm a warning letter.

GAO was asked to review FDA's efforts to use warning letters to ensure the safety of imported seafood. This report examines the extent to which FDA (1) ensures it is following key procedures and meeting key goals for its warning letter process for imported seafood and (2) assesses the effectiveness of its warning letters in ensuring the safety of imported seafood. GAO reviewed FDA procedures and data and interviewed FDA officials.

What GAO Recommends

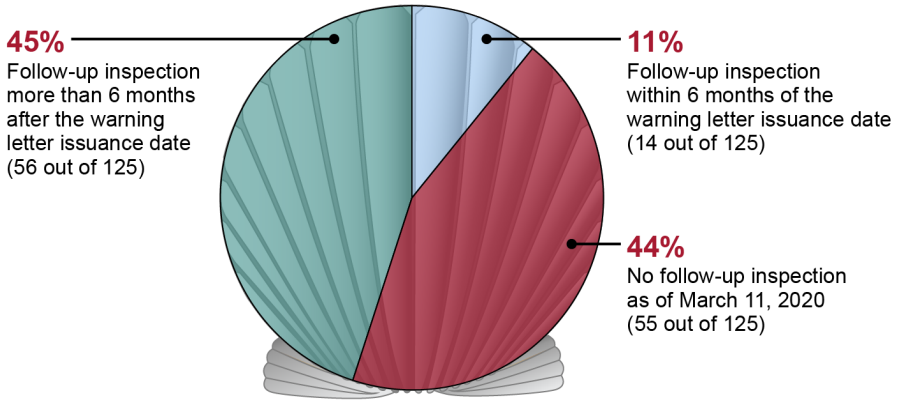
GAO recommends that FDA (1) establish a process to monitor whether the agency is following the procedures and meeting the goals established for its warning letter process for imported seafood, and (2) develop performance goals and measures to assess how effective warning letters are at ensuring the safety of imported seafood. FDA agreed with GAO's recommendations.

View GAO-21-231. For more information, contact Steve Morris at (202) 512-3841 or morriss@gao.gov.

What GAO Found

The Food and Drug Administration (FDA) issues warning letters for food safety violations that could pose a risk to public health. According to FDA, warning letters are its primary means of getting firms to voluntarily comply with food safety laws and regulations. GAO analyzed 167 imported seafood warning letters that FDA issued from January 1, 2014, through March 11, 2019, and found that FDA did not consistently follow key procedures or meet key goals for its warning letter process. For example, when FDA issues a warning letter based on significant inspection violations, the agency has a goal to conduct a follow-up inspection within 6 months of the date the warning letter was issued. Of the 167 warning letters we reviewed, 125 were based on significant inspection violations. FDA met its 6-month goal for 14 (11 percent) of these 125 letters. For 56 (45 percent) of these letters, FDA conducted a follow-up inspection more than 6 months after the warning letter was issued—on average, about 2 years. For the remaining 44 percent, FDA had not conducted a follow-up inspection, as of March 11, 2020.

Warning Letters Based on Significant Inspection Violations for Which FDA Met Its 6-Month Follow-up Inspection Goal, Issued January 1, 2014, Through March 11, 2019



Source: GAO analysis of Food and Drug Administration (FDA) data. | GAO-21-231

While FDA has some monitoring tools, the agency does not have a monitoring process that allows it to determine whether all imported seafood warning letters (to both domestic and foreign firms) consistently follow procedures and meet goals, and FDA officials stated the agency had not conducted such a review of all letters. Developing a monitoring process, which could include regularly reviewing aggregate data, would increase FDA's awareness of whether the letters adhere to procedures and goals and help FDA ensure significant food safety violations have been adequately corrected.

FDA has not established performance goals and corresponding measures for its imported seafood warning letter process—key elements for assessing effectiveness. By developing performance goals and measures, such as percentage of warning letters resolved within 1 year of being issued, FDA would be better positioned to assess how well its process ensures the safety of imported seafood.