United States Government Accountability Office

Report to Congressional Requesters

March 2021

IMPORTED SEAFOOD SAFETY

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

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GAO-21-231

GAO 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

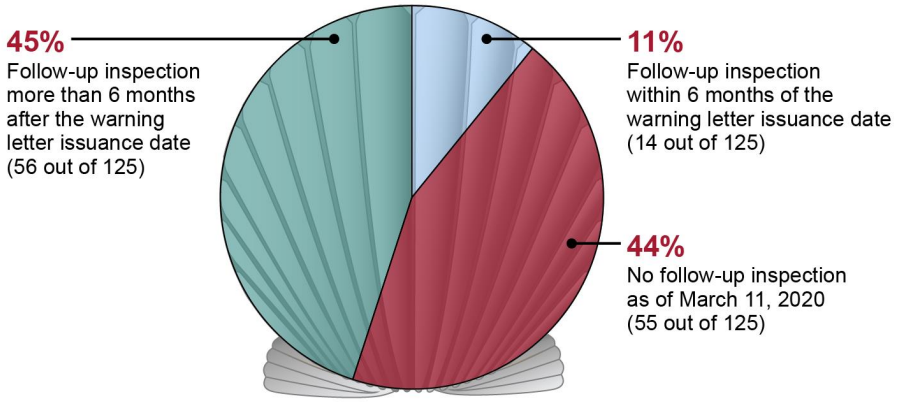
GAO recommends that FDA (1) establish a process to monitor whether the agency is following the procedures and meeting the goals established for its warning letter process for imported seafood, and (2) develop performance goals and measures to assess how effective warning letters are at ensuring the safety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

Text of 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

- Follow-up inspection within 6 months of the warning letter issuance date (14 out of 125) -- 11%
- No follow-up inspection as of March 11, 2020 (55 out of 125) -- 44%
- 45%
- Follow-up inspection more than 6 months after the warning letter issuance date (56 out of 125) -- 45%

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.

Contents

Figures

Abbreviations

CMS	Compliance Management System
COVID-19	Coronavirus Disease 2019
FACTS	Field Accomplishment and Compliance Tracking System
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
FSMA	FDA Food Safety Modernization Act
GPRA	Government Performance and Results Act of 1993
GPRAMA	GPRA Modernization Act of 2010
HACCP	Hazard Analysis and Critical Control Point
HHS	Department of Health and Human Services
NAI	no action indicated
OAI	official action indicated
OIG	Office of Inspector General
VAI	voluntary action indicated

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March 19, 2021

The Honorable Rosa L. DeLauro
Chairwoman
Subcommittee on Labor, Health and Human Services,
Education and Related Agencies
Committee on Appropriations
House of Representatives

The Honorable Richard Blumenthal
United States Senate

The Honorable Dianne Feinstein
United States Senate

The Honorable Patty Murray
United States Senate

The Honorable Elizabeth Warren
United States Senate

In 2019, the United States imported approximately 6.3 billion pounds of seafood from approximately 140 countries.[1] More than 90 percent of seafood products consumed in the United States are imported, and over half of these imports come from aquaculture (also known as fish farming).[2] Some fish can have high rates of bacterial infections, leading farmers to treat them with drugs, such as antibiotics and antifungal agents, to increase their survival rates. The residues of some drugs can cause cancer or allergic reactions, according to officials from the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA).

FDA has oversight responsibilities under the Federal Food, Drug, and Cosmetic Act (FFDCA) for most imported seafood to ensure that it is safe,

[1]U.S. seafood imports have increased in recent years, from about 5.8 billion pounds in 2014 to about 6.3 billion pounds in 2019.

[2]Based on 2017 data from the National Oceanic and Atmospheric Administration.

wholesome, sanitary, and properly labeled.[3] To carry out its oversight responsibilities for imported seafood, FDA requires seafood importers and foreign seafood processors (both of which are referred to in this report as firms) to follow its Hazard Analysis and Critical Control Point (HACCP) regulations.[4] Firms are expected to identify the critical control points in their processing systems where one or more hazards are reasonably likely to occur and develop and implement HACCP plans to control for each hazard.[5] Hazards can include drug residues such as antibiotics, pathogens such as *Salmonella*, and insanitary conditions at the processing facility.[6] Among other things, FDA uses inspections of seafood importers' facilities and foreign seafood processors' facilities to help ensure compliance with HACCP regulations and other applicable requirements under the FFDCA. According to FDA's *Compliance Program Guidance Manual* for its seafood processor inspection program, inspections should focus on the implementation of the HACCP program for targeted products and include a review of monitoring records. FDA may also conduct inspections to verify any corrective actions a firm has taken.

When FDA identifies significant violations of federal law as a result of an inspection of a seafood importer facility or foreign seafood processing

[3]Imported catfish is the exception to FDA's imported seafood responsibilities; the U.S. Department of Agriculture's Food Safety and Inspection Service inspects imported catfish—as well as other meat and poultry products—before allowing them to enter U.S. commerce.

[4]This report focuses on foreign seafood facilities and domestic seafood importer facilities. We did not review domestic seafood processors. A domestic facility means any facility located in any state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States. A foreign facility means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

[5]A HACCP plan is a written plan that defines the procedures for maintaining control of potential food safety hazards at the critical control points of food preparation or processing. It includes information on the potential hazard associated with a specific food product; the measure that will be implemented to control the hazard; the critical control point to implement the measure; minimum or maximum values (critical control limit) at which a physical, chemical, or biological parameter must be controlled to minimize the risk that a potential food safety hazard may occur; the monitoring procedures to ensure that the hazard is controlled; and the corrective actions to be taken in response to deviations from critical control limits.

[6]Under the FFDCA, food is adulterated, and thereby prohibited from commerce, if it is prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

facility, the agency may issue a warning letter to the firm. FDA's warning letter procedures are documented in the agency's *Regulatory Procedures Manual*. According to the manual, warning letters are FDA's principal means of achieving prompt voluntary compliance with the FFDCA. While the focus of this report is on warning letters for imported seafood, FDA can issue warning letters to firms for a range of products it oversees, including food, cosmetics, and human drugs. According to the manual, FDA may issue warning letters only for violations of regulatory significance.[7] The manual also states that a violation of regulatory significance is one that may lead to enforcement action if not promptly and adequately corrected.[8]

According to FDA's *Regulatory Procedures Manual*, if the agency has verified that the firm has corrected the violations identified in the warning letter, FDA may issue the firm a closeout letter. A closeout letter should acknowledge the firm's corrections and state that future inspections and regulatory activities will assess the adequacy and sustainability of the corrections. FDA's *Regulatory Procedures Manual* also states that the usual standard for verifying that corrections have been implemented by a firm is through a follow-up inspection. If the firm does not correct the violations, or if FDA finds the corrections are inadequate, the agency may take enforcement action against the firm. According to FDA officials, the typical enforcement action that FDA takes against seafood importers and foreign seafood processors is to place the firm and its products on an import alert. Import alerts, which are published on FDA's website, inform FDA field staff and the public that the agency has enough evidence that the firm's products appear to violate a federal food safety law to detain those products at U.S. ports of entry without physically examining them.[9]

You asked us 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

[7]FDA's *Regulatory Procedures Manual* is a reference manual that provides FDA personnel with the information on internal procedures to be used in processing regulatory and enforcement matters. *Regulatory Procedures Manual* Chapter 4 – "Advisory Actions" defines and establishes uniform guidance and procedures for warning letters.

[8]Other enforcement actions and tools available to FDA include seizures, injunctions, and referral for criminal prosecution.

[9]For more detailed information on import alerts, see GAO, *Imported Seafood Safety: Actions Needed to Improve FDA Oversight of Import Alert Removal Decisions*, GAO-20-62 (Washington, D.C.: Nov. 6, 2019).

effectiveness of its warning letters in ensuring the safety of imported seafood.

To address the first objective, we reviewed FDA documents, including procedures governing the use of warning letters and inspections contained in FDA's *Regulatory Procedures Manual* and *Field Management Directive 86*. We interviewed FDA officials to gain a further understanding of the warning letter process and analyzed agency data on imported seafood inspections, warning letters, and import alerts. FDA supplied this data from its Compliance Management System (CMS) and its Field Accomplishment and Compliance Tracking System (FACTS).[10] Additionally, we reviewed prior reports that evaluated FDA actions related to warning letters, including a 2017 HHS Office of Inspector General (OIG) report on FDA inspections of domestic food facilities and our 2019 report on FDA's use of import alerts for seafood.[11] These reports indicated that conducting follow-up inspections, issuing warning letters in a timely manner, and placing firms on import alert are key activities that help FDA ensure firms correct significant food safety violations.

Based on this information and on what the data FDA provided would allow us to analyze, we identified the following as key procedures related to FDA's warning letter process for our review: (1) FDA's inspection classification procedure for warning letters; (2) FDA's procedure to conduct a follow-up inspection as the usual standard for verifying a firm's corrections before issuing a closeout letter; and (3) FDA's procedure to pursue warning letter cases to their conclusion (that is, voluntary firm compliance or enforcement action). We also identified the following key goals for our review: (1) FDA's goal to issue warning letters within 4

[10]The CMS database tracks all compliance actions, including warning letters that FDA has issued to individual firms. Among other things, CMS includes information uniquely identifying affected firms, along with information identifying the nature of the violations. According to FDA officials, CMS also includes links to scans of the documentation on which FDA based its warning letter issuance and closeout letter decisions. The FACTS database contains information on firms and products that FDA regulates, foreign and domestic establishments that FDA inspects, the type of inspection conducted, and the outcome of those inspections, among other things.

[11]See Department of Health and Human Services, Office of Inspector General, Challenges Remain in FDA's Inspections of Domestic Food Facilities, OEI-02-14-00420 (Washington, D.C.: September 2017) and GAO-20-62.

months of an appropriate reference date;[12] and (2) FDA's goal to conduct a follow-up inspection within 6 months of the warning letter issuance date when the warning letter was based on significant inspection violations. We compared these key procedures and goals to FDA's actions, according to agency data on 167 warning letters issued from January 1, 2014, through March 11, 2019. This date range represents the most recent data at the time of our analysis that also allowed sufficient time to examine subsequent actions FDA took after issuing a warning letter.

To assess the reliability of FDA's data, we reviewed documentation for CMS and FACTS, conducted electronic and manual testing, and interviewed agency officials regarding controls, among other things. We determined that the data were sufficiently reliable for the purposes of reporting numbers of warning letters and related inspections and import alert placements, closeout letters, and associated time frames. We determined that federal standards for internal controls were significant to this objective, along with the underlying principle that management should design control activities to achieve objectives and respond to risks and help management fulfill its responsibilities.[13]

To address the second objective, we reviewed FDA's *Strategy for the Safety of Imported Food* and other agency documentation describing FDA's food safety performance goals and measures. We compared FDA's strategy and documentation with leading practices we have identified in our past work for assessing the effectiveness of programs. For example, we have previously reported that requirements of the Government Performance and Results Act of 1993 (GPRA), as amended by the GPRA Modernization Act of 2010 (GPRAMA),[14] such as performance goals and performance measures, can serve as leading

[12]According to FDA's *Regulatory Procedure Manual,* examples of an appropriate reference date are the last day of an inspection, the date of a sample analysis, or the date of evidence collection. According to FDA officials, the appropriate reference date is the last day of the inspection for warning letters issued based on an inspection. We used FDA inspection data to identify these dates. FDA officials stated that the agency does not have a data field that easily captures other types of reference dates, but that these dates can be located in various documents that are housed in different folders within CMS. Over 80 percent of the warning letters that we reviewed were based on an inspection, as we discuss later in this report.

[13]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014).

[14]Pub. L. No. 111-352, 124 Stat. 3866 (2011). GPRAMA amends the Government Performance and Results Act of 1993, Pub. L. No. 103-62, 107 Stat. 285.

practices for planning at lower levels, such as programs within federal agencies.[15] We also interviewed FDA officials to obtain their views on FDA's efforts to assess the effectiveness of seafood warning letters. Appendix I provides additional details on our scope and methodology.

We conducted this performance audit from December 2019 to March 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

FDA Inspections

According to FDA documentation, foreign seafood processors and seafood importers share responsibility for seafood safety. Foreign processors are responsible for complying with HACCP regulations, and importers are required to take positive steps to verify that their shipments are obtained from foreign processors that comply with HACCP regulations. According to FDA's compliance program guidance manuals, FDA inspects importer facilities and foreign processing facilities to ensure compliance with HACCP regulations (see fig. 1).[16] FDA conducts surveillance inspections, which are routine, and for-cause inspections, which are in response to a specific problem FDA has identified. For surveillance inspections of importer facilities, FDA officials stated that the agency prioritizes the importers that bring the most seafood into the

[15]GAO, *Food Safety and Nutrition: FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities*, GAO-18-174 (Washington, D.C.: Jan. 31, 2018); *Coast Guard: Actions Needed to Enhance Performance Information Transparency and Monitoring*, GAO-18-13 (Washington, D.C: Oct. 27, 2017); and *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct. 6, 2011).

[16]FDA inspections also help ensure that imported seafood products meet other applicable FFDCA requirements.

United States, as measured by importer lines of entry.[17] For surveillance inspections of foreign processing facilities, FDA uses a risk-based model to select which facilities to inspect, according to FDA officials. This model incorporates data from multiple sources, such as sampling data, recall data, foodborne illness outbreak data, and foreign inspection data.

Figure 1. FDA Field Inspectors Examining Imported Seafood

Source: The Food and Drug Administration (FDA). | GAO-21-231

According to FDA documents, at the conclusion of an inspection, FDA supervisors review inspection reports and evidence collected during the inspection to determine the appropriate inspection classification. Based on this information, FDA may classify the inspection into one of three primary categories:

- **No Action Indicated (NAI).** No objectionable conditions or practices were found during the inspection, or the significance of the objectionable conditions found do not justify further FDA action.

[17]According to FDA officials, the agency prioritizes importers that have 100 or more lines of entry per year. An entry line is a portion of an import shipment that is listed as a separate line item on an entry document. FDA's *Import Seafood Products Compliance Program Manual* states that in addition to importers that have an average of 100 or more lines of entry per year, the agency should prioritize inspections of importers with identified HACCP violations from a previous inspection.

- **Voluntary Action Indicated (VAI).** Objectionable conditions were found and documented, but FDA is not prepared to take or recommend regulatory action (including a warning letter) because the conditions do not meet the threshold for regulatory action. Uncorrected violations do not present an imminent risk to public health, and any corrective action taken by the firm is voluntary.
- **Official Action Indicated (OAI).** Objectionable conditions were found and regulatory action should be recommended. Failure to make corrections often presents a risk to public health, prompting the agency to take an action to move a firm into compliance.

FDA documents state that the agency may classify an inspection of a seafood importer or foreign seafood processing facility as OAI when it identifies significant HACCP violations.[18] Examples of significant HACCP violations that FDA has observed during an inspection include the following:

- A foreign seafood processor did not identify the food safety hazards likely to occur during processing, such as the presence of unacceptable levels of aquaculture drugs from seafood received from fish farms.
- A foreign seafood processor lacked controlled time frames for how long its seafood product was unrefrigerated during processing, rendering the product susceptible to pathogen growth.
- An importer lacked written verification procedures to ensure that its imported seafood product was processed under the same level of food safety regulation as seafood in the United States—that is, in accordance with HACCP regulations.

FDA Warning Letter Process

According to FDA officials, FDA generally takes one of two enforcement actions in response to an OAI-classified inspection of a seafood firm: (1)

[18]During an inspection, FDA is to investigate different food production processes and their associated regulations, such as compliance with HACCP regulations or compliance with labeling regulations. FDA's investigation of these different processes can result in different inspection classifications. For example, FDA may classify the HACCP process of the inspection as OAI but classify the labeling elements as NAI. In analyzing FDA's inspection data, our review consisted of inspection elements that dealt with HACCP regulations.

place the firm on an import alert,[19] or (2) issue a warning letter to the firm. An import alert informs FDA field staff and the public that the agency has enough evidence to detain the firm's products at U.S. ports of entry without physically examining them (known as detention without physical examination). FDA's *Regulatory Procedures Manual* states that warning letters are FDA's primary means of achieving prompt, voluntary compliance with food safety regulations, including seafood HACCP regulations.[20] Seafood firms can continue to import products into the United States after receiving a warning letter, according to FDA officials. According to past seafood warning letters FDA issued, the agency may issue warning letters to seafood firms based on any of the following events:

- FDA identifies significant violations during an inspection of an importer or foreign processing facility.
- FDA identifies significant violations during a review of a foreign processor's HACCP plan obtained during an inspection of an importer facility.
- FDA identifies significant violations during a review of a foreign processor's HACCP plan requested from the foreign processor.

According to FDA officials, the agency generally uses inspection findings as the basis for issuing a warning letter. Therefore, some of FDA's inspection procedures and goals overlap with FDA's warning letter process. Specifically, FDA's *Regulatory Procedures Manual* states that whenever a warning letter is issued, the inspection is to be classified as OAI. Additionally, FDA's *Field Management Directive 86* establishes a goal for the agency to conduct a follow-up inspection within 6 months of any action that the agency takes in response to an OAI-classified inspection. Therefore, when a warning letter is issued in response to an OAI-classified inspection, FDA's goal is to conduct a follow-up inspection

[19]Seafood products detained via import alerts may be (1) refused entry, in which case they must be exported to another country or destroyed, or (2) allowed to enter U.S. commerce if they can be shown to not violate the FFDCA or can be reconditioned to be brought into compliance with the act. In November 2019, we reported on FDA's use of import alerts for seafood. See GAO-20-62.

[20]FDA may also conduct regulatory meetings with the processor or importer in a variety of situations, such as a follow-up to the issuance of a warning letter to emphasize the significance of the deficiencies or to communicate documented deficiencies that do not warrant the issuance of a warning letter.

within 6 months of the warning letter issuance date, according to FDA officials.[21]

According to FDA's *Regulatory Procedures Manual*, warning letters can vary in form, style, and content, but all warning letters should have common elements. For example, they should contain a description of the violations FDA identified, acknowledgement of any corrections promised during the original inspection, the amount of time the importer or foreign processor has to respond to the letter (typically 15 working days), and a warning statement that failure to achieve prompt correction may result in enforcement action without further notice, among other things. Warning letters should also contain instructions for what the firm should include in its response to the warning letter, including:

- each step the importer or foreign processor has taken or will take to completely correct the current violations and prevent any similar violations;
- the time within which the correction will be completed;
- any reason the corrective action has not been completed within the response time; and
- any documentation necessary to show that correction has been achieved.

Once the warning letter has been drafted and reviewed by the appropriate internal offices, FDA sends the warning letter to the importer or foreign processor, according to the manual.

If the firm responds to the warning letter, FDA's *Regulatory Procedures Manual* states that the agency will evaluate the firm's response and verify that the promised corrections have been made. The manual states that, usually, the standard for verifying that corrections have been made is a follow-up inspection. The manual also states that the agency may determine that the firm replied to the warning letter with sufficient information to demonstrate that violations have been adequately corrected or that, based on other verified, appropriate, and reliable information, a follow-up inspection is not needed. If FDA conducts a follow-up inspection, the FDA Food Safety Modernization Act (FSMA)

[21]Food and Drug Administration, *Field Management Directive – Establishment Inspection Report Conclusions and Decisions*, FMD# 86 (Silver Spring, MD: Jan. 28, 2014).

directs the agency to assess and collect fees from the firm to cover the costs related to the follow-up inspection.[22] Appendix II describes the status of FDA's efforts to collect these follow-up inspection fees.

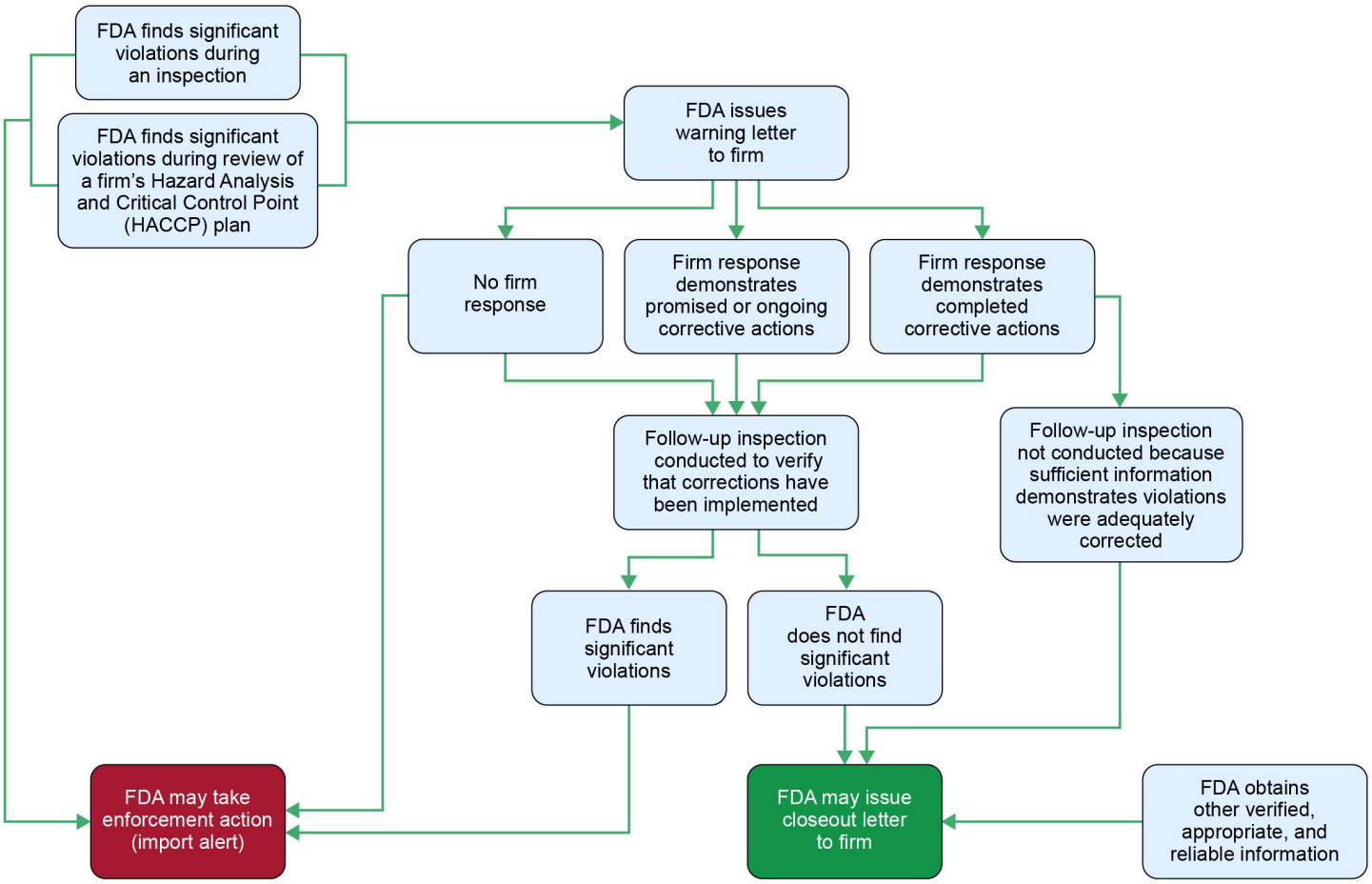
According to FDA's *Regulatory Procedures Manual*, if the agency determines that the importer or foreign processor has taken adequate actions to correct the violations outlined in the warning letter, FDA will issue a closeout letter to the firm. According to the manual, the model closeout letter must be followed and the closeout letter language should indicate that FDA has evaluated the firm's corrective actions and determined that the violations have been addressed. Closeout letters should also generally state that future FDA inspections and regulatory activities will further assess the adequacy and sustainability of the corrections and that the closeout letter does not relieve the importer or foreign processor from its responsibility to assure sustained compliance with the FFDCA.

Not all warning letters result in a closeout letter. According to FDA's *Regulatory Procedures Manual*, if the firm does not respond to the warning letter or FDA reviews the firm's response and determines that corrective actions have not been taken or that the corrective actions are inadequate, FDA will begin follow-up action as necessary.[23] According to FDA officials, the follow-up action that the agency typically takes is to place the importer or foreign processor on an import alert. See Figure 2 for the general steps in FDA's warning letter process.

[22]Pub. L. No. 111-353, § 107, 124 Stat. 3885, 3906 (codified at 21 U.S.C. § 379j-31).

[23]FDA's *Regulatory Procedures Manual* also states that if a warning letter contains violations that, by their nature, are not correctable, then no closeout letter will be issued. However, FDA officials stated that this part of the manual would not apply to imported seafood, because all seafood HACCP violations are correctable.

Figure 2. General Steps FDA Takes When Issuing Warning Letters to Seafood Importers and Foreign Seafood Processors



Source: GAO review of Food and Drug Administration (FDA) documents and interviews with FDA officials. | GAO-21-231

Note: According to FDA documentation, if a foreign seafood processor does not respond to the agency's warning letter, FDA generally will place the processor directly on an import alert (without conducting a follow-up inspection). If a seafood importer does not respond to a warning letter, FDA may or may not conduct a follow-up inspection before taking further action.

In November 2019, we reviewed FDA's use of import alerts for imported seafood. We found that while FDA established goals, requirements, and expectations related to the key activities that support import alert removal decisions (e.g., product sampling and inspections), the agency did not monitor the extent to which it was meeting them.[24] We recommended that FDA establish a process to monitor whether the agency is meeting its goals and expectations for sampling and inspections to support its

[24]See GAO-20-62.

removal decisions for seafood import alerts. FDA agreed with the recommendation and stated that developing metrics and monitoring the import alert removal process is necessary and that these efforts should be guided by the analysis of available data, as discussed later in this report.

FDA announced in March 2020 that due to the Coronavirus Disease 2019 (COVID-19) pandemic, it was postponing all routine surveillance inspections of food facilities. According to FDA officials, only inspections deemed mission critical would still be considered on a case-by-case basis. FDA officials also stated that since the March 2020 announcement, the agency had issued four warning letters to foreign seafood facilities, but these warning letters were based on inspections that occurred before FDA postponed foreign inspections. According to the announcement, while the pandemic has added new complexities, FDA officials stated that it has other tools to ensure the safety of the U.S. food supply, including imported food. For example, FDA officials stated that the agency has adjusted its import screening procedures to increase the level of examination and testing of products shipped from foreign firms for which FDA postponed inspections. In July 2020, FDA announced that it planned to resume domestic inspections, contingent on a rating system that incorporates information on COVID-19 infection trends in a geographic area.[25]

FDA Does Not Have a Process to Monitor Its Imported Seafood Warning Letter Activities to Help Ensure It Consistently Follows Key Procedures and Meets Key Goals

FDA has established key procedures and goals for its warning letter process for imported seafood. However, in our analysis of 167 warning letters that FDA issued to seafood importers and foreign seafood processors from January 1, 2014, through March 11, 2019, we found that FDA was not consistently following these key procedures or meeting these key goals. Furthermore, FDA does not have a process to monitor warning letter activities to understand whether the agency is consistently

[25]According to FDA officials, the agency is conducting prioritized domestic inspections using its COVID-19 Advisory Rating system, which uses real-time COVID-19 case data to determine where it is safest to conduct inspections.

following key procedures and meeting key goals for its imported seafood warning letters.

FDA Does Not Consistently Follow Established Key Procedures and Key Goals for Its Imported Seafood Warning Letter Process

FDA's *Regulatory Procedures Manual* and *Field Management Directive 86* establish key procedures and goals for, among other things, issuing and following up on warning letters, including warning letters for imported seafood. We compared FDA's actions for 167 warning letters it issued between January 1, 2014 and March 11, 2019, with the following key procedures and key goals we identified for our review:

- FDA's inspection classification procedure for warning letters;
- FDA's goal to issue warning letters within 4 months of an appropriate reference date, that is, the date of the last day of the inspection;[26]
- FDA's goal to conduct a follow-up inspection within 6 months of issuing a warning letter based on significant inspection violations;
- FDA's procedure to conduct an inspection as the usual standard for verifying a firm's corrections before issuing a closeout letter; and
- FDA's procedure to pursue warning letter cases to their conclusion (that is, voluntary firm compliance or enforcement action).

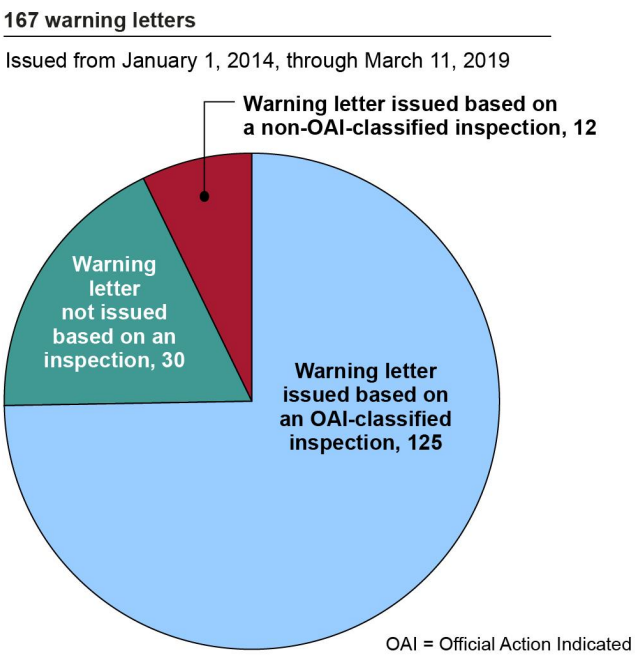
Warning Letter Inspection Classifications

For warning letters that FDA issued based on inspection findings, the agency did not consistently follow its procedure to classify the inspection as Official Action Indicated (OAI), which indicates that FDA found objectionable conditions during the inspection and that regulatory action should be recommended. FDA's *Regulatory Procedures Manual* states that inspections that lead to warning letters will be classified as OAI. According to the manual, this classification procedure is to provide for greater consistency in FDA's classification system and regulatory policies. For example, FDA's 6-month follow-up inspection goal, discussed below,

[26]According to FDA's *Regulatory Procedure Manual,* examples of an appropriate reference date are the last day of an inspection, the date of a sample analysis, or the date of evidence collection. As previously stated, we used FDA inspection date to determine whether FDA met its 4-month issuance goal.

only applies to inspections classified as OAI. Of the 167 warning letters we analyzed, 137 were issued based on inspection findings, and therefore are subject to FDA's OAI classification procedure.[27] FDA issued 125 (91 percent) of these 137 warning letters based on OAI-classified inspections. The remaining 12 warning letters were based on inspections with classifications less severe than OAI (see fig. 3).[28]

Figure 3. Basis for 167 Warning Letters FDA Issued to Seafood Importers and Foreign Seafood Processors from January 1, 2014, Through March 11, 2019



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

[27]The remaining 30 warning letters of the 167 warning letters that FDA issued from January 1, 2014, through March 11, 2019, were not based on an inspection of the firm that received the warning letter. Therefore, these 30 letters do not fall under FDA's classification procedure and were not included in our analysis of the procedure. FDA may issue a warning letter to a foreign firm after obtaining a copy of their HACCP plan during an inspection of a domestic importer, or after requesting a copy of the HACCP plan directly from the foreign firm. In either case, the warning letter is not a result of an inspection of the foreign firm.

[28]The primary inspection classifications other than OAI are Voluntary Action Indicated (VAI), which means objectionable conditions were found and documented, but FDA is not prepared to take or recommend regulatory action (including a warning letter) because the conditions do not meet the threshold for regulatory action, and No Action Indicated (NAI), which means no objectionable conditions or practices were found during the inspection, or the significance of the objectionable conditions found do not justify further FDA action.

Text of Figure 3. Basis for 167 Warning Letters FDA Issued to Seafood Importers and Foreign Seafood Processors from January 1, 2014, Through March 11, 2019

167 warning letters

- Issued from January 1, 2014, through March 11, 2019
- Warning letter issued based on an OAI-classified inspection, 125
- Warning letter not issued based on an inspection, 30
- Warning letter issued based on a non-OAI-classified inspection, 12

OAI – Official Action Indicated

Note: FDA's *Regulatory Procedures Manual* states that inspections that lead to warning letters will be classified as Official Action Indicated (OAI). At the conclusion of an inspection, FDA classifies the inspection into three primary categories based on the violations, if any, that FDA identifies during the inspection. According to FDA documents, an OAI classification means that objectionable conditions were found and regulatory action should be recommended. Failure to make corrections often presents a risk to public health, prompting the agency to take an action to move a firm into compliance. The other primary inspection classifications are Voluntary Action Indicated (VAI), which means that objectionable conditions were found and documented, but FDA is not prepared to take or recommend regulatory action (including a warning letter) because the conditions do not meet the threshold for regulatory action, and No Action Indicated (NAI), which means that no objectionable conditions or practices were found during the inspection, or the significance of the objectionable conditions found do not justify further FDA action.

Four-Month Warning Letter Issuance Goal

For warning letters that resulted from an inspection, FDA did not consistently meet its goal to issue warning letters within 4 months of the inspection date. FDA's *Regulatory Procedures Manual* states that to ensure applicability of the evidence to the present situation, the agency will strive to issue warning letters within 4 months from the appropriate reference date. For warning letters issued based on an inspection, the appropriate reference date is the last date of the inspection, according to FDA officials. Of the 167 warning letters we analyzed, 137 were issued based on an inspection, making the letters subject to FDA's 4-month goal.[29] FDA issued 77 (56 percent) of these 137 warning letters that were issued from an inspection within 4 months of the inspection date. The remaining 60 (44 percent) warning letters were issued more than 4

[29]The remaining 30 warning letters of the 167 warning letters that FDA issued from January 1, 2014, through March 11, 2019, were not based on an inspection of the firm that received the warning letter. Therefore, we did not include them in the analysis of FDA's 4-month warning letter issuance goal.

months after the inspection date. On average, FDA issued these 60 warning letters about 6 months after the inspection date.

In the September 2017 HHS OIG report, the OIG found that FDA was following its 4-month warning letter issuance procedure for domestic firms 51 percent of the time.[30] The report included a recommendation that FDA improve the timeliness of its actions, including warning letters. The agency concurred with this recommendation and stated that it would continue to examine its regulatory program for further activities to increase operational efficiencies.

Six-Month Follow-up Inspection Goal

For warning letters that resulted from an OAI-classified inspection, FDA did not consistently meet its goal of conducting a follow-up inspection within 6 months of issuing the warning letter. FDA's *Field Management Directive 86* established this goal for both domestic and foreign warning letters issued from an OAI-classified inspection. Of the 167 warning letters we analyzed, 125 were issued based on an OAI-classified inspection, and therefore were subject to FDA's 6-month follow-up inspection goal.[31] However, FDA met its 6-month goal for 14 (11 percent) of these 125 warning letters issued from an OAI-classified inspection.[32] For the remaining 111 warning letters that FDA issued from an OAI-classified inspection, 56 (45 percent) had a follow-up inspection more than 6 months after the warning letter issuance date, and 55 (44 percent) had not had a follow-up inspection as of March 11, 2020 (see fig. 4). For the 56 warning letters for which FDA conducted a follow-up inspection

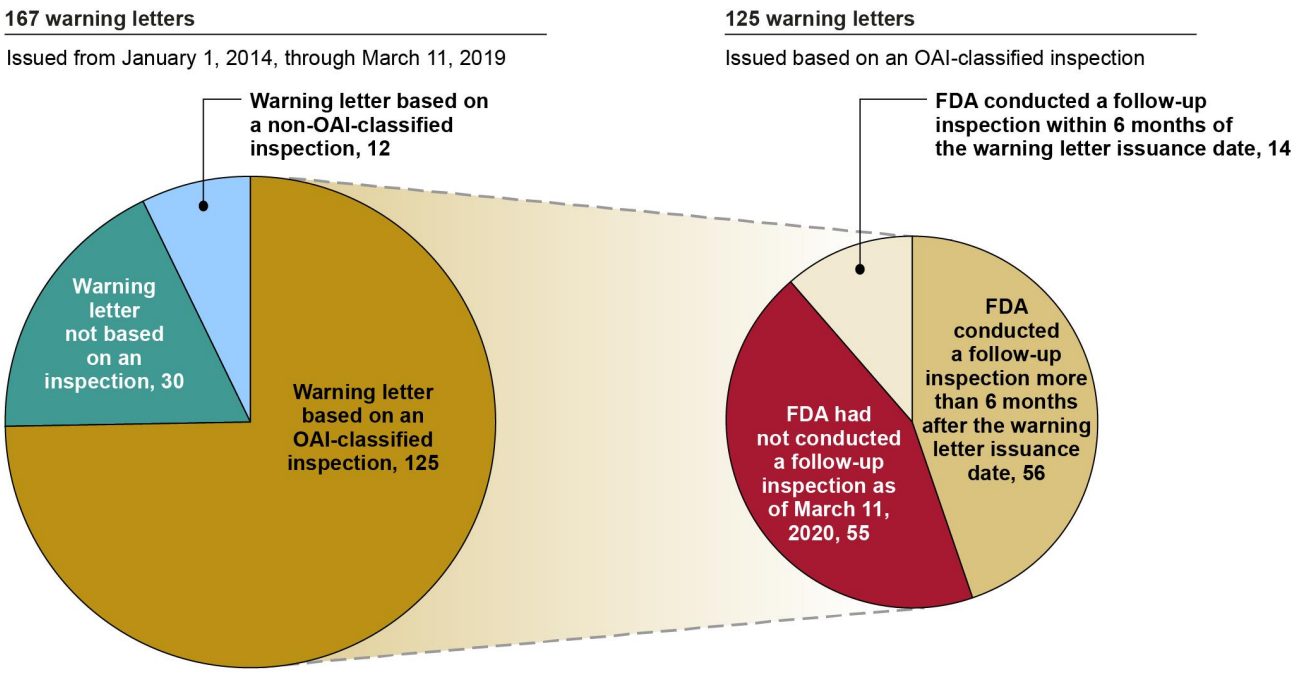
[30]See OEI-02-14-00420.

[31]The remaining 42 warning letters of the 167 warning letters that FDA issued from January 1, 2014, through March 11, 2019, were issued either based on an inspection that was not classified as OAI (12 letters) or not based on an inspection of the firm that received the warning letter (30 letters). Therefore, these 42 letters did not fall under FDA's 6-month inspection goal and were not included in our analysis of the goal. As previously stated, FDA may issue a warning letter to a foreign firm after obtaining a copy of their HACCP plan during an inspection of a domestic importer, or after requesting a copy of the HACCP plan directly from the foreign firm. In either case, the warning letter is not a result of an inspection of the foreign firm.

[32]For our analysis, we limited our review of warning letters to those issued through March 11, 2019, to ensure we captured any subsequent inspection actions taken by FDA within a year after the warning letter issuance date. We selected 1 year as the time frame for our analysis of subsequent FDA actions because in a 2017 report, HHS's OIG determined that FDA acted timely if the agency took action within 1 year of identifying significant violations. See OEI-02-14-00420.

more than 6 months after the warning letter issuance date, the average time it took FDA to conduct the follow-up inspection was about 2 years.

Figure 4. Number of Warning Letters Based on an Official Action Indicated (OAI) Classified Inspection for Which FDA Met Its 6-Month Follow-Up Inspection Goal



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

Text of Figure 4. Number of Warning Letters Based on an Official Action Indicated (OAI) Classified Inspection for Which FDA Met Its 6-Month Follow-Up Inspection Goal

167 warning letters (Issued from January 1, 2014, through March 11, 2019)

- Warning letter based on an OAI-classified inspection, 125
- Warning letter not based on an inspection, 30
- Warning letter based on a non-OAI-classified inspection, 12

125 warning letters (Issued based on an OAI-classified inspection)

- FDA conducted a follow-up inspection more than 6 months after the warning letter issuance date, 56

- FDA had not conducted a follow-up inspection as of March 11, 2020, 55
- FDA conducted a follow-up inspection within 6 months of the warning letter issuance date, 14

OAI = Official Action Indicated

Note: We reviewed warning letters issued from January 1, 2014, through March 11, 2019. FDA's *Field Management Directive 86* establishes a goal to conduct a follow-up inspection within 6 months of issuing a warning letter based on significant inspection violations. Significant inspection violations are those that FDA classifies as OAI. Warning letters that were not issued based on an inspection and warning letters that were issued based on a non-OAI-classified inspection would not be subject to FDA's 6-month follow-up inspection goal.

FDA officials stated that the 6-month goal applies to both foreign and domestic inspections but noted that, in practice, the agency only adheres to the goal for domestic inspections.[33] All 14 of the follow-up inspections FDA conducted were of domestic seafood importers. FDA met its 6-month follow-up inspection goal for domestic importers 23 percent of the time (14 of 62 warning letters issued to domestic importers after an OAI-classified inspection).[34]

FDA officials stated that they can establish a firm's corrective actions by reviewing documents, such as revised HACCP plans and accompanying monitoring records. However, according to FDA's *Compliance Program Guidance Manual* for its seafood processor inspection program, the purpose of the inspection program is not only to evaluate HACCP plans but also to determine whether the HACCP plan is being implemented. FDA's *Investigations Operations Manual* also states that OAI follow-up inspections are conducted to determine whether corrective actions have been implemented or if significant violations continue. Additionally, the firms subject to FDA's 6-month follow-up inspection goal are those where FDA had identified significant food safety violations in a prior inspection, according to the agency's management directive.

In the September 2017 HHS OIG report on FDA's inspections of domestic food facilities, the OIG found that for the OAI-classified inspection cases it

[33]As previously stated, a domestic facility means any facility located in any state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico that manufactures/processes, packs, or holds food for consumption in the United States. A foreign facility means a facility other than a domestic facility that manufactures/processes, packs, or holds food for consumption in the United States.

[34]For the remaining 48 warning letters issued to domestic importers based on an OAI-classified inspection, 30 had a follow-up inspection more than 6 months after the warning letter issuance date, and 18 did not have a follow-up inspection as of March 11, 2020.

reviewed, from 2011 to 2015, FDA conducted a follow-up inspection within 6 months of the initial inspection 11 percent of the time.[35] The report concluded that if FDA did not ensure that significant inspection violations are corrected in a timely manner, the agency would be unable to guarantee that these facilities are not producing and distributing food that is harmful to the public. The OIG recommended that FDA conduct timely follow-up inspections to ensure that significant inspection violations are corrected. The agency concurred with this recommendation and stated that it was developing a system to track activities or information relating to each specific inspection violation to ensure that all violations are corrected for all facilities that receive OAI classifications. Specifically, to address this recommendation, FDA developed a report to monitor domestic food facilities that warrant additional actions, such as follow-up inspections. FDA has also developed a dashboard that tracks, among other things, the proportion of domestic OAI-classified inspections that have had appropriate follow-up.[36] However, in developing this measure, FDA included communication with the firm as an appropriate follow-up action, which does not align with the agency's goal to conduct follow-up inspections within 6 months.

Inspections before Issuing Closeout Letters

FDA is not consistently following its procedure for verifying—through inspections—that warning letter violations have been corrected before issuing closeout letters. FDA's *Regulatory Procedures Manual* states that, usually, the standard for verifying that firms have implemented corrections in response to FDA's warning letter is a follow-up inspection.[37] The manual also states that a closeout letter will not be issued based on representations that some action will or has been taken—the corrective

[35]See OEI-02-14-00420.

[36]The dashboard also includes a measure of the proportion of follow-up inspections FDA conducted that indicated that the firm moved toward compliance (the firm is considered to be in compliance if the follow-up inspection was classified as VAI or NAI).

[37]The *Regulatory Procedures Manual* states that FDA can issue a closeout letter without conducting a follow-up inspection if the firm replied to the warning letter with sufficient information to demonstrate that any listed violations have been adequately corrected or, based on other verified, appropriate, and reliable information, FDA determines a follow-up inspection is not needed. FDA officials stated that the agency most often verifies corrections by reviewing documents, such as a revised HACCP plan, or monitoring records. However, a follow-up inspection is the only verification procedure that the manual describes as the usual standard.

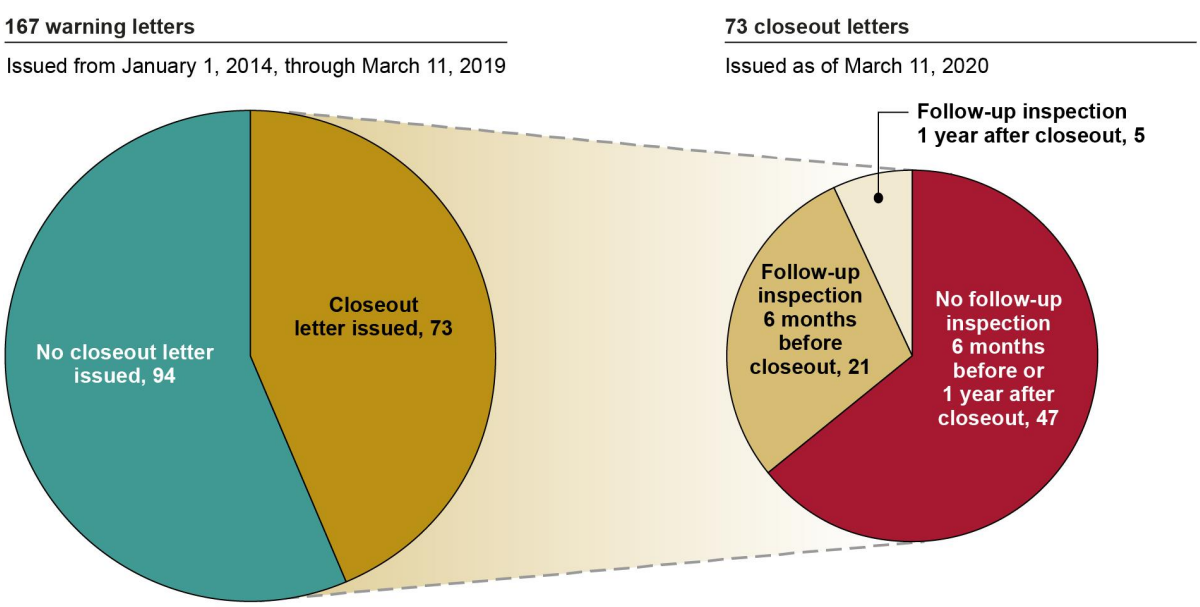
actions must actually have been made and verified by FDA. Of the 167 warning letters we analyzed, FDA issued a subsequent closeout letter to 73 firms (44 percent), making these warning letters subject to FDA's standard to inspect before issuing a closeout letter.[38] FDA conducted an inspection within 6 months prior to issuing the closeout letter for 21 (29 percent) of these 73 firms that received closeout letters.[39] FDA inspected an additional five firms (7 percent) within 1 year after issuing the closeout letter (see fig. 5).[40]

[38]The remaining 94 warning letters of the 167 warning letters issued between January 1, 2014 and March 11, 2019 did not have a subsequent closeout letter. Therefore, we did not include them in our analysis of FDA inspections prior to issuing closeout letters. For our analysis, we limited our review of warning letters to those issued through March 11, 2019, to ensure we captured any subsequent inspection actions taken by FDA within 1 year of the warning letter issuance date. Therefore, our analysis captures any closeout letter action that FDA took through March 11, 2020. We selected 1 year as the time frame for our analysis of FDA closeout letter action because in a 2017 report, HHS's OIG determined that FDA acted timely if the agency took action within 1 year of identifying significant violations. See OEI-02-14-00420.

[39]We selected this 6-month time frame for our analysis of inspections before a closeout because it is consistent with the time frame specified in an FDA directive (*Field Management Directive 86*), which establishes a goal that FDA follow up by conducting inspections within 6 months after an establishment failed to meet either regulatory or administrative requirements and may pose a hazard to public health. In addition, any inspections conducted more than 6 months prior to a closeout may not reflect the actual conditions of the facility at the time of the closeout.

[40]In our 2019 report, we determined that, according to FDA's procedures, firms or products placed on an import alert based on a violative facility inspection may generally be removed from the alert after a follow-up inspection shows that corrective actions to resolve the violation have been taken. We found that FDA conducted these follow-up inspections within 6 months prior to import alert removal 10 percent of the time. In addition, according to FDA officials, when the agency relies on documentation to support a removal decision, FDA generally relies on subsequent inspections of the importers or foreign processing facilities and sampling of their products to have confidence that the firms and their products continue to comply. We found that FDA conducted subsequent inspections within 1 year after an import alert removal decision 13 percent of the time. See GAO-20-62. We selected a 1 year time frame for our analysis of FDA's actions to verify closeout letter decisions because in a 2017 report, HHS's OIG determined that FDA acted timely if the agency took action within 1 year of identifying significant violations. See OEI-02-14-00420.

Figure 5. FDA Inspections prior to Issuing Closeout Letters for 73 Warning Letters That Had Subsequent Closeout Letters, as of March 11, 2020



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

Text of Figure 5. FDA Inspections prior to Issuing Closeout Letters for 73 Warning Letters That Had Subsequent Closeout Letters, as of March 11, 2020

167 warning letters (Issued from January 1, 2014, through March 11, 2019)

- Closeout letter issued, 73
- No closeout letter issued, 94

73 closeout letters (Issued as of March 11, 2020)

- No follow-up inspection 6 months before or 1 year after closeout, 47
- Follow-up inspection 6 months before closeout, 21
- Follow-up inspection 1 year after closeout, 5

Note: We reviewed warning letters FDA issued from January 1, 2014, through March 11, 2019 and any subsequent closeout letters FDA issued through March 11, 2020. According to FDA officials, the concluding actions FDA would take on warning letters issued to foreign seafood processors and seafood importers would be to issue a closeout letter if the firm corrects the violations in the warning letter, or to place the firm on an import alert if the firm does not correct the violation or if the corrections are inadequate. FDA's *Regulatory Procedures Manual* states that the usual standard for verifying that firms have implemented corrections after FDA issues them a warning letter is a follow-up inspection. We selected 6 months as the time frame for our analysis of inspections before a closeout because it is consistent with the time frame specified in FDA's *Field Management Directive*

86, which establishes a goal that FDA follow up by conducting inspections within 6 months after an establishment failed to meet either regulatory or administrative requirements and may pose a hazard to public health. In addition, any inspections conducted more than 6 months prior to a closeout may not reflect the actual conditions of the facility at the time of the closeout. We selected a 1 year time frame for our analysis of inspections after FDA issued a closeout letter because in a 2017 report, the Department of Health and Human Service's Office of Inspector General determined that FDA acted timely if the agency took action within 1 year of identifying significant violations. See Department of Health and Human Services, Office of Inspector General, Challenges Remain in FDA's Inspections of Domestic Food Facilities, OEI-02-14-00420 (Washington, D.C.: September 2017).

In addition, FDA issued closeout letters to firms that were on active import alerts, contrary to its warning letter procedures. FDA's *Regulatory Procedures Manual* states that the agency should only issue a closeout letter if information does not reveal other significant violations. According to FDA officials, such information includes that the firm is not on an active import alert. As previously stated, of the 167 warning letters we analyzed, 73 had a subsequent closeout letter, making them subject to FDA's procedure to not issue closeout letters when other information reveals significant violations. However, of the 73 warning letters for which FDA issued a subsequent closeout letter, FDA sent four (5 percent) of these closeout letters to firms that were on an active import alert. One of these firms was a seafood importer that, as of March 11, 2020, was on an active import alert for the same type of violations that FDA described in the warning letter.[41] The other three firms were foreign seafood processors on import alerts that were not directly related to HACCP violations but were related to decomposed products or the potential presence of pathogens or histamines in the firms' products.[42]

[41]This seafood importer was on a 16-119 import alert. A 16-119 import alert is for detention without physical examination of fish and fishery products for importer and foreign processor combinations. According to FDA import alert guidance, if FDA has determined that an importer has failed to meet HACCP verification requirements for a specific product and foreign processor, FDA may recommend that the specific importer/product/foreign processor combination be placed on a 16-119 import alert. Our analysis reviewed import alert data up through March 11, 2020.

[42]The three foreign seafood processors were on a 16-81, 16-74, or 16-105 import alert. According to FDA import alert guidance, a firm can be placed on a 16-81 import alert due to the presence of *Salmonella* in its seafood product; a firm can be placed on a 16-74 import alert if it produces certain types of uneviscerated or partially eviscerated fish that are either salt-cured, dried, smoked, pickled, fermented, or brined, due to the potential formation of *clostridium botulinum* (botulism) in such products; and a firm can be placed on a 16-105 import alert for decomposed products and/or products that contain histamines. Our analysis reviewed import alert data up until March 11, 2020.

Resolving Warning Letter Cases

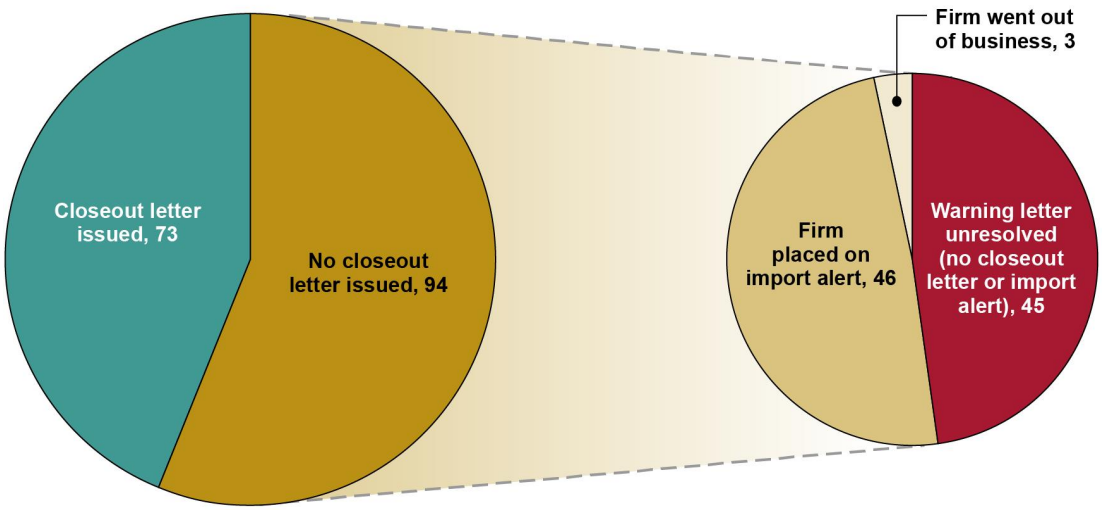
FDA did not consistently take enforcement action on warning letters that had not been closed out, according to its procedure. According to FDA's *Regulatory Procedures Manual*, the FDA personnel assigned to the warning letter should diligently pursue the progress of the case to its conclusion (that is, voluntary compliance or enforcement action). For seafood importers and foreign seafood processors, FDA officials said that the appropriate enforcement action would be placing the firm on an import alert. Of the 167 warning letters we analyzed, FDA did not issue a subsequent closeout letter for 94 of them.[43] For 45 (48 percent) of these 94 warning letters, FDA had not placed the firm on an import alert, and the firm had not gone out of business as of March 11, 2020.[44] Therefore, these 45 warning letters had not reached a conclusion of voluntary compliance, as indicated by a closeout letter, or enforcement action, as indicated by import alert placement. For the remaining 46 (49 percent) of the 94 warning letters that did not have a subsequent closeout letter, FDA took enforcement action by placing the firm on an import alert (see fig. 6).[45] According to FDA officials, foreign processors and importers with an unresolved warning letter, which indicates that FDA has not verified whether the firm corrected the identified food safety violations, can continue to bring seafood products into the United States.

[43]The remaining 73 warning letters of the 167 warning letters FDA issued between January 1, 2014, and March 11, 2019, had a subsequent closeout letter. For our analysis, we limited our review of warning letters to those issued through March 11, 2019, to ensure that we captured any firm closures or subsequent import alert or closeout letter actions taken by FDA within a year after the warning letter issuance date. We selected 1 year as the time frame for our analysis of FDA import alert actions because in a 2017 report, HHS's OIG determined that FDA acted timely if the agency took action within 1 year of identifying significant violations. See OEI-02-14-00420.

[44]Three of the 94 warning letters were issued to firms that subsequently went out of business. If a firm goes out of business, FDA does not issue a closeout letter.

[45]An import alert places responsibility on the importer to ensure that the products being imported into the United States comply with federal laws and FDA regulations. For a firm to be removed from an import alert, FDA may require one or a combination of the following: a minimum of five consecutive nonviolative commercial shipments as determined by a private laboratory hired by the firm, an on-site inspection of the importer or foreign processing facility, or documentation showing that the cause of the violation has been fully corrected. See GAO-20-62 for further information on the import alert placement and removal process.

Figure 6. Actions Taken by FDA on 94 Warning Letters without a Subsequent Closeout Letter, as of March 11, 2020



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

Text of Figure 6. Actions Taken by FDA on 94 Warning Letters without a Subsequent Closeout Letter, as of March 11, 2020

167 warning letters (Issued from January 1, 2014, through March 11, 2019)

- No closeout letter issued, 94
- Closeout letter issued, 73

94 without closeout letter (As of March 11, 2020)

- Warning letter unresolved (no closeout letter or import alert), 45
- Firm placed on import alert, 46
- Firm went out of business, 3

Note: We reviewed warning letters FDA issued from January 1, 2014, through March 11, 2019, and any subsequent closeout letter or import alert action that FDA took through March 11, 2020. According to FDA officials, the concluding actions FDA would take on warning letters issued to foreign seafood processors and seafood importers would be to issue a closeout letter if the firm corrects the violations in the warning letter, or to place the firm on an import alert if the firm does not correct the violation or if the corrections are inadequate.

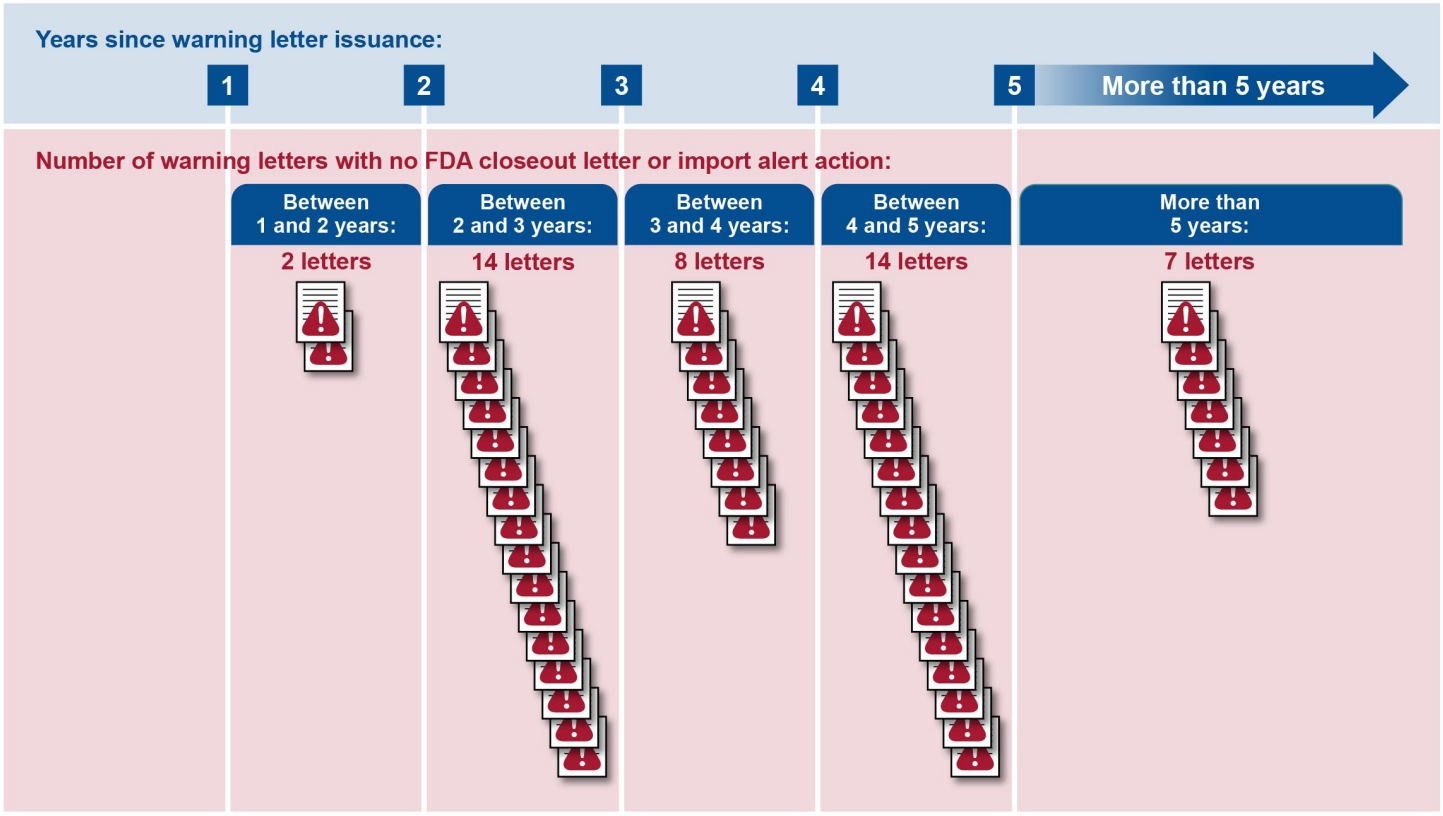
FDA officials stated that there may be situations when the agency chooses not to issue a closeout letter or take enforcement action, such as cases in which FDA conducts a follow-up inspection and holds a

subsequent meeting with the firm, or in which FDA conducts a follow-up inspection and finds one outstanding violation that does not warrant further regulatory action, but precludes a closeout letter. However, for the 45 unresolved warning letters that we identified above, FDA had not conducted a follow-up inspection as of March 11, 2020. Further, FDA's *Regulatory Procedures Manual* states that regulatory meetings with firms can be used to provide additional encouragement, direction, and assistance in achieving compliance. However, these meetings do not serve the same purpose as a closeout letter, which is a final action indicating that FDA has verified that significant violations have been adequately addressed. FDA's *Compliance Evaluation Plan* states that failure to correct significant inspection violations often poses a risk to public health.

According to a 1997 memorandum from FDA's Associate Commissioner for Regulatory Affairs, from the time an inspection is completed, the regulated industry, the judicial system, and the public have an expectation that the agency will move promptly to review and resolve any problems noted during the inspection.[46] However, as of March 11, 2020, FDA had not resolved the 45 warning letter cases that did not have a subsequent closeout letter or import alert action, over half of which FDA issued more than 3 years prior (see fig. 7).

[46]FDA officials stated that the 1997 memo is still in effect.

Figure 7. Length of Time for 45 Warning Letters for Which the Food and Drug Administration (FDA) Had Not Issued a Closeout Letter or Placed Firm on an Import Alert, as of March 11, 2020



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

Data table for Figure 7. Length of Time for 45 Warning Letters for Which the Food and Drug Administration (FDA) Had Not Issued a Closeout Letter or Placed Firm on an Import Alert, as of March 11, 2020

Years since warning letter issuance	Number of warning letters with no FDA letter or import alert action
Between 1 and 2 years	2
Between 2 and 3 years	14
Between 3 and 4 years	8
Between 4 and 5 years	14
More than 5 years	7

Note: We reviewed warning letters FDA issued from January 1, 2014, through March 11, 2019. For our analysis, we limited our review of warning letters to those issued through March 11, 2019, to ensure we captured any subsequent closeout letter or import alert actions taken by FDA within a year after the warning letter issuance date. For this reason, the figure does not show any warning letters that have remained unresolved for less than 1 year since the warning letter issuance date. We selected 1 year as the time frame for our analysis of subsequent FDA action because in a 2017

report, the Department of Health and Human Service's Office of Inspector General determined that FDA acted timely if the agency took action within 1 year of identifying significant violations. See Department of Health and Human Services, Office of Inspector General, *Challenges Remain in FDA's Inspections of Domestic Food Facilities*, OEI-02-14-00420 (Washington, D.C.: September 2017). We tracked subsequent FDA closeout letter and import alert actions through March 11, 2020, the last date of import alert data available at the time of our analysis. It is possible that the number of warning letters without FDA closeout letter or import alert action has changed since that date.

In addition, warning letters request that the firm provide a written response to FDA usually within 15 working days of receiving the letter, according to FDA's *Regulatory Procedures Manual*. FDA officials stated that if a foreign processor or importer does not respond to the warning letter, FDA generally will place the firm on an import alert. However, FDA did not receive a response from firms for 16 (36 percent) of the 45 warning letters that remain unresolved and had not placed these firms on an import alert as of March 11, 2020.

FDA Has Developed Some Monitoring Tools, but Does Not Have a Process to Monitor All Imported Seafood Warning Letters

FDA has developed the following tools to monitor certain agency actions related to imported seafood warning letters, but these tools, individually or collectively, do not allow FDA to understand whether it is consistently following key procedures and meeting key goals for its imported seafood warning letters:

- As noted above, FDA developed a dashboard that tracks, among other things, the proportion of domestic OAI-classified inspections that had appropriate follow-up.[47] However, this dashboard does not track foreign inspections, and it includes communication with the firm as an appropriate follow-up action, which does not align with the agency's goal to conduct a follow-up inspection within 6 months of issuing a warning letter based on an OAI-classified inspection.
- In 2018, FDA created a data process within its CMS database that allows the agency to better track follow-up activities for warning letters

[47]The dashboard also includes a measure on the proportion of follow-up inspections FDA conducted indicating that the firm moved toward compliance (the firm is considered to be in compliance if the follow-up inspection was classified as VAI or NAI).

issued to foreign firms from FDA headquarters.[48] According to FDA officials, examples of the follow-up activities tracked include the date a firm responds to the warning letter, information on FDA's evaluation of the adequacy of the firm's response, information about any corrective actions taken by the firm, and the status of any closeout letter. However, this process does not track key goals, such as whether the warning letter met FDA's 4-month issuance goal or its 6-month follow-up inspection goal for those warning letters issued based on an OAI-classified inspection. Additionally, the data process does not track seafood warning letters that are issued to domestic importers from FDA's field offices.

- FDA headquarters conducts a retroactive audit of a sample of the warning letters that FDA field offices issued to domestic firms as an additional method for monitoring. According to an example audit report, the audit examines whether the warning letters were supported by evidence, whether the letters contained any violations that did not meet the significance threshold to issue a warning letter, and how long it took the field offices to issue the letters after having the appropriate evidence.
- FDA has two checklists that supervisory staff use to review conformance of individual warning letter cases to the agency's requirements and processes: (1) the Warning Letter Recommendation Quality Factor Checklist and (2) the Warning Letter Post-Recommendation Quality Factor Checklist. Both checklists have components that contain direct references to the procedures in FDA's *Regulatory Procedures Manual*. For example, one component of the Warning Letter Post-Recommendation Quality Factor Checklist is that the warning letter is followed through to its conclusion in accordance with warning letter follow-up procedures contained in the manual. Such procedures include taking follow-up action as necessary when a firm does not respond to a warning letter, or verifying that corrections have been implemented when a firm does respond. According to FDA officials, the Warning Letter Recommendation Quality Factor Checklist is used to ensure conformance to procedures before a warning letter is issued, while the Warning Letter Post-Recommendation Quality Factor Checklist is used to review warning letter cases retroactively,

[48]FDA's Center for Food Safety and Applied Nutrition, a component of FDA's headquarters operations, issues warning letters to foreign seafood processors. FDA program divisions, which operate through various district offices in the field, issue warning letters to domestic seafood importers. Some warning letters originating from FDA's program divisions require concurrence with the Center for Food Safety and Applied Nutrition before being issued.

to ensure that the individual letter conforms to FDA's procedures. According to officials, FDA does not use these checklists to evaluate whether all imported seafood warning letters are consistently adhering to key procedures and goals.

While each tool may monitor some aspects of the warning letter process, none of them include monitoring of both domestic and foreign seafood firms and the key procedures and goals that FDA has established. For example, FDA's dashboard tracks some follow-up activities on inspections of domestic firms, while FDA's CMS data process tracks different follow-up activities for warning letters issued to foreign firms.

FDA officials stated that the agency had not reviewed whether all imported seafood warning letters follow established procedures. They said that such a review would consist of examining warning letter documentation on a case-by-case basis in CMS. Consequently, FDA officials were not aware of the extent to which the agency's imported seafood warning letters consistently adhered to the key procedures and goals that we reviewed, nor did they provide reasons for all of the inconsistencies that our analysis identified.

By developing a process to monitor all imported seafood warning letters, FDA would have greater awareness of whether it is consistently adhering to the key procedures and goals it has established for its warning letters. Such a monitoring process could include regularly analyzing the agency's inspection, warning letter, and import alert data, as we did, to determine the extent to which all imported seafood warning letters adhered to key procedures and goals.

In our November 2019 report, FDA officials stated that the agency could check the basis of its decisions to remove seafood firms from an import alert by looking up individual import alert cases in CMS and the agency's sampling and inspection data to determine whether the agency would conclude that sampling and inspections to support these decisions would be appropriate, and if so, whether they were done.[49] These officials added that they believed that instead of regularly analyzing sampling and inspection data, checking the data on the basis of removal decisions individually or when questions arise from sources internal or external to FDA was sufficient to ensure the appropriate level of oversight. We found, however, that this approach had not informed FDA of the extent to which

[49]See GAO-20-62.

the agency was meeting its audit goals and expectations. As discussed earlier, FDA agreed with our recommendation that it establish a process to monitor whether the agency is meeting its audit goals and expectations for sampling and inspections to support its removal decisions for seafood import alerts. In August 2020, FDA officials stated that the agency remains committed to developing metrics and monitoring the import alert removal process and is taking interim steps to address this recommendation. These steps include reviewing and modifying appropriate sections of the *Regulatory Procedures Manual* to better reflect the importance of foreign supplier's corrective actions when making decisions to remove a firm and to identify higher-risk problem areas where more robust information may be needed.

Federal standards for internal control state that, for an agency to run its operations efficiently and effectively, agency managers should design appropriate control activities to achieve agency objectives.[50] An appropriate control activity is for management to collect data to understand the reasons for any differences between the actual performance and the planned or expected results.[51] FDA has some monitoring tools and collects data on its inspection, warning letter, and import alert activities but does not have a process to monitor these activities to understand any discrepancies between the agency's warning letter actions and its key warning letter procedures and goals. Without a monitoring process, FDA does not know the extent to which both its domestic and foreign imported seafood warning letters follow the procedures or meet the goals the agency has established for its warning letter process. Further, having such a process would better position FDA to identify where the agency needs to make corrections, and what types of corrections to make, when it is not consistently following procedures or meeting goals. These procedures and goals were established to help ensure that the violations identified in the warning letters, which pose a potential risk to public health, are corrected. Developing such a process would help provide greater assurance that foreign seafood processors and seafood importers have adequately corrected the food safety violations identified in the warning letters.

[50]Control activities are the actions management establishes through policies and procedures to achieve objectives and respond to risks in the internal control system.

[51]See GAO-14-704G.

FDA Has Not Assessed the Effectiveness of Warning Letters in Ensuring the Safety of Imported Seafood

FDA has not assessed the effectiveness of its warning letters in ensuring the safety of imported seafood and the letters' more specific purpose of getting firms to voluntarily correct all agency-identified violations of law and regulations. Specifically, FDA has not established performance goals and measures—key elements of assessing the effectiveness of initiatives—for warning letters for imported seafood. Performance goals explain the purpose of agency initiatives and the results—including outcomes—that they intend to achieve. Related performance measures collect data that organizations can use to track the progress they are making toward those goals, and their mission more broadly. Performance measures also provide managers with key information on which to base their organizational and management decisions.

Under the Government Performance and Results Act of 1993 (GPRA), as amended by the GPRA Modernization Act of 2010 (GPRAMA), agencies are required to develop long-term strategic plans, establish results-oriented goals and relative performance measures aligned with their missions, and identify strategies needed to achieve those goals.[52] GPRAMA also requires agencies to use the performance information collected by the measures to assess their progress toward achieving their goals. GPRAMA requirements apply at the departmental or agency level, but we have previously reported that the requirements can serve as leading practices for strategic planning at other organizational levels within federal agencies, such as component agencies, offices, programs, and initiatives.[53]

FDA developed a strategy in December 2018 to evaluate the warning letter closeout process for imported seafood for consistency and opportunities for improvement. However, according to our review of the strategy and our interview with FDA officials, the agency has not developed performance measures for this strategy. This strategy is part of

[52]Pub. L. No. 111-352, 124 Stat. 3866 (2011). GPRAMA amends the Government Performance and Results Act of 1993, Pub. L. No. 103-62, 107 Stat. 285.

[53]See GAO-20-62 and *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct. 6, 2011).

a compliance evaluation plan FDA developed to help manage, measure, and improve the quality of compliance efforts across the agency's programs. The plan is also intended to identify goals and objectives for achieving the intended outcomes of individual programs.

In February 2019, FDA published a broad plan for the safety of imported food. According to this plan, the agency intends to develop performance measures for imported food safety. FDA's plan included a goal and objective to enhance the effectiveness and efficiency of import alerts. The plan also included a goal for effective and efficient food import programs and an underlying objective of ensuring the effectiveness of import activities through performance assessment and continuous improvement. However, this objective did not include an effort to assess the effectiveness of warning letters. According to FDA documents, both warning letters and import alerts are among the key enforcement tools FDA uses to achieve its mission of ensuring the safety of imported food, including seafood.

In our November 2019 report, we recommended that FDA establish a time frame for developing performance measures for its imported food safety program and that as the agency develops these measures for its imported food safety program, develop them specific to seafood import alerts.[54] FDA agreed with these recommendations and in August 2020 stated that it had published some performance measures for imported food safety and remained committed to developing additional measures.[55] However, the agency has not taken specific steps to develop performance goals and measures related to warning letters.

As FDA develops performance goals and measures for imported food safety and seafood import alerts, it can follow that same process to develop performance goals and measures for imported seafood warning letters. These measures would demonstrate the contributions of imported seafood warning letters to FDA's broader plan for the safety of imported food and the letters' more specific purpose of encouraging voluntary compliance by seafood importers and foreign seafood processors. For

[54]See GAO-20-62.

[55]As mandated by FSMA, FDA created a program called the Foreign Supplier Verification Program, which requires that importers verify that food imported into the United States has been produced in a manner that meets applicable U.S. safety standards. FDA has established performance measures for this program. For example, FDA developed a measure to track the number and percent of Foreign Supplier Verification inspections classified as NAI, VAI, or OAI.

example, FDA could measure the percentage of cases in which the agency has resolved warning letters, either by issuing a closeout letter to a firm or taking import alert action against the firm within 1 year of the warning letter issuance. Because firms with open warning letter cases are allowed to bring imported seafood products into the United States, such a measure could help FDA ensure that warning letter cases are resolved in a timely manner and that it has verified any firm corrections. By developing performance goals and measures for imported seafood warning letters, FDA would be better positioned to assess how well its seafood warning letter activities are progressing towards ensuring the safety of imported seafood.

Conclusions

Over 90 percent of seafood products consumed in the United States are imported. Warning letters are an important tool available to FDA to help ensure those imported seafood products, as well as other imported FDA-regulated products, are safe. FDA uses warning letters to encourage seafood importers and foreign seafood processors to voluntarily and promptly address significant food safety violations FDA identified. FDA has developed key procedures and goals for its warning letter process for imported seafood, such as conducting follow-up inspections to verify firm compliance, but it does not have a process to monitor the extent to which it consistently adheres to them. By developing a process to monitor all imported seafood warning letters, FDA would have greater awareness of whether it is consistently adhering to its warning letter process procedures and goals, thus providing greater assurance that the significant food safety violations identified in the letters have been adequately corrected.

FDA is in the process of developing performance goals and measures for its broader plan for ensuring the safety of imported food. By establishing such goals and measures for imported seafood warning letters, as it plans to do for related oversight activities such as its seafood import alert program, FDA would be better positioned to assess how well its warning letter process is contributing to the broader plan and ensure the safety of imported seafood.

Recommendations for Executive Action

We are making the following two recommendations to FDA:

- The Commissioner of FDA should establish a process to monitor whether the agency is consistently following key procedures and meeting key goals for its imported seafood warning letters, and take corrective action when necessary. This could be done through regularly analyzing data that FDA collects, such as those in CMS and FACTS. (Recommendation 1)
- The Commissioner of FDA should develop performance goals and measures to assess the effectiveness of its warning letters in ensuring the safety of imported seafood. Such measures could include, but need not be limited to, the percentage of warning letters cases that have been resolved, either through a closeout letter or import alert placement, within 1 year of being issued. (Recommendation 2)

Agency Comments and Our Evaluation

We provided a draft of this report to HHS for comment. In its comments, reproduced in appendix III, HHS's FDA agreed with our recommendations. FDA also provided technical comments, which we incorporated as appropriate. FDA stated that it will use our recommendations on performance goals, measures, and monitoring to further strengthen the safety of imported seafood and other FDA-regulated food imports.

More specifically, FDA agreed with our recommendation that it establish a process to monitor whether the agency is consistently following key procedures and key goals for its imported seafood warning letters, and take corrective action when necessary. FDA stated that it is committed to further strengthening its processes to track responses to warning letters and information about corrective actions that have been taken. Furthermore, FDA said it will also update the relevant regulatory procedures and field management directives to better reflect current practice for the warning letter follow-up procedures for imported seafood.

FDA also agreed with our recommendation to develop performance goals and measures to assess the effectiveness of its warning letters in ensuring the safety of imported seafood. The agency stated that it will evaluate and establish measures that could assist the agency in better assessing the effectiveness of its warning letter strategies to ensure the safety of imported seafood. FDA also indicated that under its strategy for the safety of imported food, the agency is committed to developing performance measures and outcome indicators for imported food safety and will publish meaningful data related to imported food, foreign food

suppliers, and importers. FDA added that it has already developed performance measures specifically related to its strategy and plans to expand on performance measures, including timely action on compliance and enforcement strategies. In its comments, FDA agreed with our recommendations and stated that it would take actions to address them. FDA's planned actions are a good start, but the agency can ensure that its actions fully satisfy our recommendations if it develops a process to monitor the application of key procedures and key goals for all its imported seafood warning letters and develops specific performance goals and measures to assess the effectiveness of its warning letters in ensuring the safety of imported seafood.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services, and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions regarding this report, please contact me at (202) 512-3841 or morriss@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix IV.

Steve D. Morris
Director, Natural Resources and Environment

Appendix I. Objectives, Scope, and Methodology

This report examines the extent to which the Food and Drug Administration (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.[1]

To review FDA's warning letter process for imported seafood, we reviewed FDA documents, including procedures governing the use of warning letters contained in FDA's *Regulatory Procedures Manual* and *Field Management Directive 86*. We interviewed FDA officials to gain further understanding of the warning letter process and reviewed agency data on imported seafood inspections, warning letters, and import alerts. FDA supplied this data from its Compliance Management System (CMS) and Field Accomplishment and Compliance Tracking System (FACTS).[2]

We also reviewed prior reports that examined FDA actions related to warning letters. Specifically, we reviewed a September 2017 Department of Health and Human Services (HHS) Office of Inspector General (OIG) report on FDA inspections of domestic food facilities, which determined that conducting timely follow-up inspections after identifying significant inspection violations, issuing warning letters in timely manner, and taking follow-up action to ensure firm compliance are important actions that help

[1]FDA is an agency of the Department of Health and Human Services.

[2]The CMS database tracks all compliance actions, including warning letters that FDA has issued to individual firms. Among other things, CMS includes information uniquely identifying affected firms, along with information identifying the nature of the violations. According to FDA officials, CMS also includes links to scans of the documentation on which FDA based its warning letter issuance and closeout letter decisions. The FACTS database contains information on firms and products that FDA regulates, foreign and domestic establishments that FDA inspects, the type of inspection conducted, and the outcome of those inspections, among other things.

FDA ensure significant food safety violations are corrected.[3] The OIG report did not review these activities for foreign food facilities. Additionally, in our 2019 report on FDA's use of import alerts for seafood, we determined that placing firms on import alert and conducting inspections before removing firms from import alert—which is similar to FDA's standard to inspect firms before issuing closeout letters—were key activities that FDA used to ensure firm compliance with food safety regulations.[4]

Based on this information and what the data FDA provided would allow us to analyze, we identified the following key procedures related to FDA's warning letter process for our review: (1) FDA's inspection classification procedure for warning letters; (2) FDA's procedure to conduct a follow-up inspection as the usual standard for verifying a firm's corrections before issuing a closeout letter; and (3) FDA's procedure to pursue warning letter cases to their conclusion (that is, voluntary firm compliance or enforcement action). We also identified the following key goals for our review: (1) FDA's goal to issue warning letters within 4 months of an appropriate reference date;[5] and (2) FDA's goal to conduct a follow-up inspection within 6 months of issuing a warning letter based on significant inspection violations.

[3]OIG specifically calculated the percentage of inspections in which FDA identified significant violations for which the agency conducted a timely follow-up inspection within 6 months. The OIG also calculated the percentage of warning letters for which FDA met its goal to issue the warning letter within 4 months of the last date of an inspection. See Department of Health and Human Services, Office of Inspector General, *Challenges Remain in FDA's Inspections of Domestic Food Facilities,* OEI-02-14-00420 (Washington, D.C.: September 2017).

[4]In our 2019 report, we specifically calculated the percentage of import alert cases in which FDA conducted an inspection within 6 months prior to removing a firm and product from an import alert and the percentage of import alert cases in which FDA conducted an inspection within 1 year after removing a firm and product from an import alert. See GAO, *Imported Seafood Safety: Actions Needed to Improve FDA Oversight of Import Alert Removal Decisions*, GAO-20-62 (Washington, D.C.: Nov. 6, 2019).

[5]According to FDA's *Regulatory Procedure Manual,* examples of an appropriate reference date are the last day of an inspection, the date of a sample analysis, or the date of evidence collection. According to FDA officials, the appropriate reference date is the last day of the inspection for warning letters issued based on an inspection. We used FDA inspection data to identify these dates. FDA officials stated that the agency does not have a data field that easily captures other types of reference dates, but that these dates can be located in various documents that are housed in different folders within CMS. Over 80 percent of the warning letters that we reviewed were based on an inspection.

To examine the extent to which FDA ensures it is following the key warning letter procedures and goals that we identified for our review, we interviewed FDA officials about the agency's procedures and goals and reviewed information that FDA posted on its website about seafood warning letters. We also analyzed the inspection, warning letter, and import alert data that FDA provided. According to its warning letter data, FDA issued 185 warning letters from January 1, 2014, through April 6, 2020.[6] We reviewed 167 of these warning letters that FDA issued from January 1, 2014, through March 11, 2019—1 year prior to the most recent FDA inspection and import alert data available at the time of our analysis.[7] We reviewed inspection records that were associated with a Hazard Analysis and Critical Control Point (HACCP) compliance review, because all of the warning letters issued during this time frame cited HACCP violations.[8] We compared FDA's warning letter activities described above to the corresponding key procedures and goals that FDA has established for these activities.

To review FDA's inspection classification and warning letter issuance activities, we compared inspection data from January 1, 2013, through March 11, 2019, to warning letter data from January 1, 2014, through March 11, 2019. We determined which warning letters were associated with an inspection that occurred within 1 year prior to the warning letter issuance date and reviewed how FDA classified those inspections. We also calculated the length of time between the inspection date and the subsequent warning letter issuance date to determine how often FDA met

[6]We identified three warning letters for imported seafood that FDA issued from January 1, 2014, through April 6, 2020, that were not included in the data FDA provided. FDA officials stated that these three warning letters were not in the warning letter data due to human data entry error. Omitting these three warning letters, which represent less than 2 percent of all imported seafood warning letters FDA issued during the time frame we reviewed, from our analysis does not materially affect the findings of our analysis.

[7]We reviewed warning letters that were issued through March 11, 2019, in order to examine any follow-up actions that FDA took within 1 year after the warning letter issuance date. We selected 1 year as the time frame for our analysis of subsequent FDA actions because in a 2017 report, HHS's Office of Inspector General determined that FDA acted timely if the agency took action within 1 year of identifying significant violations. See OEI-02-14-00420.

[8]FDA uses Program Assignment Codes to identify the activities of an inspection. We used inspection records in our analysis that were associated with the Program Assignment Codes that FDA documentation or officials identified as being HACCP-related.

its goal to issue warning letters within 4-months of the appropriate reference date.

To determine whether FDA was meeting its goal to conduct a follow-up inspection within 6 months of issuing a warning letter based on an inspection classified as Official Action Indicated (OAI), we identified 125 warning letters issued from January 1, 2014, through March 11, 2019, that were based on OAI-classified inspections.[9] We calculated the length of time between the warning letter issuance date and any follow-up inspection date, to determine how often FDA met its 6-month goal for those warning letters that were issued from an OAI-classified inspection.

To review FDA's closeout letter activities, including how often FDA inspected a firm prior to issuing a closeout letter, we identified 73 warning letters issued from January 1, 2014, through March 11, 2019, for which FDA also issued a subsequent closeout letter. We compared these warning letters to inspection data from January 1, 2014, through March 11, 2020.[10] We identified firms that received a follow-up inspection within 6 months prior to the closeout letter date.[11]

[9]FDA classifies an inspection as OAI if objectionable conditions were found during the inspection and regulatory action should be recommended. FDA's *Field Management Directive 86* states that a follow-up inspection should be conducted within 6 months of any FDA action taken in response to an OAI-classified inspection. According to FDA officials, such action includes issuing a warning letter. FDA's *Regulatory Procedures Manual* states that all inspections that result in a warning letter should be classified as OAI, thus making these warning letters subject to FDA's 6-month follow-up inspection goal.

[10]As previously stated, we reviewed warning letters that were issued through March 11, 2019, to examine any follow-up actions that FDA took within one year after the warning letter issuance date. We selected 1 year as the time frame for our analysis of subsequent FDA actions because in a 2017 report, HHS's Office of Inspector General determined that FDA acted timely if the agency took action within 1 year of identifying significant violations. See OEI-02-14-00420.

[11]FDA's *Regulatory Procedures Manual* states that FDA's usual standard for verifying firm compliance is through a follow-up inspection, but the manual does not include a time frame for conducting a follow-up inspection before issuing a closeout letter. We selected this 6-month timeframe for our analysis of FDA inspections before closeout because it is consistent with the time frame specified in an FDA directive (*Field Management Directive 86*), which establishes a goal that FDA follow up by conducting inspections within 6 months after an establishment failed to meet either regulatory or administrative requirements and may pose a hazard to public health. In addition, any inspections conducted more than 6 months prior to a closeout may not reflect the actual conditions of the facility at the time of the closeout.

To review FDA's follow-up inspection activities for firms for which FDA did not conduct a follow-up inspection prior to closing out the warning letter, we analyzed FDA warning letter data from January 1, 2014, through March 11, 2019, and FDA inspection data from January 1, 2014, through March 11, 2020. We calculated the number of closeout letters with a subsequent inspection date within 1 year after the closeout letter date.[12] Additionally, we examined whether any firms were on active import alerts at the time FDA issued a closeout letter to the firm by comparing closeout letter dates to import alert placement and removal data.

To review FDA's import alert activities, when the agency did not issue a closeout letter, we compared warning letters issued from January 1, 2014, through March 11, 2019, to FDA import alert data from January 1, 2014, through March 11, 2020. We identified firms that FDA placed on a 16-119 or 16-120 import alert after the warning letter issuance date. Current agency guidance states that FDA may place importers that fail to meet HACCP verification requirements on a 16-119 import alert and may place foreign processors that violate HACCP requirements on a 16-120 import alert.[13] We also identified warning letter cases in which FDA did not issue a closeout letter, did not place the firm on an import alert, and the firm did not go out of business. We calculated the length of time that such warning letters had no subsequent FDA closeout or import alert action through March 11, 2020, the last date for which data were available.

[12]FDA's warning letter procedures do not state a goal for when to conduct follow-up inspections after a closeout letter. However, FDA's procedures state that a follow-up inspection is the usual standard for verifying that corrections have been implemented. We selected 1 year as the time frame for our analysis of FDA follow-up inspections after warning letter closeout because as previously stated, in a 2017 report, HHS's Office of Inspector General determined that 1 year is a reasonable time frame for FDA to take action. See OEI-02-14-00420.

[13]The 16-119 import alert is for detention without physical examination of fish and fishery products for importer and foreign processor combinations. According to FDA import alert guidance, if FDA has determined that an importer has failed to meet HACCP verification requirements for a specific product and foreign processor, FDA may recommend that the specific importer/product/foreign processor combination be placed on a 16-119 import alert. A 16-120 import alert is for detention without physical examination of fish/fishery products from foreign processors not in compliance with HACCP. According to FDA guidance, if the agency has determined that a foreign processor has failed to meet HACCP requirements for a specific product, it may place that foreign processor/product(s) combination on a 16-120 import alert.

To assess the reliability of FDA's data, we reviewed documentation for CMS and FACTS, conducted electronic and manual testing, and interviewed agency officials regarding controls, among other things. We identified three warning letters for imported seafood that FDA issued in 2015 that were not included in the data FDA provided.[14] Additionally, we identified two warning letters issued to seafood firms that stated an inspection date in the warning letter but were missing from the inspection data FDA provided. As a result, these two warning letters were only included in our analyses related to placing firms on import alert.[15] Even with these few instances of missing warning letters or inspection records, we found FDA's data to be sufficiently reliable for the purposes of reporting numbers of warning letters and related inspections and import alert placements, closeout letters, and associated time frames.

We determined that federal standards for internal controls were significant to our first audit objective, along with the underlying principle that management should design control activities to achieve objectives and respond to risks and help management fulfill its responsibilities.[16]

To examine the extent to which FDA assesses the effectiveness of its warning letters in ensuring the safety of imported seafood, we reviewed FDA's *Strategy for the Safety of Imported Food* and agency documentation describing FDA's food safety performance measures. We compared FDA's strategy and documentation with leading practices we have identified in our past work for assessing the effectiveness of

[14]We located the three warning letters not included in the data on FDA's public warning letter website. FDA officials stated that these warning letters were not in the warning letter data due to human data entry error. Omitting these three warning letters—which represent less than 2 percent of the imported seafood warning letters FDA issued during the time frame we reviewed—from our analysis does not materially affect the findings of our analysis.

[15]FDA officials stated that these two inspection records were not in the inspection data provided to us because they did not meet the parameters FDA used to gather the data. As a result, the two warning letters associated with these missing inspection records were not included in our analyses related to classifying inspections, issuing warning letters, or conducting follow-up inspections, because all of these analyses relied on the existence of an inspection date prior to the warning letter issuance. In addition, neither warning letter had a closeout letter date, so they were not applicable to the analyses related to issuing closeout letters. Omitting these two warning letters—which represent about 1 percent of the seafood warning letters issued during the time frame we reviewed—from these analyses does not materially affect the findings of our analysis.

[16]GAO, *Standards for Internal Control in the Federal Government*, GAO-14-704G (Washington, D.C.: September 2014).

programs. For example, we have previously reported that requirements of the Government Performance and Results Act of 1993 (GPRA), as amended by the GPRA Modernization Act of 2010 (GPRAMA),[17] such as performance goals and performance measures, can serve as leading practices for planning at lower levels, such as programs within federal agencies.[18] We also interviewed FDA officials to obtain their views on the agency's efforts to assess the effectiveness of its seafood warning letters.

We conducted this performance audit from December 2019 to March 2021 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[17]Pub. L. No. 111-352, 124 Stat. 3866 (2011). GPRAMA amends the Government Performance and Results Act of 1993, Pub. L. No. 103-62, 107 Stat. 285.

[18]GAO, *Food Safety and Nutrition: FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities*, GAO-18-174 (Washington, D.C.: Jan. 31, 2018); *Coast Guard: Actions Needed to Enhance Performance Information Transparency and Monitoring*, GAO-18-13 (Washington, D.C.: Oct. 27, 2017); and *Environmental Justice: EPA Needs to Take Additional Actions to Help Ensure Effective Implementation*, GAO-12-77 (Washington, D.C.: Oct. 6, 2011).

Appendix II. Status of FDA's Efforts to Collect Follow-up Inspection Fees

In 2011, the FDA Food Safety Modernization Act (FSMA) directed the Food and Drug Administration (FDA)[1] to begin assessing and collecting fees to cover the cost of food facility follow-up inspections.[2] To describe the status of FDA's efforts to collect these fees, we reviewed FDA documents, including the agency's yearly budget justification reports and *Federal Register* notices, and reviewed FDA's responses to our questions about the status of collecting the fees and any challenges the agency faces in collecting them.

FDA did not collect follow-up inspection fees from food facility inspections, including inspections of foreign seafood processing facilities or seafood importers' facilities that were issued warning letters, in fiscal years 2010 through 2019, according to the agency's yearly budget justification reports. As recently as August 2020, FDA has stated that it does not intend to collect follow-up inspection fees for any food facility until it publishes a guidance document on how small businesses can request a reduction in such fees.

In its *Federal Register* notice, published August 3, 2020, FDA stated that the agency recognizes that the full cost recovery of an FDA follow-up inspection could cause severe economic hardship on small businesses.[3] Further, FDA stated that the agency does not intend to issue invoices for follow-up inspection fees until it publishes the guidance outlining the process through which firms may request a reduction in fees. According to FDA officials, the agency has prioritized work on FSMA rulemakings, such as the Laboratory Accreditation proposed rule and the Food Traceability proposed rule, which FDA published as proposals in

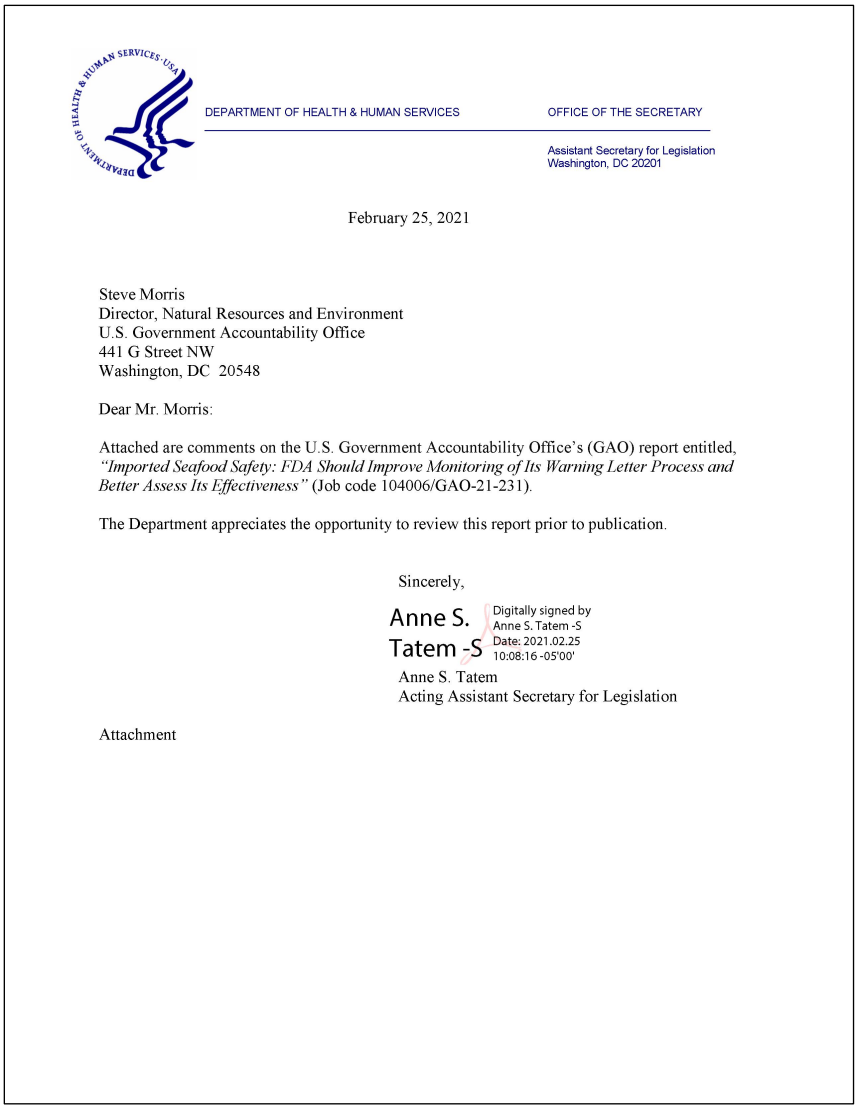
[1]FDA is an agency of the Department of Health and Human Services.

[2]Pub. L. No. 111-353, § 107, 124 Stat. 3885, 3906 (codified at 21 U.S.C. § 379j-31).

[3]According to the *Federal Register* notice, FDA set follow-up inspection fee rates for fiscal year 2021 at $263 per hour when domestic travel is required and at $310 per hour when foreign travel is required. See *Food Safety Modernization Act Domestic and Foreign Facility Reinspection, Recall, and Importer Reinspection Fee Rates for Fiscal Year 2021*, 85 Fed. Reg. 46,669 (Aug. 3, 2020).

November 2019 and September 2020, respectively. FDA has publicly committed to finalizing these proposed rules. Officials stated that FDA would continue to work on other high-priority rulemakings before beginning development of the guidance document for follow-up inspection fees. When FDA is able to devote more staff resources to the development of the guidance, the agency intends to conduct stakeholder outreach to explain the fees, how they would be collected, and how firms could request a fee reduction on the basis of their individual circumstances, according to agency officials.

Appendix III: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES — OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

February 25, 2021

Steve Morris
Director, Natural Resources and Environment
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, *"Imported Seafood Safety: FDA Should Improve Monitoring of Its Warning Letter Process and Better Assess Its Effectiveness"* (Job code 104006/GAO-21-231).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Anne S. Tatem -S
Digitally signed by Anne S. Tatem -S
Date: 2021.02.25 10:08:16 -05'00'

Anne S. Tatem
Acting Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED IMPORTED SEAFOOD SAFETY: FDA SHOULD IMPROVE MONITORING OF ITS WARNING LETTER PROCESS AND BETTER ASSESS ITS EFFECTIVENESS (GAO-21-231)

The Food and Drug Administration (FDA) thanks the Government Accountability Office (GAO) for its ongoing work on the topic of imported seafood, including this most recent report on seafood warning letters. FDA will use GAO's recommendations on performance goals, measures, and monitoring to further strengthen the safety of imported seafood and other FDA-regulated food imports.

Recommendation 1

The Commissioner of FDA should establish a process to monitor whether the agency is consistently following key procedures and key goals for its imported seafood warning letters and take corrective action when necessary. This could be done through regularly analyzing data that FDA collects, such as those in CMS and FACTS.

HHS concurs with this recommendation. CFSAN's warning letter data tracking process, established in 2018, was developed as a tool to ensure the safety of imported food, including imported seafood, by monitoring the key goals for imported seafood warning letters. CFSAN's warning letter process has significantly increased the timeliness of the warning letter follow-up process for all CFSAN-issued warning letters. The agency is committed to further strengthening its processes to track responses to warning letters and information about corrective actions that have been taken. FDA will continue to monitor the status of closeout letters and whether FDA is meeting its goal of issuing warning letters within 4-months. Additionally, the agency will continue to evaluate and implement other activities, such as increased import surveillance. FDA will update the relevant regulatory procedures and field management directives to better reflect current practice for the warning letter follow-up procedures for imported seafood.

Recommendation 2

The Commissioner of FDA should develop performance goals and measures to assess the effectiveness of its warning letters in ensuring the safety of imported seafood. Such measures could include, but need not be limited to, the percentage of warning letters cases that have been resolved, either through a closeout letter or import alert placement, within 1 year of being issued.

HHS concurs with this recommendation. FDA concurs with this recommendation and will evaluate and establish measures that could assist the agency in better assessing the effectiveness of its warning letter strategies to ensure the safety of imported seafood. FDA has published a Strategy for the Safety of Imported Food with the public health objective of reducing the number and severity of food safety problems in the foreign supply chain for imported foods, including seafood. Specifically, FDA is pursuing enhanced compliance under Goal 1 (Food Offered for Import Meets U.S. Food Safety Requirements) of the strategy, which includes strategy 1.3 on deterring noncompliance through strategic enforcement of supply chain control requirements such as those in the seafood hazard analysis and critical control point (HACCP) rule, which

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED IMPORTED SEAFOOD SAFETY: FDA SHOULD IMPROVE MONITORING OF ITS WARNING LETTER PROCESS AND BETTER ASSESS ITS EFFECTIVENESS (GAO-21-231)

requires seafood importers to verify their suppliers. Warning letters are one of the many tools that FDA uses as part of its compliance and enforcement strategies to help ensure the safety of the U.S. food supply. More generally, seafood Warning Letters further FDA's Foods and Veterinary Medicine Program's Strategic Plan Fiscal Years 2016–2025's Food Safety goal to protect America's consumers and animals from foreseeable hazards and its objective to "improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents". Moreover, under the Strategy for the Safety of Imported Food Goal 4, strategy 4.2a, FDA is committed to developing performance measures and outcome indicators for imported food safety, and strategy 4.2b, FDA will publish meaningful data related to imported food, foreign food suppliers, and importers. FDA has already developed performance measures specifically related to Strategy and plans to expand on performance measures under Goal 1, including timely action on compliance and enforcement strategies.

Text of Appendix III: Comments from the Department of Health and Human Services

Page 1

February 25, 2021

Steve Morris

Director, Natural Resources and Environment

U.S. Government Accountability Office 441 G Street NW

Washington, DC 20548

Dear Mr. Morris:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Imported Seafood Safety: FDA Should Improve Monitoring of Its Warning Letter Process and Better Assess Its Effectiveness" (Job code 104006/GAO-21-231).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Anne S. Tatem

Acting Assistant Secretary for Legislation

Attachment

Page 2

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED IMPORTED SEAFOOD SAFETY: FDA

SHOULD IMPROVE MONITORING OF ITS WARNING LETTER PROCESS AND BETTER ASSESS ITS EFFECTIVENESS (GAO-21-231)

The Food and Drug Administration (FDA) thanks the Government Accountability Office (GAO) for its ongoing work on the topic of imported seafood, including this most recent report on seafood warning letters. FDA will use GAO's recommendations on performance goals, measures, and monitoring to further strengthen the safety of imported seafood and other FDA-regulated food imports.

Recommendation 1

The Commissioner of FDA should establish a process to monitor whether the agency is consistently following key procedures and key goals for its imported seafood warning letters and take corrective action when necessary. This could be done through regularly analyzing data that FDA collects, such as those in CMS and FACTS.

HHS concurs with this recommendation. CFSAN's warning letter data tracking process, established in 2018, was developed as a tool to ensure the safety of imported food, including imported seafood, by monitoring the key goals for imported seafood warning letters. CFSAN's warning letter process has significantly increased the timeliness of the warning letter follow-up process for all CFSAN-issued warning letters. The agency is committed to further strengthening its processes to track responses to warning letters and information about corrective actions that have been taken. FDA will continue to monitor the status of closeout letters and whether FDA is meeting its goal of issuing warning letters within 4-months. Additionally, the agency will continue to evaluate and implement other activities, such as increased import surveillance. FDA will update the relevant regulatory procedures and field management directives to better reflect current practice for the warning letter follow-up procedures for imported seafood.

Recommendation 2

The Commissioner of FDA should develop performance goals and measures to assess the effectiveness of its warning letters in ensuring the safety of imported seafood. Such measures could include, but need not be limited to, the percentage of warning letters cases that have been resolved, either through a closeout letter or import alert placement, within 1 year of being issued.

Page 3

HHS concurs with this recommendation. FDA concurs with this recommendation and will evaluate and establish measures that could assist the agency in better

assessing the effectiveness of its warning letter strategies to ensure the safety of imported seafood. FDA has published a Strategy for the Safety of Imported Food with the public health objective of reducing the number and severity of food safety problems in the foreign supply chain for imported foods, including seafood. Specifically, FDA is pursuing enhanced compliance under Goal 1 (Food Offered for Import Meets U.S. Food Safety Requirements) of the strategy, which includes strategy 1.3 on deterring noncompliance through strategic enforcement of supply chain control requirements such as those in the seafood hazard analysis and critical control point (HACCP) rule, which requires seafood importers to verify their suppliers. Warning letters are one of the many tools that FDA uses as part of its compliance and enforcement strategies to help ensure the safety of the U.S. food supply. More generally, seafood Warning Letters further FDA's Foods and Veterinary Medicine Program's Strategic Plan Fiscal Years 2016–2025's Food Safety goal to protect America's consumers and animals from foreseeable hazards and its objective to "improve prevention, detection, and response to foodborne illness outbreaks and other food and feed safety incidents". Moreover, under the Strategy for the Safety of Imported Food Goal 4, strategy 4.2a, FDA is committed to developing performance measures and outcome indicators for imported food safety, and strategy 4.2b, FDA will publish meaningful data related to imported food, foreign food suppliers, and importers. FDA has already developed performance measures specifically related to Strategy and plans to expand on performance measures under Goal 1, including timely action on compliance and enforcement strategies.

Appendix IV: GAO Contact and Staff Acknowledgments

GAO Contact

Steve D. Morris at (202) 512-3841 or morriss@gao.gov

Staff Acknowledgments

In addition to the contact named above, Anne K. Johnson (Assistant Director), David Moreno (Analyst in Charge), Taylor L. Bailey, Kevin Bray, Michele Fejfar, Scott C. Hiromoto, Gwen Kirby, and Dan Royer made key contributions to this report.

Related GAO Products

Imported Seafood Safety: Actions Needed to Improve FDA Oversight of Import Alert Removal Decisions. GAO-20-62. Washington, D.C.: November 6, 2019.

Food Safety and Nutrition: FDA Can Build on Existing Efforts to Measure Progress and Implement Key Activities. GAO-18-174. Washington, D.C.: January 31, 2018.

Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues. GAO-17-443. Washington, D.C.: September 15, 2017.

Seafood Safety: Status of Issues Related to Catfish Inspection. GAO-17-289T. Washington, D.C.: December 7, 2016.

Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible. GAO-16-399. Washington, D.C.: May 26, 2016.

Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources. GAO-12-933. Washington, D.C.: September 28, 2012.

Seafood Safety: Responsibility for Inspecting Catfish Should Not Be Assigned to USDA. GAO-12-411. Washington, D.C.: May 10, 2012.

Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources. GAO-11-286. Washington, D.C.: April 14, 2011.

Seafood Fraud: FDA Program Changes and Better Collaboration Among Key Federal Agencies Could Improve Detection and Prevention. GAO-09-258. Washington, D.C.: February 19, 2009.

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