



November 2019

# IMPORTED SEAFOOD SAFETY

## Actions Needed to Improve FDA Oversight of Import Alert Removal Decisions

Accessible Version

# GAO Highlights

Highlights of [GAO-20-62](#), a report to congressional requesters

## Why GAO Did This Study

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

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

## What GAO Recommends

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

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

November 2019

## IMPORTED SEAFOOD SAFETY

### Actions Needed to Improve FDA Oversight of Import Alert Removal Decisions

## What GAO Found

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

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

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

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**Abbreviations**

CBP	Customs and Border Protection
CMS	Compliance Management System
DHS	Department of Homeland Security
FACTS	Field Accomplishment and Compliance Tracking System
FDA	Food and Drug Administration
FFDCA	Federal Food, Drug, and Cosmetic Act
GPRA	Government Performance and Results Act of 1993
GPRAMA	GPRA Modernization Act of 2010
HACCP	Hazard Analysis Critical Control Point
HHS	Department of Health and Human Services
MOU	memorandum of understanding
NOAA	National Oceanic and Atmospheric Administration
OAI	official action indicated
OASIS	Operational and Administrative System for Import Support
ORA	Office of Regulatory Affairs
PREDICT	Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting

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November 6, 2019

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

The United States is the world's second largest importer of seafood, importing from approximately 140 countries. More than 90 percent of seafood products consumed in the United States are imported, according to data from the National Oceanic and Atmospheric Administration (NOAA). These data also indicate that U.S. seafood imports have risen in recent years, from about 5.8 billion pounds of seafood in 2014 to about 6.3 billion pounds in 2017.

Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) is generally responsible for ensuring that the nation's food supply, including most imported seafood, is safe, wholesome, sanitary, and properly labeled. To carry out its oversight responsibilities for imported seafood, FDA requires processors and importers to follow its Hazard Analysis and Critical Control Point (HACCP) regulations to identify hazards and the critical control points in their processing systems where one or more hazards are reasonably likely to occur. Hazards can include drug residues such as antibiotics, pathogens

such as *Salmonella*, and insanitary conditions at the foreign processing facility.<sup>1</sup> FDA also relies on (1) inspections of importers' facilities and of processors' foreign facilities each year to ensure HACCP compliance, and (2) port-of-entry examinations and tests of imported seafood for contaminants, including unsafe drug residues.<sup>2</sup>

If FDA finds that imported seafood products from particular firms or countries appear to violate FFDCA,<sup>3</sup> FDA may place the products, firms, or countries on an import alert.<sup>4</sup> An import alert informs FDA field staff and the public that the agency has enough evidence to detain products at U.S. ports of entry without physically examining them (known as detention without physical examination).<sup>5</sup> For example, if routine FDA sampling at ports of entry detects drug residues in an imported seafood product at levels above acceptable limits, the agency can place the product and the

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<sup>1</sup>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. Such inspections generally include (1) physical examination of the catfish and (2) collecting samples from a subset of those examined to test for the presence of unsafe drug residues or other contaminants. NOAA's National Marine Fisheries Service provides fee-for-service inspection services, upon request, to the seafood industry through its Seafood Inspection Program. Among other things, this program certifies that seafood firms comply with FDA's HACCP requirements and other federal food safety standards. Some retailers request this certification as a condition for purchasing seafood products.

<sup>2</sup>Port-of-entry examinations may include physical inspection (e.g., appearance and smell) of the seafood; review of labels; or sampling and testing to detect contaminants, such as drug residues.

<sup>3</sup>According to FDA's *Regulatory Procedures Manual*, Section 801 of FFDCA explicitly authorizes FDA to refuse admission of articles that appear to violate the act. For example, according to the manual, information other than the results of examination of samples, such as an article's violative history, among other things, may cause an article to appear to violate FFDCA. The manual provides internal procedures to be used by FDA employees.

<sup>4</sup>FDA's *Regulatory Procedures Manual* calls the process for using import alerts, "detention without physical examination". According to FDA documents, import alerts are a key tool for ensuring the safety of import seafood by, among other things, placing the responsibility back on the importer to ensure that the products being imported into the United States comply with federal laws and FDA regulations.

<sup>5</sup>FDA has established import alerts for a range of products it oversees, including food, cosmetics, and human drugs. This report focuses on import alerts for seafood.

foreign firm that processed the product on an existing import alert established for similar problems.<sup>6</sup>

Products that are detained because of import alerts may ultimately be refused entry into the United States, in which case they must be exported to another country or destroyed. Alternatively, if the products are brought into compliance, they will be allowed to enter U.S. commerce. FDA can allow food products on import alerts to enter U.S. commerce if the importer (1) proves that the individual shipment complies with FFDCA or (2) “reconditions” the shipment—for example, by relabeling the product or converting it into a type of product FDA does not regulate.<sup>7</sup> To show that the shipment complies with FFDCA, the importer must provide FDA with evidence, such as private laboratory reports, to show that the importer’s products do not violate federal laws and FDA regulations. Evidence of multiple compliant shipments from an importer—based on sampling of seafood products, inspections of foreign seafood processing facilities, or documentation provided by facilities of corrective actions taken—may lead FDA ultimately to decide to remove the firm and product from the import alert. According to FDA officials, the effective use of import alerts is key to FDA’s efforts to ensure that imported products under its jurisdiction, including seafood, are safe and wholesome for U.S. consumers.

The Department of Homeland Security’s (DHS) Customs and Border Protection (CBP) also plays a role regarding imported food, including seafood. CBP is responsible for collecting customs duties on imports,

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<sup>6</sup>According to FDA documents, the agency routinely collects samples of imported products and sends them to an FDA laboratory for analysis to determine if the products meet public health standards. FDA investigators are trained in sampling strategies and techniques to collect samples that are representative of the product being imported and that can support a final admissibility decision.

<sup>7</sup>Reconditioning is a process by which the importer of record, owner, or consignee may submit to FDA a written application requesting permission to bring into compliance any article deemed adulterated, misbranded, or in violation of FFDCA by relabeling or other action, or by rendering it other than a food, drug, device, or cosmetic.

including seafood, and seeks to prevent the evasion of customs duties.<sup>8</sup> In February 2009, we reported that CBP determined that Chinese shrimp were being illegally transshipped through Malaysia to the United States. Illegal transshipment is one scheme firms use to conceal the country of origin and thereby evade applicable duties or import alerts.<sup>9</sup> Because of this illegal transshipment, importers of Chinese shrimp were not only able to evade CBP's duty requirements but also FDA's 2007 import alert that covered Chinese shrimp, among other seafood products, because of the presence of unapproved drug residues.<sup>10</sup>

You asked us to review FDA's efforts to use import alerts to ensure the safety of imported seafood. This report (1) describes FDA's import alert process for seafood products, (2) examines FDA's oversight of key activities to support its import alert removal decisions, (3) examines the extent to which FDA coordinates with DHS to help ensure firms comply with seafood import alerts, and (4) examines the extent to which FDA assesses the effectiveness of its seafood import alerts in achieving the agency's food safety mission.

To describe FDA's import alert process for seafood products, we reviewed FDA documents, including procedures governing the use of import alerts, which are documented in FDA's *Regulatory Procedures Manual* and its Office of Regulatory Affairs' (ORA) *ORA Laboratory Manual*. We also interviewed FDA officials to gain a further understanding of this process. To identify the number of active seafood import alerts, as

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<sup>8</sup>Goods imported into the United States may be subject to duties on the basis of their product type, value, and origin, among other things. CBP has a statutory responsibility to collect all revenue due the U.S. government, including antidumping and countervailing duties, resulting from the importation of goods into the United States. U.S. law authorizes the assessment of antidumping duties on products exported to the United States at unfairly low prices (i.e., dumped), and countervailing duties on products exported to the United States that are subsidized by foreign governments. CBP has specifically designated enforcement of these duties as a priority trade issue. See GAO, *Antidumping and Countervailing Duties: CBP Action Needed to Reduce Duty Processing Errors and Mitigate Nonpayment Risk*, [GAO-16-542](#) (Washington, D.C.: July 14, 2016).

<sup>9</sup>For this report, we define "illegal transshipment" as firms shipping products en route to the United States through a third country to avoid import duties or import alerts by labeling the product's country of origin as the third country. See GAO, *Seafood Fraud: FDA Program Changes and Better Collaboration among Key Federal Agencies Could Improve Detection and Prevention*, [GAO-09-258](#) (Washington, D.C.: Feb. 19, 2009).

<sup>10</sup>In April 2016, FDA issued a separate import alert covering shrimp and prawns from Peninsular Malaysia, partly because of the presence of unapproved drug residues.



of July 3, 2018,<sup>11</sup> and the number of firms and countries affected by them, we reviewed information that FDA posted on its website on seafood import alerts and data that FDA maintained on these alerts from October 1, 2011, through July 3, 2018—the most recent available data at the time of our analysis.<sup>12</sup> FDA provided these data from its Compliance Management System (CMS).<sup>13</sup> To assess the reliability of FDA’s data, we reviewed documentation for CMS, conducted electronic or manual testing, and interviewed agency officials regarding controls, among other things. We found these data to be sufficiently reliable for the purposes of our reporting objectives.

To examine FDA’s oversight of key activities (i.e., sampling and inspection activities) to support its import alert removal decisions, we reviewed FDA procedures governing the use of import alerts; information that FDA posted on its website on seafood import alerts; and data from CMS that FDA maintained on these alerts, including removal data, from October 1, 2011, through July 3, 2018. We also analyzed FDA sampling data from the agency’s Field Accomplishment and Compliance Tracking System (FACTS) and Operational and Administrative System for Import Support (OASIS)<sup>14</sup> from October 1, 2010, through August 10, 2018, and FDA inspection data from FACTS from October 1, 2010, through June 22,

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<sup>11</sup>FDA downloaded the Compliance Management System import alert data that it provided to us on July 3, 2018.

<sup>12</sup>This report is, in part, a follow-up to our 2011 report. See GAO, *Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources*, [GAO-1-286](#) (Washington, D.C.: Apr. 14, 2011). We selected October 1, 2011, as the start date to include in our analysis FDA data from fiscal year 2012 onward.

<sup>13</sup>CMS tracks all compliance actions, including import alerts that FDA has taken with regard to individual firms. Among other things, CMS includes information uniquely identifying affected firms and products, 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 import alert placement and removal decisions.

<sup>14</sup>FACTS contains information on firms and products that FDA regulates, foreign and domestic establishments that ORA inspects, the type of inspection conducted, the outcome of those inspections, sample collections, and sample analytical results, among other things. OASIS is an electronic import database that, for example, provides support for examination or sample collection during the import process.

2018.<sup>15</sup> To assess the reliability of FDA's data, we reviewed documentation for the systems that house these data, conducted electronic or manual testing, and interviewed agency officials regarding controls, among other things. We found these FDA data to be sufficiently reliable for the purposes of our reporting objectives. We compared FDA's oversight of key activities to support removal decisions with standards for internal control in the federal government,<sup>16</sup> and we compared the import alert, sampling, and inspections data with the audit goals, requirements, or general guidelines related to such activities that are specified in FDA's procedures.<sup>17</sup>

We selected a nongeneralizable sample of seven seafood import alerts for more in-depth review. We selected these seven import alerts to (1) illustrate a range of violations of FFDCA—such as the presence of drug residues, pathogens, and insanitary conditions—that led FDA to place products or firms on import alerts, (2) include import alerts that address violations for which sampling or inspections were not specifically required but would be reasonably expected prior to removal decisions, according to FDA's procedures (e.g., HACCP violations or drug residue violations), and (3) include import alerts that specifically require sampling or inspections prior to such removal. Using CMS data, we identified the firms and products that FDA removed from any of the seven seafood import alerts we selected. We then used sampling and inspection data from FACTS and OASIS to identify any sampling FDA conducted within 1 year before the removal decisions and any inspections within 6 months before

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<sup>15</sup>We requested CMS import alert data from FDA covering fiscal years 2012 through the date that FDA downloaded the data in fiscal year 2018. We also requested sampling and inspection data covering fiscal years 2011 through the date that FDA downloaded the data in fiscal year 2018 to allow us to examine sampling and inspections that occurred before FDA removal decisions in fiscal year 2012. FDA officials downloaded the requested data on different dates in fiscal year 2018, which accounts for some variation in the periods covered.

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

<sup>17</sup>FDA officials use these general guidelines in deciding whether sampling or inspection activities would be expected in order to support import alert decisions.

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those decisions.<sup>18</sup> In addition, we identified any sampling or inspections FDA conducted within 1 year after the decisions.<sup>19</sup> We also interviewed FDA officials about how the agency ensures that it is conducting the appropriate level of sampling and inspections to support its removal decisions and have confidence that seafood firms removed from import alerts continue to comply with FFDCa.

To examine the extent to which FDA coordinates with DHS to help ensure compliance with seafood import alerts, we reviewed FDA's efforts to coordinate with DHS's CBP to identify potential schemes to evade import alerts, such as through illegal transshipment. Further, we reviewed a prior GAO report related to FDA's coordination with DHS on the issue of evasion.<sup>20</sup> In addition, we interviewed officials from both agencies about their coordination efforts related to identifying potential seafood import alert evasion.

To examine the extent to which FDA assesses the effectiveness of its seafood import alerts in achieving FDA's food safety mission, we reviewed the *FDA Strategy for the Safety of Imported Food* and agency documentation describing FDA's Import Alert Effectiveness Program. We compared FDA's strategy and documentation with leading practices we have identified in our past work for assessing the effectiveness of

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<sup>18</sup>FDA procedures do not specify how soon before a removal decision sampling or inspections should occur. We selected a 1-year time frame for sampling before a removal because in a 2010 report, HHS's Office of Inspector General determined, based on its work, that a year is a reasonable amount of time for FDA to assess whether the facilities had promptly and adequately addressed violations. See Department of Health and Human Services, Office of Inspector General, *FDA Inspections of Domestic Food Facilities*, OEI-02-08-00080 (Washington, D.C.: Apr. 2010). We selected a 6-month time frame for inspections before a removal because it is consistent with the time frame in an FDA directive, 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. See Food and Drug Administration, *Field Management Directive – Establishment Inspection Report Conclusions and Decisions*, FMD# 86 (Silver Spring, Md: Dec. 29, 2011). In addition, any inspections conducted more than 6 months prior to a removal decision may not reflect the actual conditions of the facility at the time of the removal.

<sup>19</sup>FDA procedures do not specify how soon after a removal decision sampling or inspections should occur. We selected a 1-year time frame for sampling or inspections after a removal because, as discussed above, it is consistent with the time frame selected in an HHS Office of Inspector General report, which determined that a year is a reasonable amount of time for FDA to assess whether facilities addressed violations (OEI-02-08-00080).

<sup>20</sup>[GAO-09-258](#).

programs. For example, we have previously reported that requirements of the Government Performance and Results Act of 1993 (GPRA), as updated by the GPRA Modernization Act of 2010 (GPRAMA),<sup>21</sup> such as performance goals and performance measures, which apply at the departmental or agency level, can serve as leading practices for planning at lower levels, such as component agencies, offices, programs, and projects, within federal agencies.<sup>22</sup> We also interviewed FDA officials to obtain their views on FDA's efforts to assess the effectiveness of seafood import alerts.

We conducted this performance audit from October 2017 to November 2019 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.

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## Background

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### Purposes and Scope of Import Alerts

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According to FDA documents and officials, import alerts serve several purposes, including the following:

- Prevent products that appear to violate FFDCAs from being distributed in the United States.
- Free up agency resources to examine other shipments by automatically detaining shipments on import alerts on a case-by-case basis without examining them.

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<sup>21</sup>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.

<sup>22</sup>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).

- Place the responsibility on the importer to ensure that the products being imported into the United States comply with federal laws and FDA regulations.

Import alerts may apply to (1) one or more products produced by all firms in a specific geographic area, (2) one or more products produced or shipped by a specific firm, or (3) a specific product because of concerns about the product regardless of what firm produces it or where. Import alerts covering a specific geographical area may apply to an area within a country, to one or more entire countries, or worldwide.<sup>23</sup> For example, FDA established an import alert covering all firms processing shrimp in India because of the presence of filth, decomposition, and *Salmonella*.

For import alerts that apply to geographical areas, all firms in the area that produce the products specified in an import alert are initially placed on that alert, and the specified products are subject to detention without physical examination. If a firm presents evidence establishing that the conditions that gave rise to the appearance of the violation associated with the alert have been resolved and the agency has confidence that future entries will comply with FFDCA, FDA indicates that the firm may be removed from the alert by placing it on a “green list” that FDA creates for the alert. For import alerts that apply to products that a specific firm produces, FDA individually determines—for example, through testing or examination—whether a firm and its products are potentially violative and may be identified for potential detention without physical examination. If so, FDA places them on a “red list” that it creates for the alert.<sup>24</sup> Import alerts that apply to a specific product of concern generally have neither a red list nor a green list because such products cannot be removed from the alerts. 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 FFDCA or can be reconditioned to be brought into compliance with the act.

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<sup>23</sup>According to FDA documentation, FDA applies a geographic-specific import alert worldwide if no non-violative geographical areas can be identified.

<sup>24</sup>Some import alerts combine a focus on specific geographical areas and on specific firms and thus have both green lists and red lists. FDA also may create yellow lists for firms, products, or countries subject to intensified surveillance or for firms that may have satisfied concerns FDA raised about food manufacturing processes but where the nature of violations may warrant further field examinations of individual entries or additional analyses before a shipment can be released.

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## Federal Agency Roles in Overseeing Seafood Imports

DHS, through CBP, is charged with facilitating international trade at the ports-of-entry for seafood and other imports, while FDA examines or inspects certain seafood imports.

### CBP

CBP is responsible for, among other things, collecting the duties, taxes, and fees assessed on products, including seafood, and managing the import process.<sup>25</sup> CBP collects import entry data through its Automated Commercial Environment/International Trade Data System. These entry data are submitted by a filer (typically, the product importer or a broker) and include a description of the product, manufacturer information, and the country of origin.

### FDA

Generally, FDA electronically receives notification from CBP of all entries of products under FDA jurisdiction at ports of entry through the CBP system described above, which links to FDA's OASIS. Once entry information is received in OASIS, FDA uses its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) screening tool to evaluate each entry line.<sup>26</sup> PREDICT is a computerized tool designed to estimate the risk of imports using information such as the history of the importer or processing facility, inspection history, and country of origin. FDA staff use these risk estimates to target for examination shipments with high levels of risk.<sup>27</sup> FDA cannot physically examine every shipment of such products, owing in part to the volume of imported products; we previously reported that the agency examines

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<sup>25</sup>CBP has identified ensuring the safety of imported products as a priority trade issue. CBP designed this trade issue to ensure that unsafe products do not enter U.S. commerce; it ensures this by working collaboratively and collectively with partner government agencies, among other groups.

<sup>26</sup>An entry line is a portion of an import shipment that is listed as a separate line item on an entry document. See GAO, *Imported Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible*, [GAO-16-399](#) (Washington, D.C.: May 26, 2016).

<sup>27</sup>For more detailed information on PREDICT, see [GAO-16-399](#).

about 1 percent of entry lines annually.<sup>28</sup> FDA uses PREDICT to electronically screen all imported food shipment information filed electronically to determine which imports to physically examine at the border. PREDICT uses a variety of data and analyzes data by applying rules—conditional statements that tell PREDICT how to react when encountering particular information—to generate risk scores for imported food.

The electronic screening process consists of two phases:

- **Prior notice screening** is intended to protect against potential terrorist acts and other public health emergencies. Prior notice screening requires that an importer, broker, or other entity submit information to FDA on food being imported or offered for import into the United States before that food arrives at the port of entry. FDA targets, screens, and reviews the information to ensure that the information meets the prior notice requirements and to determine whether the food potentially poses a terrorism threat or other significant health risk.
- **Admissibility screening** is intended to ensure that the food is admissible under FFDCA. As part of admissibility screening, FDA electronically screens entry lines using PREDICT to determine, among other things, whether the product on the entry line is on an import alert. If the product on an entry line is on an import alert, then the entry line may be detained without physical examination. If the product is not on an import alert, then the entry line goes through the typical admissibility screening process through which FDA uses PREDICT to calculate a risk score and determine whether the entry line is identified for potential examination or sampling.<sup>29</sup>

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<sup>28</sup>According to FDA, this examination rate is based on fiscal year 2018 data and can fluctuate depending on agency resources and priorities.

<sup>29</sup>[GAO-16-399](#).

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## Under Its Import Alert Process for Seafood Products, FDA Detains Affected Products and Removes Firms and Products from Alerts When Violations Are Resolved

Our review of FDA's *Regulatory Procedures Manual* found that FDA's import alert process for seafood products includes three key components: (1) establishing new import alerts to respond to human health risks, (2) placing firms and products on new or existing import alerts (placement decisions), and (3) removing firms and products from existing import alerts when violations are resolved (removal decisions).

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### FDA Establishes New Seafood Import Alerts to Respond to Human Health Hazards

According to FDA's *Regulatory Procedures Manual*, FDA establishes new seafood import alerts to respond to human health hazards.<sup>30</sup> FDA officials may recommend new import alerts for a variety of reasons, including the following:

- FDA officials detain one or more products for a violation of FFDCA that poses a significant health hazard (e.g., the presence of *Salmonella*);
- FDA officials notice a large number of violations affecting firms or products from a specific country or area (e.g., the presence of filth in canned crabmeat from Thailand);
- FDA enforces regulatory requirements affecting importers that the agency decides could be implemented, in part, through the use of an import alert (e.g., HACCP requirements); or
- FDA addresses concerns about the safety of specific products, including puffer fish, which contain a deadly neurotoxin, or products produced in geographic areas with known contamination, such as

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<sup>30</sup>Potential hazards associated with fresh and farmed seafood include drug residues, pathogens, parasites, decomposition, chemical contaminants, and pesticides. GAO, *Imported Seafood Safety: FDA and USDA Could Strengthen Efforts to Prevent Unsafe Drug Residues*, [GAO-17-443](#) (Washington, D.C.: Sept. 15, 2017).



those from areas surrounding Fukushima, Japan, which are at risk of radionuclide contamination.<sup>31</sup>

FDA officials in the field or at headquarters may recommend new import alerts. FDA's Division of Import Operations reviews the recommendations and decides whether to approve them (called the clearance process). After approval, according to FDA officials, FDA revises its screening process at the ports of entry via PREDICT to screen for products, firms, or countries on the new alert.

According to FDA's import alert data, as of July 3, 2018, FDA had 52 active import alerts affecting imported seafood that addressed a wide range of seafood products and violations of FFDCa.<sup>32</sup> The range of violations that these alerts address included

- misbranded seafood;
- the presence of foodborne pathogens, such as *Salmonella* and *E. coli*;
- the presence of unapproved animal drug residues, such as chloramphenicol and nitrofurans;<sup>33</sup>
- the presence of pesticide chemical residues that are not allowed or do not meet tolerance levels, such as diuron;<sup>34</sup>
- the presence of decomposition or insect, rodent, or other filth;

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<sup>31</sup>After a 9.0 magnitude earthquake and subsequent tsunami in March 2011 extensively damaged the Fukushima Daiichi nuclear power plant, concerns arose as to whether seafood products from the surrounding area could affect human health.

<sup>32</sup>During the time period of import alert data we reviewed—October 1, 2011, through July 3, 2018—FDA created six new import alerts and retired eight. One import alert, 16-128: "Misbranded Catfish," was retired after responsibility for the regulation of imported catfish was transferred to the U.S. Department of Agriculture's Food Safety and Inspection Service in 2016. The 2008 Farm Bill assigned regulatory responsibility for the inspection of catfish to the U.S. Department of Agriculture once the agency issued final regulations for a mandatory catfish inspection program. The department's Food Safety and Inspection Service finalized regulations in December 2015 and assumed responsibility for inspecting catfish.

<sup>33</sup>According to HHS's National Toxicology Program, chloramphenicol was first listed as a reasonably anticipated human carcinogen in the *Tenth Report on Carcinogens* in 2002 based on limited evidence of carcinogenicity from studies in humans. In April 2011, we reported that nitrofurans are specifically not allowed for use in seafood, among other foods, by the United States because they have been shown to have a carcinogenic effect after prolonged exposure. See [GAO-11-286](#).

<sup>34</sup>Diuron is an algaecide in commercial fish production, residential ponds, and aquariums.

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- the presence of illegal or undeclared colors, undeclared food additives, such as high fructose corn syrup, or undeclared food allergens, such as milk;
  - the failure of the firm to meet HACCP requirements; and
  - the failure of the firm to operate in conformity with current good manufacturing practices.<sup>35</sup>

According to FDA's import alert data, overall, from October 1, 2011, through July 3, 2018, the 52 import alerts for imported seafood affected a total of 3,765 unique firms in 111 countries. (See app. I for information describing these 52 alerts.)

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### FDA Places Certain Seafood Firms and Products on Existing Import Alerts and Detains Affected Products

According to FDA's *Regulatory Procedures Manual*, after an import alert has been established, FDA places certain seafood firms or products on the alert and may detain affected products at the port of entry to prevent them from entering U.S. commerce pending the importer of record's response.<sup>36</sup> The manual specifies that FDA may place firms or products on a new or existing import alert for the following violations of FFDC: (1) products are manufactured, processed, or packed under insanitary conditions; (2) products are forbidden or restricted for sale in the country in which they were produced or from which they were exported; or (3) products appear to be adulterated or misbranded based on information such as the product's history of violations, among other things.<sup>37</sup> Examples of adulteration may include pathogens, such as *Salmonella*, and residues of drugs or pesticides above accepted levels.

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<sup>35</sup>Current good manufacturing practices are regulations that FDA enforces for products that it regulates, including seafood, that describe the methods, equipment, facilities, and controls for producing processed food. According to FDA documents, as the minimum sanitary and processing requirements for producing safe and wholesome food, they are an important part of regulatory control over the safety of the nation's food supply. These practices also serve as one basis for FDA inspections.

<sup>36</sup>According to FDA documents, the importer of record is the person or firm that guarantees, by bond, proper custody and handling of the imported shipment in compliance with the laws governing such shipment.

<sup>37</sup>Food is deemed to be adulterated under FFDC if, among other things, it bears or contains any poisonous or deleterious substance which may render it injurious to health. Food is deemed misbranded if, among other things, its labeling is false or misleading in any particular.

FDA's *Regulatory Procedures Manual* also specifies the following types of evidence that FDA generally may rely on to show that violative conditions exist:

- one violative sample from FDA's examination of the product,<sup>38</sup> if the product may have adverse health consequences;
- information and historical data, such as a firm showing a pattern of exporting violative products, if evidence indicates the product could pose a health hazard;
- multiple violative samples, for violations (such as decomposition, filth, or labeling) that do not pose a significant public health hazard; and
- violations identified during inspections of importers or foreign processing facilities.

According to FDA officials, about 90 percent of the recommendations to place firms or products on an import alert result from FDA analysis of imported seafood samples that identified product violations, such as drug residues above acceptable levels. Officials stated that the remaining 10 percent of the recommendations arise from FDA inspections of importers or processing facilities that identify firm violations, such as violations of FFDCAs related to HACCP requirements.

According to FDA's *Regulatory Procedures Manual*, once a firm or product has been placed on an import alert, future shipments may be detained without physical examination, and the importer of record must decide how to respond. The importer of record receives a notice stating that the associated entry line is being detained and subject to refusal. The importer of record may request that FDA immediately refuse entry of the product, in which case the product must either be exported or destroyed. Alternatively, the importer of record may (1) submit evidence showing that the product does not appear to be violative<sup>39</sup> or (2) request to "recondition" the product—for example, relabel the product or convert the product into a type of product FDA does not regulate.

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<sup>38</sup>For example, the sample may show an actionable level of a pesticide residue or some other violation.

<sup>39</sup>Evidence (which FDA refers to as testimony) typically consists of the results of sample analyses that private laboratories hired by the owner or consignee perform showing that the product does not appear to be adulterated.

According to FDA's *Regulatory Procedures Manual*, FDA will hold a hearing to determine whether the detained product should be released. If FDA determines that the importer of record has provided sufficient information to overcome the appearance of a violation, the importer of record receives a notice stating that the product is released. If FDA determines that the importer of record's actions did not bring the product into compliance, the product would be refused and must be exported elsewhere or destroyed.

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### FDA May Remove Firms and Products from Existing Import Alerts When Violations Are Resolved

FDA may decide to remove a firm or product from an import alert if there is evidence that the conditions that led to placement on the alert have been resolved, according to FDA's *Regulatory Procedures Manual*.<sup>40</sup> Our review of the manual and interviews with FDA officials indicate that FDA sampling and inspections are key activities that support the agency's removal decisions. Generally, firms petition FDA to remove one or more products or the firms themselves from seafood import alerts,<sup>41</sup> and FDA's Division of Import Operations reviews the petitions. FDA's procedures specify the evidence that firms are to submit, which varies depending on the nature of the import alert and the violation of FFDCa.

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,<sup>42</sup> an on-site inspection of the importer

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<sup>40</sup>For some import alerts, products cannot be removed from the alert—for example, products such as puffer fish or products from contaminated areas.

<sup>41</sup>FDA officials also may initiate independent recommendations to remove firms and products without a petition, according to agency officials.

<sup>42</sup>These procedures apply specifically to products detained without physical examination because they appear to be adulterated, misbranded, or otherwise violative under FFDCa. FDA's procedures describe circumstances, such as firms with multiple products on an import alert, for which more than five nonviolative commercial shipments would be required.

or foreign processing facility,<sup>43</sup> or documentation showing that the cause of the violation has been fully corrected. For example, 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 following a reinspection that shows that corrective actions to resolve the violation have been taken. Private laboratories usually collect and analyze the samples used as evidence to indicate that a commercial shipment does not violate FFDCa and provide support for FDA's decisions to remove firms and products from import alerts. The procedures also call for the agency to have confidence that future shipments will comply with FFDCa, but they do not specify how FDA should ensure continued compliance. 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.

FDA's *Regulatory Procedures Manual*, as supplemented by the ORA *Laboratory Manual*, specifies that the agency should conduct checks to review whether the work performed by such laboratories can be used as an appropriate basis for FDA's removal decisions. These checks include the following:

- **Audit samples.** FDA's manuals specify the following two audit goals to ensure that the private laboratories' analyses that FDA uses to support its removal decisions are valid: (1) to audit samples from at least one of the five nonviolative entries, as determined by a private laboratory that the firm hired, to support a removal decision to ensure the validity of the laboratory's analysis and (2) to audit at least 10 percent of the work that a private laboratory performed to ensure that

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<sup>43</sup>For products that appear to be violative under FFDCa and are detained because they appear to be manufactured, processed, or packed under insanitary conditions or forbidden or restricted in sale in the country in which they were produced or from which they were exported, FDA's procedures specify that analysis of samples from representative shipments will generally not be sufficient to overcome the appearance of the violation and warrant removal from the import alert. An inspection of the importer or foreign processing facility or other appropriate action may be required. According to FDA documents, inspections should focus on the implementation of the HACCP program for those targeted products. They are also to include a review of monitoring, corrective action, and sanitation monitoring records. FDA may also conduct inspections to verify that corrective actions have been implemented.

the laboratory submits scientifically sound data.<sup>44</sup> In the course of its audits, FDA is to collect samples, called audit samples, to verify analytical results from a private laboratory that demonstrates a product complies with FFDCA. According to FDA, private laboratory analyses are a critical element in public health protection because they support FDA decisions to release detained goods.<sup>45</sup> FDA's collection of audit samples is intended to provide confidence in the laboratories' analytical results.

- **On-site assessments.** FDA's *ORA Laboratory Manual* states that, at times, FDA visits a private laboratory to ascertain that it has the capability or capacity to perform analyses that FDA often relies on to support removal decisions. The manual also states that on-site assessments provide the opportunity to observe that equipment and standards, among other things, needed to conduct the proposed analyses are present and in good order; to review the adequacy of the laboratory's quality assurance and record-keeping programs; and to observe the techniques and practices of the analysts. Furthermore, the manual states that the on-site assessments are voluntary and that a private laboratory may decline to participate.<sup>46</sup>

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<sup>44</sup>FDA's *Regulatory Procedures Manual*, as supplemented by the *ORA Laboratory Manual*, specifies the first goal, and the laboratory manual specifies the second goal. The *ORA Laboratory Manual* does not specify a time period over which FDA should audit the work that a private laboratory performed.

<sup>45</sup>Food and Drug Administration, *Poor Private Sample Collection Practices Undermine Confidence in Non-FDA Analytical Results Submitted during the Importation Process: Audit Samples* (Jan. 17, 2014).

<sup>46</sup>According to FDA officials, the FDA Food Safety Modernization Act directed FDA to establish a program for laboratory accreditation bodies that meet FDA quality standards. Accredited laboratories under the program could include private laboratories and laboratories run and operated by a federal agency, state, or locality. According to FDA officials, the results of testing conducted under the program could be used to help FDA make general admissibility decisions and also specifically to support removal of products under an import alert that requires successful consecutive tests. FDA officials also said that this program could achieve the same purpose as on-site assessments.

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## FDA's Oversight of Key Activities to Support Import Alert Removal Decisions Is Limited

FDA has established audit goals, requirements, and expectations related to sampling and inspections—key activities to support import alert removal decisions—but does not monitor the extent to which it is meeting them.

In our review of FDA's CMS data for 274 removal decisions from a nongeneralizable selection of seven import alerts from October 1, 2011, through July 3, 2018, we found that FDA conducted audit sampling and inspections to support removal decisions and subsequent sampling and inspections to ensure continued compliance for a small percentage of the decisions.<sup>47</sup> Specifically:

- **Audit samples prior to removal decisions.** For almost all of the 274 removal decisions we reviewed, FDA did not meet its first audit goal—to audit samples from at least one of the nonviolative shipments used to support a removal decision to ensure the validity of the analysis of the private laboratory hired by the firm. All seven of the import alerts we reviewed were established for violations of FFDCAs for which FDA's *Regulatory Procedures Manual* specifies that firms should enter into U.S. commerce at least five consecutive nonviolative commercial shipments, as determined by a private laboratory hired by the firm, before FDA may consider a removal. Therefore, FDA should have audited samples from at least one nonviolative shipment for all 274 removal decisions related to these seven import alerts. As described earlier, FDA collects audit samples from shipments of imported seafood to conduct such audits. However, we found that FDA did not conduct any sampling, including audit sampling, within 1 year prior to removal for 260 (or 95 percent) of the 274 removal decisions we reviewed.<sup>48</sup> FDA officials told us that they do not monitor the extent to which the agency is meeting its audit goal, such as through analyzing CMS sampling data across all firms and products

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<sup>47</sup>An individual import alert could cover multiple firms and products, each of which could lead to separate removal decisions.

<sup>48</sup>According to FDA officials, in the sample data they provided us, they did not differentiate audit samples from other samples the agency collects. However, we concluded that if FDA conducted no sampling at all prior to a removal, no audit samples were collected.

affected by the alerts and therefore were not aware that the agency had not met the audit goal.

Conversely, FDA officials told us that they were aware that the agency historically had not met its second audit goal specified in its procedures—to audit at least 10 percent of each private laboratory’s work to support removal decisions to ensure that each laboratory submits scientifically sound data. While FDA does not regularly monitor whether it is meeting its 10 percent audit goal, in 2014, the agency analyzed data on the audit samples it collected during its audits of shipments covering fiscal years 2003 through 2013. FDA conducted this analysis in response to concerns that district staff raised about the quality of the analyses performed by private laboratories for one of its districts.<sup>49</sup> These concerns included the following:

- Failure to obtain representative samples from throughout a shipment.
- Failure to obtain samples randomly from throughout the shipment.
- Failure to ensure an unbroken chain of custody from the site of collection of a sample to the private laboratory as necessary to ensure the integrity of the sample.
- Use of untrained temporary employees to collect samples and representing these individuals as employees of the private laboratory.

FDA’s 2014 analysis showed that the agency did not achieve its 10 percent audit goal during the 11-year period.<sup>50</sup> According to the analysis, FDA audited about 1 to 2 percent of work performed by private laboratories to support removal decisions.

In response to our request, FDA updated its analysis through fiscal year 2018. The updated analysis shows that this percentage has improved in recent years, with FDA auditing about 3 percent of the work that private laboratories performed for fiscal year 2018. However, this level of auditing remains far below the goal of at least

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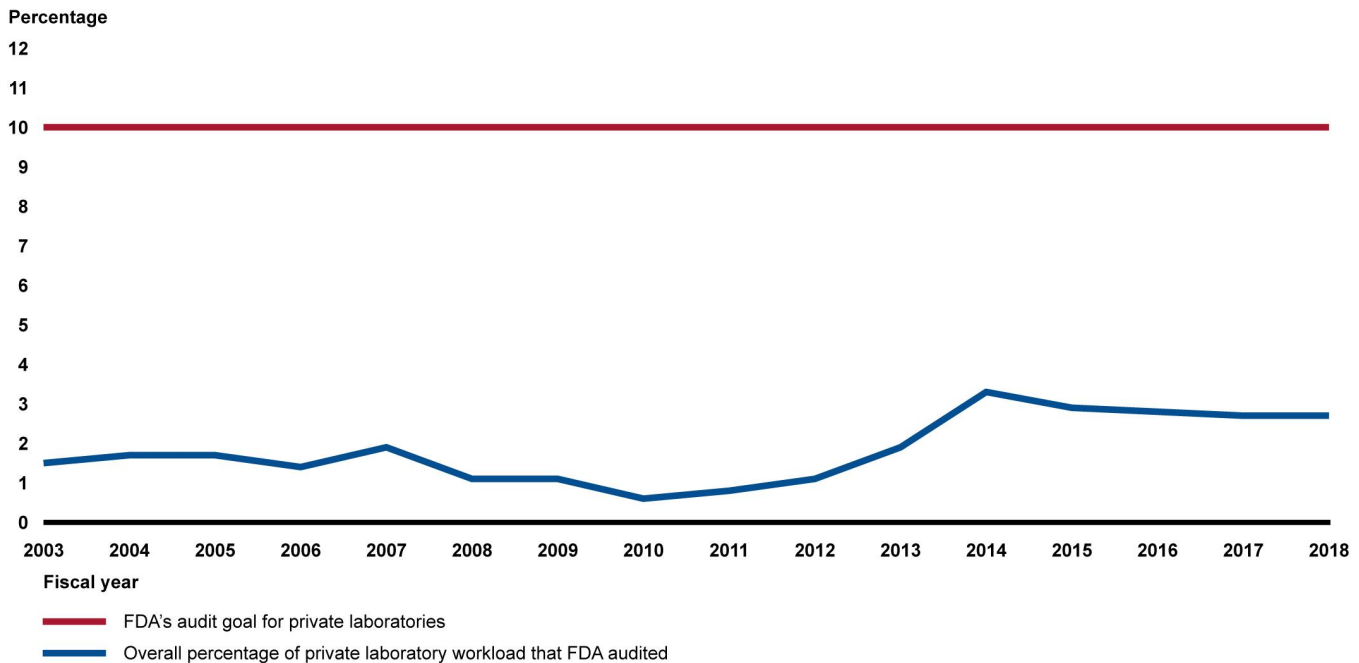
<sup>49</sup>Food and Drug Administration, *Poor Private Sample Collection Practices Undermine Confidence in Non-FDA Analytical Results Submitted during the Importation Process: Audit Samples* (Jan. 17, 2014).

<sup>50</sup>FDA divided the total number of lines of entry at U.S. ports subjected to FDA audit samples collected during its audits by the total number of lines of entry sampled by private laboratories to support removal decisions to determine the percentage of work that FDA audited across all private laboratories.



10 percent, as shown in figure 1. According to FDA officials, the agency has not met this audit goal largely because it has limited resources.

**Figure 1: Percentage of Private Laboratory Work That the Food and Drug Administration (FDA) Audited, Fiscal Years 2003 through 2018**



Source: GAO presentation of Food and Drug Administration data. | GAO-20-62

Note: For a given fiscal year, FDA calculates the percentage of the private laboratory workload that it audited by dividing the total number of lines of entry at U.S. ports subjected to FDA audit samples by the total number of lines of entry sampled by private laboratories. These data include private laboratory samples of all imported products subjected to FDA audit samples, including imported seafood.

- **Inspections prior to removal decisions.** For the 274 removal decisions we reviewed, FDA conducted inspections of importers or foreign processing facilities for 28 (about 10 percent) of the removal decisions in the 6 months prior.<sup>51</sup> According to FDA's procedures,

<sup>51</sup>As noted earlier, we selected this 6-month time frame for inspections before a removal 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 removal decision may not reflect the actual conditions of the facility at the time of the removal.

firms or products placed on an import alert based on a violative facility inspection may generally be removed from the alert following a reinspection of the importer or foreign processing facility. In some instances, a firm may present information or documentation sufficient to demonstrate that appropriate corrections are in place to overcome the appearance of a violation and, with appropriate concurrence, may be removed from the import alert. FDA officials added that, regardless of the basis for placement on an import alert, FDA could require an on-site inspection prior to removal, depending on the hazard the violation posed. For example, certain violations may result in a finding of “official action indicated” (OAI), which indicates that an establishment failed to meet regulatory or administrative requirements and may pose a hazard to public health. FDA’s Field Management Directive 86 establishes a goal for FDA staff to conduct a follow-up inspection within 6 months after an OAI finding to verify that the facility has corrected violations. In our review of the 274 removal decisions, we found that for 32 firms that received an OAI inspection finding after FDA issued the directive in December 2011, FDA did not conduct a follow-up inspection for 31 of these firms before removing them from an import alert. According to FDA officials, the agency did not monitor whether its staff decided that inspections would be expected for the 274 removal decisions or whether the facilities that received an OAI inspection finding were reinspected. FDA officials told us that the agency relied on reviewing data on removal decisions individually to ensure that expected inspections had been conducted. Consequently, FDA was not aware of the extent to which the facilities associated with the removal decisions were actually inspected.

- **Sampling or inspections following removal decisions.** As shown in figure 2, for the 274 removal decisions we reviewed, FDA subsequently conducted sampling for 6 percent of the products at ports of entry and inspections for 13 percent of the importers or foreign processing facilities within 1 year after removal.<sup>52</sup> FDA does not have a goal for the amount of sampling or inspections that should be conducted following removal decisions; however, as described above, FDA’s procedures call for the agency to base removal

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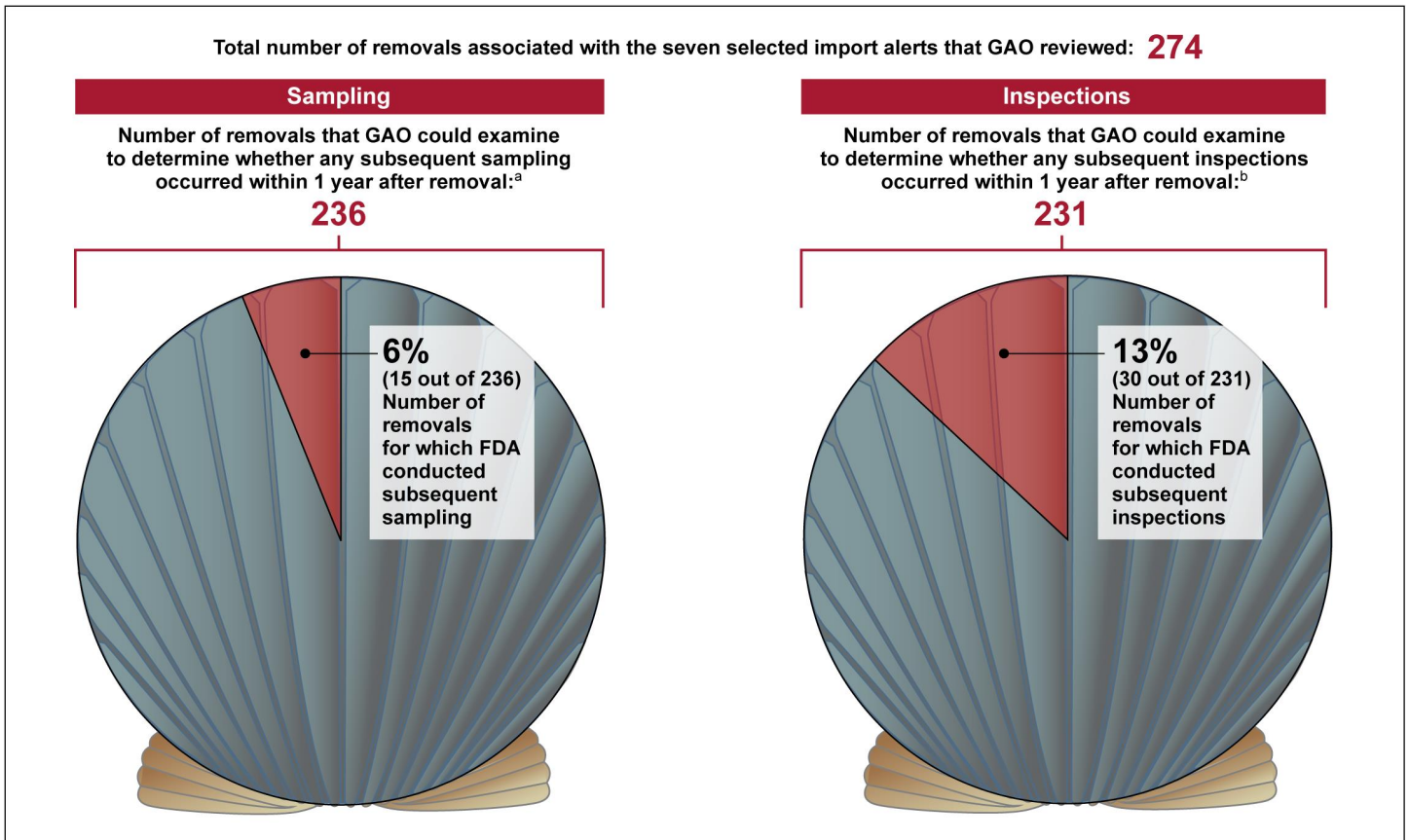
<sup>52</sup>For the sampling and inspections analyses, 236 and 231 removal decisions, respectively, had sufficient time after the removal for us to analyze whether subsequent sampling or inspections had been conducted within 1 year after removal. The 1-year time frame yielded different numbers of removal decisions that we could include in the analysis because FDA downloaded the sampling and inspection data that it provided to us on different days. FDA downloaded the sampling data on August 10, 2018, and the inspection data on June 22, 2018.

decisions on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and that the agency has confidence that future shipments will comply with FFDC. FDA officials said that when the agency does not inspect a facility and relies on documentation describing the actions the firm has taken to address the appearance of a violation to support a removal decision, the agency relies on subsequent sampling and inspections to have confidence in continued compliance. According to FDA, the past violative history of a firm is reflected in the PREDICT screening rules for the examination of future shipments and in the process of prioritizing inspections of foreign facilities. It was unclear from the CMS data that FDA provided the extent to which the agency relied on documentation to support the remainder of its removal decisions. However, based on FDA officials' statements about subsequent sampling or inspections, we would expect to see a larger percentage of products sampled and firms inspected after their removal from import alerts for FDA to have confidence in continued compliance given the low percentage of inspections we found before removal decisions.<sup>53</sup> FDA officials said they were not monitoring whether staff decided that subsequent sampling and inspections would be expected for these removals, and staff do not continuously monitor post-removal activities. Consequently, FDA officials were not aware of the extent to which the products and foreign processing facilities associated with removal decisions were subsequently sampled and inspected.

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<sup>53</sup>As noted earlier, for the 274 removal decisions we reviewed, FDA conducted inspections on about 10 percent of them in the 6 months prior to the removal decisions.

**Figure 2: Number and Percentage of Removals GAO Reviewed for Which the Food and Drug Administration (FDA) Conducted Subsequent Sampling or Inspections**



Source: GAO review of Food and Drug Administration data. | GAO-20-62

Note: For this analysis, we identified 274 firms that FDA removed from the seven selected seafood import alerts during October 1, 2011, through July 3, 2018. We identified any sampling FDA conducted within 1 year before the removal decisions or any inspections within 6 months before the removal decisions to support those decisions and any subsequent sampling or inspections FDA conducted within 1 year after the removal decisions. We reviewed sampling data for October 1, 2010, through August 10, 2018, and inspection data for October 1, 2010, through June 22, 2018. According to FDA, it is possible that a firm ceased operating or ceased producing the product affected by the relevant import alert within 1 year after the removal decision.

<sup>a</sup>For us to examine removals for subsequent sampling, a removal had to occur on or before August 10, 2017—at least 1 year prior to the end date of sample data that FDA provided. Of the 274 removals we reviewed, 236 (86 percent) occurred on or before this time frame.

<sup>b</sup>For us to examine removals for subsequent inspections, a removal had to occur on or before June 22, 2017—at least 1 year prior to the end date of inspection data that FDA provided. Of the 274 removals we reviewed, 231 (84 percent) occurred on or before this time frame.

FDA officials told us that they were generally aware that FDA had conducted limited sampling and inspections to support removal decisions and have confidence in continued compliance. They attributed this limited sampling and inspections to their belief that many import alert removal decisions can be supported by reviewing documentary evidence that FDA requested and the firms provided that describes the actions the firms have taken to address the appearance of a violation. According to FDA officials, such reliance on firm-provided documentation to support removal decisions is, in part, how FDA prioritizes its use of limited laboratory and inspection resources.

FDA officials stated that the agency can check the basis of its removal decisions by looking up individual import alert cases in CMS and the agency's sampling and inspection data in FACTS and OASIS 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. These officials said that they believed that checking the data on the basis of removal decisions individually and when questions arise from sources internal or external to FDA, instead of regularly analyzing sampling and inspections data, was sufficient to ensure the appropriate level of oversight. However, as discussed above, this approach has not informed them of the extent to which the agency is meeting its audit goals and expectations.

Standards for internal control in the federal government state that management should design control activities to achieve objectives and respond to risks.<sup>54</sup> An example of such control activities includes management comparing actual performance with planned or expected results. Such a comparison could include FDA comparing audits conducted with its audit goal (e.g., auditing at least 10 percent of a private laboratory's work) to ensure that its goal was met. Monitoring the extent to which the agency is meeting its audit goals and expectations for conducting sampling and inspections to support its import alert decisions would enhance its oversight of these activities to better protect U.S. consumers from imported seafood that is not safe and wholesome.

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<sup>54</sup>[GAO-14-704G](#)

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## FDA Generally Has Not Coordinated with DHS to Help Ensure Firms Comply with Seafood Import Alerts

FDA and DHS have established a mechanism for coordinating the use of certain resources, but they generally have not coordinated to help ensure that firms comply with seafood import alerts by identifying potential instances of evasion of alerts, according to agency officials.<sup>55</sup> FDA officials stated that the agency can coordinate with CBP in situations that could involve evasion of import alerts, but the agency does not have a formal mechanism for regularly and proactively coordinating to identify evasion. FDA officials said that such coordination could include CBP sharing information that could help FDA identify instances of evasion.

As previously noted, CBP is responsible for collecting customs duties on imports, including seafood, and seeks to prevent the evasion of customs duties. As we reported in 2012, CBP personnel are to analyze trends in import data, among other things, to look for anomalies that may indicate evasion and also follow up on allegations from external sources. Once CBP identifies a potential instance of evasion, it can use a variety of techniques at different points in the import process to determine whether evasion is actually occurring. These techniques include collecting samples from shipments of products at U.S. ports of entry and conducting laboratory analyses of these samples to identify their true country of origin.<sup>56</sup> Through its efforts, CBP has identified illegal transshipments—a scheme to conceal the country of origin and thereby evade applicable duties or FDA’s import alerts. For example, CBP reported that in 2016, customs officers seized about 42 tons of Chinese honey that had been transshipped through Taiwan to evade U.S. duties applicable to Chinese honey. According to FDA documents, at the same time, FDA had an import alert for honey because of unsafe drug residues. This alert included Chinese firms, but did not include any firms from Taiwan.

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<sup>55</sup>In this report, we use “evasion” of alerts to refer to any activity whereby companies improperly attempt to avoid the restrictions of the import alert.

<sup>56</sup>See GAO, *Antidumping and Countervailing Duties: Management Enhancements Needed to Improve Efforts to Detect and Deter Duty Evasion*, [GAO-12-551](#) (Washington, D.C.: May 17, 2012). CBP officials that we interviewed indicated that the process described in this report was still in effect in 2019. These officials stated that they did not want to disclose the precise techniques they would use to identify potential evasion.

In February 2009, we reported on CBP’s expertise in detecting illegal transshipment that could enhance FDA’s ability to detect import alert evasion. We stated that FDA and CBP could work together to help ensure that importers were not attempting to evade duties or import alerts. However, we found that the agencies had not identified ways to maximize and leverage their resources or established processes and policies for working together systematically across agency lines. We recommended, among other things, that FDA and CBP develop mechanisms to share information related to the evasion of import alerts.<sup>57</sup> FDA and CBP agreed with our recommendation, but as of July 2019, the agencies had not fully implemented it.

Specifically, FDA and CBP signed a memorandum of understanding (MOU), effective May 2013, to set forth terms for CBP to coordinate with FDA on staffing, space, and equipment requirements for the National Targeting Center. However, the MOU does not address CBP sharing information on potential evasion of import alerts with FDA regularly or the agencies working proactively to identify such evasion.<sup>58</sup> According to CBP officials, FDA and CBP do not coordinate specifically on targeting to detect evasion, but CBP would be willing to coordinate with FDA and provide any applicable expertise in this area.

While a collaborative mechanism such as an MOU is not needed to share information, we continue to believe that FDA and CBP should develop a mechanism to help the agencies formally coordinate to identify potential evasion of seafood import alerts. Until these agencies develop such a mechanism, they may be missing opportunities to share information regularly that could benefit each agency’s efforts to detect illegal transshipment and help FDA proactively identify and prevent evasion of seafood import alerts.

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<sup>57</sup>[GAO-09-258](#).

<sup>58</sup>At another CBP facility, known as the Commercial Targeting and Analysis Center, because of FDA’s proximity to CBP staff—irrespective of the MOU for the National Targeting Center—FDA may request access to CBP entry declaration information not otherwise available to FDA, such as information on the volume of the imported seafood products, according to FDA officials. According to our previous work, the Commercial Targeting and Analysis Center facilitates information sharing among partner government agencies on targeting and enforcement at all stages of the import process—pre-entry, entry, and post-entry—focusing on a variety of issues, including import safety and environmental crime, natural resources, wildlife trafficking, and cultural property. GAO, *Customs and Border Protection: Improved Planning Needed to Strengthen Trade Enforcement*, [GAO-17-618](#) (Washington, D.C.: June 12, 2017).

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## FDA Has Not Assessed the Effectiveness of Its Seafood Import Alerts in Achieving Its Food Safety Mission

FDA has not assessed the effectiveness of its seafood import alerts in helping to achieve its food safety mission. Specifically, FDA has not established performance goals and measures for seafood import alerts—key elements of assessing the effectiveness of programs.<sup>59</sup> Performance goals explain the purpose of agency programs and the results—including outcomes—that they intend to achieve. Performance measures provide organizations with the ability to track the progress they are making toward their mission and goals and provide managers with information on which to base their organizational and management decisions. Under GPRAMA, agencies are required to develop long-term strategic plans and establish results-oriented goals in alignment with their missions and identify objectives and strategies needed to achieve those goals. GPRAMA also requires agencies to use performance information to assess their progress toward achieving their goals.<sup>60</sup>

According to FDA officials, the agency is implementing a program, which it refers to as an import alert effectiveness program, to review its import alerts. FDA documents note that the focus of this program includes (1) determining if FDA identified the firms on import alerts during its admissibility screening and took the appropriate action, (2) ensuring the accuracy of data FDA maintains in CMS on firms on import alerts, and (3) determining whether the reasons for the alerts are still relevant, and ensuring that the import alerts are accurately posted for clear communication to industry and FDA field staff. We commend FDA for these efforts. However, according to our review of FDA documents describing the activities planned for this program, the program does not include performance goals and measures for import alerts. FDA officials stated that this is because the program is new.

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<sup>59</sup>GAO-12-77.

<sup>60</sup>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 projects. See [GAO-18-174](#) and [GAO-12-77](#).



Additionally, in February 2019, FDA published a broad plan for the safety of imported food that includes a goal, objective, and strategy related to import alerts.<sup>61</sup> Under its goal to detect and refuse entry of unsafe foods at the border, FDA has an objective to strategically use import alerts and import certifications by using data and information from oversight activities, regulatory cooperation, and other reliable sources to enhance the effectiveness and efficiency of import alerts. However, FDA's strategy for achieving this objective does not include performance goals or measures that would allow the agency to assess the effectiveness of its seafood import alerts in helping to achieve FDA's food safety mission. In its 2019 plan for the safety of imported food, FDA states that it intends to develop performance goals and measures for imported food safety.

However, FDA has not established a time frame for doing so. Once FDA has developed goals and measures for imported food safety, FDA would be able to establish corresponding performance goals and measures specific to seafood import alerts. By developing such goals and measures, FDA would be better positioned to assess how well its seafood import alert activities are supporting the agency in achieving its food safety mission.

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## Conclusions

Import alerts play an important role in keeping the U.S. food supply—as well as other FDA-regulated products—safe, and FDA has numerous active import alerts affecting imported seafood that address a wide range of seafood products and violations of FFDCa. However, FDA does not have a process to monitor the extent to which it is conducting key activities to support its removal decisions—sampling and inspections. Establishing such a process would provide greater assurance that FDA is conducting its expected level of sampling and inspections to support its removal decisions and have confidence in continued compliance.

Additionally, FDA and CBP have yet to develop mechanisms to share information regularly and proactively that can help detect noncompliance with import alerts through evasion. We continue to believe that doing so, as we previously recommended, would enhance the agencies' efforts to identify potential evasion of seafood import alerts.

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<sup>61</sup>Food and Drug Administration, *FDA Strategy for the Safety of Imported Food* (Washington, D.C.: February 2019).

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Further, by establishing a time frame for developing goals and measures for assessing the effectiveness of its imported food safety efforts and also developing such goals and measures specific to seafood import alerts, FDA would be better positioned to assess how well its import alert activities are supporting the agency in achieving its food safety mission.

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## Recommendations for Executive Action

We are making the following three recommendations to FDA:

- The Commissioner of FDA should 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. This could be done through regularly analyzing data that FDA collects, such as those in CMS, FACTS, and OASIS. (Recommendation 1)
- The Commissioner of FDA should establish a time frame for developing performance goals and measures for its imported food safety program. (Recommendation 2)
- The Commissioner of FDA should, as the agency develops goals and measures for its imported food safety program, develop performance goals and corresponding performance measures specific to seafood import alerts. (Recommendation 3)

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## Agency Comments and Our Evaluation

We provided a draft of this report to HHS and DHS for comment. In its comments, reproduced in appendix II, HHS's FDA agreed with all three of our recommendations. FDA also provided technical comments, which we incorporated as appropriate. DHS provided technical comments, which we incorporated as appropriate.

More specifically, 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. FDA stated that it agrees 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. FDA also stated that it plans to develop goals for its auditing process to ensure audit sampling targets products of higher public health concern and provides the agency support to guide decisions

to release individual shipments that have been detained as a result of an import alert. FDA further stated that it intends to enhance its case management system to include checklists for FDA reviewers who process petitions for removal from import alerts to better document that all necessary information is present and has been evaluated to support the removal decision.

FDA agreed with our recommendation that it should establish a time frame for developing performance goals and measures for its imported food safety program. FDA stated that the agency is developing performance measures and outcome indicators for imported food safety to help support the agency's overall goal of reducing the incidence of illness and death attributable to preventable contamination of FDA-regulated foods.

Finally, FDA agreed with our recommendation that it should, as it develops goals and measures for its imported food safety program, develop performance goals and corresponding performance measures specific to seafood import alerts. FDA stated that the agency will use the results of its import alert effectiveness program to develop metrics to demonstrate the effectiveness of the program and its use of import alerts. The extent to which FDA's planned actions will satisfy our recommendations will depend on how FDA implements those actions.

As agreed with your offices, unless you publicly announce the contents earlier, we plan no further distribution of this report until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of Health and Human Services, the Secretary of Homeland Security, 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](mailto: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 III.



Steve D. Morris  
Director, Natural Resources and Environment

# Appendix I: Food and Drug Administration Import Alerts Affecting Seafood Products

Table 1 includes information posted on the Food and Drug Administration’s website describing the 52 import alerts affecting seafood that were active as of July 3, 2018.

**Table 1: Description of the 52 Food and Drug Administration (FDA) Import Alerts Affecting Seafood Products Active as of July 3, 2018**

Number	Name	Products	Violation(s)
16-02	Detention without Physical Examination of All Dried Shark Fins and Dried Fish Maws Due to Filth	Dried shark fins, dried fish maws, and dried shark cartilage powder	Insect, rodent, or other animal filth
16-04	Misbranded Seafood	Various seafood products	Fictitious names, incorrect common or usual name, and species substitution
16-05	Detention without Physical Examination of Mahi-Mahi because of Histamine and Decomposition	Mahi-mahi (dolphin fish)	Scombroid poisoning, histamine, and decomposition
16-07	Detention without Physical Examination of Dried or Pickled Finfish from Thailand	Dried or pickled finfish	Filth from insects, rodents, birds, or cats, or a combination of these, in addition to mold; decomposition, and violative labeling
16-09	Detention without Physical Examination of Frozen Kingfish from Tri-Tree Seafood Company	Frozen kingfish	Decomposition
16-12	Detention without Physical Examination of Frog Legs	Frog legs	<i>Salmonella</i>
16-13	Detention without Physical Examination of Anchovy or Bagoong Products from the Philippines	Anchovies and bagoong products	Insect filth, rodent filth, or both; <i>E. coli</i> ; and coliforms
16-17	Detention without Physical Examination of <i>Salmonella</i> in Frozen Whole Fish from Thailand	Frozen raw fish (all species)	<i>Salmonella</i>
16-18	Detention without Physical Examination of Shrimp	Fresh (raw) and fresh frozen shrimp	Filth, decomposition, and <i>Salmonella</i>
16-20	Detention without Physical Examination of Puffer Fish	Puffer fish, globe fish, swell fish, fugu, or other members of the Tetraodontidae family	Potential presence of toxin

**Appendix I: Food and Drug Administration  
Import Alerts Affecting Seafood Products**

<b>Number</b>	<b>Name</b>	<b>Products</b>	<b>Violation(s)</b>
16-22	Detention without Physical Examination of Canned Shrimp from Thailand for Decomposition	Canned shrimp (except products manufactured from dried shrimp/prawns)	Decomposition
16-23	Detention without Physical Examination of Fresh and Fresh Frozen Lobster/Lobster Tails from India	Fresh and frozen lobster/lobster tails	Decomposition
16-25	Detention without Physical Examination of Canned Crabmeat from Thailand	All processed crabmeat in containers	Insect, rodent, bird, cat, and other filth
16-31	Detention without Physical Examination of Frozen Raw and Cooked Conchmeat	Frozen raw and cooked conchmeat	Decomposition
16-35	Detention without Physical Examination of Raw and Cooked Shrimp from India	Fresh (raw), fresh frozen, and cooked shrimp	Filth, decomposition, and <i>Salmonella</i>
16-39	Detention without Physical Examination of Processed Seafood and Analogue Seafood (Surimi) Products for <i>Listeria Monocytogenes</i>	Processed seafood and analogue seafood (surimi) products	<i>Listeria Monocytogenes</i>
16-50	Detention without Physical Examination of Molluscan Shellfish	Raw molluscan shellfish	<i>Salmonella</i> , <i>Vibrio cholera</i> , and other bacteria or viruses (e.g., Hepatitis A, Norwalk, etc.); mislabeled as cooked; and manufactured, processed, or packed under insanitary conditions
16-74 <sup>a</sup>	Detention without Physical Examination of Uneviscerated Fish or Partially Eviscerated Fish That Are Either Salt-Cured, Dried, Smoked, Pickled, Fermented or Brined	Various species of uneviscerated fish or partially eviscerated fish that are either salt-cured, dried, smoked, pickled, fermented, or brined (excluding acidified products)	<i>Clostridium botulinum</i>
16-81	Detention without Physical Examination of Seafood Products Due to the Presence of <i>Salmonella</i>	Various seafood products from firms and countries that do not readily fit into previously existing import alerts	<i>Salmonella</i>
16-95	Detention without Physical Examination of Canned Tuna Due to Decomposition	Canned tuna	Decomposition
16-100	Detention without Physical Examination of Langostinos due to the Presence of <i>Staphylococcus Aureus</i> and <i>E. Coli/Coliforms</i>	<i>Frozen langostinos</i>	<i>Staphylococcus aureus</i> and <i>E. coli/coliforms</i>
16-105	Detention without Physical Examination of Seafood and Seafood Products from Specific Manufacturers/Shippers Due to Decomposition and/or Histamines	Various seafood and seafood products	Decomposition, histamines, and scombroid poisoning

**Appendix I: Food and Drug Administration  
Import Alerts Affecting Seafood Products**

<b>Number</b>	<b>Name</b>	<b>Products</b>	<b>Violation(s)</b>
16-114	Detention without Physical Examination of Frozen Shrimp Imported by Sigma International, Inc., St. Petersburg, Florida	Frozen shrimp	Decomposition; filth (cockroach excreta, human hair); <i>Salmonella</i> ; incorrectly identified the manufacturer or shipper; laboratory shopping; may be entering products through other ports under alternate names, or both; other firms, such as a bank, may be identified as the importer of record
16-118	Detention without Physical Examination of Salted Jellyfish and Dried Squid from Hang Loong Marine Products, Hong Kong	Salted jellyfish and dried squid	Filth from numerous insects (whole and fragments), striated hairs (rat/mouse, cat/dog, bat), and feathers
16-119	Detention without Physical Examination of Fish and Fishery Products for Importer and Foreign Processor (Manuf) Combinations	Various fish and fishery products	Failure to meet Hazard Analysis and Critical Control Point (HACCP) verification requirements
16-120	Detention without Physical Examination of Fish/Fishery Products from Foreign Processors (Mfrs.) Not in Compliance with Seafood Hazard Analysis and Critical Control Point (HACCP)	Various fish and fishery products	Failure to meet HACCP requirements
16-121	Detention without Physical Examination of Processed Seafood Products Due to E. Coli	Processed seafood products (initiated with frozen cooked clam meat and clams)	Excessively high levels of E. coli
16-124	Detention without Physical Examination of Aquaculture Seafood Products Due to Unapproved Drugs	Aquaculture seafood products	Unapproved new animal drugs and misuse of approved new animal drugs
16-125	Detention without Physical Examination of Refrigerated (Not Frozen) Raw Fish and Fishery Products That Are Vacuum Packaged or Modified Atmosphere Packaged or Packaged in a Material That Is Not Oxygen-Permeable Due to the Potential for <i>Clostridium Botulinum</i> Toxin Production	Refrigerated (not frozen) raw fish and fishery products that are vacuum packaged or modified atmosphere packaged or packaged in material that is not oxygen-permeable	Potential for <i>Clostridium botulinum</i>
16-127	Detention without Physical Examination of Crustaceans Due to Chloramphenicol	Crustaceans (crab, shrimp, lobster, crayfish, and langostino)	Product bears or contains chloramphenicol
16-129	Detention without Physical Examination of Seafood Products Due to Nitrofurans	All seafood products	Nitrofurans residues
16-131	Detention without Physical Examination of Aquacultured, Shrimp, Dace, and Eel from China-Presence of New Animal Drugs and/or Unsafe Food Additives	Aquacultured shrimp, dace, and eel	Presence of new animal drugs; unsafe food additives, particularly malachite green, leucomalachite green, nitrofurans, fluoroquinolones, gentian violet, and leucogentian violet; or both

**Appendix I: Food and Drug Administration  
Import Alerts Affecting Seafood Products**

<b>Number</b>	<b>Name</b>	<b>Products</b>	<b>Violation(s)</b>
16-133	Detention without Physical Examination of Tuna from Moon Fishery India PVT Ltd.	Raw fresh and frozen tuna	<i>Salmonella Bareilly</i>
16-136	Detention without Physical Examination of Aquacultured Shrimp and Prawns from Peninsular Malaysia Due to Presence of Drug Residues from Unapproved Animal Drugs or the Presence of Unsafe Food Additives	Aquacultured shrimp and prawns	Presence of drug residues from unapproved animal drugs, particularly chloramphenicol and nitrofurans, or presence of unsafe food additives
16-137	Detention without Physical Examination of Seafood Due to Hepatitis A Contamination	Fresh or frozen raw seafood, particularly frozen raw tuna (excludes low-acid canned foods which are and canned and pouched)	Hepatitis A and insanitary conditions (e.g., poor worker hygiene, inadequate worker sanitation, contaminated water supply, or a combination of these)
45-02	Detention without Physical Examination and Guidance of Foods Containing Illegal and/or Undeclared Colors	Various food products, not specific to seafood products, but includes various seafood products	Illegal colors, undeclared colors, or both
54-14	Detention without Physical Examination of Dietary Supplement Products from Firms Which Have Not Met Dietary Supplement GMPs	Dietary supplement products, including various fishery/seafood products	Firm not operating in conformity with current good manufacturing practices (GMPs)
66-41	Detention without Physical Examination of Unapproved New Drugs Promoted in the U.S.	Unapproved and misbranded drugs promoted in the United States, not specific to seafood products	Serious safety and effectiveness concerns
71-04	Detention without Physical Examination of Animal Feeds, Other Than Pet Treats, Due to the Presence of <i>Salmonella</i>	Animal feed products, including various fishery/seafood products	<i>Salmonella</i>
99-08	Detention without Physical Examination of Processed Human and Animal Foods for Pesticides	Processed human and animal foods, not specific to seafood products, but includes various seafood products	Illegal pesticide chemical residues
99-12	Detention without Physical Examination of Canned Foods Due to Contamination from Lead Soldered Cans	Canned foods, not specific to seafood products, but includes various seafood products	Contamination from lead-soldered cans
99-19	Detention without Physical Examination of Food Products Due to the Presence of <i>Salmonella</i>	Various food products, not specific to seafood products, but includes various seafood products	<i>Salmonella</i>
99-21	Detention without Physical Examination and Surveillance of Food Products Containing Sulfites	Various food products, not specific to seafood products, but includes various seafood products	Undeclared sulfites, which could pose a life-threatening hazard to a sulfite-sensitive individual—primarily a misbranding issue

**Appendix I: Food and Drug Administration  
Import Alerts Affecting Seafood Products**

<b>Number</b>	<b>Name</b>	<b>Products</b>	<b>Violation(s)</b>
99-22	Detention without Physical Examination of Foods Containing Undeclared Major Food Allergens or Foods That Fail to Properly Label Major Food Allergens	Various food products, not specific to seafood products, but includes various seafood products	Undeclared major food allergens or failure to properly label major food allergens—major food allergens defined as milk; egg; fish (e.g., bass, flounder, or cod); crustacean shellfish (e.g., crab, lobster, or shrimp); tree nuts (e.g., almonds, pecans, or walnuts); wheat; peanuts; and soybeans, as well as any food ingredient that contains protein derived from one of these foods, except for highly refined oils or certain exempt ingredients
99-32	Detention without Physical Examination of Products from Firms Refusing FDA Foreign Establishment Inspection	Various food products, not specific to seafood products, but includes various seafood products	Refusal of FDA foreign establishment inspection
99-33	Detention without Physical Examination of Products from Japan Due to Radionuclide Contamination	Various food products, not specific to seafood products, but includes various seafood products	Radionuclide contamination
99-35	Detention without Physical Examination of Fresh Produce That Appears to Have Been Prepared, Packed, or Held under Insanitary Conditions	Fresh produce (fruit or vegetable), with fishery/seafood products identified for some firms	Exposure to insanitary conditions during growing, harvesting, packing, holding, manufacturing, processing, or transportation; implicated in foodborne illness outbreak
99-36 <sup>b</sup>	Detention without Physical Examination of Low-Acid Canned Foods and Acidified Foods from Commercial Processors for Failure to Provide Process Information	Low-acid canned foods and acidified foods, not specific to seafood products, but includes various seafood products	Failure to provide process information in a timely manner
99-37 <sup>c</sup>	Detention without Physical Examination of Low-Acid Canned Foods and Acidified Foods without Filed Scheduled Processes	Low-acid canned foods and acidified foods, not specific to seafood products, but includes various seafood products	Failure to file with FDA information as to their scheduled processes for each low-acid canned food and acidified food product in each container size no later than 60 days after registering it as a low-acid canned food, acidified food, or both, commercial processor and prior to packing any new product
99-38 <sup>d</sup>	Detention without Physical Examination of Low-Acid Canned Foods or Acidified Foods Due to Inadequate Process Control	Low-acid canned foods and acidified foods, not specific to seafood products, but includes various seafood products	Products not properly manufactured to control growth and toxin production from <i>Clostridium botulinum</i> or other microorganisms of significance to public health
99-39 <sup>e</sup>	Detention without Physical Examination of Imported Food Products That Appear to Be Misbranded	Various food products, not specific to seafood products, but includes various seafood products	Product appears to be misbranded within the meaning of specific provisions of section 403 of the FFDCA
99-40 <sup>f</sup>	Genetically Engineered (GE) Salmon	Any product with genetically engineered salmon	Genetically engineered

Source: GAO analysis of Food and Drug Administration data. | GAO-20-62



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**Appendix I: Food and Drug Administration  
Import Alerts Affecting Seafood Products**

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Note: During the time period of import alert data we reviewed—October 1, 2011, through July 3, 2018—FDA retired eight import alerts: (1) 16-08, “Detention without Physical Examination of Swordfish for Methyl Mercury;” (2) 16-11, “Chilean Langostinos;” (3) 16-21, “Filth in Imported Fresh or Frozen Raw Shrimp;” (4) 16-47, “Detention without Physical Examination of Red Snapper from Thailand;” (5) 16-66, “Detention without Physical Examination of Shark and Tuna for Methyl Mercury;” (6) 16-128, “Misbranded Catfish;” (7) 99-04, “Detention without Physical Examination of Manufacturers of Low Acid Canned Foods and Acidified Foods;” and (8) 99-20, “Detention without Physical Examination of Imported Food Products due to NLEA Violations.” One import alert, 16-128, “Misbranded Catfish,” was retired after regulatory responsibility for the inspection of Siluriformes, including catfish, was transferred to the U.S. Department of Agriculture’s Food Safety and Inspection Service.

<sup>a</sup>This alert excludes low-acid canned foods and acidified products filed under 21 C.F.R. §§ 108, 113, or 114.

<sup>b</sup>FDA created this import alert to cover detention without physical examination of products because of failure to provide process information previously covered under import alert 99-04.

<sup>c</sup>FDA created this import alert to cover detention without physical examination of products without filed scheduled processes previously covered under import alert 99-04.

<sup>d</sup>FDA created this import alert to cover detention without physical examination of products because of inadequate process control previously covered under import alert 99-04.

<sup>e</sup>FDA revised this import alert on October 2, 2015, to transition all violations covered by import alert 99-20 to this import alert. Import alert 99-20 was deactivated upon publication of this major revision. All firms listed on the red list of import alert 99-20 were moved to the red list of this alert.

<sup>f</sup>FDA deactivated this import alert on March 8, 2019.

# Appendix II: Comments from the Department of Health and Human Services



**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENTAL ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – IMPORTED SEAFOOD SAFETY: IMPORT ALERT REMOVAL DECISIONS (GAO-20-62)**

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report on seafood import alerts. We find the recommendations to be timely and helpful in advancing the Food and Drug Administration's Strategy for the Safety of Imported Food, issued in February 2019, and the new Import Alert Effectiveness Program. 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 meeting its audit goals and expectations for sampling and inspections to support its removal decisions for seafood import alerts. This could be done through regularly analyzing data FDA collects, such as those in CMS, FACTS, and OASIS.

**HHS Response**

FDA concurs with this recommendation. FDA agrees that developing metrics and monitoring the import alert removal process is necessary and that these efforts should be informed by the analysis of data available. FDA will develop specific goals for auditing to ensure audit sampling targets products of higher public health concern and provides the agency support to guide decisions to release individual shipments that have been detained as a result of an import alert. By the end of 2020, FDA intends to review and amend appropriate sections of the Regulatory Procedures Manual including the section related to removal from detention without physical examination (DWPE), to better reflect the importance of the foreign supplier's corrective actions when making decisions to remove a firm and their products from DWPE, and identify higher-risk problem areas (microbiological contamination, decomposition in histamine-forming seafood species, etc.) where more robust information may be needed.

FDA also intends to enhance the case management system to include checklists for FDA reviewers who process petitions for removal from DWPE to better document that all necessary information is present and has been evaluated to support the removal decision. In addition, FDA will look to develop and implement an internal audit program to assure there are adequate internal controls for the import alert program. In reviewing the import alert removal process, FDA noted the need for improvement in the notification process with the workgroup that coordinates foreign inspections. Refining this internal communication will better assure that firms that have recently been removed from an import alert are also considered for an inspection, if needed, based on risks and other inspection planning considerations.

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HEALTH SERVICES (HHS) ON THE GOVERNMENTAL ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – IMPORTED SEAFOOD SAFETY: IMPORT ALERT REMOVAL DECISIONS (GAO-20-62)**

**Recommendation 2**

Establish a time frame for developing performance goals and measures for its imported food safety program.

**HHS Response**

FDA concurs with this recommendation. FDA is developing performance measures and outcome indicators for imported food safety, under the aegis of the FDA's Strategy for the Safety of Imported Food (Strategy), to help support FDA's overall goal of reducing the incidence of illness and death attributable to preventable contamination of FDA-regulated food products.

FDA has already begun to publish some performance measures and outcome metrics, as well as non-confidential data about imported food, foreign suppliers, and importers, related to Strategy Objectives 1.1, 1.2, 1.3, and 3.2.

*Objective 1.1: Optimize use of foreign inspections*

In 2017, FDA launched a Data Dashboard that allows for trending data on inspections. The Dashboard currently offers data on the annual number of inspections, with inspection classifications and citation details, for foreign food inspections conducted between FY 2009 and FY 2019.<sup>1</sup>

On September 30, FDA announced an initial metric that begins to track outcomes for the Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls rules for human food (PCHF) by measuring effectiveness through PCHF inspection data. This initial PCHF metric is posted on a Dashboard that, when fully populated, will contain metrics for each of the FDA Food Safety Modernization Act (FSMA) foundational rules.<sup>2</sup>

*Objective 1.2: Ensure importer use of verified foreign suppliers through effective implementation of the Foreign Supplier Verification Program (FSVP) final rule*

On September 30, FDA also announced an initial metric for the FSVP rule, which requires importers to verify that their foreign suppliers of human and animal food meet applicable FDA safety standards. The initial FSVP metric will measure effectiveness through data on FSVP inspections and is posted on the Food Safety Dashboard.

<sup>1</sup> See <https://datadashboard.fda.gov/ora/cd/inspections.htm>

<sup>2</sup> See <https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-food-safety-dashboard>.

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENTAL ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – IMPORTED SEAFOOD SAFETY: IMPORT ALERT REMOVAL DECISIONS (GAO-20-62)**

*Objective 1.3: Take into account the public health assurances of reliable audits such as those issued under FDA's Accredited Third-Party Certification Program or pursuant to other assurance programs aligned with FDA food safety requirements*

FDA has established a public registry of recognized accreditation bodies (ABs) and accredited certification bodies (CBs) participating in the FSMA Accredited Third-Party Certification Program.<sup>3</sup> To date, FDA has recognized four ABs, three of which are authorized to accredit CBs to conduct seafood Hazards Analysis and Critical Control Points (HACCP) audits. A total of seven CBs have been accredited under the program, including five CBs that are accredited for seafood HACCP audits. FDA will continue to monitor and report on participation in the FSMA Accredited Third-Party Certification Program through the public registry on the FDA website.

*Objective 3.2: Enhance the efficiency and effectiveness of imported food safety recalls*

FDA posts food recall metrics on its FDA Data Dashboard,<sup>4</sup> including recalls of imported food that has entered domestic commerce. Information on recalls associated with individual firms is also available through the Data Dashboard by clicking on a firm's hyperlinked FEI number.

FDA is evaluating the potential to establish additional performance measures within one to two years. Measures under consideration are:

*Objective 1.4: Incentivize importers to use verified suppliers of safe food through the Voluntary Qualified Importer Program (VQIP)*

*Objective 1.5: Leverage the oversight efforts of regulatory counterparts with strong food safety systems*

*Objective 2.2: Optimize use of physical examination and sampling of imported food*

*Objective 2.3: Strategically utilize import alerts (IAs) and import certifications*

FDA is also exploring longer-term performance options for meaningful public health measures for other objectives in the Strategy.

<sup>3</sup> See <https://datadashboard.fda.gov/ora/fd/tp.htm>

<sup>4</sup> See <https://datadashboard.fda.gov/ora/cd/recalls.htm>

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH AND HEALTH SERVICES (HHS) ON THE GOVERNMENTAL ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED – IMPORTED SEAFOOD SAFETY: IMPORT ALERT REMOVAL DECISIONS (GAO-20-62)**

**Recommendation 3**

Develop performance goals and corresponding measures specific for seafood import alerts.

**HHS Response**

FDA concurs with this recommendation. FDA's new Import Alert Effectiveness Program (IAEP) creates a systematic process for regular review of all FDA IAs to evaluate their effectiveness. The evaluation will involve review of the IAs for content, system screening, firm listings, and field activities for import entries flagged by the IA. We are in the initial phase of establishing the program. With the information gained in developing the procedures during the IAEP pilot and the initial round of import alerts reviewed under the program, FDA is planning to develop metrics to demonstrate the effectiveness of the IAEP program and as well as the import alert.

Under the Imported Food Strategy Objective 2.3, we are considering options for meaningful public health measures around IAs, which may include data points such as number of food line entries each year, the number of food-related IAs currently in place, the types of violations, and the number of food firms and products on these IAs.

We believe these changes will provide for better oversight, confidence, and accountability in FDA's import alert program.

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## Agency Comment Letter

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

#### Page 1

October 10, 2019

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: Actions Needed to Improve FDA Oversight of Import Alert Removal Decisions" (GAO-20-62).

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

Sincerely,

Sarah Arbes  
Acting Assistant Secretary for Legislation

Attachment

#### Page 2

### **REMOVAL DECISIONS (GAO-20-62)**

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on the Government Accountability Office's (GAO) draft report on seafood import alerts. We find the recommendations to be timely and helpful in advancing the Food and Drug Administration's Strategy for the Safety of Imported Food, issued in February 2019, and the new Import Alert Effectiveness Program. 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 meeting its audit goals and expectations for sampling and inspections to support its removal decisions for seafood import alerts. This could be done through regularly analyzing data FDA collects, such as those in CMS, FACTS, and OASIS.

### **HHS Response**

FDA concurs with this recommendation. FDA agrees that developing metrics and monitoring the import alert removal process is necessary and that these efforts should be informed by the analysis of data available. FDA will develop specific goals for auditing to ensure audit sampling targets products of higher public health concern and provides the agency support to guide decisions to release individual shipments that have been detained as a result of an import alert. By the end of 2020, FDA intends to review and amend appropriate sections of the Regulatory Procedures Manual including the section related to removal from detention without physical examination (DWPE), to better reflect the importance of the foreign supplier's corrective actions when making decisions to remove a firm and their products from DWPE, and identify higher risk problem areas (microbiological contamination, decomposition in histamine-forming seafood species, etc.) where more robust information may be needed.

FDA also intends to enhance the case management system to include checklists for FDA reviewers who process petitions for removal from DWPE to better document that all necessary information is present and has been evaluated to support the removal decision. In addition, FDA will look to develop and implement an internal audit program to assure there are adequate internal controls for the import alert program. In reviewing the import alert removal process, FDA noted the need for improvement in the notification process with the workgroup that coordinates foreign inspections. Refining this internal communication will better assure that firms that have recently been removed from an import alert are also considered for an inspection, if needed, based on risks and other inspection planning considerations. Page 3



Page 3

**Recommendation 2**

Establish a time frame for developing performance goals and measures for its imported food safety program.

**HHS Response**

FDA concurs with this recommendation. FDA is developing performance measures and outcome indicators for imported food safety, under the aegis of the FDA's Strategy for the Safety of Imported Food (Strategy), to help support FDA's overall goal of reducing the incidence of illness and death attributable to preventable contamination of FDA-regulated food products.

FDA has already begun to publish some performance measures and outcome metrics, as well as non-confidential data about imported food, foreign suppliers, and importers, related to Strategy Objectives 1.1, 1.2, 1.3, and 3.2.

**Objective 1.1: Optimize use of foreign inspections**

In 2017, FDA launched a Data Dashboard that allows for trending data on inspections. The Dashboard currently offers data on the annual number of inspections, with inspection classifications and citation details, for foreign food inspections conducted between FY 2009 and FY 2019.<sup>1</sup>

On September 30, FDA announced an initial metric that begins to track outcomes for the Current Good Manufacturing Practice, Hazard Analysis and Risk-Based Preventive Controls rules for human food (PCHF) by measuring effectiveness through PCHF inspection data. This initial PCHF metric is posted on a Dashboard that, when fully populated, will contain metrics for each of the FDA Food Safety Modernization Act (FSMA) foundational rules.<sup>2</sup>

**Objective 1.2: Ensure importer use of verified foreign suppliers through effective implementation of the Foreign Supplier Verification Program (FSVP) final rule**

On September 30, FDA also announced an initial metric for the FSVP rule, which requires importers to verify that their foreign suppliers of human and animal food meet applicable FDA safety standards. The initial FSVP metric will measure effectiveness through data on FSVP inspections and is posted on the Food Safety Dashboard.

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Objective 1.3: Take into account the public health assurances of reliable audits such as those issued under FDA's Accredited Third-Party Certification Program or pursuant to other assurance programs aligned with FDA food safety requirements

FDA has established a public registry of recognized accreditation bodies (ABs) and accredited certification bodies (CBs) participating in the FSMA Accredited Third-Party Certification Program.<sup>3</sup> To date, FDA has recognized four ABs, three of which are authorized to accredit CBs to conduct seafood Hazards Analysis and Critical Control Points (HACCP) audits. A total of seven CBs have been accredited under the program, including five CBs that are accredited for seafood HACCP audits. FDA will continue to monitor and report on participation in the FSMA Accredited Third-Party Certification Program through the public registry on the FDA website.

Objective 3.2: Enhance the efficiency and effectiveness of imported food safety recalls

FDA posts food recall metrics on its FDA Data Dashboard,<sup>4</sup> including recalls of imported food that has entered domestic commerce. Information on recalls associated with individual firms is also available through the Data Dashboard by clicking on a firm's hyperlinked FEI number.

FDA is evaluating the potential to establish additional performance measures within one to two years. Measures under consideration are:

Objective 1.4: Incentivize importers to use verified suppliers of safe food through the Voluntary Qualified Importer Program (VQIP)

Objective 1.5: Leverage the oversight efforts of regulatory counterparts with strong food safety systems

Objective 2.2: Optimize use of physical examination and sampling of imported food  
Objective 2.3: Strategically utilize import alerts (IAs) and import certifications

FDA is also exploring longer-term performance options for meaningful public health measures for other objectives in the Strategy.

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**Recommendation 3**

Develop performance goals and corresponding measures specific for seafood import alerts.

**HHS Response**

FDA concurs with this recommendation. FDA's new Import Alert Effectiveness Program (IAEP) creates a systematic process for regular review of all FDA IAs to evaluate their effectiveness. The evaluation will involve review of the IAs for content, system screening, firm listings, and field activities for import entries flagged by the IA. We are in the initial phase of establishing the program. With the information gained in developing the procedures during the IAEP pilot and the initial round of import alerts reviewed under the program, FDA is planning to develop metrics to demonstrate the effectiveness of the IAEP program and as well as the import alert.

Under the Imported Food Strategy Objective 2.3, we are considering options for meaningful public health measures around IAs, which may include data points such as number of food line entries each year, the number of food-related IAs currently in place, the types of violations, and the number of food firms and products on these IAs.

We believe these changes will provide for better oversight, confidence, and accountability in FDA's import alert program.

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# Appendix III: GAO Contact and Staff Acknowledgments

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## GAO Contact

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

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## Staff Acknowledgments

In addition to the contact named above, Anne K. Johnson (Assistant Director), David Moreno (Analyst in Charge), Kevin Bray, Steven Campbell, Stephen Cleary, Michele Fejfar, Ellen Fried, Juan Garay, Caitlyn Leiter-Mason, Ying Long, Cynthia Norris, Dan Royer, and Kiki Theodoropoulos made key contributions to this report.

# Appendix IV: Accessible Data

## Data Tables

**Data Table for Figure 1: Percentage of Private Laboratory Work That the Food and Drug Administration (FDA) Audited, Fiscal Years 2003 through 2018**

Fiscal Year	Percentage of Private Laboratory Workload that FDA Audit Sampled	FDA's Audit Sample Goal
2003	1.5	10
2004	1.7	10
2005	1.7	10
2006	1.4	10
2007	1.9	10
2008	1.1	10
2009	1.1	10
2010	0.6	10
2011	0.8	10
2012	1.1	10
2013	1.9	10
2014	3.3	10
2015	2.9	10
2016	2.8	10
2017	2.7	10
2018	2.7	10

## Related GAO Products

*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.

*2015 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits.* [GAO-15-404SP](#). Washington, D.C.: April 14, 2015.

*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.

*Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms.* [GAO-12-1022](#). Washington, D.C.: September 27, 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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**Related GAO Products**

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*Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies.* [GAO-06-15](#). Washington, D.C.: October 21, 2005.

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