



Report to the Chairman
Subcommittee on Europe, Eurasia, and
Emerging Threats,
Committee on Foreign Affairs
House of Representatives

May 2016

IMPORTED FOOD SAFETY

FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible

Accessible Version

GAO Highlights

Highlights of [GAO-16-399](#), a report to the Chairman, Subcommittee on Europe, Eurasia, and Emerging Threats, Committee on Foreign Affairs, House of Representatives

Why GAO Did This Study

Imported food makes up a substantial and growing portion of the U.S. food supply. FDA is responsible for oversight of more than 80 percent of the U.S. food supply. However, because the volume of imported food is so high, FDA physically examines only about 1 percent of imported food annually. In 2011, FDA implemented PREDICT, a computerized tool intended to improve FDA's targeting of imports for examination by estimating the risk of imported products.

GAO was asked to review how FDA is using PREDICT to protect the U.S. food supply. This report examines (1) the data used by PREDICT and how PREDICT analyzes these data to identify high-risk food shipments for examination, (2) how implementation of FSMA will affect PREDICT, and (3) the extent to which FDA has assessed the effectiveness of PREDICT and used the assessments to improve the tool. To address these issues, GAO analyzed FDA documents, interviewed FDA officials, and analyzed data from fiscal years 2012 through 2014.

What GAO Recommends

GAO recommends that FDA take two actions to improve the effectiveness of PREDICT: (1) document the process by which FDA is to identify, obtain, and use open source data and (2) establish a timeline for implementing the remaining recommendations from FDA's 2013 evaluation of PREDICT. FDA generally agreed with GAO's recommendations.

View [GAO-16-399](#). For more information, contact Steve Morris at (202) 512-3841 or morris@gao.gov.

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What GAO Found

The Food and Drug Administration's (FDA) Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) tool 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. Many of the data used by PREDICT come from internal FDA sources, such as FDA databases. PREDICT also uses data from sources outside of FDA, such as other federal agencies, states, and foreign governments. Some of the data are open source data—information that is publicly available, such as information from newspapers and websites. FDA's Office of Regulatory Affairs (ORA) relies on other FDA offices and federal agencies to provide open source data for PREDICT, but ORA does not have a documented process for identifying, obtaining, and using the data, relying instead on an ad hoc process. Federal standards for internal control call for agencies to document internal controls. Without a documented process for identifying, obtaining, and using open source data, FDA does not have reasonable assurance that ORA will consistently identify, obtain, and use such data for PREDICT.

The implementation of the FDA Food Safety Modernization Act (FSMA), enacted in 2011, will provide PREDICT with additional data for estimating the risk of imported food. FDA identified FSMA provisions likely to generate data, including the Foreign Supplier Verification Program (FSVP), which requires importers to verify that their foreign suppliers use processes and procedures that provide the same public health protection as applicable U.S. requirements. Because FSVP and other FSMA-related programs are still new and not yet fully implemented, the details of how PREDICT will use the data have not been worked out. However, according to FDA officials, the data will be useful. For example, FSVP data will identify suppliers that are not in compliance with standards, and PREDICT will use those data in assigning risk scores to imports from those suppliers.

FDA has assessed the effectiveness of PREDICT by monitoring of key data and by conducting an internal evaluation of the system, and it has implemented many, but not all, of its recommendations from the evaluation. GAO's analysis of FDA data from fiscal year 2012 through 2014 shows that in general, PREDICT is working as intended: imported food with higher-risk scores is more likely to be physically examined and to be found in violation of food safety standards or labeling requirements. In May 2013, FDA completed an evaluation of PREDICT that examined five key processes. As a result of the evaluation, FDA developed 24 recommendations for improving PREDICT and prioritized these recommendations based on feasibility and impact. According to FDA, the agency has fully implemented 15, partially implemented 6, and not implemented 3 of the recommendations. FDA officials said that the agency has not fully implemented all recommendations because of a lack of resources. However, federal standards for internal control specify that agencies are to ensure that the findings of reviews are promptly resolved. To that end, agencies are to complete, within established time frames, all actions that correct or otherwise resolve the matters brought to management's attention. Establishing a timeline for implementing the remaining recommendations as resources become available would help ensure that PREDICT continues to remain an effective tool for screening imported food.

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Abbreviations

CBP	U.S. Customs and Border Protection
CFSAN	Center for Food Safety and Applied Nutrition
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
FSIS	Food Safety and Inspection Service
FSMA	FDA Food Safety Modernization Act
FSVP	Foreign Supplier Verification Program
HACCP	Hazard Analysis Critical Control Point
NMFS	National Marine Fisheries Service
OASIS	Operational and Administrative System for Import Support
OIP	Office of International Programs
ORA	Office of Regulatory Affairs
PREDICT	Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting
USDA	U.S. Department of Agriculture
VQIP	Voluntary Qualified Importer Program

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May 26, 2016

The Honorable Dana Rohrabacher
Chairman
Subcommittee on Europe, Eurasia, and Emerging Threats
Committee on Foreign Affairs
House of Representatives

Dear Mr. Chairman:

Imported food makes up a substantial and growing portion of the U.S. food supply. According to a 2013 report by the Food and Drug Administration (FDA), 15 percent of the U.S. food supply was imported, including nearly 50 percent of fresh fruits and 20 percent of fresh vegetables. In addition, according to the National Marine Fisheries Service (NMFS) about 94 percent of seafood consumed in the United States was imported in 2014.¹ FDA, under the Department of Health and Human Services, is responsible for oversight of more than 80 percent of the U.S. food supply.² In fiscal year 2002, imported entry lines—an entry line is each portion of an import shipment that is listed as a separate item on an entry document—of FDA-regulated food totaled approximately 4.4 million.³ According to FDA, by 2015, this number had nearly tripled to approximately 12 million. The total volume of U.S. food imports under FDA’s jurisdiction has increased from approximately 39 million metric tons in 1999 to 67 million metric tons in 2014, based on data compiled by the U.S. Department of Agriculture’s (USDA) Economic Research Service (see fig. 1). Given the volume of imports into the country, there is

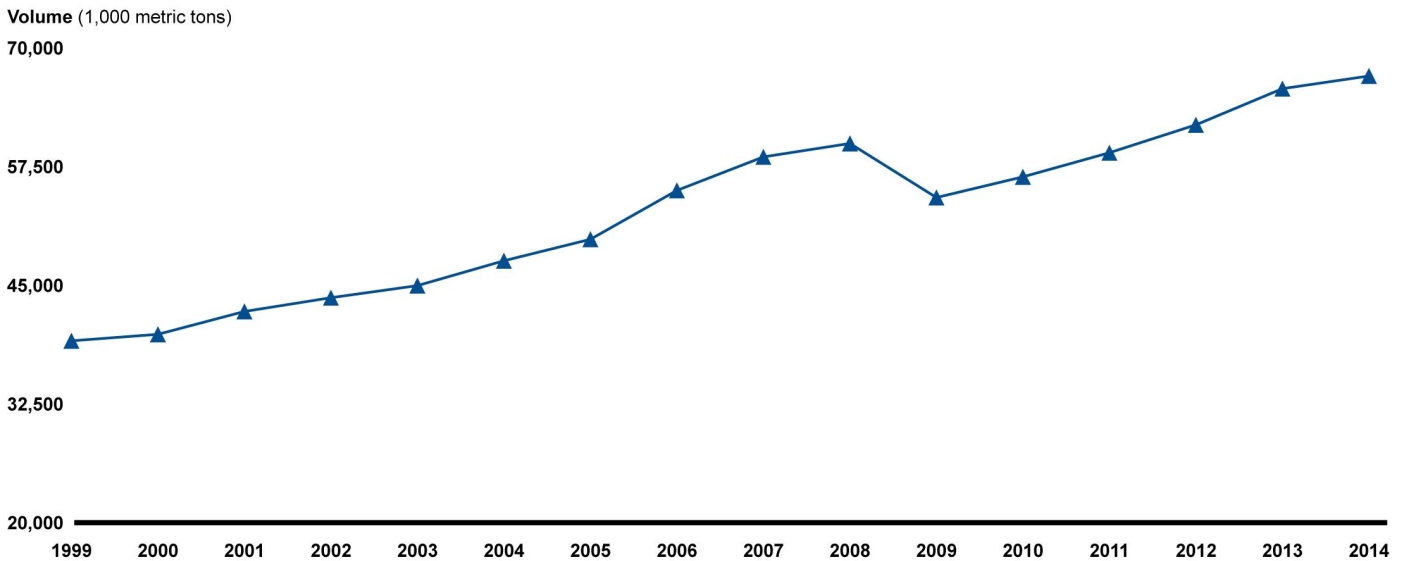
¹NMFS, an agency under the Department of Commerce, reported that the model used to calculate this amount may overestimate this percentage because of a number of factors, including the inclusion of a substantial amount of domestic catch that was exported for further processing and returned to the United States as an import in processed form. Therefore, while seafood imports do appear to be rising, the exact percentage is difficult to know precisely.

²The Food Safety and Inspection Service (FSIS), under the U.S. Department of Agriculture, is responsible for the safety of most domestic and imported meat, poultry, catfish, and processed egg products, while FDA is responsible for the safety of virtually all other foods, including milk, seafood, fruits, and vegetables.

³An entry is a unique shipment of imported products or items offered for admission into U.S. commerce. An entry may include one imported item or hundreds; each item is identified as an entry line.

considerable potential for violative items—products that do not meet U.S. safety standards or labeling requirements—to enter the U.S. food supply.

Figure 1: Food and Drug Administration-Regulated Food Imports by Volume, 1999–2014



Source: GAO analysis of U.S. Department of Agriculture data. | GAO-16-399

Note: The data from the U.S. Department of Agriculture (USDA) included all food groups. Our analysis excludes meat subject to USDA oversight.

FDA is responsible for helping to ensure that certain food products marketed in the United States meet certain statutory and regulatory requirements, whether the products are produced in the United States or another country.⁴ FDA staff work with personnel from the Department of Homeland Security’s U.S. Customs and Border Protection (CBP) to

⁴Under the Federal Food, Drug, and Cosmetic Act (FDCA) “food” means (1) articles used for food or drink for humans or animals, (2) chewing gum, and (3) articles used for components of any such article. FDA also regulates dietary supplement products under FDCA as amended by the Dietary Supplement Health and Education Act of 1994. In addition, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 directs the agency to require the submission of prior notice for food imported into the United States.

examine violative products.⁵ In 2007, we added the federal oversight of food safety to our list of high-risk areas needing broad-based transformation, largely because of inconsistent oversight, ineffective coordination, and inefficient use of resources.⁶ Since then, we have found shortcomings with FDA's oversight of imported food safety. We made numerous recommendations, and the agency has implemented all of them.⁷

The FDA Food Safety Modernization Act (FSMA), enacted in January 2011, expanded and modified previously existing FDA authorities, giving FDA several new authorities that enhance the agency's oversight of imported food. Also, in December 2011, FDA fully implemented its Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT), a computerized tool intended to improve the screening of FDA-regulated imports and the targeting of entry lines for examination.⁸ PREDICT is designed to estimate the risk of imports using information such as the history of the facility, inspection records, and country of origin. FDA staff called entry reviewers use these risk estimates to target for examination shipments with high levels of risk, while the tool encourages entry reviewers to allow shipments with low levels of risk to enter the United States with minimal review.

⁵Screening is the automated review of electronic import information to target for examination those shipments that pose the greatest risk. Examination is the physical review of imported food. Examination is different from inspection, which is the on-site review of food facilities to assess compliance with U.S. food safety regulations.

⁶GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007). For our most recent list, see GAO, *High-Risk Series: An Update*, [GAO-15-290](#) (Washington, D.C.: Feb. 11, 2015).

⁷GAO, *Food Safety: Agencies Need to Address Gaps in Enforcement and Collaboration to Enhance Safety of Imported Food*, [GAO-09-873](#) (Washington, D.C.: Sept. 15, 2009). At the time, FDA was still developing the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting tool.

⁸FDA has the authority to conduct examinations to determine whether the imported product is in compliance with food safety laws and FDA regulations. As part of the entry review process, FDA entry reviewers designate entries for examination. This examination may consist of any combination of a field examination, label examination, or sample collection and analysis. A field examination is a physical inspection performed on a product and may be conducted at locations including trucks, trains, cold storage warehouses, importers' warehouses, or border entry points. A label examination is the review of a product's label to determine compliance with labeling requirements. A sample collection involves taking a portion of the product from the shipment and sending it to a laboratory for analysis.

In 2014, we found that FDA did not examine for pesticide residues the majority of entry lines that had the highest PREDICT risk scores and that the agency's plan to test the tool's reliability lacked statistically valid measures. The Department of Health and Human Services indicated that it would investigate the feasibility and potential costs of implementing this recommendation and described its ongoing efforts.⁹ In 2015, we found that FDA was not conducting the number of foreign food facility inspections—the results of which are used in PREDICT—mandated under FSMA.¹⁰ We recommended that the agency complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food and, if appropriate, recommend appropriate legislative changes. FDA concurred with this recommendation, pending the acquisition of the resources necessary to conduct the analysis.

With imported food making up a substantial and growing portion of the U.S. food supply, you asked us to review how FDA is using PREDICT to protect the safety of the U.S. food supply. This report examines (1) the data used by PREDICT and how PREDICT analyzes these data to identify high-risk food shipments for examination, (2) how implementation of FSMA will affect PREDICT, and (3) the extent to which FDA has assessed the effectiveness of PREDICT and used the results of those assessments to improve the tool.

To determine what data were used by PREDICT and how PREDICT analyzes these data to identify high-risk food shipments for examination, we reviewed FDA data and interviewed FDA officials. We also assessed the data used by PREDICT and determined that they were sufficiently reliable to describe factors considered by PREDICT and system rules used to generate PREDICT risk scores. We examined the data sources, data quality controls, and methodology used by PREDICT and assessed them to ensure that they were sufficiently reliable to support accurate descriptions of the system inputs, processes, and resulting risk scores. To determine how implementation of FSMA will affect PREDICT, we reviewed FDA proposed and final rules implementing FSMA, reviewed

⁹GAO, *Food Safety: FDA and USDA Should Strengthen Pesticide Residue Monitoring Programs and Further Disclose Monitoring Limitations*, [GAO-15-38](#) (Washington, D.C.: Oct. 7, 2014).

¹⁰GAO, *Food Safety: Additional Actions Needed to Help FDA's Foreign Offices Ensure Safety of Imported Food*, [GAO-15-183](#) (Washington, D.C.: Jan. 30, 2015).

FDA documents, and interviewed FDA officials. To determine the extent to which FDA has assessed the effectiveness of PREDICT and used the results of those assessments to improve the tool, we interviewed FDA officials about the ways in which FDA has assessed PREDICT, reviewed the evaluation that FDA has conducted, and assessed the extent to which FDA has implemented the recommendations from the evaluation.

As discussed above, we examined the data sources, data quality controls, and methodology used by PREDICT and assessed them to ensure that they were sufficiently reliable to support accurate descriptions of the system inputs, processes, and resulting risk scores.¹¹ To inform all three objectives, we conducted site visits at FDA and CBP facilities located at ports of entry located in Baltimore, Maryland; Long Beach, California; Los Angeles, California; and San Diego, California. We selected these sites to include air, ship, and truck ports of entry; variable geographic locations; the variability of food products that enter through the ports; and proximity to an FDA office. The information we obtained is not generalizable to all facilities and ports of entry. Additional information on our scope and methodology is included in appendix I.

We conducted this performance audit from January 2015 to May 2016 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

This section discusses the offices within FDA and other federal agencies that help oversee imported food products. It also discusses FDA's approach for overseeing the safety of the imported food products for which it is responsible, including milk, seafood, fruits, and vegetables.

¹¹We did not assess whether the individual data sources were complete and accurate, but rather whether they were a reasonable representation of the intended inputs into PREDICT's analytical functions.

Responsibilities for Oversight of Imported Food Products

FDA's responsibilities for overseeing the safety of imported food products are divided among its product centers and program offices. For example, the Center for Food Safety and Applied Nutrition (CFSAN) is responsible for regulating food and cosmetics products.¹² FDA's Office of Regulatory Affairs (ORA) is the lead office for ensuring the safety of imported food through various field activities, such as inspections of firms, review of imported products, examination of products, and sample collection and analysis. ORA works closely with the centers and with the Office of International Programs (OIP), which coordinates some of the agency's international activities. FDA has staff in China, Chile, Costa Rica, India, Mexico, and the European Union. These foreign offices help ORA obtain foreign scientific and regulatory information, conduct investigations and facility inspections in foreign countries, and facilitate collaboration with foreign regulators in areas of common interest.

Primary responsibility for imported food safety is divided between FDA and FSIS, but other federal agencies play a role. For example, CBP supports FDA in its enforcement of its food safety regulations at the border, among other things. CBP's automated systems process all imported shipments, including food. In addition, NMFS provides fee-for-service inspection services, upon request, to the seafood industry—including domestic and foreign processors, distributors, and other firms—for example, to certify that these seafood firms comply with FDA's Hazard Analysis and Critical Control Point regulations and other federal food

¹²FDA's other centers are the Center for Veterinary Medicine, the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, the Center for Drug Evaluation and Research, the Center for Tobacco Products, and the National Center for Toxicological Research.

safety standards.¹³ Some retailers request this certification as a condition for purchasing seafood products.

FDA's Approach to Overseeing the Safety of Imported Food

FDA oversees the safety of imported food by promoting corporate responsibility, examining food prior to it entering into U.S. commerce to help ensure that unsafe food does not enter the country, and responding when unsafe food does enter the country.

In 2011, FSMA provided FDA with new provisions that hold imported foods to the same standards as domestic foods and prevent unsafe food from entering the country. These new provisions included new requirements and authorities for FDA, including

- a requirement to develop a comprehensive plan to expand the food safety capacity of foreign governments;
- a requirement to increase inspections of foreign food facilities and the authority to enter into cooperative arrangements with foreign governments to facilitate the inspection of foreign food facilities;
- the authority, under certain circumstances, to require as a condition of admission that imported food be accompanied by certifications or assurances from accredited third-party certification bodies, agencies, or representatives of foreign governments where the food originated; and

¹³Under FDA's Hazard Analysis Critical Control Point (HACCP) requirements, seafood processing firms, including firms that manufacture, pack, or label, are responsible for conducting a hazard analysis and for developing and implementing HACCP plans whenever an analysis shows that one or more hazards are reasonably likely to occur. Food safety hazards may result from, among other things, drug residues, pesticides, parasites, and decomposition. HACCP requires (1) food processors to identify and develop strategies to prevent, eliminate, or reduce to an acceptable level the hazard and (2) importers to ensure that the products they import have been processed in accordance with HACCP requirements or that the products have been obtained from a country with an active cooperative arrangement with FDA covering the product that documents equivalence or compliance with the U.S. system. FDA enforces HACCP requirements by inspecting a number of foreign seafood processing facilities each year to ensure that they are in compliance and by inspecting a number of U.S. importers to determine whether they have maintained the appropriate documents to prove that the processors from which they import seafood meet HACCP requirements.

-
- the authority to require importers to verify that their foreign suppliers meet applicable U.S. food safety standards.

Owing in part to the volume of imported food, FDA cannot physically examine every shipment; the agency examines about 1 percent of entry lines annually. FDA electronically screens all imported food shipments to determine which imports to physically examine at the border and which imports to allow into U.S. commerce.

The electronic screening process consists of two phases: (1) Prior Notice screening, which is intended to protect against potential terrorist acts and other public health emergencies, and (2) admissibility screening, which is intended to ensure that the food is admissible under the Food, Drug, and Cosmetic Act (FDCA). Imported food products are generally considered admissible if they are in compliance with applicable FDCA regulations that ensure food is not adulterated, misbranded, manufactured or packed under insanitary conditions, or restricted in sale in the country in which it was produced or from which it was exported, among other things.

The first phase, Prior Notice screening, requires that an importer, broker, or other entity submit notification to FDA of food being imported or offered for import into the United States before that food arrives at the port of entry. Prior Notice information includes data such as the names and addresses of the manufacturer or grower, importer, owner, and ultimate consignee (the “deliver to” location); FDA product code for the food item; and country of production. Information that FDA uses for Prior Notice review can either be submitted electronically through CBP’s system, which passes the information to FDA, or submitted electronically directly to FDA. 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. If such risks are identified, FDA is to work with CBP to examine the shipment upon arrival at the port. If adequate Prior Notice information is not provided, the food is subject to refusal of admission and may not be delivered to the importer, owner, or consignee. If FDA subsequently verifies that adequate Prior Notice information is provided and the food does not appear to pose a terrorism threat, the shipment is allowed to proceed to FDA’s admissibility screening.

During the second phase, admissibility screening, FDA electronically screens entry lines using PREDICT to determine their level of risk.¹⁴ “Risk”—reflected by the PREDICT risk score—includes factors such as the inherent health risk of the product, compliance risk associated with firms, facility inspection results, and broker history, among others, and is then compared to all other entry lines within a specified commodity over the past 30 days.¹⁵ If PREDICT determines that an entry line poses a low risk, PREDICT recommends the entry be allowed to enter into U.S. commerce, and another FDA system, called the Operational and Administrative System for Import Support (OASIS), issues a system-generated “May Proceed” message, allowing the product into U.S. commerce without further review.¹⁶ If PREDICT determines that the entry line poses a high risk, an entry reviewer decides whether to examine the entry line for admissibility. The entry reviewer determines if the entry line is under import alert.¹⁷ If the entry line is not under import alert and no further examination is needed, the entry reviewer allows the entry line into U.S. commerce by issuing a manual “May Proceed” message through OASIS. The entry reviewer may determine that a field or laboratory examination is needed for an entry line that is not under an import alert. In this case, an FDA investigator examines the entry either at the port of entry or at another location, such as the importer’s or consignee’s warehouse or a cold storage facility. The investigator may examine a product’s label to determine whether it meets labeling requirements. Additionally, the investigator may examine the shipment for rodent or insect activity or inadequate storage while in transit, among other things. Figure 2 shows FDA investigators examining imported food.

¹⁴PREDICT electronically screens all FDA-regulated products, including food, drugs, biologics, cosmetics, medical devices, radiation-emitting electronic products, and tobacco products.

¹⁵Inherent risk of the product includes factors related to the product such as outbreaks, recalls, or adverse events. Compliance risk includes factors specific to the firm and its past compliance with food safety regulations. Facility inspection results of manufacturers are based on 3 years of historical data. Broker history includes an analysis of the quality of data provided by the broker or importer in the previous 12 months.

¹⁶OASIS is an electronic import database that, for example, provides support for examination or sample collection during the import process and for FDA’s Prior Notice system.

¹⁷Import alerts inform FDA field staff that products covered by the alert may be subject to detention without physical examination. According to FDA, an entry line that is flagged for an import alert, regardless of the risk score, will never be allowed to automatically proceed into U.S. commerce and will always be subject to manual review.

Figure 2: Food and Drug Administration (FDA) Investigators Examining Shipments of Imported Food



Source: GAO. | GAO-16-399

FDA investigators examining shipments of imported avocados at the Otay Mesa truck port in San Diego, California.

FDA investigators testing the temperature of imported frozen seafood at the Los Angeles Airport.

If the product does not appear to be violative after the examination, the owner or consignee receives a notice stating that the line is released, and the product is allowed into U.S. commerce.¹⁸

If the product appears to be violative, the investigator may decide to take samples from the product for a laboratory examination to test for rodent or insect activity and other such elements that could confirm that the entry is violative. If the samples indicate that the food is not violative, the owner or consignee receives a notice stating that the line is released, and the product is allowed into U.S. commerce. If the samples are violative, the owner or consignee receives a notice stating that the line is being detained and is subject to refusal. Once the owner or consignee receives a notice stating that the line is being detained and is subject to refusal, the owner or consignee may request that FDA immediately refuse the product, and the product must either be exported or destroyed. If the owner or consignee does not request refusal, then the owner or consignee decides whether to submit testimony or request to “recondition” the product—for example, relabeling the product or

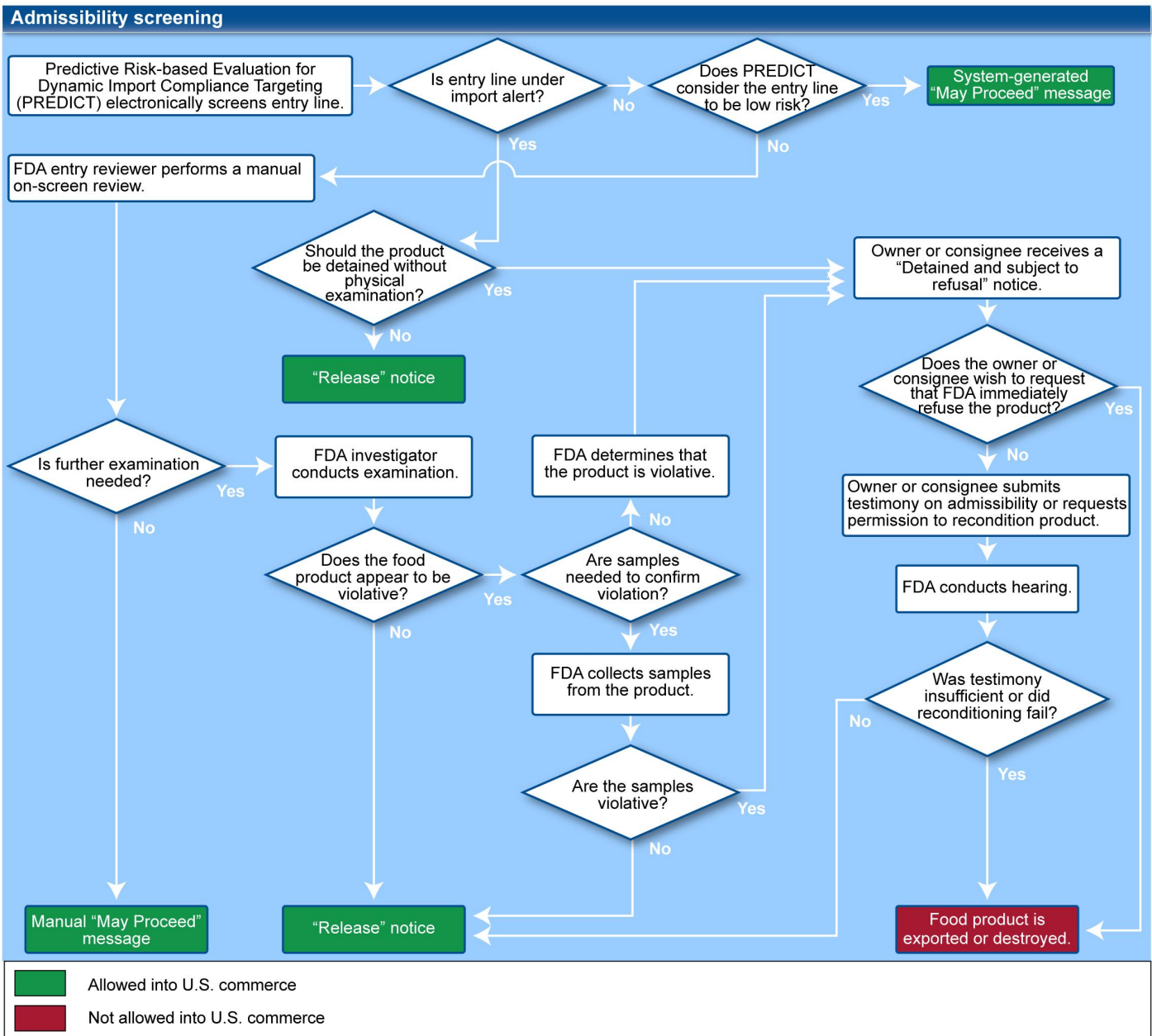
¹⁸OASIS generates a Notice of FDA Action, which provides more specific information on the actions taken broken down by each entry line (e.g., “may proceed,” “sample collected” or “intended for sampling,” “detained,” “released,” or “refused”). As the status changes for a particular entry line, a new Notice of FDA Action is issued to advise the appropriate individuals of the changes.

converting the product into a type of product not regulated by FDA.¹⁹ If the owner or consignee submits testimony regarding the admissibility of the food or FDA approves a request to recondition the product, then an FDA hearing determines whether the product should be released. If FDA determines that the owner or consignee has provided sufficient information to overcome the appearance of a violation, the owner or consignee receives a notice stating that the product is released. If FDA determines that the owner or consignee's actions failed to bring the product into compliance, the food must be exported or destroyed.

If the product is subject to an import alert, FDA determines whether the product should be detained without physical examination. If FDA determines that the product should not be detained, the owner or consignee receives a notice stating that the product is released. If FDA determines that the product should be detained, FDA issues a notice stating that the line is being detained and is subject to refusal, and the owner or consignee decides whether to export or destroy the product. Figure 3 illustrates the key elements of FDA's screening process.

¹⁹Reconditioning 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 by relabeling or other action, or by rendering it other than a food, drug, device, or cosmetic.

Figure 3: Overview of the Food and Drug Administration’s (FDA) Process for Screening Imported Food Shipments for Entry Admissibility



Source: GAO analysis of FDA data. | GAO-16-399

From 2012 to 2014, about 0.1 percent of all food entry lines were refused and exported or destroyed each year.²⁰ During this period the countries with the highest number of entry lines that were refused were India, Mexico, and China and the most commonly refused items included rice, herbals and botanicals (not teas), tuna, shrimp and aquaculture-harvested seafood products, and vitamins and minerals.

When unsafe food enters the country, FDA may respond by issuing advisories about the affected food. Depending on the circumstances, FDA may also use other enforcement tools, such as seizure, injunction, and administrative detention.²¹ FDA can also seek voluntary recalls of unsafe food. If a responsible party does not voluntarily recall the food, FDA may issue a mandatory recall order, provided that certain criteria are met.

In early 2010, FDA began an effort to assess foreign food safety systems to determine whether certain other countries have a regulatory system—including food safety statutes, regulations, and an implementation strategy—that is comparable to the U.S. food safety system. Under this effort, FDA in 2010 developed a systems recognition tool to assess the overall food safety systems of foreign countries for foods under FDA’s jurisdiction. FDA completed its on-site review for a systems recognition pilot with New Zealand food safety authorities in late 2010 and established a Systems Recognition Arrangement in 2012. In May 2016, FDA reported that it had established a similar arrangement with Canada.

²⁰According to our analysis of FDA data, there were 11,843 refusals of food entry lines in 2012 (out of 9,282,926 food entry lines), 11,690 in 2013 (out of 9,826,400), and 8,845 in 2014 (out of 10,358,414).

²¹According to FDA, a seizure is an action taken to remove a product from commerce because it is in violation of the law. FDA initiates a seizure by filing a complaint with the U.S. District Court where the product is located. An injunction is a civil process initiated to stop or prevent violation of the law, such as to halt the flow of violative products in interstate commerce and to correct the conditions that caused the violation to occur. Administrative detention occurs when FDA requires that imported articles that appear violative under the laws FDA administers be held intact. Articles detained under an administrative detention order are released if brought into compliance with or rendered not subject to FDCA, or are refused entry if not brought into compliance. Administrative detention orders are temporary and usually expire in 20-30 days.

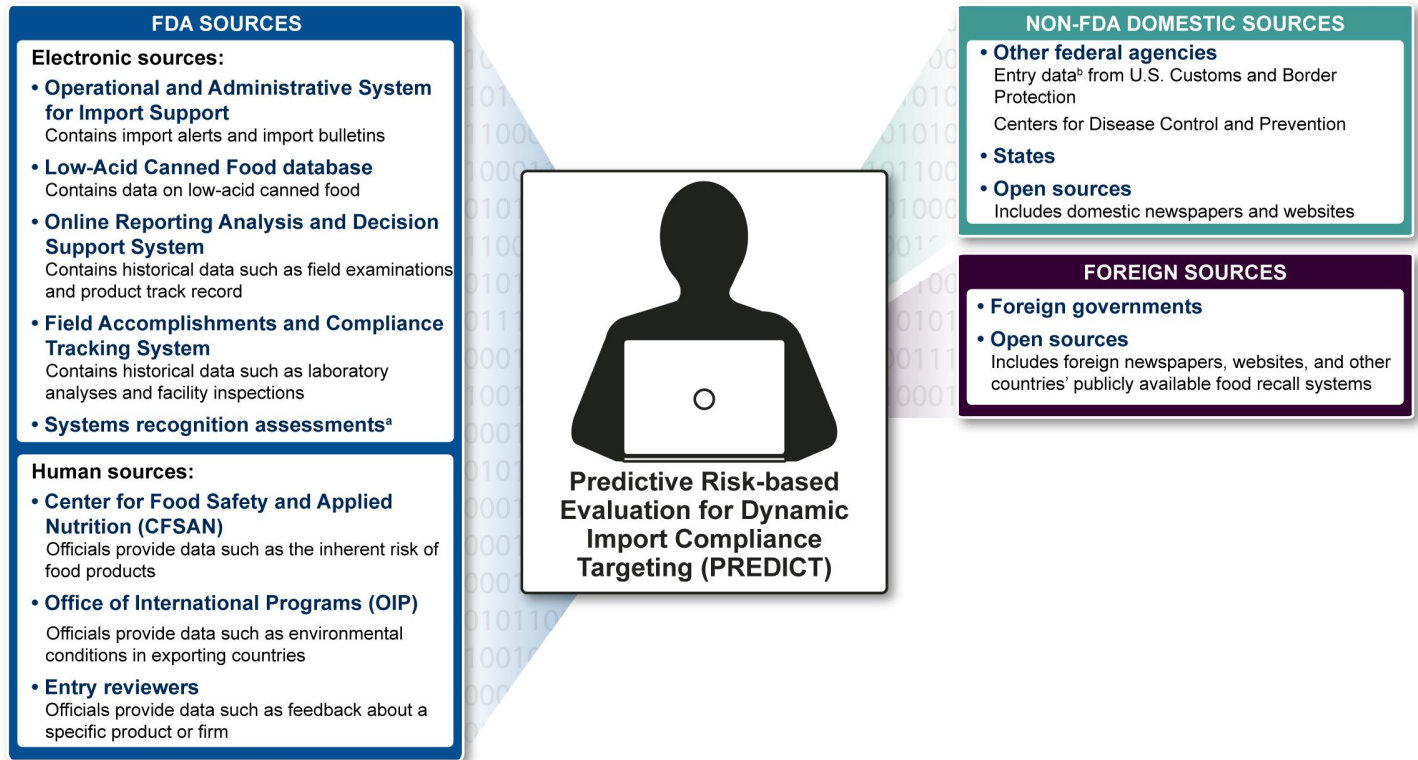
PREDICT Uses Data and Analyzes the Data by Applying Rules That Contribute to Risk-Based Scores, but FDA Does Not Have a Documented Process for Obtaining Some Data

PREDICT uses a variety of data and FDA-created rules—conditional statements that tell PREDICT how to react when encountering particular information—to analyze these data and to identify high-risk imported food shipments. These data include information from FDA sources; non-FDA domestic sources, such as other federal and state agencies; and foreign sources, such as foreign governments. Some of the domestic and foreign sources are open sources—that is, publicly available. FDA does not currently have a documented process for obtaining open source data. PREDICT analyzes all of the data by applying rules that contribute to risk-based scores. PREDICT then recommends potential FDA actions, such as holding an entry line for examination or allowing it to proceed into commerce.

PREDICT Uses a Variety of Data, but FDA Does Not Have a Documented Process for Obtaining Open Source Data

PREDICT uses a variety of data to estimate the risk of imported food. These data come from internal FDA sources, other domestic sources, and foreign sources. Figure 4 provides an overview of the types of data sources PREDICT uses.

Figure 4: Data Sources Used by the Food and Drug Administration’s PREDICT Import Screening Tool



Source: GAO analysis of Food and Drug Administration (FDA) documents and interviews with FDA officials. | GAO-16-399

Note: The figure is not intended to list every source used by PREDICT to estimate the risk of imported food.

^aSystems recognition assessments—formerly known as comparability studies—involve a review of a foreign country’s domestic and export systems for all food products that are under FDA’s jurisdiction. Such studies could enable FDA to leverage other countries’ oversight capacity and enforcement authority. See *Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries’ Oversight Resources*, GAO-12-933 (Washington, D.C.: Sept. 28, 2012).

^bEntry data are information submitted by a filer (typically, the broker or importer) about the imported product(s), including product description, manufacturer information, and country of origin.

Data from FDA Sources

Many of the data PREDICT uses come from sources within FDA. These include electronic sources, such as databases, and human sources, such as FDA officials.

- **Electronic sources.** Most of the electronic FDA sources that PREDICT uses are databases that contain historical data about products, firms, and other elements of imported shipments, such as the geographic location of facilities. PREDICT uses numerous kinds of

historical data stored in various FDA databases, such as data about (1) the previous field examination and facility inspection history of foreign firms, (2) the track record of importers and brokers, and (3) the types of food products historically imported from other countries. One of the other databases that PREDICT uses contains official FDA safety violation data, such as FDA import alerts and import bulletins.²² Another database that PREDICT uses contains registration data for facilities that manufacture, process, or pack a specific type of food product, acidified and low-acid canned foods, which are specifically tracked because growth of the *botulinum* bacterium in canned food may cause a deadly form of food poisoning.

- **Human sources.** The human FDA sources that PREDICT draws upon include FDA officials who compile and report data based on their knowledge of products, firms, and other elements of imported shipments, such as country of origin. For example, certain PREDICT rules use FDA's knowledge and experience to determine the inherent risk of certain food products, and certain other PREDICT rules draw from data reported by FDA entry reviewers about the past record of products or firms.

Data from Non-FDA Domestic Sources

According to FDA officials, PREDICT also uses data from sources outside of FDA, including domestic sources, such as databases from states and other federal agencies. For example, PREDICT uses data from CBP. Specifically, CBP collects entry data from importers for products being imported into the United States and electronically transfers the data to FDA.²³ PREDICT also uses data from other federal agencies, such as from NMFS. NMFS maintains a list of approved seafood establishments, based on its fee-for-service inspections, on its website and may provide this list electronically to FDA upon request. However, FDA only requests information from NMFS on an occasional, as-needed basis. For example, FDA requested information from NMFS in 2010 during the Gulf of Mexico

²²Import bulletins are internal notices to FDA field offices that generally provide information on a new or developing problem affecting imported products. Import bulletins may result in increased surveillance of imported products, including sample examination and analysis. Unlike import bulletins, import alerts inform FDA field staff that products covered by the alert may be subject to detention without physical examination.

²³Entry data are information about the imported product(s) submitted by a filer (typically, the product importer or a broker)—including a description of the product, manufacturer information, and country of origin—into CBP's electronic system. Once CBP determines that the product is under FDA jurisdiction, it electronically transfers these data into FDA's OASIS.

oil spill. More recently, FDA requested NMFS audit reports and facility approvals for certain overseas locations.²⁴

Data from Foreign Sources

FDA officials told us that PREDICT also uses data from foreign sources, such as foreign governments. Specifically, FDA's domestic and overseas offices obtain information from foreign regulatory counterparts on an occasional, as-needed basis about food safety in their respective countries and provide summary information to ORA that may be used in PREDICT. FDA officials told us that the agency may receive nonpublic information from foreign governments only in cases where formal arrangements called Confidentiality Commitments are in place. Of the more than 230 entities from which the United States imports food, FDA has 39 foods-related Cooperative Arrangements with 24 foreign governments—including 1 arrangement with the European Union, which has 28 member countries. FDA officials told us that they are in the process of developing additional cooperative arrangements.

An FDA office that is involved in obtaining information from foreign regulatory counterparts is OIP, which has offices in the United States and abroad that help obtain foreign scientific and regulatory information by coordinating with foreign regulators or accessing foreign media sources. One country covered by OIP's Office of Regional and Country Affairs is Japan. In March 2011, after a 9.0 magnitude earthquake and subsequent tsunami in Japan, the Fukushima Daiichi nuclear power plant suffered extensive damage. The Office of Regional and Country Affairs coordinated with the Japanese government to identify Japanese exports that have a high risk of contamination. As a result, FDA issued Import Alert 99-33: "Detention Without Physical Examination of Products from Japan Due to Radionuclide Contamination." This alert informs FDA field personnel that they may detain without physical examination certain food shipments from Japan. FDA officials told us that years after the disaster, the agency continues to obtain information from the Japanese government, and the import alert is still in place and was last revised in

²⁴In 2011, we recommended that to better ensure the safety of seafood imports, FDA develop a strategic approach with specific time frames for enhancing collaborative efforts with NMFS and better leveraging NMFS inspection resources. The Department of Health and Human Services neither agreed nor disagreed with this recommendation, and FDA has not implemented it. See GAO, *Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources*, [GAO-11-286](#) (Washington, D.C.: Apr. 14, 2011).

April 2016. As of March 10, 2014, FDA had tested 1,345 import and domestic samples specifically to monitor for Fukushima contamination. Of the 1,345 samples, 2 were found to contain detectable levels of a contaminant, but the levels posed no public health concern.

Open Source Data

Both the non-FDA domestic sources and the foreign sources may include open sources—that is, sources that are publicly available, such as newspapers and Internet blogs. Data from open sources may provide information about events—such as food recalls and natural disasters—that could affect the risk of imported foods. Although ORA collects some open source data on its own, it also relies on other FDA offices and federal agencies that gather open source data for their own purposes and that may communicate to ORA information that seems relevant to the import screening mission. For example, OIP’s Europe office monitors news related to FDA-regulated products in Europe. If OIP obtains recall information that it deems significant to FDA-regulated commodities, it communicates the information to ORA and other relevant FDA offices. ORA may also obtain open source data from other federal agencies, such as from the agencies represented at CBP’s Commercial Targeting and Analysis Center, which targets and screens commercial shipments that may pose a threat to the health and safety of U.S. consumers. Open source data have proven useful in the past. For example, in August 2015, an explosion occurred at a warehouse in the port of Tianjin, China, involving hazardous chemicals, including cyanide, posing a potential threat to public health. In the aftermath, OIP, through its China Office, collected information about the explosion from local media sources. As a result, FDA increased surveillance of FDA-regulated imports from manufacturing, processing, and/or packing facilities in the Tianjin area. In this particular instance, FDA also notified importers of this increased level of surveillance.

Prior to 2015, FDA had a formal contract dedicated to the collection of open source data for PREDICT. FDA’s 2013 PREDICT operating manual, *PREDICT Guide: Rules and Scoring*, documented how the agency was to obtain open source data, the type of data to be provided by the contracted company—such as data about natural disasters—and how PREDICT used the data. According to the manual, the PREDICT Open-Source Intelligence Team used open source data to locate news stories pertaining to food safety around the world, looking specifically for geophysical events (e.g., tsunamis, typhoons, and earthquakes) or ecological events (e.g., algal blooms, overuse of antibiotics, and contamination from various spills that could affect FDA-regulated commodities). Analysts then researched each event or action to

understand the content and context of the issue, develop an analytic conclusion, and recommend a risk score and expiration date.

FDA terminated that contract because the agency determined that it was not cost-effective, given the availability of information from other public sources, such as the Internet and other offices within the agency. The 2015 version of FDA's PREDICT operating manual does not document the process for identifying the type of open source data to collect, obtaining such data, and determining how PREDICT is to use the data. Instead, FDA relies on ORA officials to informally communicate and obtain information from officials in other FDA offices and from other federal agencies on an ad hoc basis. FDA told us that because the agency did not renew the contract, the 2015 version omitted references to obtaining and using open source information. ORA officials told us they now use a variety of informal and situation-dependent methods to obtain open source intelligence, but these methods are not formally documented. We have previously found that by using informal coordination mechanisms, agencies may rely on relationships with individual officials to ensure effective collaboration and that these informal relationships could end once personnel move to their next assignments.²⁵ Under federal standards for internal control, agencies are to clearly document internal control, and the documentation is to appear in management directives, administrative policies, or operating manuals.²⁶ Without a documented process, FDA does not have reasonable assurance that it is consistently identifying the type of open source data to collect, obtaining such data, and determining how PREDICT is to use the data in a regular and systematic manner. A senior ORA official in its Division of Import Operations told us that formalizing and documenting the process by which FDA receives information from other entities would improve the current process for using open source information.

²⁵GAO, *Live Animal Imports: Agencies Need Better Collaboration to Reduce the Risk of Animal-Related Diseases*, [GAO-11-9](#) (Washington, D.C.: Nov. 8, 2010), and *National Security: Key Challenges and Solutions to Strengthen Interagency Collaboration*, [GAO-10-822T](#) (Washington, D.C.: June 9, 2010).

²⁶GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999). GAO has revised and reissued *Standards for Internal Control in the Federal Government*, with the new revision effective as of October 1, 2015. [GAO-14-704G](#) (Washington, D.C.: September 2014).

PREDICT Analyzes Data by Applying Rules That Contribute to Risk-Based Scores and Recommended Actions

FDA creates rules, conditional statements that tell PREDICT how to react when encountering particular situations. For example, if a certain PREDICT rule encounters the term “tamarind” in the description of a product, it should recommend detaining the item without physical examination. This rule was created as the result of an incident in which filth was found in tamarind products.²⁷ PREDICT’s application of rules generates a cumulative risk score for each entry line; the cumulative risk score includes factors such as the product’s inherent risk and the manufacturing firm’s facility inspection history. The risk score can indicate a negative risk value (signifying low risk) or a positive risk value (signifying higher risk). The individual risk values assigned to the various elements of the entry line help produce the cumulative risk score for the entire entry line and possibly also one or more recommended actions.

The application of a rule may prompt a flag (for example, an import alert flag), which may provide information—such as that a manufacturer’s product was recently examined or that the product was refused admission by one or more foreign countries—and recommended an action. For example, it may point out that some of the entry line data are missing or invalid—based on a comparison with other FDA databases—and recommend performing a manual review of databases.

After PREDICT has applied the rules to the entry data, entry reviewers analyze the results. The first thing an entry reviewer sees is the main entry review screen, which lists all the current entry lines to be reviewed and their PREDICT risk scores and flags. The entry reviewer can click on a PREDICT risk score to see a table, referred to as the PREDICT Mashup. The PREDICT Mashup displays the individual risk values that contributed to the overall PREDICT risk score for that entry line. For example, the PREDICT Mashup may show that PREDICT assigned the product’s manufacturer a risk-based score of 10 for its facility inspection history, which would signify a high risk.²⁸ The same Mashup may show that PREDICT assigned the product’s country of origin a risk-based score of 3 for its history, which would signify a lower risk. The entry reviewer can also “roll over,” or move the cursor over, flags to obtain more information. For example, an entry reviewer may roll over a “recent

²⁷The related import alert refers to filth as appearing “to consist in whole or in part of a filthy, putrid, or decomposed substance (insect, rodent, and/or other animal filth, and mold), or to be otherwise unfit for food.”

²⁸The higher the score assigned by PREDICT in the Mashup, the higher the risk.

targeted activity” flag—which indicates that this product from this manufacturer was recently examined—to obtain information (sometimes through another database) about when the product was examined and the results of the examination.

The entry reviewer uses all of this information to decide how to proceed. For example, the entry reviewer may decide to allow the entry line to proceed into commerce or to hold it for examination or laboratory analysis. Any action taken by the entry reviewer, including the results of any examination, will become part of the history of the facility, which will then contribute to future PREDICT scores.

The Implementation of FSMA Will Provide PREDICT with Additional Data on Imported Food

FSMA, which was enacted in 2011, contains provisions that will provide PREDICT with additional data to analyze (i.e., from additional sources) when estimating the risk of imported food. FDA officials told us that even with the changes brought about by FSMA, PREDICT will continue to be used to target imports for examination but will now draw data from even more sources. FDA officials identified five FSMA provisions and authorities as likely to generate the most data for use in PREDICT. Of these five, the first three are as follows:

- **Foreign Supplier Verification Program (FSVP):** The FSVP rule requires importers to verify that their foreign suppliers use processes and procedures that provide the same level of public health protection as the hazard analysis and risk-based preventive controls and other applicable requirements of FDCA. For example, importers must develop, maintain, and follow an FSVP that provides adequate assurances that the foreign supplier is producing food that is, among other things, not adulterated (e.g., that it does not contain *Salmonella*) and is not misbranded with respect to labeling for the presence of major food allergens.²⁹ Verification activities could include monitoring records, annual on-site inspections or review of such inspections performed by a qualified auditor, and testing and sampling of

²⁹Food is deemed to be adulterated under FDCA if, among other things, it bears or contains any poisonous or deleterious substance that may render it injurious to health.

shipments.³⁰ The date by which importers must comply with the FSVP regulations depends on a number of factors.³¹

- **Inspection of foreign food facilities:** FSMA includes a provision that authorizes FDA to direct resources according to the known safety risks of facilities, especially those that present a high risk.³² The law directs FDA to inspect at least 600 foreign facilities within 1 year of enactment of FSMA and, in each of the 5 years following that period, to inspect at least twice the number it inspected during the previous year.³³
- **Laboratory accreditation:** FSMA also includes a provision that requires FDA to establish a program for the testing of food by accredited laboratories and to recognize accreditation bodies for accrediting the laboratories, including independent private laboratories. The provision requires owners or consignees to have food products tested by an accredited laboratory in certain circumstances, including when a food product is under an import alert that requires successful consecutive tests. The results of these tests may be submitted to FDA electronically and used to determine

³⁰Certain categories of imported food are exempt from the FSVP regulation, including certain juice, fish, and fishery products (which are already subject to verification under FDA's HACCP regulations for those products), food for research or evaluation, food for personal consumption, and alcoholic beverages.

³¹The date by which importers must comply with the FSVP regulations is the latest of the following dates: 18 months after publication of the final rule; for the importation of food from a supplier that is subject to the preventive controls or produce safety rules, 6 months after the foreign supplier is required to meet the relevant regulations; or for an importer that is itself a manufacturer or processor subject to the supply-chain program provisions in the preventive controls regulations, the date by which it has to comply with those provisions.

³²Under FSMA, high-risk facilities are determined by several factors, including the known safety risks of the food manufactured, processed, packed, or held at the facility; the compliance history of a facility; and the rigor and effectiveness of the facility's preventive controls.

³³As noted earlier, we found in January 2015 that FDA was not keeping pace with the number of inspections of foreign food facilities because of limited resources and questions about the usefulness of increased inspections. We recommended that FDA complete an analysis to determine the annual number of foreign food inspections that is sufficient to ensure comparable safety of imported and domestic food. If the inspection numbers from that evaluation are different from the inspection targets mandated in FSMA, FDA should report the results to Congress and recommend appropriate legislative changes. FDA agreed with the recommendation but has not yet taken action. See [GAO-15-183](#).

compliance and admissibility of the food product. FDA has not yet issued a proposed rule for establishing the program, but an agency official stated that the agency is working on a rule now.

The other two FSMA provisions likely to generate data for use in PREDICT are related to third-party certification, for which FDA issued the final rule in November 2015. FSMA directs the establishment of a system for the recognition of accreditation bodies to accredit third-party certification bodies (also known as auditors) to certify that a foreign facility, or any product produced by the facility, meets the applicable FDA food safety requirements.³⁴ If an accredited third-party certification body or its audit agent discovers a condition that could cause or contribute to a serious risk to public health, the certification body must immediately notify FDA.³⁵ The following two FSMA provisions rely on third-party certifications and will likely generate data for use in PREDICT:

- **Voluntary Qualified Importer Program (VQIP):** FSMA requires FDA to establish a program that offers expedited review and entry to certain participating importers that import food from foreign facilities certified by accredited third-party certification bodies. FDA published draft guidance for VQIP in the *Federal Register* in June 2015.³⁶ According to an FDA Fact Sheet on VQIP, the agency expects to begin receiving applications for the program in January 2018.
- **Import certifications:** Under FSMA, FDA has the authority, under certain circumstances, to require certifications or other assurances from agencies, or representatives of foreign governments where the food originated, or an accredited third-party certification body. FDA

³⁴Under FSMA, “accreditation body” means an authority that performs accreditation of third-party auditors. (FDA’s third-party certification final rule uses the term “certification bodies”) “Third-party auditor” means a foreign government, agency of a foreign government, foreign cooperative, or any other third party determined by the Secretary of Health and Human Services that is eligible to be considered for accreditation to conduct food safety audits to certify that eligible entities meet the applicable requirements. “Accredited third-party auditor” means a third-party auditor accredited by an accreditation body to conduct audits of eligible entities to certify that such eligible entities meet the applicable requirements of this section.

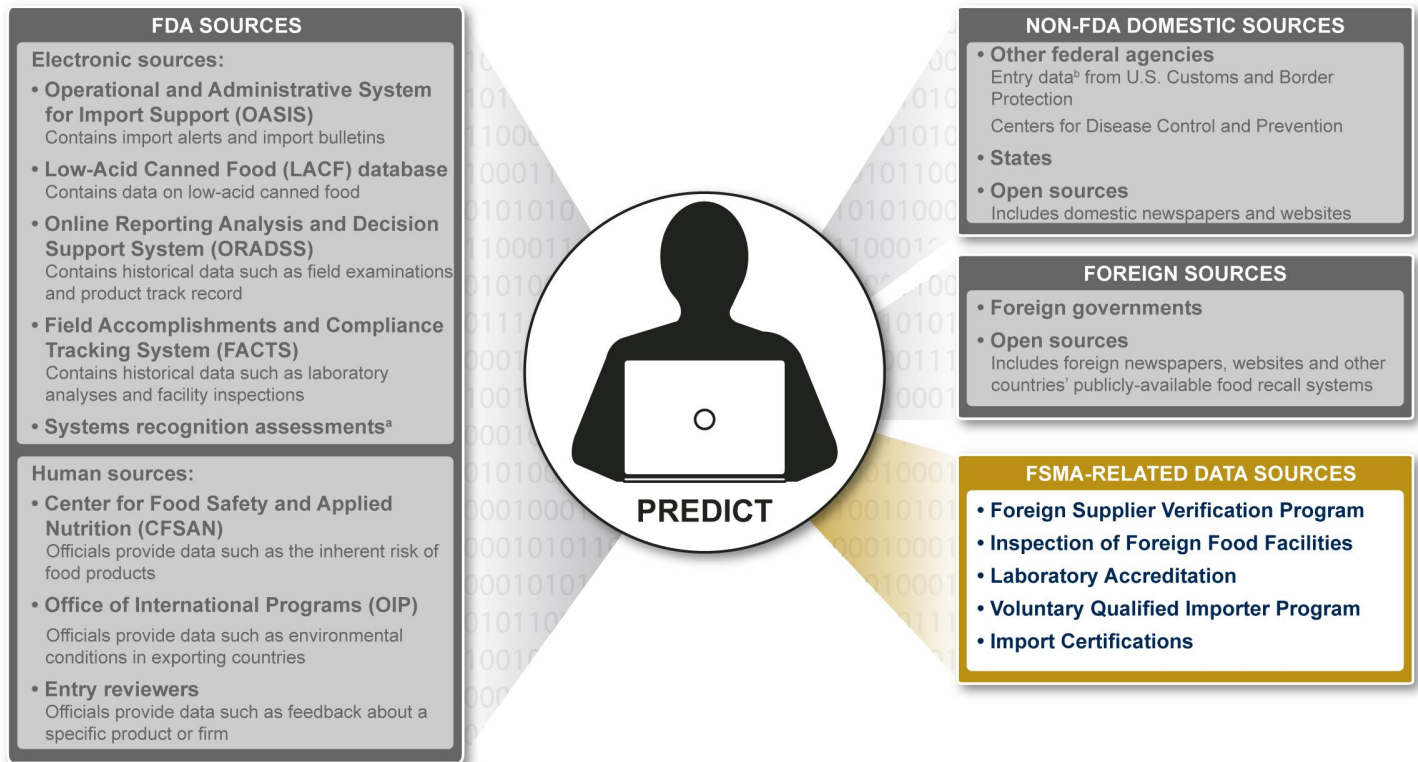
³⁵An audit agent is an individual who is an employee or other agent of an accredited third-party auditor/certification body who, although not individually accredited, is qualified to conduct food safety audits on behalf of an accredited auditor/certification body. An audit agent includes a contractor of the accredited third-party auditor/certification body.

³⁶80 Fed. Reg. 32,136 (June 5, 2015).

can determine that an article of food requires certification based on, among other factors, the known safety risks associated with the food; the country, territory, or region of origin of the food; or evidence that the food safety systems for that product are inadequate. FDA published the final rule on accreditation of third-party certification bodies in the November 27, 2015, *Federal Register*.

Because some of these FSMA-related programs are still new and not yet fully implemented, the details of how certain data generated by these programs will be integrated into PREDICT are not finalized, but according to FDA officials, PREDICT will use data produced by these programs and authorities in a variety of ways. Implementation of FSVP, for example, will identify importers that are not in compliance, and PREDICT would use that information in assigning risk scores to products from those importers. The food products from suppliers and importers that have a history of noncompliance with food safety regulations will receive higher PREDICT risk scores than those that are consistently in compliance. In addition, if the results from an inspection of a foreign food facility show that the facility is noncompliant, that information would be provided to PREDICT, and PREDICT would use that information in assigning risk scores to imports from that facility. Figure 5 shows how the implementation of FSMA will add to the data sources already used by PREDICT.

Figure 5: How the FDA Food Safety Modernization Act Will Add to the Data Sources Used by the Food and Drug Administration’s PREDICT Import Screening Tool



Sources: GAO analysis of Food and Drug Administration (FDA) documents and interviews with FDA officials and FSMA-related FDA sources. | GAO-16-399

Note: The figure is not intended to list every source used by PREDICT to estimate the risk of imported food.

^aSystems recognition assessments—formerly known as comparability studies—involve a review of a foreign country’s domestic and export systems for all food products that are under FDA’s jurisdiction. Such studies could enable FDA to leverage other countries’ oversight capacity and enforcement authority. See *Food Safety: FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries’ Oversight Resources*, [GAO-12-933](#) (Washington, D.C.: Sept. 28, 2012).

^bEntry data are information submitted by a filer (typically the broker or importer) about the imported product(s), including product name and description, manufacturer information, and country of origin.

FDA Assessed the Effectiveness of PREDICT in 2013, but Some Recommended Improvements Have Yet to Be Implemented

FDA has assessed the effectiveness of PREDICT by ongoing monitoring of key program data and by conducting an evaluation of the tool in 2013, and it has implemented many, but not all, of the 2013 evaluation's recommendations to improve PREDICT. Data maintained by agency officials show that PREDICT is working properly to focus reviewers' attention on food items that have a high probability of being violative. Moreover, when FDA officials conducted an evaluation of the system in 2013, results showed that PREDICT was working well to provide staff with the data they need to make informed entry review decisions. However, the agency has not yet implemented all of the 24 recommendations resulting from that evaluation.

FDA's Ongoing Monitoring Shows That PREDICT Is Effectively Targeting Higher-Risk Items for Examination

FDA officials told us that they conduct monitoring of PREDICT on an ongoing basis and that the data they collect as part of this monitoring show that PREDICT is working as intended—that is, PREDICT is focusing entry reviewers' attention on items determined to be of higher risk. Data provided by FDA from fiscal years 2012 to 2014 confirmed that in general, PREDICT is fulfilling this role. Our analysis of these data showed that in general, the higher the PREDICT risk score, the more often entry lines were examined and the more often they were found violative.³⁷ As tables 1, 2, and 3 show, for fiscal years 2012 through 2014, entry lines that received higher PREDICT scores generally were more often selected for a field examination, for a label examination, or for sampling, and entry lines with higher PREDICT scores were more often found violative.

³⁷In October 2014, we reported that high violation rates did not necessarily correspond with high risk scores generated by PREDICT among the entry lines that FDA tested for pesticide residues. See [GAO-15-38](#). The current engagement looks more broadly at all potential sources of violation—not just pesticides.

Table 1: Relationship between the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) Score, Percentage of Food Entry Lines Examined, and Percentage of Food Entry Lines Found Violative, Fiscal Year 2012

PREDICT score	Total entry lines ^a	Entry lines examined ^b	Percentage of entry lines examined	Number of lines examined that were violative	Percentage of lines found violative
0–10	1,924,431	18,031	0.94	82	0.45
11–20	1,158,018	10,276	0.89	127	1.24
21–30	1,010,559	8,500	0.84	173	2.04
31–40	927,457	7,913	0.85	163	2.06
41–50	623,504	6,494	1.04	267	4.11
51–60	549,595	7,466	1.36	396	5.30
61–70	676,093	16,279	2.41	1,019	6.26
71–80	751,775	19,494	2.59	1,797	9.22
81–90	442,646	15,269	3.45	1,839	12.04
91–100	598,367	39,014	6.52	5,285	13.55
Total^c	9,282,926	160,657	No data	12,456	No data

Source: GAO analysis of FDA data. | GAO-16-399

^aIncludes entry lines only for food not for other imported products, such as medical devices or tobacco.

^bEntry lines examined includes those items subjected to a field examination, a label examination, or a sample collection.

^cThe numbers in this table do not add to totals because this table does not include those entry lines that received a “no rank” classification. PREDICT screening is designed to “time out” after 2 hours, which means PREDICT stops attempting to connect with internal data sources. If PREDICT times out and the entry reviewer was unable to successfully access PREDICT on subsequent attempts, the item is assigned a “no rank” classification.

Table 2: Relationship between the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) Score, Percentage of Food Entry Lines Examined, and Percentage of Food Entry Lines Found Violative, Fiscal Year 2013

PREDICT score	Total entry lines ^a	Entry lines examined ^b	Percentage of entry lines examined	Number of lines examined that were violative	Percentage of lines found violative
0–10	2,245,852	29,215	1.30	148	0.51
11–20	1,389,552	17,465	1.26	356	2.04
21–30	1,174,412	12,598	1.07	327	2.60
31–40	974,664	11,133	1.14	468	4.20
41–50	945,668	11,031	1.17	464	4.21
51–60	651,910	10,277	1.58	565	5.50
61–70	627,291	16,156	2.58	1,208	7.48
71–80	1,010,148	33,457	3.31	3,598	10.75
81–90	427,027	19,257	4.51	2,467	12.81

PREDICT score	Total entry lines ^a	Entry lines examined ^b	Percentage of entry lines examined	Number of lines examined that were violative	Percentage of lines found violative
91–100	210,568	12,109	5.75	2,152	17.77
Total^c	9,826,400	177,598	No data	12,798	No data

Source: GAO analysis of FDA data. | GAO-16-399

^aIncludes entry lines only for food not for other imported products, such as medical devices or tobacco.

^bEntry lines examined includes those items subjected to a field examination, a label examination, or a sample collection.

^cThe numbers in this table do not add to totals because this table does not include those entry lines that received a “no rank” classification. PREDICT screening is designed to “time out” after 2 hours, which means PREDICT stops attempting to connect with internal data sources. If PREDICT times out and the entry reviewer was unable to successfully access PREDICT on subsequent attempts, the item is assigned a “no rank” classification.

Table 3: Relationship between the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) Score, Percentage of Food Entry Lines Examined, and Percentage of Food Entry Lines Found Violative, Fiscal Year 2014

PREDICT score	Total entry lines ^a	Entry lines examined ^b	Percentage of entry lines examined	Number of lines examined that were violative	Percentage of lines found violative
0–10	1,166,542	14,794	1.27	41	0.28
11–20	1,091,116	11,039	1.01	60	0.54
21–30	1,248,219	12,387	0.99	107	0.86
31–40	1,290,736	14,140	1.10	251	1.78
41–50	1,256,653	14,257	1.13	454	3.18
51–60	840,168	10,817	1.29	374	3.46
61–70	673,331	14,460	2.15	572	3.96
71–80	530,776	12,171	2.29	567	4.66
81–90	819,664	18,791	2.29	1,186	6.31
91–100	1,286,507	45,160	3.51	5,363	11.88
Total^c	10,358,414	173,470	No data	9,746	No data

Source: GAO analysis of FDA data. | GAO-16-399

^aIncludes entry lines only for food not for other imported products, such as medical devices or tobacco.

^bEntry lines examined includes those items subjected to a field examination, a label examination, or a sample collection.

^cThe numbers in this table do not add to totals because this table does not include those entry lines that received a “no rank” classification. PREDICT screening is designed to “time out” after 2 hours, which means PREDICT stops attempting to connect with internal data sources. If PREDICT times out and the entry reviewer was unable to successfully access PREDICT on subsequent attempts, the item is assigned a “no rank” classification.

In all 3 years we reviewed, items with the highest PREDICT scores—those from 91 to 100—were selected for examination more often than items with lower PREDICT scores. For example, in fiscal year 2012, FDA

examined or sampled more than 39,000 entry lines with a PREDICT score from 91 to 100, or about 6.5 percent of all entry lines in this range, nearly double the percentage of entry lines examined in the next-highest 10 point risk score range and at least 6 times more than entry lines with a score of 50 or less.

The tables also show that in each of the 3 years we reviewed, the higher the PREDICT score, the higher the percentage of entry lines that were found to be violative. For example, in fiscal year 2014, FDA selected for examination about 45,000 of the nearly 1.3 million entry lines with PREDICT scores of 91 to 100. Of these, nearly 12 percent, or 5,363 line items, were found to be violative, almost double the percentage of violation rates found in the next-highest range of PREDICT scores.

FDA Conducted an Internal Evaluation of PREDICT and Developed 24 Recommendations to Improve the Tool

In May 2013, FDA completed an internal evaluation of PREDICT's effectiveness that examined five processes: work planning, examinations and sampling, entry review, rules management, and communication.³⁸ To conduct this evaluation, FDA officials gathered information through a variety of methods, including analysis of entry line data and the entry review process, interviews with stakeholders from the various FDA centers, and surveys of PREDICT users in the field. Overall, the evaluation showed that PREDICT is helping to expedite the release of low-risk items and to identify violative imports.

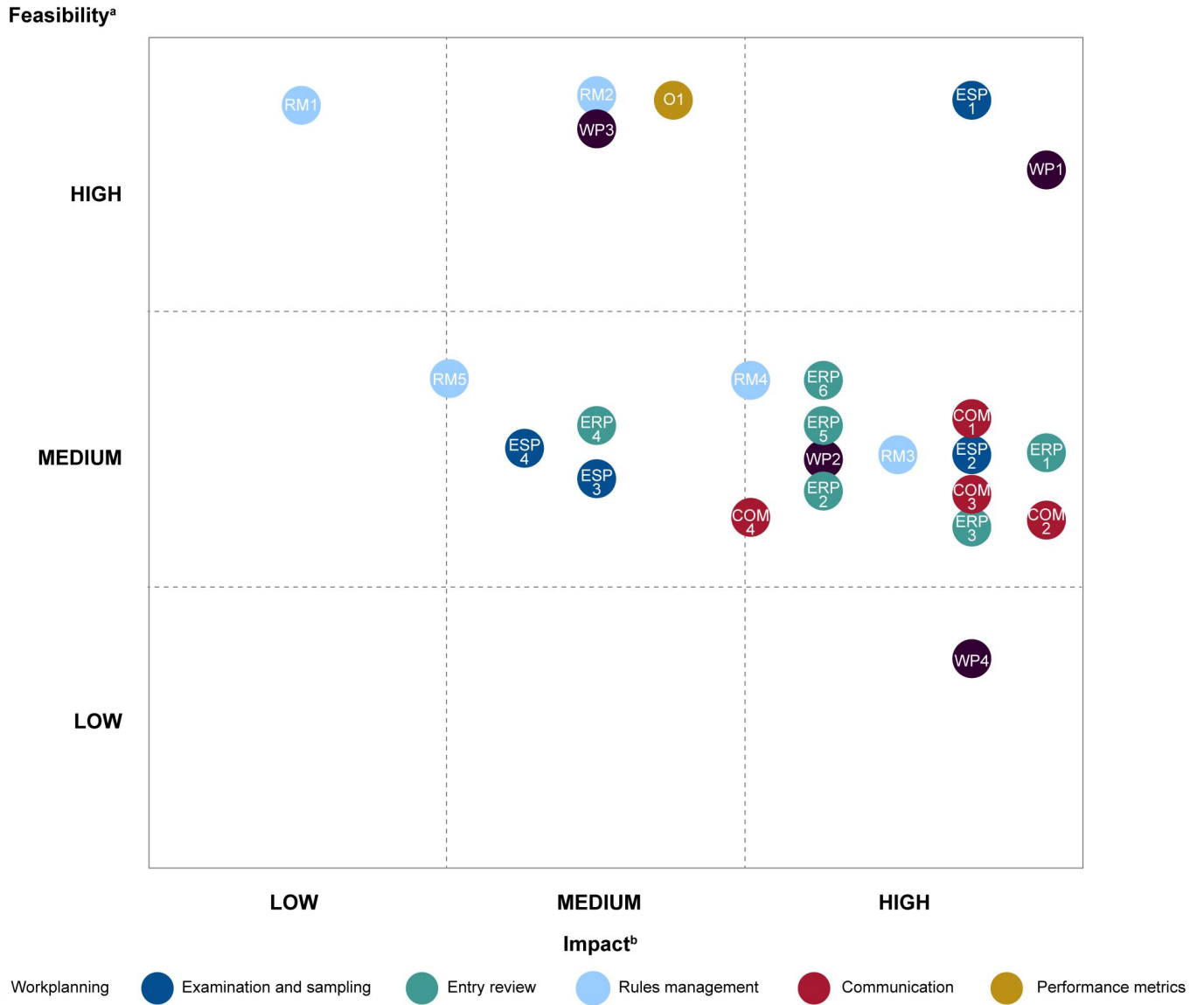
As a result of the internal evaluation, FDA developed a total of 24 recommendations: 23 for improving the five processes noted above and another recommendation concerning the development of performance metrics. The list below shows the categories of recommendations and the number of recommendations in each category:

- work planning (4),
- examination and sampling (4),
- entry review (6),
- rules management (5),
- communication (4), and
- performance metrics (1).

³⁸Although the evaluation was conducted by FDA, it was carried out by an entity that had little knowledge of import operations. FDA officials told us it was important to have an "outside entity" conduct the evaluation to ensure objectivity.

FDA prioritized each of its 24 recommendations according to the feasibility of near-term implementation and the impact on operations or public health, among other things. A recommendation was determined to have high feasibility if resources were available to implement it and the implementation plan was clear. A recommendation was determined to have high impact if, for example, many stakeholders cited the problem that the recommendation was intended to solve. As figure 6 shows, of the 24 recommendations, 6 were determined to be highly feasible, and 16 were determined to be of high impact or medium/high impact; 2 recommendations were determined to be both highly feasible and of high impact.

Figure 6: Prioritization of the Food and Drug Administration’s 24 Recommendations to Improve the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting Import Screening Tool



Source: FDA. | GAO-16-399

^aFeasibility refers to the feasibility of near-term implementation.

^bImpact refers to the impact on operations, public health, or other things.

Examples of FDA’s recommendations and how they were prioritized include

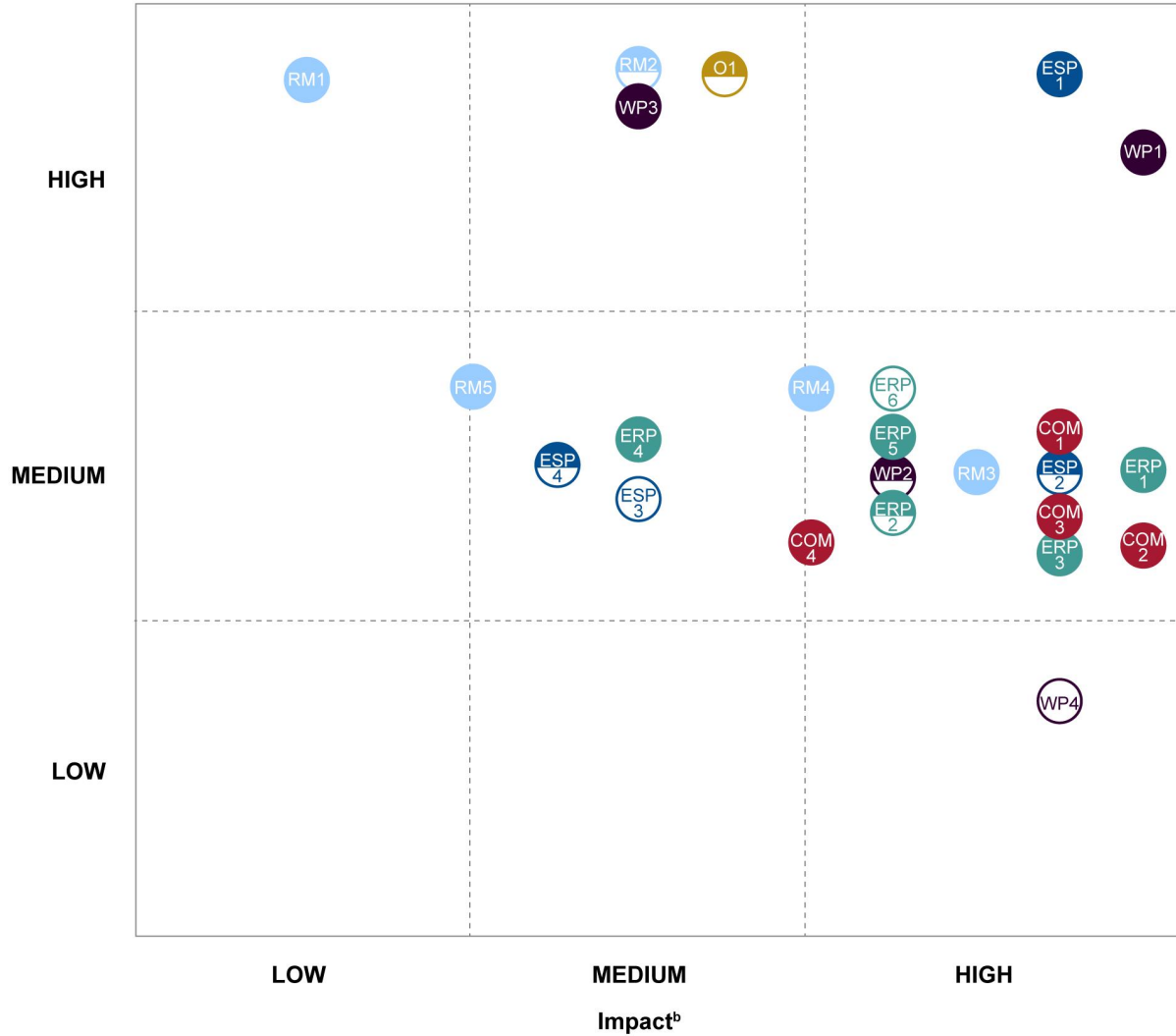
-
- analyze and set specific “May Proceed” thresholds by commodity (designated as both highly feasible and of high impact),
 - develop a system to test PREDICT rules (designated as highly feasible and of medium impact), and
 - identify sources of delays associated with the sampling process (designated as of medium feasibility and medium impact).

FDA Has Implemented Many, but Not All, of Its Recommendations

FDA has evaluated the 24 recommendations and has implemented many, but not all, of them. According to agency officials, the agency has implemented 15, partially implemented another 6, and not implemented 3 (see fig. 7).

Figure 7: Implementation Status of the Food and Drug Administration’s 24 Recommendations to Improve the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting Import Screening Tool

Feasibility^a



Source: FDA. | GAO-16-399

^aFeasibility refers to the feasibility of near-term implementation.

^bImpact refers to the impact on operations, lead time, or public health.

Of the 15 recommendations that were implemented, 13 were designated either as highly feasible or of high or medium/high impact. Both of the recommendations determined to be both highly feasible and of high impact were implemented, including the recommendation to analyze and set specific “May Proceed” thresholds by commodity. Of the 6 that were partially implemented—which includes the recommendation to develop a system to test PREDICT rules—5 were designated as either highly feasible or of high or medium/high impact. Finally, of the 3 that were not implemented—which includes the recommendation to identify sources of delays associated with the sampling process—1 was of low feasibility and high impact, 1 was of medium feasibility and high impact, and 1 was of medium feasibility and medium impact.

Federal standards for internal control state that agencies are to ensure that the findings of audits and other reviews are promptly resolved. To that end, agencies are to complete, within established time frames, all actions that correct or otherwise resolve the matters brought to management’s attention.³⁹ According to FDA officials, the reason for partially implementing or not implementing recommendations was often a lack of resources. For example, FDA officials said that a lack of resources was why they only partially implemented the recommendation to develop a system to test PREDICT rules and did not implement the recommendation to identify sources of delays associated with the sampling process. Agency officials agree that implementing the remaining recommendations would improve the effectiveness of PREDICT, but the agency has not yet established time frames for completing the implementation of the remaining recommendations. Establishing a practical timeline for implementing the remaining recommendations as resources become available would provide FDA with reasonable assurance that the improvements are made and that PREDICT remains an effective tool for screening imports.

Conclusions

The volume of FDA-regulated imported food continues to grow, as does the need to ensure that such imports are safe. FDA physically examines about 1 percent of food shipment entry lines annually. The agency developed PREDICT to help target food shipments deemed higher risk and subject them to additional scrutiny. FDA’s assessment of PREDICT

³⁹See [GAO/AIMD-00-21.3.1](#). GAO has revised and reissued *Standards for Internal Control in the Federal Government*, with the new revision effective as of October 1, 2015. GAO-14-704G (Washington, D.C.: September 2014).

shows that the tool is generally working to focus FDA's resources on the examination of food items determined to be of highest risk and expediting the release of lower-risk food items.

PREDICT analyzes imported food entry lines using data from various sources, including FDA sources, other domestic sources, and foreign sources. Some of the domestic and foreign sources are open sources, and FDA uses such sources to obtain information about imported foods on an ad hoc basis. However, FDA does not have a documented process for identifying the type of open source data to collect, obtaining such data, and determining how PREDICT is to use the data. Without such a documented process, FDA does not have reasonable assurance that it will consistently obtain open source data for PREDICT in a regular and systematic manner.

In addition, FDA's May 2013 evaluation of PREDICT identified 24 recommendations to improve the tool, and FDA has fully implemented 15 of these recommendations. FDA officials explained that resource constraints have often limited their ability to fully implement all the remaining recommendations. Agency officials agree that implementing these recommendations would improve the effectiveness of PREDICT, but the agency has not yet established time frames for doing so. Establishing a practical timeline for implementing the remaining recommendations would help FDA ensure that the improvements are made and that PREDICT remains an effective tool for helping to prevent high-risk foods from entering the United States.

Recommendations for Executive Action

To further enhance FDA's PREDICT tool and its ability to ensure the safety of imported food, we recommend that the Secretary of Health and Human Services direct the Commissioner of FDA to take the following two actions:

- document the process for identifying the type of open source data to collect, obtaining such data, and determining how PREDICT is to use the data and
- establish a timeline for implementing, as resources become available, the remaining recommendations from FDA's 2013 evaluation of PREDICT.

Agency Comments and Our Evaluation

We provided the departments of Commerce, Health and Human Services, and Homeland Security a draft of this report for their review and comment. In an e-mail, the Department of Commerce stated that it had no comments. The Department of Health and Human Services generally concurred with the recommendations and provided written comments on the draft, which are summarized below and presented in their entirety in appendix II of this report. The Department of Homeland Security provided technical comments, which we incorporated as appropriate.

In its written comments, the Department of Health and Human Services concurred with our first recommendation and concurred in part with the second. For our first recommendation, HHS stated that ORA plans to work with appropriate units across the agency to develop and document a formal process to identify the type of information to collect, how to obtain the information, and how PREDICT may use it. For our second recommendation, HHS stated that it has recently fully implemented one of the internal recommendations from the 2013 internal evaluation that was previously designated as “partially implemented.” However, because HHS did not provide evidence of fully implementing the recommendation, we were unable to verify such implementation and made no change to the report. The Department also stated that it is supportive of the remaining recommendations from its 2013 internal evaluation but noted that establishing an implementation timeline is based on consideration of the feasibility and impact relative to available FDA resources and other FDA priorities, such as FSMA. The department indicated that the goals of the unimplemented recommendations may ultimately be achieved via these other FDA initiatives.

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

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

Sincerely yours,

A handwritten signature in black ink that reads "Steve D. Morris". The signature is written in a cursive style with a large, stylized "S" and "M".

Steve D. Morris
Director
Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

You asked us to examine how the Food and Drug Administration (FDA) is using Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) to protect the safety of the U.S. food supply. Our objectives in this report were to examine (1) the data used by PREDICT and how PREDICT analyzes these data to identify high-risk food shipments for examination; (2) how implementation of the FDA Food Safety Modernization Act (FSMA) will affect PREDICT; and (3) the extent to which FDA has assessed the effectiveness of PREDICT and used the results of those assessments to improve the tool.

To determine the data used by PREDICT and how PREDICT analyzes these data to identify high-risk food shipments for examination, we reviewed documents that described the data used by PREDICT and interviewed FDA officials. We assessed the data sources, data quality controls, and the methodology used by PREDICT and determined that they were sufficiently reliable to support accurate descriptions of the system inputs, processes, and resulting risk scores. We also assessed the data used by PREDICT to ensure that they were sufficiently reliable to describe factors considered by PREDICT and system rules used to generate risk scores.¹ We interviewed FDA officials in the Office of International Programs to understand how FDA coordinates with foreign governments to obtain data for PREDICT. We also reviewed how the agency identifies, obtains, and uses open source information and compared this process to criteria for documentation found in the federal standards for internal control.² To determine the extent to which the implementation of FSMA will affect PREDICT, we reviewed FSMA, FDA's rules implementing FSMA, and FDA planning documents and interviewed FDA officials. To determine the extent to which FDA has assessed the effectiveness of PREDICT and used the results of those assessments to improve the tool, we interviewed FDA officials about ongoing monitoring of PREDICT, reviewed the 2013 evaluation that FDA has conducted on PREDICT, and assessed the extent to which FDA has implemented the recommendations from the evaluation. We then compared FDA's actions to the criteria found in the federal standards for internal control regarding

¹We did not assess whether the individual data sources were complete and accurate, but rather whether they were a reasonable representation of the intended inputs into PREDICT's analytical functions.

²GAO, *Standards for Internal Control in the Federal Government*, [GAO/AIMD-00-21.3.1](#) (Washington, D.C.: November 1999). GAO has revised and reissued *Standards for Internal Control in the Federal Government*, with the new revision effective as of October 1, 2015. GAO-14-704G (Washington, D.C.: September 2014).

the findings of audits and other reviews. In addition, we examined data provided by FDA on PREDICT risk scores and violation rates from fiscal years 2012 through 2014, the most recent years for which data were available, and determined that the data were sufficiently reliable for our purposes, as discussed above.

To inform all three objectives, we conducted site visits at four FDA and U.S. Customs and Border Protection (CBP) facilities located at ports of entry located in Baltimore, Maryland; Otay Mesa in San Diego, California; Long Beach California; and Los Angeles, California. We selected these sites to include air, ship, and truck ports of entry; variable geographic locations; the variability of food products that enter through the ports; and proximity to an FDA office. The information we obtained at these sites is not generalizable to all facilities and ports of entry. In addition, we interviewed officials from CBP and the National Marine Fisheries Service to understand how FDA coordinates with other federal agencies to protect the safety of the U.S. food supply. We also interviewed officials from a number of stakeholder organizations that are affected by PREDICT or contributed to PREDICT's development.

We conducted this performance audit from January 2015 to May 2016 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.

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



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

MAY 05 2016

Mr. Steve D. Morris
Director, Health Care Team
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 Food Safety: FDA's Targeting Tool Has Enhanced Screening, but Further Improvements Are Possible*" (GAO-16-399).

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

Sincerely,

A handwritten signature in blue ink that reads "K-S. Esquea".

for
Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: IMPORTED FOOD SAFETY: FDA'S TARGETING TOOL HAS ENHANCED SCREENING, BUT FURTHER IMPROVEMENTS ARE POSSIBLE (GAO-16-399)

The U.S Department of Health and Human Services (HHS) appreciates the opportunity from the Government Accountability Office to review and comment on this draft report.

Recommendation #1: To further enhance FDA 's PREDICT tool and its ability to ensure the safety of imported food, GAO recommends that the Secretary of Health and Human Services direct the Commissioner of FDA to document the process for identifying the type of open source data to collect, obtaining such data, and determining how PREDICT is to use the data.

HHS Response: HHS concurs with this recommendation. ORA plans to work with appropriate units across the agency to develop and document a formal process to identify the type of information to collect, how to obtain such information, and how PREDICT may use the information.

Recommendation #2: To further enhance FDA's PREDICT tool and its ability to ensure the safety of imported food, GAO recommends that the Secretary of Health and Human Services direct the Commissioner of FDA to establish a timeline to implement, as resources become available, the remaining recommendations from FDA's 2013 evaluation of PREDICT.

HHS Response: HHS concurs in part with this recommendation. Of the twenty-four recommendations from the 2013 evaluation, FDA has now fully implemented sixteen and partially implemented five. These numbers reflect a change in status to "fully implemented" for one of the recommendations previously categorized as "partially implemented" in the GAO report.

FDA is supportive of the remaining recommendations from the 2013 evaluation, but establishing an implementation timeline is based on consideration of the feasibility and impact of implementation relative to available FDA resources and other FDA priorities such as implementation of the Automated Commercial Environment (ACE), the Food Safety Modernization Act (FSMA), etc. While the recommendations not implemented from the 2013 evaluation are directly related to import operations (including a multi-year hiring plan, modification of sampling procedures, and improved entry review processes), they do not necessarily have a direct impact on PREDICT's functionality as a screening tool for imports. As such, the goals of the unimplemented recommendations may ultimately be achieved via other FDA initiatives, such as FDA Program Alignment, ACE implementation, and FSMA implementation.

Appendix III: GAO Contact and Staff Acknowledgments

GAO Contact

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

Staff Acknowledgments

In addition to the contact named above, Anne K. Johnson (Assistant Director), Kevin Bray, Ellen Fried, Steven Putansu, Gloria Ross, Stuart Ryba, Sara Sullivan, Vasiliki Theodoropoulos, and Karen Villafana made key contributions to this report.

Appendix IV: Accessible Data

Agency Comment Letter

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

Page 1

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Washington, DC 20201

MAY 05 2016

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Director, Health Care Team

U.S. Government Accountability Office

441 G Street NW

Washington, DC 20548

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Jim R. Esquea

Assistant Secretary for Legislation

Attachment

Page 2

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Data
Tables/Accessible
Text

Data Table for Figure 1: Food and Drug Administration-Regulated Food Imports by Volume, 1999–2014

Year	FDA-Regulated Food Import Volume (in 1,000 metric tons)
1999	39159.89
2000	39845.64
2001	42252.31
2002	43700.82
2003	44974.79
2004	47592.2
2005	49853.42
2006	54998.83
2007	58534.62
2008	59947.44
2009	54251.89
2010	56430.95
2011	58972.44
2012	61909.26
2013	65720.04
2014	67054.42

Accessible Text for Figure 4: Data Sources Used by the Food and Drug Administration’s PREDICT Import Screening Tool

FDA Sources

Electronic sources:

- **Operational and Administrative System for Import Support**
Contains import alerts and import bulletins
- **Low-Acid Canned Food database**
Contains data on low-acid canned food
- **Online Reporting Analysis and Decision Support System**
Contains historical data such as field examinations and product track record
- **Field Accomplishments and Compliance Tracking System**
Contains historical data such as laboratory analyses and facility inspections
- **Systems recognition assessments^a**

Human sources:

-
- **Center for Food Safety and Applied Nutrition (CFSAN)**
Officials provide data such as the inherent risk of food products
 - **Office of International Programs (OIP)**
Officials provide data such as environmental conditions in exporting countries
 - **Entry reviewers**
Officials provide data such as feedback about a specific product or firm

Non-FDA Domestic Sources

- **Other federal agencies**
Entry data^b from U.S. Customs and Border Protection
Centers for Disease Control and Prevention
- **States**
- **Open sources**
Includes domestic newspapers and websites

Foreign Sources

- Foreign governments
- Open sources
Includes foreign newspapers, websites, and other countries' publicly available food recall systems

Accessible Text for Figure 5: How the FDA Food Safety Modernization Act Will Add to the Data Sources Used by the Food and Drug Administration's PREDICT Import Screening Tool

FSMA-Related Data Sources:

- Foreign Supplier Verification Program
- Inspection of Foreign Food Facilities
- Laboratory Accreditation
- Voluntary Qualified Importer Program
- Import Certifications

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