

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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IMPORTED FOOD SAFETY

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

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.