

Why GAO Did This Study

U.S. reliance on imported food increased from 2000 through 2011. For some products, imports make up a considerable share of the total amount consumed in the United States. FDA—responsible for ensuring the safety of most imported foods—received new authority under FSMA to enhance its oversight of food imports, including express authority to establish a system for accrediting third parties, which may include foreign governments and private auditing firms, to certify foreign food facilities' compliance with U.S. food safety requirements. FDA has also begun to assess selected foreign food safety systems to determine if these systems provide the same level of public health protection, among other things.

GAO was asked to (1) identify major actions FDA is to take to implement a system for accrediting third parties and challenges, if any, it and others report with these actions and (2) examine FDA's approach for using comparability assessments to leverage other countries' oversight capacity and enforcement authority. GAO reviewed FDA documents and interviewed officials from FDA and other agencies, and stakeholders, such as consumer groups and industry representatives.

What GAO Recommends

GAO recommends that FDA revise its comparability approach to one that also includes assessing foreign food safety systems for particular food products, such as seafood. FDA neither agreed nor disagreed with the recommendation.

FOOD SAFETY

FDA Can Better Oversee Food Imports by Assessing and Leveraging Other Countries' Oversight Resources

What GAO Found

We identified five major actions the Food and Drug Administration (FDA) is to complete under the FDA Food Safety Modernization Act (FSMA) to establish a reliable system that uses third-party audits conducted by foreign governments or other third parties to help ensure food safety. FDA officials and others report that each of these actions presents challenges that must be addressed. First, FDA is to develop new preventive controls and related guidance for all of the foods under its jurisdiction—such as produce, milk, cheese, spices, soft drinks, and processed foods—and will need to develop appropriate training, particularly for foreign producers and processors, which poses a challenge because FDA is responsible for a variety of food industries. Second, FDA is to establish a voluntary user fee program for importers that encourages the use of third-party certifications, and it faces a challenge in developing a program that encourages importers to participate. Third, FDA has to develop a system for recognizing accreditation bodies that can accredit third parties to certify foreign food facilities and is likely to face a challenge in addressing foreign governments' concerns about being evaluated by an entity other than FDA. Fourth, FDA is to develop model standards for accreditation bodies to use in evaluating and accrediting third parties and faces challenges in, among other things, determining third-party auditors' competency and deciding on how to avoid potential conflicts of interest. Fifth, FDA is to oversee the third-party accreditation system, including periodically evaluating accreditation bodies and third parties, and faces a challenge in deciding the level of oversight it will provide to the multiple parties involved in third-party certification.

FDA's approach for using comparability assessments can enable the agency to leverage other countries' oversight capacity and enforcement authority. This could result in some of the same advantages as the equivalence approach used by the U.S. Department of Agriculture's Food Safety Inspection Service (FSIS) and the European Union (EU) before specific food products can be imported. These advantages include having a foreign competent authority address any identified problems and take regulatory actions across the supply chain, as necessary. However, according to FDA officials, the agency expects few countries to seek comparability with the United States because, in part, most countries will not meet the FDA requirement that a foreign government's domestic and export food safety systems be comparable to the U.S. system for food products under FDA's jurisdiction. According to FDA documents, some countries have robust export certification programs for a specific food product, but their overall food safety systems, including domestic production systems, may not be comparable with those of the United States. Consequently, FDA would be unable to leverage the resources of countries with comparable systems for just one food product, such as seafood, which FDA has experience in assessing through its foreign country assessments. Representatives from major seafood exporting countries GAO interviewed stated that they would like to have agreements with FDA covering seafood that are similar to those they have with the EU, which uses a targeted approach through equivalence to determine whether certain exported food products are safe for domestic consumption.