

## Why GAO Did This Study

About half of the seafood imported into the U.S. comes from farmed fish (aquaculture). Fish grown in confined aquacultured areas can have bacterial infections, which may require farmers to use drugs like antibiotics. The residues of some drugs can cause cancer and antibiotic resistance. The Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) is charged with ensuring the safety of seafood against residues from unapproved drugs, and the Department of Commerce's National Marine Fisheries Service (NMFS) provides inspection services on request. In 2009, these agencies signed a memorandum of understanding (MOU) to enhance seafood oversight and leverage inspection resources. GAO was asked to assess the extent to which (1) FDA's program is able to ensure the safety of seafood imports against residues from unapproved drugs and (2) FDA and NMFS have implemented the 2009 MOU. GAO reviewed data and documents from each agency and interviewed agency officials and other key stakeholders.

## What GAO Recommends

GAO recommends that FDA study the feasibility of adopting practices used by other entities to better ensure the safety of imported seafood, enhance its import sampling program, and develop a strategic approach for enhancing collaboration with NMFS and better leveraging resources. HHS neither agreed nor disagreed with GAO's recommendations but cited actions in process or planned that are generally responsive to them.

View [GAO-11-286](#) or key components. For more information, contact Lisa Shames at (202) 512-3841 or [shamesl@gao.gov](mailto:shamesl@gao.gov).

## SEAFOOD SAFETY

### FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources

## What GAO Found

FDA's oversight program to ensure the safety of imported seafood from residues of unapproved drugs is limited, especially as compared with the European Union (EU). FDA's program is generally limited to enforcing the Hazard Analysis and Critical Control Point—the internationally recognized food safety management system—by conducting inspections of foreign seafood processors and importers each year. These inspections involve FDA inspectors reviewing records to ensure the processors and importers considered significant hazards, including those resulting from drug residues if the seafood they receive are from fish farms. The inspectors generally do not visit the farms to evaluate drug use or the capabilities, competence, and quality control of laboratories that analyze the seafood. In addition, FDA has conducted foreign country assessments in five countries to gather information about those countries' aquaculture programs. However, these assessments have been limited by FDA's lack of procedures, criteria, and standards. In contrast, the EU reviews foreign government structures, food safety legislation, the foreign country's fish farm inspection program, and visits farms to ensure that imported seafood products come from countries with seafood safety systems equivalent to that of the EU. In addition, the scope of FDA's sampling program, which supplements its oversight program, is limited. Specifically, the sampling program does not generally test for drugs that some countries and the EU have approved for use in aquaculture. Consequently, seafood containing residues of drugs not approved for use in the United States may be entering U.S. commerce. Further, FDA's sampling program is ineffectively implemented. For example, for fiscal years 2006 through 2009, FDA missed its assignment plan goal for collecting import samples by about 30 percent. In addition, in fiscal year 2009, FDA tested about 0.1 percent of all imported seafood products for drug residues. Moreover, FDA's reliance on 7 of its 13 laboratories to conduct all its aquaculture drug residue testing raises questions about the agency's use of resources.

FDA and NMFS have made limited progress in implementing their 2009 MOU. The agencies have developed procedures for certain MOU activities, such as notifying NMFS of pending FDA regulatory actions. However, because FDA believes NMFS inspectors need training to conduct inspections according to FDA standards, it has not utilized NMFS' inspection resources or results in a systematic manner. Better leveraging available resources is critical, especially in places like China, where FDA has inspected 1.5 percent of Chinese seafood processing facilities in the last 6 years.