



Testimony

Before the Subcommittee on Health,
Committee on Energy and Commerce,
House of Representatives

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SEAFOOD SAFETY

Status of Issues Related to Catfish Inspection

Statement of Steve D. Morris, Director,
Natural Resources and Environment

GAO Highlights

Highlights of [GAO-17-289T](#), a testimony before the Subcommittee on Health, Committee on Energy and Commerce, House of Representatives

Why GAO Did This Study

The volume of seafood imported to the United States has increased. In 2009, 80 percent of the seafood in the U.S. food supply was imported, but by 2015, more than 90 percent was imported. Catfish accounted for about 4 percent of all seafood imports. Since 2007, federal oversight of food safety has been on GAO's list of high-risk areas, largely because of fragmentation that has caused inconsistent oversight, ineffective coordination, and inefficient use of resources.

The Food, Conservation, and Energy Act of 2008, the 2008 Farm Bill, split responsibility for seafood safety between FSIS, for catfish inspection, and FDA, for seafood in general. The bill directed FSIS to issue catfish inspection regulations, and FSIS prepared a risk assessment to determine risks associated with catfish and identified *Salmonella* as the primary food safety hazard.

For this testimony, GAO focused on (1) the transfer of responsibility for the inspection of catfish from FDA to FSIS, (2) the status of the FSIS catfish program's implementation, and (3) information on GAO's ongoing work on seafood safety. GAO based this testimony primarily on a May 2012 report, for which it reviewed FSIS's then-proposed program and related documents and interviewed FDA and FSIS officials. GAO updated that work with publicly available information on FSIS's program implementation efforts.

View [GAO-17-289T](#). For more information, contact Steve Morris, 202-512-3841, morriss@gao.gov

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What GAO Found

In reviewing the transfer of responsibility for the inspection of catfish from the Food and Drug Administration (FDA) to the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS), GAO found in May 2012 that FSIS's then-proposed catfish inspection program would further divide responsibility for overseeing seafood safety and introduce overlap at considerable cost. For example, while FSIS would be responsible for catfish, FDA would be responsible for other types of seafood, and the Department of Commerce's National Marine Fisheries Service would provide fee-for-service inspections of some seafood-processing facilities at their request. GAO identified four areas of concern regarding the potential for overlap or inefficient use of resources if FSIS were to implement the catfish inspection program. Specifically, there could be: (1) an increase in paperwork requirements for catfish processors; (2) overlapping inspections or unnecessary inspection frequency; (3) inconsistent oversight of imported seafood; and (4) additional costs of setting up FSIS's inspection program. In addition, FSIS identified *Salmonella* as the primary catfish health hazard, but a study FSIS cited in its risk assessment of *Salmonella* in catfish reported that the hazards from *Salmonella* and other bacteria in catfish were practically zero. Furthermore, GAO found that FSIS used outdated information in its risk assessment as its scientific basis for a catfish inspection program. We concluded that the FSIS catfish inspection program would likely not enhance the safety of catfish but would duplicate other federal seafood inspections at an annual cost to taxpayers of about \$14 million, as estimated by FSIS.

The Agricultural Act of 2014, also known as the 2014 Farm Bill, required FSIS to coordinate with FDA to execute a memorandum of understanding (MOU) that would, among other things, ensure that inspections of catfish conducted by both agencies were not duplicative. The agencies signed the MOU in April 2014. In December 2015, FSIS issued the final regulation for the catfish inspection program as required and also significantly reduced its 2011 estimate of the program's annual cost to the government, from about \$14 million to about \$2.6 million. In March 2016, FSIS assumed responsibility for inspecting domestic catfish and in April 2016 assumed responsibility for screening catfish imports.

GAO has ongoing work for the Senate Appropriations Committee examining federal oversight of seafood safety. GAO is examining how FDA and FSIS ensure the safety of imported seafood, including catfish, and any opportunities to strengthen their programs. GAO is also reviewing the coordination between FDA and FSIS and the extent to which these agencies are leveraging each other's resources to more effectively conduct their imported seafood oversight programs.

Chairman Pitts, Ranking Member Green, and Members of the Subcommittee:

I am pleased to be here today to discuss the U.S. Government's efforts to oversee the safety of catfish.

The volume of seafood imported to the United States has increased over the past several years. For example in 2009, we reported that 80 percent of the seafood consumed in the United States was imported. By 2015, this percentage had grown to more than 90 percent, of which almost half was raised on fish farms, a practice known as aquaculture. In 2015, catfish imports accounted for more than 4 percent of all seafood imports. Almost all catfish is raised on farms. Seafood, like other food products, can present food safety risks, such as from the presence of pathogens or chemical contamination.¹ Effective federal oversight of seafood is important to help ensure that safe seafood is available to U.S. consumers. Since 2007, federal oversight of food safety has been on GAO's list of high-risk areas, largely because of fragmentation that has caused inconsistent oversight, ineffective coordination, and inefficient use of resources.²

My testimony focuses on (1) the findings of our May 2012 report on the transfer of responsibility for the inspection of catfish from the Food and Drug Administration (FDA) to the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS),³ (2) the status of the implementation of FSIS's catfish inspection program, and (3) information describing our ongoing work examining the federal oversight of imported seafood, including catfish. For this testimony, we primarily drew from our May 2012 report on FSIS's proposed catfish inspection program and updated that work with publicly available information as of November 2016 on FSIS's efforts to implement the program. For our May 2012 report, we reviewed FSIS's then-proposed catfish inspection program and related documents. We interviewed officials from FDA, FSIS, the Department of Commerce's National Marine Fisheries Services (NMFS),

¹Such contamination can include residues of drugs that are unapproved for use in the United States and would render the seafood adulterated under the Federal Food, Drug, and Cosmetic Act.

²GAO, *High-Risk Series: An Update*, [GAO-07-310](#) (Washington, D.C.: January 2007).

³GAO, *Seafood Safety: Responsibility for Inspecting Catfish Should Not Be Assigned to USDA*, [GAO-12-411](#) (Washington, D.C.: May 10, 2012).

and other federal agencies, as well as representatives from industry and consumer advocacy groups. We conducted site visits of two domestic processing facilities that process catfish and other seafood. We also reviewed components and costs of FSIS's then-proposed catfish inspection program, FDA's seafood inspection program, and the fee-for-service seafood inspection program of NMFS. More details on the scope and methodology for our work can be found in the issued report.⁴ The work on which this statement is based was conducted 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

According to U.S. Department of Commerce and U.S. Customs and Border Protection Agency data, the volume of imported catfish has been increasing in recent years. In 2005, the United States imported over 30 million pounds of catfish. In 2010, the United States imported about 137 million pounds; the major catfish exporters were Vietnam, with 79 percent, and China with 13 percent. By 2015, total catfish imports were at almost 250 million pounds, with Vietnam alone accounting for more than 95 percent of all such imports. For 2016, total catfish imports as of September were more than 221 million pounds, again with Vietnam accounting for most of the imports. Domestically, catfish production is concentrated in Alabama, Arkansas, Louisiana, and Mississippi.

FSIS and FDA are the two primary U.S. food safety agencies. FSIS is responsible for the safety of meat; poultry; processed egg products; and more recently, catfish. FDA is responsible for virtually all other food, including seafood. Under the Federal Food, Drug, and Cosmetic Act, FDA is responsible for ensuring that most of the nation's food supply, including seafood, is safe, wholesome, sanitary, and properly labeled. NMFS provides fee-for-service inspections, primarily under the authority of the Federal Agricultural Marketing Act of 1946. Specifically, NMFS provides inspection services on request to the seafood industry—including domestic and foreign processors, distributors, and other firms—to certify that these seafood firms comply with federal food safety standards,

⁴[GAO-12-411](#).

among other things. Some retailers require this certification as a condition for purchasing seafood products.

The Food, Conservation, and Energy Act of 2008, also referred to as the 2008 Farm Bill, assigned regulatory responsibility for the inspection of catfish to USDA once the agency issued final regulations for a mandatory catfish inspection program. Until USDA's FSIS issued the final regulations, FDA continued to be responsible for the safety of all seafood, including catfish. In February 2011, FSIS published and sought comments on a proposed rule outlining possible regulations for a new catfish inspection program.⁵ Among other things, FSIS's then-proposed program would require (1) processors to implement written sanitation and hazard control plans; (2) FSIS inspectors to conduct continuous inspection of domestic catfish processing;⁶ and (3) for imported catfish, foreign countries to demonstrate equivalence to U.S. standards. Regarding equivalence, countries that wish to export meat, poultry, and processed egg products to the United States must demonstrate to FSIS that their food safety systems for these food products are equivalent to those of the U.S. system.

The Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 requires an analysis of the health risks and costs and benefits for major proposed regulations issued by USDA that regulate human health, human safety, or the environment (i.e., defined as regulations the Secretary of Agriculture estimates are likely to have an annual impact on the U.S. economy of \$100 million or more in 1994 dollars). In response to this requirement, FSIS prepared a risk assessment and an impact analysis and made them available for public review. FSIS used the risk assessment to determine the primary hazard of concern associated with consuming farm-raised catfish in the United States, and the agency conducted an impact analysis to examine the costs and benefits of the proposed regulations. FSIS focused on *Salmonella* as the most significant hazard associated with catfish. FSIS prepared the risk assessment and impact analysis to evaluate the potential public health benefits of its proposed program if the primary hazard were addressed.

⁵76 Fed. Reg. 10,434 (Feb. 24, 2011).

⁶According to FSIS documents, this generally means that agency inspection program personnel will conduct inspections during all hours of operation.

The FDA Food Safety Modernization Act (FSMA), enacted in January 2011, gave FDA new authorities to oversee the safety of imported foods. For example, FSMA contains provisions on laboratory accreditation that enable FDA to leverage state, foreign government, and private laboratory resources for food testing.⁷ These laboratories must meet model standards developed by FDA that ensure quality and reliability of the test results used to verify the safety of any food product, including imports. FDA also has the authority, which predates FSMA, to undertake systems recognition assessments to determine whether a foreign food safety system is comparable to the U.S. food safety system in terms of legal authorities and similar oversight and monitoring activities.⁸ With these assessments, FDA can leverage the work of foreign governments to help ensure the safety of imported food.

The Transfer of Responsibility for the Inspection of Catfish from FDA to FSIS

In reviewing the transfer of responsibility for the inspection of catfish from FDA to FSIS, we found in our May 2012 report that FSIS's then-proposed catfish inspection program would further divide responsibility for overseeing seafood safety and introduce overlap at considerable cost.⁹ We noted that supporters of FSIS's then-proposed program stated that there were several problems with FDA's oversight system, such as limited inspection and sampling of imported seafood, and that FSIS's proposed catfish program regulations, if implemented, would enhance catfish safety. They added that FSIS staff would review foreign catfish safety systems to ensure these systems met U.S. requirements before such products were admitted into U.S. commerce. In addition, FSIS inspectors would reinspect catfish imports at the ports of entry.

We identified the following four areas that raised concerns about the potential for overlap or inefficient use of resources if FSIS were to implement the catfish inspection program:

⁷As of November 30, 2016, FDA had not finalized its regulations on laboratory accreditation.

⁸According to FDA documents, the agency has systems recognition agreements in place with New Zealand and Canada.

⁹[GAO-12-411](#).

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- **Similar Hazard Analysis and Critical Control Point (HACCP) system requirements.**¹⁰ FSIS, FDA, and NMFS essentially did not differ from each other in their HACCP system requirements. FSIS acknowledged that many domestic processing facilities were already meeting many of its proposed requirements. Nevertheless, in our May 2012 report, we noted that if FSIS implemented its then-proposed inspection program, catfish processors were likely to see their paperwork requirements increase. For example, FSIS would require written sanitation plans,¹¹ while FDA inspectors did not require written sanitation plans and instead required only that sanitation be monitored and records kept, according to FDA officials. Therefore, under FSIS's then-proposed inspection program, catfish processing facilities without written sanitation plans would be required to develop them.
 - **Inspection overlap and unnecessary inspection frequency.** With the implementation of FSIS's catfish inspection program, facilities that processed only catfish could be inspected by FSIS and NMFS, and facilities that processed both catfish and other seafood could be inspected by all three agencies—FSIS, FDA, and NMFS. In addition, FSIS proposed continuous monitoring in the form of daily inspections for catfish processing facilities. However, FDA inspected facilities that processed only catfish every 3 to 5 years because it considered catfish a low-risk product, but it could inspect other facilities that processed catfish, along with other seafood, more frequently, depending on the risks associated with the other seafood.
 - **Inconsistent oversight of imported seafood.** FSIS would use the equivalence approach (i.e., foreign countries demonstrating equivalence to U.S. standards) to oversee the safety of catfish, and FDA used a different approach—primarily the HACCP system (i.e., processors having primary responsibility for the safety of the seafood they process)—for the seafood it regulated.
 - **Cost of implementing FSIS's catfish inspection program.** FDA estimated that it spent less than \$700,000 annually to inspect catfish

¹⁰Under a HACCP system, processors are primarily responsible for the safety of the seafood they process. That is, processors are responsible for identifying where in their processing system one or more hazards are reasonably likely to occur (hazard analysis) and implementing control techniques to prevent or mitigate these hazards. Processors are to describe their hazard analysis and control techniques in HACCP plans.

¹¹Among other things, these plans contain the procedures that an establishment develops and implements to prevent direct contamination or adulteration of product, including those to be conducted prior to operations, and address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.

processing facilities, and in 2011, FSIS estimated that the implementation of its proposed catfish inspection program would cost the federal government and industry an additional \$14 million annually. In addition, FSIS estimated that it spent a total of \$15.4 million from fiscal years 2009 to 2011 to develop the catfish inspection program, including costs related to catfish sampling studies. In fiscal year 2012, FSIS planned to spend an additional \$4.4 million to support further program development.

We found in our May 2012 report that FSIS's proposed catfish inspection program further fragmented the federal oversight system for food safety without demonstrating that there was a problem with catfish or a need for a new federal program.¹² Since FDA introduced its HACCP requirements for seafood processing facilities in 1997, no reported outbreaks of illnesses caused by *Salmonella*—the hazard identified by FSIS in its 2010 risk assessment—had been reported in catfish, indicating the low risk presented by this pathogen in catfish. FSIS stated in its risk assessment of *Salmonella* in catfish that, among other things, there was substantial uncertainty about the number of illnesses caused by *Salmonella* that could be attributed to catfish consumption. Moreover, a study that FSIS cited in its risk assessment reported that the health hazards from *Salmonella* and other bacteria in catfish were practically zero because their incidence in catfish was low and because catfish are cooked prior to consumption. However, FSIS still identified *Salmonella* as the primary catfish health hazard in its risk assessment.

We also found that FSIS used outdated data in its risk assessment as its scientific basis for a catfish inspection program seeking to mitigate that hazard. For example, FSIS's risk assessment provided one example of a *Salmonella* outbreak associated with catfish consumption. This outbreak occurred in 1991, and the Centers for Disease Control and Prevention was not completely sure that catfish was the source of the *Salmonella* that resulted in the illnesses. We concluded that, if implemented, the catfish inspection program would likely not enhance the safety of catfish but would duplicate other federal catfish inspections at a cost to taxpayers. In addition, we further concluded that, with FDA's new authorities under FSMA, the federal government had an opportunity to enhance the effectiveness of the food safety system of all imported seafood, including catfish, and avoid the duplication of effort and costs that would result from FSIS's implementation of its proposed catfish

¹²[GAO-12-411](#).

inspection program. We therefore suggested that, to enhance the effectiveness of the food safety system for catfish and avoid duplication of effort and cost, Congress should consider repealing provisions of the 2008 Farm Bill that assigned USDA responsibility for examining and inspecting catfish and for creating a catfish inspection program. Congress has not acted on our matter for its consideration.

Status of the Implementation of the FSIS Catfish Inspection Program

With the Agricultural Act of 2014, also known as the 2014 Farm Bill, Congress reaffirmed its commitment to assigning USDA's FSIS the responsibility for inspecting catfish. Specifically, the 2014 Farm Bill required FSIS to coordinate with FDA to execute a memorandum of understanding (MOU) that would, among other things, ensure that inspections of catfish conducted by both agencies were not duplicative and provided FSIS a timeline for issuing final program regulations and implementing the program. In April 2014, FDA and FSIS signed an MOU to improve interagency cooperation on seafood safety and fraud prevention and to maximize the effectiveness of personnel and resources related to the examination and inspection of catfish. Specifically, FSIS agreed to assume primary regulatory oversight over catfish and inform FDA if an apparent violation was encountered involving fish and fish products other than catfish. FDA agreed, in part, not to inspect catfish at domestic and foreign establishments unless requested by FSIS and not to sample or analyze catfish bearing an official USDA inspection legend or official USDA import mark, unless requested to do so by FSIS.

In December 2015, FSIS issued the final regulation for the catfish inspection program and significantly reduced its 2011 estimate of the program's annual cost to the government from about \$14 million to about \$2.6 million.¹³ USDA indicated in its recent budget documents that it would not know the actual cost of FSIS's catfish inspection program until the program was fully implemented in September 2017.

In March 2016, FSIS assumed responsibility for inspecting domestic catfish processing facilities, including those facilities that slaughter and process and those that only process. In addition, FSIS required foreign countries that were exporting catfish to the United States as of that date and intended to continue exporting during the subsequent 18 months, which FSIS considered a transition period, to submit (1) a list of all foreign

¹³80 Fed. Reg. 75,590 (Dec. 2, 2015).

establishments (slaughter and processing facilities) that will continue to export catfish to the United States and (2) documentation to demonstrate the foreign government's authority to regulate the growing and processing of fish for human food and ensure compliance with U.S. food safety requirements. According to FSIS's website, as of November 21, 2016, 10 countries, including Vietnam and China—the two largest exporters of catfish to the United States—had submitted the required documentation to FSIS to continue exporting catfish to the United States.

In April 2016, FSIS assumed responsibility for screening catfish imports, including testing imports for drug residues. According to agency documents, a foreign country seeking to continue exporting catfish to the United States after September 1, 2017, when the program is scheduled to be fully implemented, must initiate a request for equivalence and provide additional, more extensive documentation showing that its system is equivalent to that of the United States.

Ongoing Seafood Safety Audit

In January 2016, we began work for the Senate Appropriations Committee examining federal oversight of seafood safety. More specifically, we are examining how FDA and FSIS ensure the safety of imported seafood and opportunities, if any, to strengthen their programs. As part of this work, we will review information on FDA's primary oversight mechanisms, including its seafood port-of-entry sampling and testing program. We will also review FSIS's equivalence determination process and reinspection program.¹⁴ In addition, we will also gather information on the European Union's equivalence process to determine whether its practices for ensuring the safety of seafood imports have the potential for enhancing the U.S. agencies' programs. Finally, we will review the coordination between FDA and FSIS and the extent to which these agencies are leveraging each other's resources to more effectively conduct their imported seafood oversight programs. We plan to issue this report in the spring of 2017.

¹⁴Reinspection is when FSIS randomly samples the food products it regulates as they enter the United States. The purpose of reinspection is to ensure that exporting country certificates are authentic and accurate and that products meet all U.S. food safety and quality standards. These reinspections also provide evidence of how the foreign inspection system is functioning.

Chairman Pitts, Ranking Member Green, and Members of the Subcommittee, this completes my prepared statement. I would be pleased to respond to any questions that you may have at this time.

GAO Contact and Staff Acknowledgments

If you or your staff have any questions about this testimony, please contact Steve D. Morris, Director, Natural Resources and Environment Team 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 statement. GAO staff who made key contributions to this testimony are Anne K. Johnson, James R. Jones, Jr., David Moreno, Beverly Peterson, Zachary Sivo, and Kiki Theodoropoulos.

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