Attachment — Additional Questions for the Record

The Honorable Joseph R. Pitts

1. **Is catfish (siluriformes) considered by the Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) to be a low-risk food?**

As we reported in 2012,[1] according to FDA officials, based on the agency's experience and information from its own testing programs, catfish is a low-risk product. However, according to an FDA official with the Center for Food Safety and Applied Nutrition, aquacultured catfish may contain residues of unapproved antibiotics or other chemotherapeutics given that catfish typically live in environments that may be affected by unapproved drug residues or other chemical contaminants.

2. **Does domestic or imported catfish (siluriformes) present any unique food safety issues that would warrant a separate government program from all other seafood?**

According to FDA documents, the same potential hazards associated with catfish are also associated with most other aquacultured seafood. For example, there are concerns about the presence of drug residues associated with aquacultured seafood products, including catfish.

3. **Did FDA, USDA or any other U.S. government agency produce a scientific assessment of the risk domestic or imported catfish (siluriformes) poses to human health before the enactment of the 2008 Farm Bill (P.L. 110-246)?**

We did not identify any risk assessments produced by either FDA or USDA's Food Safety and Inspection Service (FSIS) before the enactment of the 2008 Farm Bill (P.L. 110-246). As part of our 2012 report,[2] we only reviewed a 2010 Draft FSIS Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish.

4. **If a seafood company processes domestic or imported catfish (siluriformes) and any other seafood species (salmon, tilapia, lobster, shrimp, etc), is it accurate that USDA would regulate that company for catfish and FDA would regulate that facility for the other seafood species? Is it accurate to say that in that situation there would be two government agencies regulating the same facility regardless of any Memorandum of Understanding between FDA and USDA?**

While FSIS has begun to implement the catfish inspection program and FSIS and FDA have begun to implement provisions of their 2014 Memorandum of Understanding, facilities that process both catfish and other seafood may potentially still be inspected by both FSIS and FDA. In addition, there are seafood processing facilities that are under contract for fee-for-service inspections by the National Marine Fisheries Service (NMFS). We have not

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

undertaken any recent work to determine the number of seafood processing facilities that may be subject to inspections by FDA, FSIS, and NMFS.

5. Is it accurate that the Government Accountability Office (GAO) has issued reports to Congress in 2013, 2014, 2015 and 2016 recommending that the USDA catfish program be repealed concluding that a repeal of the USDA catfish program "would avoid duplication of federal programs and could save taxpayers millions of dollars annually without affecting the safety of catfish intended for human consumption"?

As we have reported in 2013, 2014, 2015, and 2016 repealing provisions of the 2008 Farm Bill that assigned FSIS responsibility for examining and inspecting catfish and for creating a catfish inspection program may avoid duplication of federal programs and save taxpayers millions of dollars annually. In 2014, Congress reaffirmed its commitment to assigning USDA this responsibility. In March 2016, FSIS assumed responsibility for inspecting domestic catfish and FDA ceased all domestic regulatory activities involving catfish. FDA discontinued screening catfish imports in April 2016, when FSIS assumed that task. Implementation of the catfish inspection program will be phased in, with full implementation scheduled for September 2017.

6. If Congress were to repeal the USDA catfish program, does GAO believe FDA could resume inspections of domestic and imported catfish (siluriformes) in a manner that ensures the food safety of catfish?

FSIS assumed responsibility for inspecting domestic catfish in March 2016 and for imported catfish in April 2016. Prior to that time, FDA had responsibility for all seafood, including catfish. In prior reports, we identified problems with FDA's oversight of imported seafood. In 2011,[3] we reported that FDA's oversight program to ensure the safety of imported seafood from residues of unapproved drugs was limited. In addition, FDA's sampling program was ineffectively implemented. In our 2012 report[4] on the transfer of responsibility for catfish inspection from FDA to FSIS, we stated that new FDA Food Safety and Modernization Act (FSMA) authorities given to FDA, such as third party certification and existing authority to conduct comparability assessments—now known as systems recognition assessments—could help enhance the effectiveness of the food safety system under FDA for all imported seafood, including catfish. In 2012,[5] we reported that according to FDA officials, the agency expected a limited number of countries to seek comparability with the United States because, in part, most countries would not meet the FDA requirement that the foreign government's domestic and export food safety systems be comparable with the U.S. system for all their food products. We are currently undertaking a new review that will examine, in part, how FDA ensures the safety of imported seafood from violative drug residues. This report will provide further information on the status of FDA's oversight of imported seafood.

[3]GAO, *Seafood Safety: FDA Needs to Improve Oversight of Imported Seafood and Better Leverage Limited Resources*, GAO-11-286 (Washington, D.C.: April 14, 2011)
[4]GAO-12-411
[5]GAO, *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)

7. **Your testimony implies that Congress fully intended to implement this program and that there are not conflicting views of the program. As a committee we have sent several letters in the past congresses since the programs enactment in the 2008 farm bill. The Senate voted to repeal the program and obviously we are holding this hearing today to discuss why the program should be repealed. Are you including those congressional actions and perspectives in your examination of congressional intent in the report you are currently working on?**

   Generally, when GAO discusses the intent of the Congress, it limits itself to discussing actions taken jointly by both houses of Congress. In addition, we stated that Congress reaffirmed the 2008 bill in terms of the catfish inspection program, because Congress revisited the relevant provisions of the statute, provided a timeline for USDA to complete the required regulations, and modified additional language without repealing the requirement that USDA establish and implement regulations for the examination and inspection of catfish. Furthermore, we are aware of differing perspectives regarding FSIS's catfish inspection program, and as part of our current audit, we have discussed the catfish inspection program with a consumer organization that is an association of numerous consumer groups and also seafood industry groups.

The Honorable Frank Pallone, Jr.

1. **In a May 2012 GAO Report entitled, "Responsibility for Inspecting Catfish Should Not be Assigned to USDA", GAO cited reasons why catfish inspection should remain at FDA and a number of concerns with the USDA program. In this report, GAO noted that under the USDA program as many as three agencies could inspect facilities that process both catfish and other types of seafood. Concerns were raised about overlapping inspections and an unnecessary inspection frequency. GAO highlighted that continuous inspection would not improve catfish safety.**

   Mr. Morris, your testimony noted that USDA and FDA signed a Memorandum of Understanding (MOU) in April 2014. You stated that under this MOU, it is still possible that three separate Federal agencies could inspect a single seafood processing facility. Is it still GAO's position that continuous inspection would not improve catfish safety and that having three separate agencies inspecting seafood in a single facility is duplicative?

   As we reported in 2012,[6] both FDA and NMFS officials stated that continuous inspection would not improve catfish safety and was counter to the use of FDA's hazard analysis requirements, in which systems are most efficiently monitored periodically rather than daily. In addition, facilities that process both catfish and other seafood may potentially still be inspected by both FSIS and FDA. In addition, there are also seafood processing facilities that are under contract for fee-for-service inspections by NMFS. We have not undertaken any recent work to determine the number of seafood processing facilities that may be subject to inspections by FDA, FSIS, and NMFS.

[6]GAO-12-411

GAO raised concerns in its 2012 report about inconsistent oversight of seafood, including imported seafood, under the new program. Mr. Morris, did the MOU you referenced address this problem or are you aware of other actions taken to harmonize regulatory requirements?

Our discussion about inconsistent oversight by FDA and FSIS of seafood dealt with the different approaches each agency would use to ensure the safety of imported seafood. In addition, we had noted in 2011,[7] that FDA's oversight of imports was limited when compared with FSIS's more comprehensive reviews of food safety systems under its equivalence program. FDA uses the Hazard Analysis and Critical Control Point (HACCP) system as its main oversight tool for seafood safety. Under this system, seafood processors are primarily responsible for the safety of the seafood they process and FDA inspects domestic and foreign seafood processors in an effort to ensure their compliance with HACCP regulations. FDA supplements its HACCP oversight activities with an import oversight program that includes examination and testing of some imported seafood at ports of entry to ensure the products meet U.S. requirements.

In contrast, FSIS plans to apply an equivalence approach for catfish that is similar to the one it uses for imported meat, poultry, and processed egg products. Under FSIS's equivalence approach, meat, poultry and processed egg products are not eligible for export to the United States unless FSIS has determined that the exporting country has a food safety system equivalent to that of the United States. Among other things, FSIS reviews documents provided by foreign governments, conducts on-site evaluations of government inspections of processing facilities, and audits laboratories to ensure their food safety regulations and oversight are adequate. In addition, FSIS reinspects products at U.S. ports of entry to promote compliance.

As part of our current audit, 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.

2. **I understand GAO is currently engaged in a seafood safety audit at the request of Senate Appropriators, which includes an assessment of USDA's catfish program. However, I want to be certain that the perspectives of all stakeholders are considered by GAO when conducting this work.**

   As you know, in June of this year 34 members of the Energy and Commerce Committee signed a bipartisan letter calling for repeal of the USDA catfish program. Additionally, in September 2016, Representatives Roybal-Allard (D-CA) and Hartler (R-MO) sent another bipartisan letter, signed by 206 members, calling for the program's repeal. Between these two letters, 220 members of the House of Representatives are on record this year supporting the repeal of the USDA catfish inspection program. Also, in May 2016, the Senate passed a bipartisan joint

[7]GAO-11-286

resolution by a vote of 55-43 to end the duplicative and wasteful USDA catfish inspection program.

Mr. Morris, understanding there are strong voices on both sides of this issue, how will GAO take into account that the majority of Congress and a large portion of the catfish producing and processing industry views this program as duplicative, wasteful, and supports its repeal?

We are aware of differing perspectives regarding FSIS's catfish inspection program, and as part of our current audit, we have discussed the catfish inspection program with a consumer organization that is an association of numerous consumer groups and also seafood industry groups. However, the focus of our audit is to determine how these separate programs are working to ensure the safety of imported seafood, and if opportunities exist for FDA and FSIS to strengthen their programs.

3. **To date, the GAO has cited catfish as an example of a duplicative government program in 10 different reports. In a May 10, 2012 report on seafood safety entitled Responsibility for Inspection Catfish Should Not Be Assigned to USDA, the GAO concluded that FDA's new authority under the Food Safety Modernization Act gives the federal government an opportunity to enhance the safety of all imported seafood—including catfish. GAO stated the new USDA catfish program further divides responsibility for overseeing seafood safety and costs taxpayers by duplicating existing federal programs without evidence that catfish pose a food safety problem that requires a new federal program to address.**

   Mr. Morris, to what extent does FSIS's catfish program mirror existing FDA or National Marine Fisheries Service programs? Does this introduce potential overlap and inefficiencies?

   Mr. Morris, if overlap exists, does it provide additional benefit to American consumers by improving the safety of our catfish supply?

   In our 2012 report,[8] we stated that if FSIS's proposed catfish inspection program were implemented, we expected that the program, in part, would cause inefficient use of resources in several key areas. First, the program required implementation of hazard analysis plans that are essentially the same as FDA's hazard analysis requirements. Second, if the program was implemented, as many as three agencies—FDA, FSIS, and NMFS—could inspect facilities that process both catfish and other types of seafood. Third, FSMA would give FDA authority to establish a system to accredit third party auditors, including foreign governments, to certify imported seafood meets FDA regulatory requirements. FDA officials stated that this new authority complements FDA's existing authority to obtain assurances about the safety of seafood exports from countries with food safety systems FDA determined are comparable to the United States. We determined that with FDA's new authority under FSMA, the federal government had an

[8]GAO-12-411

opportunity to enhance the safety of all imported seafood—including catfish—and avoid, in part, the cost that would result from FSIS's implementation of its proposed program.

Our current audit will examine, in part, how FDA and FSIS ensure the safety of imported seafood. This report will provide further information on the status of these agencies' oversight of imported seafood, including the use of third party certification. In our 2012 report[9] in which we discussed FDA's use of comparability assessments—now known as systems recognition assessments—we determined that FDA expected a limited number of countries to seek comparability with the United States because, in part, most countries would not meet the FDA requirement that the foreign government's domestic and export food safety systems be comparable with the U.S. system for all their food products.

[9]GAO-12-933