

ONE HUNDRED FOURTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
2125 RAYBURN HOUSE OFFICE BUILDING  
WASHINGTON, DC 20515-6115

Majority (202) 225-2927  
Minority (202) 225-3641

**MEMORANDUM**

**December 5, 2016**

**To: Subcommittee on Health Democratic Members and Staff**  
**Fr: Committee on Energy and Commerce Democratic Staff**  
**Re: Hearing on “Waste and Duplication in the USDA Catfish Inspection Program”**

On **Wednesday, December 7<sup>th</sup>, at 10:00 a.m. in Room 2322 of the Rayburn House Office Building**, the Subcommittee on Health will hold a hearing entitled, “Waste and Duplication in the USDA Catfish Inspection Program” to examine the costs and consequences of the USDA catfish inspection program.

**I. HISTORY OF CATFISH REGULATION**

Charged with overseeing more than 80 percent of the food Americans eat, including seafood, the Food and Drug Administration (FDA) is the primary regulator of our food supply. Until 2008, the FDA had jurisdiction over all seafood products.

FDA operates a mandatory safety program for all fish and fishery products, with the exception of catfish, under the provisions of the Federal Food, Drug and Cosmetic (FD&C) Act, the Public Health Service Act, and related regulations. The FDA program includes research, inspection, compliance, enforcement, outreach, and the development of regulations and guidance and helps ensure that the nation’s seafood supply – both domestic and imported – is safe, sanitary, wholesome, and labeled properly.<sup>1</sup>

FDA uses a Hazard Analysis and Critical Control Point (HACCP) approach to seafood regulation. HACCP addresses food safety through analysis and control of biological, chemical, and physical hazards. These hazards can be found and are present in raw material production, procurement and handling, manufacturing, distribution and consumption of finished seafood

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<sup>1</sup> U.S. Food and Drug Administration (FDA), *Seafood* (<http://www.fda.gov/Food/PopularTopics/ucm341987.htm>).

products. HACCP is designed to identify and prevent hazards that could cause foodborne illnesses, rather than relying on spot-checks of finished seafood products to ensure safety. Given the program's success, Congress used the seafood HACCP system as a model when drafting the Food Safety Modernization Act and expanded HACCP requirements to all food under FDA's jurisdiction.

FDA uses a risk-based approach to inspect domestic and foreign seafood processors to verify industry compliance with HACCP. Such an approach allows FDA to focus on critical points in the process most likely to affect product safety.<sup>2</sup> FDA regulates imported seafood products by inspecting foreign seafood manufacturers and importers and by collecting samples of imported seafood at the time of entry. FDA prioritizes these import-related activities based on risk; i.e., foreign processors and importers of products with the greatest potential for contamination that can cause serious harm to consumers<sup>3</sup> are the highest priority for surveillance activities. Lower priority products, processors, and importers are sampled or inspected less frequently with remaining resources.

FDA's Seafood HACCP Regulation is complemented by other pre-existing regulations, including the Current Good Manufacturing Practice regulations.<sup>4</sup> These regulations act as the basis for determining whether products have been processed under sanitary conditions. They are also the basis for the Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers and Acidified Food regulations<sup>5</sup>, which addresses *Clostridium botulinum*, the bacteria that causes botulism, in these products. Together, these regulations provide the food safety controls to which almost all processors of fish or fishery products are subject.

## II. REMOVAL OF CATFISH FROM FDA OVERSIGHT

In 2008, Farm Bill conferees stripped FDA of its jurisdiction over catfish and added language creating a new catfish program at the U.S. Department of Agriculture (USDA). The jurisdiction-stripping language did not appear in either the House or Senate Farm Bill nor was the language ever discussed or considered publicly at a hearing or markup prior to its addition to

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<sup>2</sup> FDA, *Enhanced Aquaculture and Seafood Inspection - Report to Congress* (Nov. 20, 2008) (<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm150954.htm>).

<sup>3</sup> Examples of high priority products are the same, regardless if produced domestically or internationally, and include ready-to-eat products such as hot- or cold-smoked fish, scombrototoxin-forming fish, such as tuna or mahi mahi, aquacultured seafood products, and fish packed in reduced oxygen packages.

<sup>4</sup> 21 CFR Part 110.

<sup>5</sup> 21 CFR Parts 113 and 114, respectively

the bill by the conferees. The House never formally supported removing catfish from FDA's jurisdiction and establishing this new program at USDA.<sup>6</sup>

While USDA's Food Safety and Inspection Service (FSIS) has a long history of ensuring that our nation's meat, poultry, and processed egg supply is wholesome, safe, and properly labeled, USDA has never regulated seafood products. By removing only catfish from FDA jurisdiction this created a situation where some American seafood companies must accommodate two sets of federal inspectors and inspections overseeing the same facility: one set for catfish inspections and another set for all other inspections of seafood. Both USDA and the Government Accountability Office (GAO) agree that there is no food safety justification for this regulatory divide.

### III. CONCERNS OVER USDA PROGRAM

A number of concerns have been raised about the effectiveness, efficiency, and cost of FSIS in relation to catfish product, product inspections, and production safety. GAO has cited catfish as an example of a duplicative government program in ten of its products and reports. In a May 10, 2012 report on seafood safety entitled *Responsibility for Inspection Catfish Should Not Be Assigned to USDA*, the 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. GAO went on to conclude 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.<sup>7</sup>

USDA has acknowledged that catfish is a "low-risk food."<sup>8</sup> In its peer reviewed risk assessment USDA concluded that "[t]he true effectiveness of FSIS inspection for reducing catfish-associated human illnesses is unknown."<sup>9</sup> However, the USDA catfish program is very costly to American taxpayers. GAO predicted that USDA's new catfish program would be 20 times more expensive than FDA's regulation of catfish and "would likely not enhance the safety of catfish but

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<sup>6</sup> The House Agricultural Committee passed an amendment repealing the USDA catfish program by a bipartisan vote of 31-15 in the 2014 Farm Bill and the full House agreed to this language, sending it to the Senate.

<sup>7</sup> U.S. Government Accountability Office (GAO), *Seafood Safety –Responsibility for Inspecting Catfish Should Not Be Assigned to USDA* (May 2012) (<http://www.gao.gov/assets/600/590777.pdf>).

<sup>8</sup> Department of Agriculture, Food Safety and Inspection Service, *Mandatory Inspection of Catfish and Catfish Products*, 76 Fed. Reg. 37 (Feb. 24, 2011) (proposed rule) (<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/2008-0031.pdf>).

<sup>9</sup> Department of Agriculture, Food Safety and Inspection Service, *Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish* (July 2012) ([http://www.fsis.usda.gov/wps/wcm/connect/80a428f3-43fb-4421-b97d-885909e5a228/Catfish\\_Risk\\_Assess\\_July2012.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/80a428f3-43fb-4421-b97d-885909e5a228/Catfish_Risk_Assess_July2012.pdf?MOD=AJPERES)).

would duplicate FDA and NMFS inspections at a cost to taxpayers.”<sup>10</sup> In April 2016, GAO concluded repealing the USDA catfish program “would avoid duplication of federal programs and save taxpayers millions of dollars annually without affecting the safety of catfish intended for human consumption.”<sup>11</sup>

Industry has also expressed significant concerns with the USDA catfish program. In a May 23, 2016 letter to Senate leadership, the Food Marketing Institute, the National Retail Federation, and the Retail Industry Leaders Association, wrote:

“The USDA program is of great concerns to our member companies. The shift of food safety oversight from FDA to FSIS for this specific product establishes a nontariff trade barrier against imported pangasius. Exporting countries will have to obtain an “equivalency” determination from FSIS if they wish to preserve their producers’ ability to export to the United States. Because the FSIS equivalency process routinely takes five years and sometime over a decade to complete, this will create for those producers an insurmountable barrier to the U.S. market. Thus, in a single stroke more than a fifth of the ‘value white fish’ supply in the United states-about 250 million pounds a year-will disappear. This reduction in supply will cause a dramatic increase in prices for our companies and our customers who rely on an affordable product.”<sup>12</sup>

#### **IV. SENATE JOINT RESOLUTION TO REPEAL USDA CATFISH PROGRAM**

On May 25, 2016, the Senate passed (by a vote of 55-43) a bipartisan joint resolution of disapproval under the procedures of the *Congressional Review Act* to end the USDA catfish inspection program.<sup>13</sup> The resolution, if enacted, would nullify USDA’s mandatory inspection program for catfish and catfish products and return oversight responsibility back to the FDA.

On June 22, 2016, Chairman Fred Upton and Ranking Member Frank Pallone, Jr. led a bipartisan letter to House leadership urging Majority and Minority leaders to bring S.J.Res 28 for consideration before the House. This letter was signed by 34 members of the House Energy and Commerce Committee. Later, on September 13, 2016, Reps. Roybal-Allard (D-CA) and Hartler (R-MO) sent another bipartisan letter, signed by 206 members, to House leadership requesting that S.J.Res 28 be brought for consideration before the full House. Between both letters there are 220 members on record in support of bringing the resolution to the floor for a vote on whether to eliminate USDA’s catfish inspection program.

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<sup>10</sup> GAO, *Seafood Safety –Responsibility for Inspecting Catfish Should Not Be Assigned to USDA* (May 2012) (<http://www.gao.gov/assets/600/590777.pdf>).

<sup>11</sup> GAO, *2016 Annual Report: Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits* (April 2016) (<http://www.gao.gov/assets/680/676473.pdf>).

<sup>12</sup> Letter from Food Marketing Institute, National Retail Federation, and Retail Industry Leaders Association to Senators Mitch McConnell and Harry Reid (May 23, 2016) (<http://www.ayotte.senate.gov/files/documents/052316%20Trade%20Association%20Letter%20Supporting%20SJRes28%20-%20USDA%20Catfish%20Inspec....pdf>).

<sup>13</sup> S.J. Res. 28

**V. WITNESSES**

**Panel 1:**

**William Jones**

Deputy Director  
Office of Food Safety  
Food and Drug Administration

**Steve Morris**

Acting Director  
Natural Resources and Environment  
Government Accountability Office

**Panel 2:**

**Kim Gorton**

President and CEO  
Stade Gorton & Co., Inc.

**Bart Farrell**

Director of Food and Beverage  
Clyde's Restaurant Group

**Justin Conrad**

CEO  
Bay Hill Seafood  
President  
Libby Hill Seafood

**Steve Otwell**

Seafood Safety and Technology Emeritus  
UF Food and Science and Human Nutrition  
Aquatic Food Products Lab  
University of Florida