

WASTE AND DUPLICATION IN THE USDA CATFISH INSPECTION PROGRAM

HEARING BEFORE THE SUBCOMMITTEE ON HEALTH OF THE COMMITTEE ON ENERGY AND COMMERCE HOUSE OF REPRESENTATIVES ONE HUNDRED FOURTEENTH CONGRESS SECOND SESSION

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WASTE AND DUPLICATION IN THE USDA CATFISH INSPECTION PROGRAM

WEDNESDAY, DECEMBER 7, 2016

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON HEALTH,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 10:02 a.m., in room 2322, Rayburn House Office Building, Hon. Joseph R. Pitts (chairman of the subcommittee) presiding.

Present: Representatives Pitts, Guthrie, Barton, Burgess, Blackburn, Lance, Griffith, Bilirakis, Long, Bucshon, Brooks, Collins, Green, Schrader, Kennedy, and Pallone (ex officio).

Also Present: Representative Harper.

Staff Present: Paul Eddatel, Chief Counsel, Health; Blair Ellis, Digital Coordinator/Press Secretary; Jay Gulshen, Legislative Clerk, Health; Carly McWilliams, Professional Staff Member, Health; Tim Pataki, Professional Staff Member; Jennifer Sherman, Press Secretary; Heidi Stirrup, Health Policy Coordinator; John Stone, Counsel, Health; Josh Trent, Professional Staff Member, Health; Jeff Carroll, Minority Staff Director; Tiffany Guarascio, Minority Deputy Staff Director and Minority Chief Health Advisor; Samantha Satchell, Minority Policy Analyst; and Megan Velez, Minority FDA Detailee.

OPENING STATEMENT OF HON. JOSEPH R. PITTS, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEALTH OF PENNSYLVANIA

Mr. PITTS. The time of 10 o'clock having arrived, I will call this subcommittee meeting to order. This is the last hearing of the session, so an interesting hearing. And we have one of our colleagues on Energy and Commerce, Mr. Harper of Mississippi, waived on to take part as well. But thank you all for coming.

The chair will now recognize himself for an opening statement.

Today's hearing will take a closer look at what some consider an unnecessary and duplicative program at the U.S. Department of Agriculture, the catfish inspection program.

Why is it considered unnecessary and duplicative? Because we already have a Federal agency responsible for overseeing the safety and inspection of other types of seafood: it is the FDA, the Food and Drug Administration.

As members of the Health Subcommittee of the Energy and Commerce Committee, with direct oversight of the FDA, it seems illogical that the USDA would be given the exclusive authority to over-

see and regulate catfish only while the FDA regulates all other seafood.

What is it about catfish? Well, catfish is an extremely low-risk food product. Explicitly creating a program exclusively for catfish seems to be unnecessary, and it directs resources away from high-risk foods to focus on food that is one of the safest.

Think for a moment what this means to American seafood companies, who are put in the untenable position of complying with two sets of Federal inspectors overseeing their facilities—one set for catfish and one set for all other seafood. Why would companies continue to purchase catfish given this additional burden?

What makes this scenario even more troubling is the fact that both the FDA and the General Accountability Office agree that there is no food safety justification for this regulatory divide.

I, along with some of my colleagues on the committee, Chairman Upton and then-Ranking Member Waxman and current Ranking Member Pallone, sent a letter in 2013 to our Agriculture Committee colleagues expressing this very point. In 2014, we sent another letter to the Director of the Office of Management and Budget expressing our concerns about this program. And in June of 2016, we sent yet another letter to House leadership urging the House to consider S.J. Res. 28, which would repeal the program. And the Senate had already passed Senate Resolution 28 by a vote of 55 to 43.

Since the very beginning of this transfer of regulation from FDA to USDA, the justification was to ensure food safety. But USDA's expertise is meat and poultry, not fish. The real move seems to be to hinder foreign firms from importing catfish so that they will be unable to compete with domestic catfish farmers. Such actions could trigger a WTO lawsuit.

Another concerning aspect is that this USDA program has cost the American taxpayers a lot of money without much to show for it. GAO has issued no less than nine reports indicating that the responsibility of inspecting catfish should not be assigned to the USDA. Charged with overseeing over 80 percent of the food Americans eat, we have long entrusted FDA to be the primary regulator of our food supply, and the FDA has the scientific expertise and regulatory experience to oversee the entirety of the seafood market.

Many of you know that I am also a critic of the sugar program. It exists primarily, some would say solely, to create barriers to competition, ensure the profits of a special interest group. And so I view this duplicative catfish program in the same light.

The jurisdictional grab serves only to shield catfish farmers against competition at the expense of U.S. consumers. So such duplicative programs can negatively impact the U.S. economy at a time when we can ill afford that.

So this seems to smack of food politics, not public health. And the consequences are more than just waste and duplication; the program will increase costs for consumers and ultimately hurt the catfish market.

But we are going to hear both sides on this issue today, and I applaud all those who have come in—people, organizations—to voice their concern, to weigh in and educate our Members on both sides of the issue.

I welcome you to this hearing and now yield the rest of my time to Vice Chairman Guthrie.

[The prepared statement of Mr. Pitts follows:]

PREPARED STATEMENT OF HON. JOSEPH R. PITTS

Today's hearing will be taking a close look at what many consider an unnecessary and duplicative program at the U.S. Department of Agriculture (USDA)—the catfish inspection program.

Why is it considered unnecessary and duplicative? Because we already have a federal agency responsible for overseeing the safety and inspection of other types of seafood—it is the Food and Drug Administration (FDA).

As Members of the Health Subcommittee of the Energy and Commerce Committee with direct oversight of the FDA, it is illogical (and wasteful) that the USDA would be given the exclusive authority to oversee and regulate catfish only, while the FDA regulates all other seafood. What is it about catfish? Interestingly enough—nothing! Catfish is an extremely low risk food product. Explicitly creating a program exclusively for catfish is unnecessary and directs resources away from high risk foods to focus on a food that is one of the safest.

Think for a moment what this means to American seafood companies who are put in the untenable position of complying with two sets of federal inspectors overseeing their facilities: one set for catfish and one set for all other seafood. Why would companies continue to purchase catfish given this additional burden?

What makes this scenario even more troubling is the fact that both the FDA and the General Accountability Office (GAO) agree that there is no food safety justification for this regulatory divide and I, along with my colleagues on this committee—Chairman Upton, then-Ranking Member Waxman, and current Ranking Member Pallone, sent a letter in 2013 to our Agriculture Committee colleagues expressing this very point. In 2014, we sent another letter to the Director of the Office of Management and Budget expressing our concerns about this program, and in June of 2016, we sent yet another letter to House Leadership urging the House to consider S.J. Res. 28, which would repeal the program.

The Senate has already passed S.J. Res. 28 by a vote of 55–43, a significant vote indeed.

Since the very beginning of this transfer of regulation (from FDA to USDA) the justification was to ensure food safety. But USDA's expertise is meat and poultry, not fish. Frankly, the real aim of this move was to hinder foreign firms importing catfish so they would be unable to compete with domestic catfish farmers. Such actions could trigger a World Trade Organization (WTO) lawsuit.

Another concerning aspect is that this USDA program has cost the American taxpayers an exorbitant amount of money without much to show for it.

The GAO has issued no less than nine reports indicating that the responsibility for inspecting catfish should not be assigned to the USDA. Charged with overseeing over 80 percent of the food Americans eat, we have long entrusted FDA to be the primary regulator of our food supply. And, FDA has the scientific expertise and regulatory experience to oversee the entirety of the seafood market.

Many of you know I am also a fierce critic of the sugar program. It exists primarily—and some would say solely—to create barriers to competition and ensure the profits of a special interest group. I view this wasteful catfish program in the same light.

This jurisdictional grab, when weighed against its duplicity, serves only to shield catfish farmers against competition at the expense of U.S. consumers. Such wasteful and duplicative programs can negatively impact the U.S. economy at a time we can ill afford that. If you want an example of what's wrong with Washington, the catfish program is a textbook example.

Sadly, this smacks of food politics, not public health. And the consequences are more than just waste and duplication. The program will increase costs for consumers and ultimately hurt the catfish market.

Experts in public health, public policy, economics, trade and regulation have called for the repeal of the catfish inspection program that does not improve food safety but does cost American jobs and wastes American tax dollars. I applaud the people and organizations that have voiced concerns about the program and I am glad we are holding this hearing today to ensure it is clear that this committee does not support this program and we urge its repeal immediately.

Mr. GUTHRIE. Thank you very much, Mr. Chairman.

And I just want to say, when the full chairman came to me, Chairman Upton, and said would you like to serve as vice chairman, I was excited because I was going into a lot of good policy. But what I didn't realize is how, serving with Chairman Pitts, I was going to make a dear friend.

And so this is his last hearing scheduled as chair, so I just want to point out that Chairman Pitts is a wonderful person, a great person to work with, done a great job running this subcommittee ever since I have been on this subcommittee. He is also from Asbury University, which is in my district. And he will be having honors there, and I look forward to doing that in the spring.

And the other thing that I have thoroughly enjoyed is getting to sit by Heidi. Heidi runs a great meeting, and, as I found out, she is also a NASCAR fan, which is fun.

And then the people behind us, the people that—Chairman Pitts has run a great committee, but it is because of the staff here.

And so I have had an honor of serving with you, Mr. Chairman. I think you have done a great job. And congratulations on your retirement.

Mr. PITTS. Thank you. And I second the motion on Heidi——

[Applause.]

Mr. PITTS. Thank you. And I second your sentiments on the staff. You are only as good as your staff. They are the best. So, Heidi and all of you, Paul, thank you very much.

At this point, we recognize Mr. Green.

**OPENING STATEMENT OF HON. GENE GREEN, A
REPRESENTATIVE IN CONGRESS FROM THE STATE OF TEXAS**

Mr. GREEN. Thank you, Mr. Chairman.

Well, let me follow that up. I want to thank you for serving as chair of the committee. I know we have done some really good things in these 2 years that I have been the ranking member and you have been the chair. And obviously, we will miss you, Joe, but keep in touch with us.

Again, your staff has been great to work with, and particularly Heidi. Thank you. Because, like you said, we all know that our staff is the one that makes us look good to make sure we can say these points.

Well, let me go into my statement now.

In my part of the country, catfish is a staple, and that is why it is so important in east Texas and all through the South. And I think this resolution is a good resolution. I didn't particularly like the way it was done in the ag bill, but—the FDA actually regulates other food sources, including fish. But I also know there are some issues with competition from overseas, as the chairman said, and some of the places where they raise catfish would not be allowed in our country. But I think the FDA has that authority to be able to do that, and we can encourage them through our committee.

The Food and Drug Administration has for many years been the first line of defense when it comes to food safety. Under provisions of the Food, Drug, and Cosmetic Act and Public Health Service Act, the FDA has historically been responsible for regulation of seafood within the U.S., a job which it has done admirably.

The 2008 farm bill conferees removed the FDA of its jurisdiction over catfish and added language creating a new program at the USDA. It is important to note that this language has never appeared in either the House bill or the Senate farm bill and was never publicly discussed at the hearing or markup in committee. The establishment of a new program under the USDA is a textbook example of a solution in search of a problem.

The USDA has the responsibility for ensuring much of the Nation's food supply is safe and properly labeled but until the creation of the separate catfish program never had jurisdiction over seafood products. Unfortunately, we have heard from many companies, including those represented here today, this has established two varying sets of Federal standards, which has created undue complexity and regulatory burdens for American companies that does nothing to advance consumer wellbeing.

Both the USDA and the GAO have agreed that there are no food safety concerns to justify this dual regulatory system. The GAO has conducted multiple reports that identify the USDA catfish program as duplicative and a waste of taxpayer dollars.

In May of this year, the Senate passed a bipartisan joint resolution, SJR 28, to end the USDA catfish inspection program. In September, Representatives Roybal-Allard and Hartzler sent a bipartisan letter with more than 206 signatures to the House leadership requesting we as a body pick up the SJR 28. Bipartisan members of the Energy and Commerce Committee wrote leadership, as well, asking the chamber to take up the resolution and restore the FDA's authority and ensure the review of seafood is comprehensive and not arbitrarily split among agencies.

There are more than 220 Members on record as supporting the return of the program to USDA oversight, more than enough to show that leadership should bring up this for a vote before the end of the 114th Congress.

It is my hope that in today's hearing we can hear from expert witnesses at the FDA and within the industry to ensure that we are not only using the best regulatory system to protect consumers but also being fiscally prudent.

I would like to thank the chair for this important meeting and thank our witnesses for taking time to be here.

And thank you, Mr. Chairman, and I will yield a minute to anyone who wants it.

Hearing no takers, I will yield it back.

Mr. PITTS. The gentleman yields back.

Is there anyone on our side of the podium seeking attention?

If not, the chair recognizes the gentleman from Mississippi, Mr. Harper, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. GREGG HARPER, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MISSISSIPPI

Mr. HARPER. Thank you, Chairman Pitts. And thank you for your great leadership and service here in Congress. You will be missed.

And thank you, Ranking Member Green and members of the subcommittee, for providing me the opportunity to participate in today's hearing.

Reviewing the efficiency and effectiveness of executive activities is necessary to ensure the proper and responsible use of tax dollars, and I take our congressional oversight responsibilities very, very seriously.

Despite being a strong supporter of the catfish inspection program currently being administered by the USDA Food Safety and Inspection Service, I didn't request to attend this hearing to debate about whether or not catfish jurisdiction should be under USDA or FDA. That has been decided by Congress, not once but twice. The merits of the catfish inspection program have been debated at length in Congress during the deliberations of the last two farm bills.

Overwhelming evidence suggests that imported catfish and catfish-like products represent a significant food safety threat to the American public. And, accordingly, Congress transferred inspection authority from FDA to USDA's Food Safety Inspection Service, FSIS.

Unfortunately, the FDA inspection system was inadequate, and it conducted inspections on a mere 0.2 percent of imported catfish species. Since USDA already inspects farm-raised meats, including foreign beef, pork, and poultry, Congress decided that the same standards should apply to farm-raised catfish so that these products receive comprehensive inspection.

Arguments made by opponents certainly are understood. But first, USDA projects the program would cost much less than what has been stated. And remember, too, that there is no duplication, as FDA no longer inspects catfish, and all inspection activities have been transferred, pursuant to the provisions of the 2008 and 2014 farm bills.

Finally, the rule simply requires foreign suppliers to meet an equivalent safety standard as our domestic producers, a policy that allows all market participants to compete on a level playing field.

The catfish inspection program is critical to public health. In 2007, Congress acknowledged an alarming amount of farm-raised seafood was entering the country containing banned substances and dangerous chemicals, but FDA was not appropriately inspecting to assure the safety of U.S. consumers. This is a reason this happened. There is much support for what we are doing now with it remaining with the USDA since it is already there.

You have many States, including Louisiana, Mississippi, Arkansas, and the American Farm Bureau Federation, to name a few, that are supportive of what we are doing. I think it is fine to have this hearing, but I do believe that the program is working, it is cost-effective, and it is a good use of taxpayer dollars.

And, with that, Mr. Chairman, I thank you and yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the ranking member of the full committee, Mr. Pallone, 5 minutes for an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Mr. Chairman.

I just wanted to say some nice things about you. I know that you are leaving. Because there was never an occasion, really, in the time that you were the chairman of the subcommittee, including when I was the chairman—and I think you were the ranking member then, I don't exactly remember—when you were not cooperating and trying to do everything on a bipartisan basis. And many times when I would ask you to do something that maybe you didn't even want to do, you still paid attention and tried to accommodate.

So I just want to say that, really, your friendship and your willingness to work with Democrats is unparalleled, and I thank you for that. And I see that the people that leave this place always seem to be much happier. I am sure that will be true for you, as well.

Mr. GREEN. He won't have to beg for money.

Mr. PALLONE. Right.

I also wanted to say how important this hearing is, because ensuring that our Nation's seafood supply is safe, sanitary, and wholesome is really essential. And seafood, including catfish, is a healthy source of protein, and it is critical that we do our part to ensure this commodity is readily and easily available to American consumers.

I don't know, maybe, actually, Gene, maybe catfish is not considered seafood. I keep thinking about seafood because I am along the coast, but maybe—it is really freshwater, right? It is not saltwater.

Mr. GREEN. Yes.

Mr. PALLONE. So the FDA is the primary watchdog of our food supply, and it oversees approximately 80 percent of the food Americans eat. Unfortunately, FDA was stripped of its oversight of catfish when, in 2008, conferees secretly inserted language into the farm bill creating a new catfish program at USDA. And this was done without any formal support of the House and without any evidence that there was an existing food safety problem associated with catfish that warranted a new program.

And the fact is the new program was and is not needed. The GAO has cited the USDA's catfish program as an example of a duplicative government program in 10 different reports. As recently as April, GAO concluded that repealing the USDA catfish program would eliminate a duplicate Federal program and save the American taxpayers millions of dollars each year without affecting the safety of catfish.

And earlier this year, the Senate passed a bipartisan Congressional Review Act joint resolution to end the duplicative and wasteful USDA catfish inspection program. If this resolution were enacted, it would return catfish oversight back to FDA, where it belongs.

That is why Chairman Upton and I sent a bipartisan letter signed by 34 members of this committee to the House leadership urging that the Senate joint resolution be brought up for consideration before the House. And a subsequent bipartisan letter to leadership was sent by Representatives Lucille Roybal-Allard and Vicky Hartzler, this one signed by 206 Members, also urging the House to consider the Senate joint resolution.

Between these two letters, there are 220 Members on record in support of bringing the resolution to the floor and eliminating the

USDA's catfish inspection program. That is a clear majority of the House.

So I look forward to hearing more from our witnesses today about how FDA's existing seafood inspection program is sufficient to ensure the safety of catfish for American consumers and why USDA's program is not necessary to protect public health. And I am also interested in learning more about the cost of this program to taxpayers and the impact USDA's duplicative seafood inspection program has on the seafood industry and American consumers.

And I just hope, Mr. Chairman, this hearing helps highlight why the House must take action on the Senate joint resolution quickly and move to nullify USDA's inspection program. And I am just glad our committee continues its track record of working together to ensure that food safety is fiscally sound.

Thanks again, Mr. Chairman. I yield back.

Mr. PITTS. The chair thanks the gentleman.

I have a UC request. I ask unanimous consent to submit the following: 10 reports from GAO on this topic¹ and 3 bipartisan letters the committee has sent out over the past 3 years. One from June 2016 to House leadership, one from September 2014 to OMB, and one from November 2013 to the House Committee on Agriculture.

Without objection, so ordered.

[The information appears at the conclusion of the hearing.]

Mr. PITTS. That concludes the opening statements of members present. As usual, all written opening statements of members will be made a part of the record.

We have two panels of witnesses today. Our first panel is comprised of William Jones, Acting Deputy Director, Office of Food Safety, Food and Drug Administration; and Steve Morris, Acting Director of the Natural Resources and Environment, Government Accountability Office.

Thank you for coming today. Your written testimony will be made part of the record. You will each be recognized for 5 minutes to summarize your testimony.

And so, at this point, Dr. Jones, you are recognized for 5 minutes.

STATEMENTS OF WILLIAM JONES, PH.D., ACTING DEPUTY DIRECTOR, OFFICE OF FOOD SAFETY, FOOD AND DRUG ADMINISTRATION; AND STEVE MORRIS, ACTING DIRECTOR, NATURAL RESOURCES AND ENVIRONMENT, GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF WILLIAM JONES, PH.D.

Mr. JONES. Good morning, Chairman Pitts, Ranking Member Green, and members of the committee. I am Bill Jones, Deputy Director of the Center for Food Safety and Applied Nutrition's Office of Food Safety at the Food and Drug Administration. Thank you for the opportunity to appear before you today to discuss the agency's ongoing efforts to oversee the safety of the U.S. seafood supply.

FDA has had a strong regulatory program in place since the mid-1990s to ensure the safety of domestic and imported seafood. In fact, the hazard analysis and risk-based preventive controls frame-

¹ The reports were unavailable at the time of printing.

work of FDA's seafood safety program is a basis for the preventive controls requirements for other FDA-regulated foods, as called for in the FDA Food Safety Modernization Act.

The agency has a variety of tools to ensure compliance with seafood safety requirements, including inspections of domestic and foreign processing facilities, 100 percent electronic screening of all import products, examination and sampling of domestic seafood and seafood offered for import into the United States, inspections of seafood importers, and foreign country program assessments.

As required by Congress in May 2014, FDA and USDA's Food Safety Inspection Service established a memorandum of understanding intended to move primary regulatory oversight of Siluriformes and Siluriformes products from FDA to FSIS. Since that time, FDA has worked closely with FSIS to provide training and technical expertise. For example, during the transition, FDA provided assistance regarding FDA historical inspection and enforcement activities concerning Siluriformes and Siluriformes products, guidance and interpretation on FDA's previously issued import alerts related to Siluriformes, and lab sampling and species identification techniques.

While FSIS currently has primary regulatory oversight over catfish, in my testimony today I will discuss FDA's regulatory framework for overseeing the safety of all other fish and fishery products, both imported and domestic, emphasizing the agency's risk-based efforts.

Because fish are cold-blooded and live in an aquatic environment, fish and fishery products pose food safety challenges different from those posed by land animals. FDA has developed extensive expertise in these areas over decades of regulating seafood.

Processors of fish and fishery products are subject to FDA's Hazard Analysis Critical Control Point, or HACCP, regulation. In short, this regulation requires both domestic and foreign processors of fish and fishery products to understand the food safety hazards associated with their process and product and requires a preventive system to control for those hazards. Every processor is required to have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards reasonably likely to occur.

Foreign processors who export seafood products to the United States must operate in conformance with seafood HACCP regulation. In addition, the HACCP regulation requires the importers to understand the hazards associated with the products they are importing and to take positive steps to verify that they obtain shipments from foreign processors who comply with the regulations requirements.

FDA has numerous tools and authorities that enable the agency to take appropriate action regarding imported products. The agency conducts inspections of foreign food manufacturers, and if FDA requests to inspect a foreign facility but is refused, FSMA gave the agency the authority to refuse the facility's food admission into the United States.

Besides HACCP inspections of foreign facilities, the agency also conducts surveillance of food offered for import at the border to check for compliance with U.S. requirements. FDA reviews all im-

port entries electronically prior to the products being allowed into the country. The agency has implemented an automated screening tool, referred to as the PREDICT system, which takes into account a variety of risk factors. Based on this electronic screening, the agency focuses its inspection and sampling resources on those entries with the potential for the greatest impact on public health.

Another key regulatory tool for controlling imported goods is the import alert. Import alerts inform FDA field personnel that the agency has sufficient evidence or other information about a particular product or producer or shipper or importer, geographic region, or even entire country to believe that future shipments of an imported product may be violative. On that basis, FDA field personnel may detain future shipments of the article that is being offered for import into the United States without physically examining or even testing the product.

The agency has approximately 50 active import alerts that identify a seafood product from a firm and/or country based upon past violations. In March 2016, FDA provided FSIS a complete list of firms that process catfish and are subject to detention without physical examination, including under import alerts for the presence of unapproved drugs in aquaculture, for seafood products contaminated with salmonella, and for misbranded seafood.

In closing, food safety continues to be a top priority for FDA. The agency has a strong regulatory program in place for seafood products, and FDA will continue to work with our domestic and international partners to ensure the safety of both domestic and imported seafood.

Thank you again for the opportunity to appear before you today. I would be happy to answer any questions.

[The prepared statement of Mr. Jones follows:]



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

STATEMENT OF

WILLIAM R. JONES, PH.D.

DEPUTY DIRECTOR, OFFICE OF FOOD SAFETY
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON HEALTH

COMMITTEE ON ENERGY AND COMMERCE

U.S. HOUSE OF REPRESENTATIVES

“WASTE AND DUPLICATION IN THE USDA CATFISH
INSPECTION PROGRAM”

DECEMBER 7, 2016

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INTRODUCTION

Good morning Chairman Pitts, Ranking Member Green, and members of the Committee. I am Bill Jones, Deputy Director of the Center for Food Safety and Applied Nutrition's Office of Food Safety, at the Food and Drug Administration (FDA or the Agency), which is part of the Department of Health and Human Services (HHS). Thank you for the opportunity to appear before you today to discuss the Agency's ongoing efforts to oversee the safety of the U.S. seafood supply.

FDA has had a strong regulatory program in place since the mid-1990s to ensure the safety of domestic and imported seafood. In fact, the hazard analysis and risk-based preventive controls framework of FDA's seafood safety program is a basis for the preventive controls requirements for other FDA-regulated foods called for in the FDA Food Safety Modernization Act (FSMA), enacted in 2011.

The Agency has a variety of tools to ensure compliance with seafood safety requirements, including inspections of domestic and foreign processing facilities, examination and sampling of domestic seafood and seafood offered for import into the United States, domestic surveillance sampling of imported products, inspections of seafood importers, evaluations of filers of seafood products offered for import, and foreign country program assessments. FDA works closely with our foreign, Federal, state, local, and Tribal partners to share relevant information and ensure that products in U.S. commerce meet applicable FDA requirements.

As you know, the Agriculture Act of 2014 required the U.S. Department of Agriculture (USDA) to issue final regulations for Siluriformes and Siluriformes products, which includes catfish. As

required by Congress, in May 2014, FDA and USDA's Food Safety and Inspection Service (FSIS) established a Memorandum of Understanding (MOU) intended to move primary regulatory oversight of Siluriformes and Siluriformes products from FDA to USDA/FSIS. Since that time, FDA has worked closely with USDA/FSIS to provide training and technical expertise. For example, during the transition, FDA provided assistance to USDA/FSIS regarding FDA historical inspection and enforcement activities concerning Siluriformes and Siluriformes products; guidance and interpretation on FDA's previously issued Import Alerts related to Siluriformes; facility and firm registration information; lab sampling techniques and species identification; information about inspection and follow-up activities related to facility inspection observations; and technical assistance concerning the harmonized tariff schedule codes used for Siluriformes import shipments submitted to Customs and Border Protection's electronic import entry system. Earlier this year, USDA/FSIS began its primary regulatory oversight of catfish and catfish products. FDA continues to exercise regulatory oversight over all other fish and fishery products, including in dual jurisdiction establishments that prepare, pack, hold, or otherwise handle both catfish and other fish and fishery products.

While USDA/FSIS currently has primary regulatory oversight over catfish, I would be happy to discuss FDA's regulatory framework for overseeing the safety of all other fish and fishery products, both imported and domestic.

FDA'S SEAFOOD SAFETY PROGRAM

Because fish are cold-blooded and live in aquatic environments, fish and fishery products pose food safety challenges different from those posed by land animals. For example, certain fish species, like tuna and mahi mahi, produce toxins upon spoilage. These toxins can cause severe

food poisoning and are not destroyed by cooking. In addition, fish that live in contaminated waters can carry contaminants in their bodies. The contaminants generally do not cause food poisoning but contaminated fish can cause health risks if continually consumed over a long time. Fish raised in aquaculture, particularly if raised in unhealthful conditions, may contain residues of unapproved antibiotics or other chemotherapeutics they received for treatment or prevention of diseases or infections associated with those conditions.

FDA has developed extensive expertise in these areas over decades of regulating seafood. Experts in FDA's Center for Food Safety and Applied Nutrition (CFSAN) are responsible for evaluating the hazard to public health presented by chemical contaminants, toxins, and microbiological contaminants in fish and fishery products. FDA operates the Gulf Coast Seafood Laboratory in Alabama, which specializes in seafood microbiological, chemical, and toxins research. In addition, seafood research is conducted at CFSAN's research laboratory in College Park, Maryland. FDA, in collaboration with the National Oceanic and Atmospheric Administration at the Department of Commerce, also represents the United States at the Codex Alimentarius Commission's Committee on Fish and Fishery Products, the international food safety standard-setting body for this commodity, to which I serve as the U.S. Delegate.

FDA operates a mandatory safety program for the processing of fish and fishery products. As a cornerstone of that program, FDA publishes the Fish and Fishery Products Hazards and Controls Guidance, an extensive compilation of the most up-to-date science and policy on the hazards that affect fish and fishery products and effective controls to prevent their occurrence. The document, currently in its fourth edition, has become the foundation of fish and fishery product regulatory programs around the world.

Seafood Hazard Analysis Critical Control Point (HACCP) Regulation and Inspections

Processors of fish and fishery products are subject to FDA's hazard analysis critical control point, or HACCP, regulation. In short, this regulation requires both domestic and foreign processors of fish and fishery products to understand the food safety hazards associated with their process and product and requires a preventive system to control for those hazards. Every processor is required to have and implement a written HACCP plan whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur. Foreign processors who export seafood products to the United States must operate in conformance with the seafood HACCP regulation. In addition, the HACCP regulation requires importers to understand the hazards associated with the products they are importing and to take positive steps to verify that they obtain shipments from foreign processors who comply with the regulation's requirements.

The field staff in FDA's Office of Regulatory Affairs (ORA) are responsible for overseeing regulatory compliance for fish and fishery products produced in the United States and for those products imported from abroad. The field staff conduct inspections of fish and fishery product processing establishments, conduct follow-up investigations to track foodborne illnesses, and perform other activities, such as sampling, designed to oversee the safety of these products. The HACCP inspection approach is used by FDA during domestic and foreign inspections of seafood processors to focus its attention on the parts of seafood production and processing that are most likely to affect the safety of the product. Specifically, the approach allows FDA to evaluate processors' overall implementation of their HACCP systems over a period of time by having access to the firms' HACCP plans, including monitoring, corrective action, and verification records. In this model, it is the seafood industry's responsibility to develop and implement

HACCP controls, and FDA's responsibility to oversee industry compliance.

FDA allocates its inspection resources based primarily on the risk of the product. Examples of high-risk products include ready-to-eat products, such as hot or cold smoked fish, scombrototoxin-forming fish, such as tuna or mahi-mahi, and fish in reduced oxygen packaging. Catfish and related fish species are identified in FDA's Fish and Fishery Products Hazards and Controls Guidance as having the potential hazard of chemical contaminants, which could include industrial chemicals such as heavy metals, and pesticides. Chemical exposure is a concern for fish harvested from aquaculture ponds, freshwater bodies, estuaries, and near-shore coastal waters that may be subject to shore-side contaminant discharges, as opposed to the open ocean. Chemical contaminants and pesticides may also accumulate in aquacultured fish through contaminated feed ingredients. In addition, 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, when catfish were under FDA's HACCP program, a processor of catfish and related species would have had to address the hazard in its HACCP plan.

Catfish typically pose less of an acute food poisoning risk to consumers than certain other types of fish. This is in part because catfish are generally not eaten raw or packaged in ready to eat form and are neither scombrototoxic nor prone to other natural toxins. Historically, FDA sometimes found violations in domestic catfish product and, when we did, took appropriate regulatory action. Generally, when unapproved antibiotic chemicals were detected in imported catfish, FDA placed these products on Import Alert to prevent contaminated product from entering the country, as described in greater detail later in the testimony.

FDA has a number of regulatory tools that apply to domestic and foreign processors of fish and fishery products that are non-compliant, including Warning Letters, seizure of products, injunction against further non-compliant practices, and/or prosecution of an individual or establishment. FSMA provided FDA with additional tools, such as the authority to issue a mandatory recall for foods (other than infant formula, for which FDA already has recall authority) when a company fails to voluntarily recall regulated foods that meet certain criteria, after having been asked to do so by the Agency. In addition, FDA can now order administrative detention of any article of food if there is reason to believe that it is adulterated or misbranded. In addition to these new enforcement tools, FDA also has new authority under FSMA to suspend the registration of a facility if the Agency determines that food manufactured, processed, packed, received, or held by such facility has a reasonable probability of causing serious adverse health consequences or death. These new authorities enable the Agency to more effectively prevent unsafe food from entering commerce.

For example, in 2016, FDA performed environmental sampling of establishments regulated under the seafood HACCP regulation. The environmental sampling from these establishments resulted in a number of seafood recalls because FDA detected *Listeria monocytogenes*. This also led to the registration suspension of one seafood HACCP establishment, which prevents food from the establishment from entering commerce until appropriate measures are taken to protect food safety.

REGULATION OF FOOD IMPORTS

FDA's authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) provides a broad

statutory framework to ensure that imported foods are safe, wholesome, and accurately labeled. The Agency has numerous tools and authorities that enable it to take appropriate action regarding imported products. The Agency conducts inspections of foreign food manufacturers and, if FDA requests to inspect a foreign facility but is refused, FSMA gave the Agency the authority to refuse that facility's food admission into the United States.

Besides HACCP inspections of foreign facilities, the Agency also conducts surveillance of food offered for import at the border, referred to as import entries, to check for compliance with U.S. requirements. FDA reviews all import entries electronically prior to the products' being allowed into the country. The Agency has implemented an automated screening tool, the Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting (PREDICT) system, which has significantly improved FDA's screening of all imported entries. PREDICT uses automated data mining and pattern discovery to identify data anomalies with regard to imports. The system utilizes the admissibility history for the firm and/or specific product and also incorporates the inherent risk of the product, facility inspection history, data quality concerns and sample analyses, as well as types of products that the firm offers for entry into U.S. commerce. Based on this electronic screening, the Agency focuses its inspection and sampling resources on those entries with the potential for the greatest impact on public health.

Another key tool for screening imported goods is the Import Alert. Import Alerts inform FDA field personnel that the Agency has sufficient evidence or other information about a particular product, producer, shipper, importer, geographical region, or country to believe that future shipments of an imported product may be violative. On the basis of that evidence, FDA field personnel may detain future shipments of the article that is being offered for import into the

United States without physically examining or testing the product. The Agency has approximately 50 active Import Alerts that identify a seafood product from a firm and/or country based upon past violations.

When an Import Alert is issued and FDA detains an import entry, the importer has an opportunity to introduce evidence to demonstrate that the product is not violative. The Import Alert shifts the burden to the importer to provide testimony to demonstrate that the product meets FDA regulatory requirements. If the testimony includes laboratory analysis, FDA laboratory staff will review the laboratory report to verify that the results are accurate and had been analyzed using a valid method, and that the sample had been collected properly before accepting the results as a basis to release the entry into U.S. commerce. FDA decisions to remove a product, manufacturer, packer, shipper, grower, country, or importer from detention without physical examination (DWPE) would be based on evidence establishing that the conditions that gave rise to the appearance of a violation have been resolved and on the Agency's having confidence that future entries would be in compliance with the FD&C Act.

In March 2016, FDA provided USDA/FSIS a complete list of firms that process catfish and are subject to DWPE, including under Import Alerts for the presence of unapproved drugs in aquaculture, for seafood products contaminated with salmonella, for misbranded seafood, and one related to uneviscerated fish. FDA also provided USDA/FSIS a list of firms that had imported catfish in the previous three years and continues to provide USDA/FSIS with FDA inspection, testing, and import history for firms that have been identified by their competent country authority as intending to import catfish into the United States. It is FDA's understanding that USDA/FSIS has used this information to identify incoming shipments of catfish products for

testing. For example, in May 2016, USDA/FSIS refused shipments of Siluriformes from two Vietnamese companies that FDA had previously flagged for residues of unapproved drugs.

FDA also performs laboratory analysis on a sampling of products offered for import into the United States and performs periodic filer evaluations to ensure that import data being provided to FDA is accurate.

Working with Foreign Counterparts

It is worth noting that FDA is working globally to better accomplish its mission to promote and protect the public health of the United States. As one example, the Agency has conducted foreign country assessments to evaluate the other country's laws for, and implementation of, good aquaculture practices. Specifically, FDA evaluates the country's controls, including licensing and permitting, inspections, and training programs for aquaculture products. FDA uses the information from country assessments to better target surveillance sampling of imported aquaculture products, inform planning of foreign seafood HACCP inspections, provide additional evidence for potential regulatory actions, such as Import Alerts, and improve collaboration with foreign government and industry contacts to achieve better compliance with FDA's regulatory requirements.

CONCLUSION

Food safety continues to be a top priority for FDA. The Agency has a strong regulatory program in place for fish and other seafood products. FDA will continue to work with our domestic and international partners to ensure the safety of both domestic and imported seafood.

Thank you, again, for the opportunity to appear before you today. I would be happy to answer any questions.

Mr. PITTS. The chair thanks the gentleman and now recognizes Mr. Morris, 5 minutes for your summary.

STATEMENT OF STEVE MORRIS

Mr. MORRIS. Thank you, Chairman Pitts, Ranking Member Green, and members of the subcommittee. I appreciate the opportunity to be here today.

Today, I would like to discuss the government's efforts to inspect catfish.

In 2015, catfish accounted for about 4 percent of seafood imports to the United States, almost all of it coming from fish farms in Vietnam. Domestically, catfish production is concentrated in Mississippi and Alabama.

Catfish, like other food products, can present food safety risk from the presence of pathogens or contamination from chemicals and drugs. Effective oversight is critically important to help ensure that all food, including catfish, is safe.

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.

USDA's Food Safety and Inspection Service and the FDA are the Nation's two primary food safety agencies. In the 2008 farm bill, Congress transferred the responsibility for the inspection of catfish from FDA to USDA. FDA would be responsible for inspecting all other types of seafood. In addition, the Department of Commerce's National Marine Fisheries Service would provide fee-for-service inspections of seafood processing facilities at their request.

In May 2012, we reported that USDA's proposed catfish inspection program would further fragment responsibility for overseeing seafood safety, introduce overlap at additional cost to taxpayers, and would likely not enhance the safety of catfish.

Specifically, we identified four areas of concern.

First, catfish processors would be required to implement plans to identify and address food safety hazards similar to the ones already in use by FDA. As a result, paperwork requirements for catfish processors could increase.

Second, overlapping inspections might occur. For example, facilities that process only catfish could be inspected by two agencies, and facilities that process both catfish and other seafood could be inspected by three: USDA, FDA, and the National Marine Fisheries Service.

Third, inconsistent oversight of imported seafood could result. For example, USDA would require foreign countries to demonstrate equivalence to U.S. food safety standards for catfish, and FDA would require processors to identify and address food safety hazards for all other types of seafood.

Fourth, additional costs to the government could be incurred. For instance, FDA estimated it spent less than \$700,000 annually to inspect catfish processing facilities, while USDA estimated in 2011 that its program would cost \$14 million annually.

Based on our findings, we suggested that Congress consider repealing provisions of the 2008 farm bill assigning USDA responsibility for inspecting catfish. Congress did not act on our suggestion

and in the 2014 farm bill reaffirmed its commitment to the transfer.

USDA has moved forward to implement its catfish inspection program and reduced its initial estimate of the program's annual costs from \$14 million to about \$2.6 million. USDA acknowledges that the program's actual cost is yet to be determined.

In March 2016, USDA began conducting continuous inspections at domestic catfish facilities and in April 2016 began selective inspections and testing of catfish imports at U.S. ports of entry. USDA reports it has rejected several shipments of catfish for containing residues of unapproved drugs. USDA plans to fully implement its catfish inspection program by September 2017.

We have an ongoing review examining Federal efforts to ensure the safety of imported seafood, including catfish. As part of this review, we will review coordination between FDA and USDA and how these agencies are leveraging resources to conduct seafood oversight. We plan to issue this report in the spring of 2017.

This completes my prepared remarks, and I would be happy to answer any questions you have. Thank you.

[The prepared statement of Mr. Morris follows:]

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United States Government Accountability Office

Testimony

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

For Release on Delivery
Expected at 10:00 a.m. EST
Wednesday, December 7, 2016

DRAFT

SEAFOOD SAFETY

Status of Issues Related to Catfish Inspection

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

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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. Of these seafood imports, 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, smorris@gao.gov

December 7, 2016

SEAFOOD SAFETY

Status of Issues Related to Catfish Inspection

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 and 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.

United States Government Accountability Office

DRAFT

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. Of these seafood imports, catfish 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), and other federal agencies, as well as representatives from industry and consumer advocacy groups. We

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).

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

⁴GAO-12-411.

food safety standards, 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; and (3) for imported catfish,⁶ 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.

In addition, 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.

⁹GAO-12-411.

- 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 primarily responsibility for the safety of the seafood they process)—for the seafood it regulated.

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.

- **Cost of implementing FSIS's catfish inspection program.** FDA estimated that it spent less than \$700,000 annually to inspect catfish processing facilities, and in 2010, 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

¹²GAO-12-411.

that would result from FSIS's implementation of its proposed catfish 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,

¹³80 Fed. Reg. 75,590 (Dec. 2, 2015).

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 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 morris@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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Mr. PITTS. The chair thanks the gentleman.

And I will begin the questioning, recognize myself for 5 minutes for that purpose.

Dr. Jones, the GAO found that the memorandum of understanding between FDA and USDA, "does not address the fundamental problem, which is that the USDA Food Safety and Inspection Service catfish program, if implemented, would result in duplication of activities and an inefficient use of taxpayer funds."

Do you agree that the memorandum of understanding does not address duplication?

Mr. JONES. I believe that the memorandum of understanding does address duplication, in that it imposes upon us the obligation to remain in contact with each other to make sure that we are able to identify firms that are under dual jurisdiction so that we can avoid duplication of effort wherever possible.

Mr. PITTS. In your testimony, you note the robust expertise FDA has regulating food safety. And, prior to this program, USDA did not have any experience regulating seafood, correct?

Mr. JONES. Correct.

Mr. PITTS. I assume that USDA has learned more since they started the catfish inspection program, but USDA is still not as well-versed as the FDA. Based on FDA's experience and knowledge, is it more appropriate for catfish to be placed back in your jurisdiction?

Mr. JONES. I wouldn't be in a position to say which would be more appropriate. That decision remains up here. But we would be able to accommodate that program, as we did in the past, if called upon to do so.

Mr. PITTS. Now, the GAO report states that, "FDA officials told us Food Safety and Inspection Service's continuous monitoring approach is counter to Hazard Analysis and Critical Control Point, HACCP, -based requirements for seafood and not based on risk."

Would you explain how the USDA continuous monitoring approach runs counter to the FDA program?

Mr. JONES. Well, the goal of our HACCP program is to be a little bit more proactive and preventive in the way we regulate seafood and make sure that it is safe.

The inception of that program back in 1997 was for the purpose of being more efficient and effective and not relying as heavily on inspection in order that we could have a multipronged, risk-based approach to prioritizing our activities, our sampling, our inspection, and our regulation of seafood. And we do believe that that program has been incredibly effective.

Mr. PITTS. How does FDA's risk-based approach determine the frequency of FDA-regulated seafood activities?

Mr. JONES. Well, one example would be—it is often cited that we do a minimal number of sampling, but that sampling that we do is risk-based, for example. And there is a broad range of rates at which that sampling occurs, and risk-based factors figure into that.

So there is surveillance sampling, where, for example, sampling of seafood from Canada would occur at a much lower rate than the sampling of seafood from Vietnam. And, in fact, if we find problems and implement an import alert, the burden of that sampling shifts

to the importer and rises to 100 percent for those problem products.

Mr. PITTS. Well, how does FDA's approach to inspecting seafood through the seafood HACCP system ensure consumers have safe products?

Mr. JONES. Well, because it is a risk-based approach and because we have a long history of information awareness, background on the firms, the processors, the history of violative product, and are able to continuously prioritize our efforts, we are able to focus on the areas where there are problems and address those and put the most efficient use of resources to the problem areas.

Mr. PITTS. So, if Congress were to repeal the USDA catfish program, does FDA have the capability to inspect catfish in a seamless manner that ensures food safety of catfish?

Mr. JONES. I am quite sure that, if called upon to do so, we would be able to work very closely with our counterparts at FSIS to effect a seamless transition and avoid any gaps and to be able to reinsert that into our program.

Mr. PITTS. Thank you.

Mr. Morris, I have just a half-minute left. In the "2015 High-Risk Series: An Update," did GAO recommend that Congress consider repealing these provisions of the 2008 farm bill?

Mr. MORRIS. Yes. That is still our position, yes.

Mr. PITTS. Yes.

Did you find that the memorandum of understanding between FDA and USDA does not address the fundamental problem, which is that the USDA Food Safety Inspection Service catfish program, if implemented, would result in duplication of activities or an inefficient use of taxpayer funds?

Mr. MORRIS. Well, we have an ongoing review looking at the coordination between FDA and USDA.

In terms of the duplication of inspection, it is still the case that a catfish processing facility could be inspected by USDA but also be inspected by the National Marine Fisheries Service, which would conduct inspections upon request on a periodic basis.

Mr. PITTS. My time has expired. Thank you.

The chair recognizes Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

I would like to thank our witnesses for your testimony today and have a number of questions for Mr. Jones about catfish and the industry itself.

How many domestic seafood firms process both catfish and other seafood and are therefore now subject to both FDA and USDA oversight?

Mr. JONES. I know that there are quite a few, but I don't have a number for you at this point.

Mr. GREEN. If you could just get some amount, because, obviously, that would show the duplicate effort instead of expanding it.

In the proposed rule USDA published to establish its catfish program, the Food Safety and Inspection Division stated that catfish is a low-risk food. Does FDA agree with this assessment?

Mr. JONES. That would be our assessment as well. It is never eaten raw, and it is not usually a ready-to-eat product, and we rarely see illnesses that can be attributed to catfish.

Mr. GREEN. OK.

The FDA has a long history of ensuring the safety of all seafood products. Mr. Jones, you testified that the FDA's seafood risk program—and, in particular, I am interested in learning about the FDA's risk-based approach, which identifies and prevents hazards, better protects the American food supply.

Can you explain the benefits of the FDA HACCP program that focuses on prevention as compared to the program that relies solely on spot checks of finished seafood?

First, you do have inspectors on the docks, I know, at the Port of Houston and also at our border with Mexico, because I have met those. Sometimes they will come from Laredo to Houston and go back. But how often do you do the spot checks?

Mr. JONES. The spot checks are conducted routinely. They are exactly that, spot checks, so it is hard to put a number on them. But they are conducted at all ports of entry, and it is an ongoing thing.

Mr. GREEN. OK.

And the other part of it, you have your risk prevention as a compared program. So you have spot checks along with the analysis of the risk prevention, looking at where those particular products are coming from.

Mr. JONES. That is right. In fact, the whole purpose of the surveillance sampling is to try and identify areas where we need to focus our efforts.

Mr. GREEN. OK.

Is that true for both domestic and foreign producers of seafood? Are they subject to the same regulatory regimen?

Mr. JONES. Absolutely. The foreign firms are required to meet all of our requirements, and their importers are required to verify that they do.

Mr. GREEN. Given the FDA's long history of regulating catfish and other food, do you anticipate the agency would be able to handle the responsibility if the authority over catfish were returned to the FDA?

Mr. JONES. Yes. I anticipate that would not be a problem for us.

Mr. GREEN. Thank you. And it is reassuring to hear about the FDA's program, which Congress used as a model when we drafted the Food Safety Modernization Act that expanded that risk requirement to all food under FDA's jurisdiction.

And I will yield back my time.

Mr. PITTS. The chair thanks the gentleman and now recognizes the chair emeritus of the full committee, Mr. Barton, 5 minutes for questions.

Mr. BARTON. Thank you, Mr. Chairman. And I can tell you, we are going to miss you next year. I would assume that this is your last chairmanship hearing.

Mr. PITTS. This is the last.

Mr. BARTON. It shows your dedication to duty that you are holding a hearing on catfish, which in all probability are only eaten in your district, certainly not grown. We appreciate your service.

Mr. PITTS. Thank you.

Mr. BARTON. Gentlemen, I am not an expert on catfish. Mr. Harper of Mississippi is probably our catfish expert, I would assume. So my questions are going to be fairly basic.

How many States in the Union have catfish commercial production? It is not a trick question.

Mr. MORRIS. There are four primary States: Mississippi, Alabama, Arkansas, Louisiana.

Mr. BARTON. OK.

Mr. MORRIS. Four key states.

Mr. BARTON. And how many nations export catfish to the United States?

Mr. MORRIS. Currently, there are 10 countries that have provided documentation and comply with requirements to allow exports into the U.S., Vietnam being the largest exporter.

Mr. BARTON. Do you know what are the top two or three besides—

Mr. MORRIS. Vietnam would cover about 90 percent of that; China and Taiwan—

Mr. BARTON. OK.

Mr. MORRIS [continuing]. Are the top three.

Mr. BARTON. So Asian countries.

So we have 10 nations that export to the United States, and we have four states that produce it. Is there any reason to believe that those four states couldn't guarantee the safety of the catfish eaten in their states? Why do we need a Federal program?

Mr. JONES. Well, I would say that the main reason for that is that a great deal of this product is in interstate commerce, so there is an obligation for us to ensure the safety of that product.

Mr. BARTON. So you don't think the great State of Mississippi or Alabama or Arkansas or Louisiana or Texas could guarantee the other 46 states that the catfish that we grow is safe to eat?

Mr. JONES. I wouldn't doubt their capabilities at all, but it is a statutory requirement, and we do have the obligation to oversee product that is in interstate commerce.

Mr. BARTON. Well, I understand that, but we have a President-elect who has decided that it is time to change the status quo. And I believe I could trust Mr. Harper and the State of Mississippi to guarantee the catfish I eat, if it is not in Texas, if I don't catch it myself, is safe for me to eat.

I do understand on the foreign side you have to have some standard on imported product. But if it is Vietnam, Taiwan, and China, I believe we could just say, if we ever catch you doing something bad, we are going to close our market. I mean—

Mr. JONES. Well, my response to that would be that that is effectively what we achieve through our import alert program. When we identify a problem, those products are stopped and they are checked 100 percent.

Mr. BARTON. Which is the bigger problem, if there is a significant problem? Is it imported catfish or domestic catfish? I mean, how often do you really see somebody trying to provide tainted catfish?

Mr. JONES. Well, we do—

Mr. BARTON. I know it happened, because—

Mr. JONES. We do, in fact, occasionally find HACCP violations at domestic firms and have issued warning letters at domestic firms. What we have not found in domestic product is residues of unapproved drugs. We do find those in some imported products. And that is the reason for our—

Mr. BARTON. So the primary problem is the imported catfish. Would that be safe to say?

Mr. JONES. I am not sure if I would characterize it as a problem. It is something that we are very vigilant about and are on top of. And, as I mentioned earlier, we have rarely, if ever, seen illnesses attributed to catfish, foreign or domestic.

Mr. BARTON. OK.

Well, I know our committee has a vested interest in your agency because we have jurisdiction over the Food and Drug Administration and we have limited jurisdiction over the United States Department of Agriculture. So you have probably got more allies in this room for FDA regulation than USDA regulation.

But if you look at it in the overall scope of what the mission statement of the FDA is, I wouldn't think catfish protection would be in the top 10. I believe new drug development and all of the cures for cancer that Chairman Upton and Chairman Pitts just worked so hard—and Mr. Pallone—to pass the 21st Century Cures bill would probably be a little bit higher priority.

So my time has expired, Mr. Chairman. I am not real sure where we are going with this. If I am still here, I will listen to Mr. Harper, because I have a feeling he is the one who has the real essence of the issue here. But I will certainly work with the committee if this is something we need to take action on.

And I appreciate you gentlemen's testimony.

Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman and now recognizes the ranking member of the full committee, Mr. Pallone, 5 minutes for questions.

Mr. PALLONE. Thank you, Mr. Chairman.

I wanted to ask Mr. Jones a few questions.

We heard a lot about the benefits of FDA's HACCP program. However, I am also interested in learning more about other aspects of FDA's risk-based approach to seafood inspection. First, how does FDA prioritize what seafood processors or importers to inspect?

Mr. JONES. Well, we do have electronic review of all entries, and we have factors included in that review that include things such as firm and product history, inherent product risk, processing risks, facility inspection history, sample analysis results. And we also have a team of people that reviews and prioritizes that information and makes selections for those priorities based on current events.

Mr. PALLONE. And can you describe how FDA's new authority under the Food Safety Modernization Act strengthened the agency's ability to protect the seafood that millions of Americans eat each day?

Mr. JONES. Well, in fact, that new authority strengthens it in several significant ways.

It gives us authority to issue mandatory recalls for foods so that if a firm were to refuse to conduct a recall when we thought it was necessary we could force them to do so.

We can order administrative detention of any article of food if we feel that there is a reason to believe that it is either adulterated or misbranded.

And we also have, through FSMA, the authority to suspend the registration of a facility if the agency determines that food that is

manufactured or processed or held or packed there has some reasonable probability of causing harm or even death.

And we also have authority now that if we request inspection of a foreign facility but that inspection is refused, we now have the authority to refuse admission of that firm's product into the country.

Mr. PALLONE. All right.

Now, in May, we heard about how USDA's FSIS stopped shipments of imported catfish because of illegal drug residues. Did FDA take similar action when the agency regulated catfish?

Mr. JONES. We did, in fact. And I have spoken earlier about the import alerts, which is a very effective tool for us. And I also mentioned that we worked very closely with FSIS in transferring the program to them. In the process of doing so, we shared with them all of the information in the import alerts, and some of that information covered those firms and allowed them to focus their efforts there.

Mr. PALLONE. All right.

Well, thanks. In my opinion, it is clear from your testimony that FDA has a robust food safety system in place that is capable of ensuring the safety of all seafood products, including catfish. Although I keep saying catfish is seafood, which it really isn't, but same thing.

All right. Thank you so much.

Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman and now recognizes the vice chair of the subcommittee, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you very much.

It is interesting to have our final meeting on catfish. One of my dad's first attempts at business was a catfish farm. And we put a bunch of catfish about this big, about the size of a minnow, in the pond. It rained really hard, the tank broke, and they went downstream to the creek on our farm. So there was record catfish farming downstream from us, so that was interesting.

But it is serious. It is a great product. I feel like I am an aficionado, if you can be, of catfish, so it is something that I am interested in.

So, Dr. Jones, how is your program different than what the—I know you have it in your testimony, but I am going to let you expand on this. So how is your program different than the USDA's Food Safety Inspection Service? How are you different from them?

Mr. JONES. Well, I think the main difference is that we are not doing continuous inspection of all of these firms and we are not requiring equivalence. We have taken a very different approach with all of the other seafood that we regulate.

It is a multipronged approach, it is risk-based, and it is data-driven. And it allows us to focus our efforts to work both efficiently and effectively without having to burden firms and our own agency with continuous inspection and equivalence determinations.

Mr. GUTHRIE. So why do you have different approaches then? Why do they do it differently, the other agency?

Mr. JONES. Well, the main thing that we do, through the HACCP program, is prioritize our efforts, focus our efforts, and take an ap-

proach that involves inspections at the docks, surveillance sampling, and collection of any manner of data having to do with firm history, product history, and relative risk ranking of various products, various commodities, and the hazards associated with them, so that our efforts are extremely focused, and the majority of our resources can be put towards the areas where there are known to be specific problems with particularly high-risk products.

Mr. GUTHRIE. OK.

And so is the FDA equipped to inspect and incorporate catfish back into your program if the FSIS program is repealed?

Mr. JONES. If we were called upon to do so, we would put it back where it was before.

Mr. GUTHRIE. Great. Thanks.

And, Mr. Morris, is it true that in the 2015 annual report entitled "Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits: An Update" that the GAO identified catfish inspection as a duplicative program and noted that repealing provisions of the 2008 farm bill that assigned USDA's Food Safety and Inspection Service responsibility for examining and inspecting catfish and for creating a catfish inspection program would avoid duplication of Federal programs and save taxpayers millions of dollars annually without affecting the safety of catfish intended for human consumption?

Mr. MORRIS. Yes, that is still our position. I would also say, though, that, you know, events have moved forward; USDA has implemented their program. And we do have an ongoing review looking at both the FDA and USDA's program to see how well they are doing.

Mr. GUTHRIE. OK.

Thank you, Mr. Chairman. Those are my questions. I yield back my time.

Mr. PITTS. The chair thanks the gentleman and now recognizes Dr. Schrader, 5 minutes for questions.

Mr. SCHRADER. Thank you very much, Mr. Chairman. Another good, bipartisan hearing on a good subject. I want to thank you for your leadership over the last few years. It has been a pleasure to work on this committee and Energy and Commerce in general.

I don't have a lot of questions, just a few statements for the record to help inform the members. I served on the Ag Committee prior to coming to Energy and Commerce. And I think as has been indicated here, many of you know in the 2008 farm bill, without any public testimony or any language from either the Senate or the House, considerations of the farm bill, the provision that stripped FDA authority for catfish was put in at the last minute. A classic case of pork politics—well, catfish politics, I guess, here in Washington, D.C.

And I would like to think we are past that stage. Since that time, there have been Members of both sides of the aisle, Blue Dog Democrats like myself, Freedom Caucus and other Members on the other side, that are really concerned about duplication and waste in government. This is probably one of the most classic and best-case examples.

GAO—thank you—has done a very thorough study on this and made it very clear. It has been stated again and again that catfish

is a low-threat food source for America. We don't inspect—FDA and, I guess, at this point, USDA to some degree inspect. The duplication is indeed there, because we have two separate agencies doing fish inspection. We actually have FDA wasting time training USDA folks, which is sad.

So I think this is pretty straightforward. I appreciate the opportunity to discuss the issue, draw another light on this. I can assure you that the Ag Committee still feels the same way. In 2013, the House Ag Committee overwhelmingly passed an ag bill that restored jurisdiction, if you will, and does not favor this. We have the SJR 28 from the Senate, indicating their disapproval of the separation of having these two duplicative fish inspection programs.

So it would be nice to start a new Congress or finish this Congress with a good, bipartisan hearing and, hopefully, ultimately, a bill to restore FDA's authority over the catfish program, reduce waste, and help the taxpayer.

Thank you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you very much. I appreciate it.

I don't know that I really have an interest in who inspects the fish other than the economic one.

Now, Mr. Morris, you indicated that—and the question was commercial operations. And you left Virginia out, and I assume that you did that because we don't do catfish farming per se. But because of bad decisions that our state made, we introduced the blue catfish into the James River in the 1970s. And now the best way to eliminate it is to eat it—or to at least control the numbers. Apparently, this fish lives up to 20 years, can grow to 100 pounds.

Mr. MORRIS. Wow.

Mr. GRIFFITH. So, keeping in mind that we are not talking about fish farming, you would include Virginia as an area where there is a commercial operation, but it is catching it out of the river as opposed to fish farming per se.

Mr. MORRIS. Yes.

Mr. GRIFFITH. Now, here is the dilemma that some of our folks—and we are going to have a witness on the next panel who will talk about this as well—that some of our folks are having, and that is, if the inspection process has to be both—and I will ask both of you to give your thoughts on this. If the inspection process has to be two—and I can't say whether it ought to be FDA or USDA, but nobody has proposed that USDA take over all seafood inspection, so that is why I would have to lean towards FDA.

But if these folks catching the blue catfish out of the James River and the Chesapeake Bay—apparently, it is spreading now into other parts of the bay—if they are having to be inspected by two, both the written testimony of the witness on the next panel and Todd Haymore, who wrote a letter on June 3 out of the Office of the Governor of the Commonwealth of Virginia, indicated that there are going to be some businesses that just decide they are not going to process or deal with the blue catfish because they don't want to be inspected and operate under the rules of both the USDA and the FDA and they can deal with all the other fishes by just doing one.

So how do we solve this problem? Because, recognizing Mr. Harper, who is sitting in front of me, I have to believe it was shifted to the USDA because something wasn't going right at the FDA. So how do we solve these problems that the catfish farms in Mississippi, et cetera, are having with the problems that it will create for Virginia and other states of the Chesapeake Bay in trying to eliminate a predatory fish?

Help me out. How do we thread that needle? Any solutions?

Mr. MORRIS. Well, that is a good question. I don't know if I have a specific answer to you. But you did mention resources, how much the program would cost. I could comment on that.

In terms of the USDA program, originally they estimated it would cost about \$14 million a year. They reduced that estimate to about \$2.6 million. But they have spent \$20 million to develop the program since 2009, so that is already a sunk cost into the program. So just to give you some perspective in terms of what is being spent.

On the FDA side, the estimate would be more in the \$700,000 range, just to give you some perspective.

Mr. GRIFFITH. Dr. Jones, how do we solve Mr. Harper's problem and the problem that apparently arose—or else Congress wouldn't have passed something—with the FDA inspecting the catfish and my state's problem, where if we have the dual inspection we are probably going to greatly hamper commercial fishing operations? Which will actually have the benefit of cleaning up the Chesapeake Bay in part.

Mr. JONES. Well, I am not in a position to propose a solution to that problem. But, if I could, I would like to comment on something you mentioned earlier—

Mr. PITTS. Please.

Mr. JONES [continuing]. Which was your belief that this transfer of primary authority may have occurred because there was some sort of a problem with FDA's seafood inspection program. And I just want to go on record as saying that I don't believe that to be the case.

Mr. GRIFFITH. All right. And I appreciate that. And I will look into it further. And I suspect Mr. Harper may have some comment about that later.

It is interesting, and it goes to prove we shouldn't be just dropping species from one ecosystem into another one without thinking it through very, very carefully.

But just so that you all will know, I represent the western part of Virginia, so I don't have what typically people would think of as a bay district. However, 3 of my 29 jurisdictions are in the Chesapeake Bay watershed, and I have the headwaters of the James in my district. So, while the blue catfish haven't gotten there yet, when I look at data that indicates they are 75 percent of the biomass in the James River today because they eat everything and squeeze out the others, I am concerned that it will hurt some of our tourist industries which deals more with the smaller fishes and trouts as you get further up the stream at some point in the future. So I am concerned about this issue.

And I appreciate it and yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Missouri, Mr. Long, 5 minutes for questions.

Mr. LONG. Thank you, Mr. Chairman.

And, for the record, I just want to say that I went to the dictionary a while ago and looked up “gentleman” and there was your picture. So thank you for all that you have done for all of us over all these years, and the best to you in your retirement. I enjoyed working with you and hope to in the future. I hope we run into you.

Mr. Morris, in the 2012 GAO report on seafood safety, it stated that Federal oversight of food safety is a high-risk area, largely because of fragmentation, and that directing the food safety inspection program to issue catfish inspection regulations further fragments that system.

Could you discuss what areas within the FSIS inspection system would lead to further fragmentation?

Mr. MORRIS. Yes, absolutely. Well, in that report, we identified basically four areas of concern.

So the first would be that the FSIS program would require processes pretty much to implement requirements that were already in place through FDA, so that would be one area of inefficiency and duplication.

Another one would be in the area of overlapping inspections. So, for example—

Mr. LONG. That was going to be my next question. Yes.

Mr. MORRIS. OK. So, for example, in a facility that would process catfish and other seafood, you may have USDA inspecting the catfish, you might have FDA inspecting the other seafood, and you may have the National Marine Fisheries Service there inspecting both. So we noted that as an area of duplication as well.

Also, in terms of the seafood imports, we noted that there is inconsistent oversight in seafood. For example, as Bill mentioned, FDA would be responsible for all other types of seafood, and it would essentially depend on processors to identify and address food safety hazards, whereas with the case of USDA, they would have to determine foreign equivalence to USDA standards.

So those are some examples of where the duplication would occur, and inconsistencies.

Mr. LONG. Well, what are some of the differences in the two systems on the inconsistent oversight of imported seafood? What are the—

Mr. MORRIS. So, for example, USDA would require foreign governments to demonstrate equivalence to our standards, so it would deal on the government level. FDA would deal with the processors and oversee them to ensure that they are identifying and addressing any hazards. So it is a different focus.

Also, in terms of the USDA program for imports, eventually, USDA wants to reinspect all of the imports coming in, whereas FDA, as Bill mentioned, uses more of a risk-based approach.

Mr. LONG. So how does that affect the overall approach for ensuring the safety within our system?

Mr. MORRIS. Well, it goes back to what is the identified hazard. In the case of USDA, they identified salmonella as the primary

hazard to catfish, but we found that that hazard was pretty much nonexistent.

Mr. LONG. OK. Thank you.

And, Dr. Jones, FDA continues to exercise oversight of dual-jurisdiction establishments that process both catfish and other seafood products. Could you discuss the impact this dual jurisdiction has on these facilities that process both catfish and other seafood? Are you concerned that there would be unnecessary overlap within these inspections?

Mr. JONES. Well, it is part of our arrangement with FSIS to work closely on that, and I am not in a position to say anything to disparage the work that they do in concert with us.

Mr. LONG. OK.

The FDA has the authority to undertake systems recognition assessments to determine whether a foreign food safety system is compatible to the U.S. food safety system. Could you discuss this process and how it affects the FDA's overall primary oversight?

Mr. JONES. Absolutely. It is something that we have been working on for several years now. In a sense, it offers an alternative to equivalence.

Equivalence determinations are an extraordinarily cumbersome prospect. Things are done in different ways, and so you can't find things that are different to be equivalent very easily. However, you can find them to deliver equivalent levels of food safety, to provide same outcomes.

And so what our process for determining that comparability of systems is is to look at the food safety programs that others country have in place and evaluate them against ours to see if the outcomes are the same.

Mr. LONG. OK. Thank you.

And after my trip to the dictionary, it gives new meaning to saying that I yield back to the "gentleman" from Pennsylvania.

Mr. PITTS. The chair thanks the gentleman and recognizes Dr. Bucshon, 5 minutes for questions.

Mr. BUCSHON. Thanks, Mr. Chairman.

I don't have too much to add, but I am just curious about how the inspection process works in general. How do you determine, when you are doing spot checks, what constitutes a representative sample that gives you an idea of the overall content of the product coming into the United States?

Mr. JONES. Well, it is an ongoing process, so it doesn't occur in one set of sampling. So the sampling is taken as a whole over a period of years, and we evaluate that sampling on an ongoing basis, and we adjust it accordingly. So you don't have a fixed set of a certain number of samples of a certain kind of product from a certain place. It changes routinely, and when we start to see a problem, we increase that sampling dramatically to understand the scope of that problem.

And some potential outcomes of that goes back to something I discussed earlier, import alerts. In some cases, we have found that there are individual firms that have problems and need to be on import alerts. And in other cases, we have found that the problem is pervasive enough to encompass an entire geographic region, and in yet other examples, it is an entire country. And we use that

sampling to target those resources and identify the scope of the problem.

Mr. BUCSHON. OK. So it is a directed sample. It is not like for every 10,000 catfish that come in you sample a certain percentage. Because there is a way to statistically analyze, right—

Mr. JONES. Yes.

Mr. BUCSHON [continuing]. What a representative sample would be? But what you are saying is not only do you do that, but you also look at other variables like where the origin of the product comes from and if they have had previous problems.

Mr. JAMES. That is exactly right. We do both.

An example of the kind of sampling you were originally discussing would be when we are sampling for histamine in fish that could be partially decomposed. That would be a statistically significant sampling for a particular shipment.

Mr. BUCSHON. OK.

Thank you, Mr. Chairman. I yield back.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentlelady from Tennessee, Mrs. Blackburn, 5 minutes for questions.

Mrs. BLACKBURN. Thank you, Mr. Chairman. And I join others in saying we are really going to miss you. I know you are looking forward to some good time and some good travel out and about and some teaching in the classroom, but we are going to miss you here. So we do wish you and Ginny well.

I have to tell you, some of my college buddies were real excited that we were doing that hearing, because I want to Mississippi State University and they know a lot about catfish.

And I am one of those kiddos that grew up on a farm that had a catfish pond. Now, Mr. Guthrie talked about how theirs kind of broke apart and spilled out. Ours stayed in place, but I can tell you those catfish were talented. They could hear my dad walking down there to the pond to spread the catfish food, and by the time he got there, they were jumping out of the water and ready to be fed.

So this is a fun hearing for us to do.

Mr. Jones, I just want to ask you—we have talked about the economics, we have talked about duplications. Is there a public health need to have two separate inspection programs? Is there a justification from a public health point of view?

Mr. JONES. Our assessment of that, in fact, aligned with FSIS's assessment, that catfish is, in fact, a low-risk food and certainly would not be in the higher list of priorities within our program.

Mrs. BLACKBURN. OK. So, in your opinion, there would be no public health need for duplicative programs—

Mr. JONES. Well, I would say—

Mrs. BLACKBURN [continuing]. Or two programs or separated duties.

Mr. JONES. I would say that it is low-risk with regard to imminent health risk. I can't comment on the duplication of authorities, but I can comment on the idea that it is essential that catfish be sampled—

Mrs. BLACKBURN. Sure.

Mr. JONES [continuing]. And be monitored and be regulated, especially—

Mrs. BLACKBURN. I think we all agree with that.

Mr. JONES [continuing]. With regard to unapproved drug——

Mrs. BLACKBURN. Yes.

Mr. Morris, do you think the farm bill provision—should that be revisited and repealed, do you think?

Mr. MORRIS. Yes. We have been on record to say that is the case, and we are still on record to say that.

Mrs. BLACKBURN. To simplify it. Well, OK. I think that sounds good.

We are all concerned about saving taxpayer dollars. We are concerned about public safety. We know if you do it right the first time, when it comes to food and food inspections, that you don't have the expense of contaminated product in the pipeline. Also, programs that run efficiently are going to do a better job of monitoring the product that they are to be monitoring.

And Mr. Morris, we see this repeatedly in reports that you all give us. The streamlining of fish and sea sometimes brings things more into focus. So that is a part of what we want to do.

But, with that, Mr. Chairman, I am going to yield back and thank you for the hearing.

Mr. PITTS. The chair thanks the gentlelady and now recognizes the gentleman from Mississippi, Mr. Harper, 5 minutes for questions.

Mr. HARPER. Thank you, Mr. Chairman.

And, Mr. Morris, you testified earlier almost like this was a Mississippi and Alabama issue, and then you expanded it to a few more states. But, according to USDA, there are at least nine states who participated in a catfish farm survey. Those States were Alabama, Arkansas, California, Georgia, Louisiana, Mississippi, Missouri, North Carolina, and Texas.

So it is much more than just Mississippi and Alabama, you would agree, in that situation?

Mr. MORRIS. Sure.

Mr. HARPER. And when we look at this—and, Dr. Jones, there is no duplicative activity. FDA doesn't inspect anymore, correct?

Mr. JONES. Correct.

Mr. HARPER. So we are only talking about one program. And you would agree that if this was transferred back from USDA to FDA there would be costs for FDA to do that inspection, correct?

Mr. JONES. I couldn't necessarily identify what those costs would be. It would be integrated into part of a much larger program.

Mr. HARPER. But there would have to be additional people, and those folks who would be doing—what was the previous cost when you were doing farm-raised catfish inspections?

Mr. JONES. We never looked to see what specifically farm-raised catfish alone would have cost. I don't know if we could get you those numbers.

Mr. HARPER. Well, we have talked, and Mr. Morris has used the figure of \$14 million several times as an estimate. Why do we keep using that figure when that was an estimate and is actually not accurate and the cost now is about, what, \$2.6 million, which is estimated to be about \$1.4 million more than maybe what FDA projected?

But I want to point out—this was earlier in the year, back in probably July. This program, USDA's FSIS program, one example, stopped more than 40,000 pounds of unsafe catfish products that were coming in from Vietnam. The shipment tested positive for malachite green, which is a drug that could have possible carcinogenic effects. That was caught.

Now, if it is low-risk and not considered a priority in FDA, if FDA had it, that is not something you would catch in your 100 percent electronic testing, correct? Because you are not sampling 100 percent. Is that a fair statement?

Mr. JONES. Actually, it wouldn't have been caught through surveillance sampling, necessarily, for that particular shipment, but it would have been on an import alert and would have been stopped, and it would not have been allowed entry without having been tested.

Mr. HARPER. All right. That is your belief, but you are not capturing everything that comes in. Because you don't personally inspect, even on the seafood that comes in now, everything. Is that a fair statement?

Mr. JONES. No, we do not inspect everything. That is the purpose of HACCP, to avoid having to inspect everything and eliminating good food from the food supply.

Mr. HARPER. The main point being here that we only have one program right now for farm-raised catfish inspection, and that is through USDA.

And would it be fair to say, Mr. Morris, that until there has been enough time—because this started in officially April of this year—you can't do a GAO study right now. You would delay a little bit to see the effectiveness of a program. Is that a fair statement?

Mr. MORRIS. Well, we are taking a look at the ongoing implementation. It is a phased-in implementation over about a year-and-a-half period. So we are taking a look at that.

Mr. HARPER. Sure, to be up, fully operational. And you will look at that. And if you get to the end of this, the full implementation, and your studies show, you know, maybe I didn't agree with this at the beginning but it is working now, it is possible you might have a different opinion at that point.

Mr. MORRIS. Well, we will take a look at the results, and that would inform our position.

Mr. HARPER. You would be fair—

Mr. MORRIS. Sure.

Mr. HARPER [continuing]. As to look at it.

Mr. MORRIS. Sure.

Mr. HARPER. OK.

Other examples we have had of shipments coming in, I know that in May of this year a shipper from China refused to let FSIS inspect, and they turned around and went back. Now, why would they have done that?

So we are showing many examples of things that are showing that the program is working at this point in time. And the real issue here is about food safety. And so it may be something that is considered a low risk, but if families in this country are eating farm-raised catfish, we want to make sure that it is safe for that

family. It is a high risk if you are eating something that is contaminated.

So I believe we have to give this an opportunity, that we don't need to reopen the farm bill on this issue. It has been decided not once but twice. Let's give this program the opportunity to be successful, and then let's discuss it.

So, with that, I thank you, Mr. Chairman, and I yield back.

Mr. PITTS. The chair thanks the gentleman.

That concludes the questions of the members present. We will send followup questions and written questions from any members who are not here to you, ask that you would please respond to those.

Thank you very much for your testimony today.

We will now go to our second panel.

On our second panel, we have—and I will introduce them in the order of their presentation: Kim Gorton, President and CEO of Slade Gorton & Company, Inc.; Bart Farrell, Director of food and beverage, Clyde's Restaurant Group; Justin Conrad, CEO, Bay Hill Seafood, President, Libby Hill Seafood; and Steve Otwell, Seafood Safety and Technology Emeritus, UF Food Science and Human Nutrition, Aquatic Food Products Lab, University of Florida.

I will ask the witnesses to take their seats.

As usual, your written testimony will be made a part of the record. You will each be recognized for 5 minutes to summarize. Welcome.

And the chair recognizes Ms. Gorton, 5 minutes for her summary.

STATEMENTS OF KIM GORTON, PRESIDENT AND CEO, SLADE GORTON & CO., INC.; BART FARRELL, DIRECTOR OF FOOD AND BEVERAGE, CLYDE'S RESTAURANT GROUP; JUSTIN CONRAD, CEO, BAY HILL SEAFOOD, PRESIDENT, LIBBY HILL SEAFOOD; AND STEVE OTWELL, SEAFOOD SAFETY AND TECHNOLOGY EMERITUS, UF FOOD SCIENCE AND HUMAN NUTRITION, AQUATIC FOOD PRODUCTS LAB, UNIVERSITY OF FLORIDA

STATEMENT OF KIM GORTON

Ms. GORTON. Mr. Chairman, ranking member, and members of the subcommittee, my name is Kim Gorton, and I am President and CEO of Slade Gorton.

My company is a third-generation family business with operations across the country. We are one of America's largest distributors and manufacturers of fresh, frozen, and premium value-added seafood products. We provide over 200 million seafood meals to Americans every year.

Regarding catfish, we buy and sell roughly equal amounts of domestic catfish and imported catfish and pangasius. So I am coming at this issue with a balanced portfolio and an overall interest in feeding Americans with healthy and safe food.

Until recently, the FDA regulated all seafood using the Hazard Analysis Critical Control Point program, or HACCP, as we call it, for both domestic and imported seafood. HACCP requires any problems to be identified and eliminated or mitigated at their source.

For imported seafood, that means problems must be fixed thousands of miles from the U.S. border.

As someone with decades of firsthand experience in the American seafood industry, I can say that this program works. The seafood Americans enjoy is safe. That is to the credit of this committee for the laws you wrote, to the FDA for its enforcement of regulations, and to the private sector for its implementation. In nearly 90 years, my company has had no food safety violations for products we produce whatsoever.

I also strongly oppose the USDA's catfish inspection program. It is a duplicative burden that will not improve public health. To suggest that my company does not now have two sets of seafood regulations to follow, where one did the job before, is just plain wrong.

Supporters of this program point to a 2014 MOU between FDA and USDA and claim that it addresses the duplication concerns. This MOU only commits the agencies to create a list of facilities that are subject to USDA and FDA regulations. How does a list reduce my burden and my costs? The reality for my small business is that we will still have two sets of regulations to meet and two sets of regulators to deal with.

And to answer a previous question about how many companies process both imported catfish and pangasius as well as domestic, the answer is thousands of companies here in the United States.

So moving this one type of fish over to a separate regulator has also caused other problems. We at Slade Gorton process a good deal of fresh seafood in our plants, including domestic catfish, a product that is highly perishable and needs to move through the supply chain in an expeditious manner. We now must schedule a USDA inspector 2 weeks in advance of processing and packing catfish. Most of our customers place their orders up to 8 hours in advance.

The result? We are unable to fill customers' orders for catfish with any consistency, so we have begun to focus on other species. So have our customers. That out-of-touch regulatory burden is not going to grow seafood consumption, my business, or our economy, and it is what makes Americans so frustrated with our government.

Pangasius, the fish targeted by supporters of the USDA program, provides roughly 1.3 billion meals each year for American families. These are meals that lower- and middle-income families, such as a single mother of two in Lancaster, Pennsylvania, can afford. This is not a fish to replace lobster and caviar. So how is a law that eliminates more than 1.3 billion affordable meals fair to the average American who wants to feed her family with healthy food?

Here in the U.S., we are working to combat any number of health-related challenges such as obesity, heart disease, and mental illness. Now, more than ever, Americans are focused on a more healthful lifestyle and are turning to seafood, and public health officials are encouraging Americans to eat more seafood. So is this a good public policy, to take away the choice of this fish, which represents 29 percent of the value white fish in the market, and to have seafood prices increase dramatically?

Domestic catfish sells for \$5.40 a pound, and pangasius, \$1.95 a pound. My customers will not shift from pangasius to domestic catfish. They are two different markets. They will just skip buying

any of it. This means lower sales for my company, which could mean I have to cut my workforce.

If catfish was a health risk, I could understand this program, yet both the CDC and USDA have cited catfish as a low-risk food. USDA's own risk assessment suggested they did not believe USDA oversight would improve public safety, stating the effectiveness of the USDA regulation of catfish was unknown.

This program could place American farm exports at risk, as some of the nations that sell us their fish have made it clear that they will retaliate against American farm products when they win the trade dispute over pangasius.

I want to end with a visual. This fish is regulated by FDA. This fish is regulated by FDA. This crab is regulated by FDA. I could bring out 98 more species that are regulated by FDA. This product is going to be regulated by USDA, if we don't overturn this.

So, in hearing promises from Congress that they want to free small businesses of burdensome regulations, on Sunday, Speaker Ryan, in an interview on "60 Minutes," called for elimination of wasteful and unnecessary regulations. I hear promises and commitments; I see no action or accountability.

So there is a Senate-passed bill that has the support of this committee and more than half of the House of Representatives, the People's House. It is time to move from promises to small business to action for small businesses. Please urge the House leadership to call up the Senate bill to repeal this ridiculous program.

Thank you.

[The prepared statement of Ms. Gorton follows:]

*Statement of Kimberly G. Gorton
President & Chief Executive Officer
Slade Gorton & Co., Inc.*

*Statement before the Energy & Commerce Health Subcommittee
“Waste and Duplication in the USDA Catfish Inspection Program”
United States House of Representatives
Washington, D.C.
December 7, 2016*

Mr. Chairman, Ranking Member Green, and distinguished members of the Subcommittee, my name is Kim Gorton, and I am the President and Chief Executive Officer of Slade Gorton & Company, a seafood company based in Boston, Massachusetts. I also am the 2016 Chairperson of the National Fisheries Institute, the nation’s largest trade association for the commercial seafood industry. I am pleased to have the opportunity to appear before the Subcommittee today on a vitally important topic affecting thousands of businesses, large and small, along the entire seafood value chain.

Slade Gorton & Company is a third generation family business. Our mission is to bring wholesome, nutritious seafood from around the world to America’s table in support of well-being and overall quality of life. Our company is one of America’s largest distributors and manufacturers of fresh, frozen and premium value-added seafood products, and we provide over 200 million seafood meals to Americans every year. We develop and manage fresh and frozen seafood programs for some of our nation’s largest retailers, distributors and chain restaurants. We are proud of our record of supplying healthful and safe seafood to American families in all 50 states for nearly 90 years.

Regarding catfish: our company buys nearly an equal amount of domestic and imported catfish. Our challenge has become that some companies refuse to acknowledge that other species have important markets in the United States also.

Today I would like to articulate the reasons why my company strongly opposes the United States Department of Agriculture catfish inspection program, and why we urge the House of Representatives to immediately take up legislation now before the House that, if enacted, would eliminate this harmful, duplicative program.

Let me begin with some basic facts concerning the Federal Government’s regulation of seafood and our industry’s role in helping to ensure that the fish Americans eat is safe and wholesome.

U.S. Food and Drug Administration Responsibility

For decades, the Food and Drug Administration (“FDA”) has been responsible for regulating the food safety of all seafood in the United States. Indeed, FDA regulates all food safety with the exception of meat, pork, poultry, and processed eggs, which are the responsibility of the USDA’s Food Safety and Inspection Service (“FSIS”). In all, FDA has jurisdiction of over 80 percent of

the food Americans eat and oversees food industry subsectors that together contribute \$1 trillion to the nation's GDP.

The FDA's regulation of commercial seafood begins of course with the Federal Food, Drug, and Cosmetics Act and includes FDA regulations, the FDA's Current Good Manufacturing Practices, and – arising from all these sources – the Hazard Analysis Critical Control Points program. The seafood "HACCP" program is a critical piece of FDA's food safety approach. It applies to all seafood processors, importers, and wholesalers—foreign and domestic – and directs all FDA-regulated seafood companies to meet specific requirements in a seven-step process:

1. Conduct a hazard analysis and identify preventative measures;
2. Identify critical control points (CCP);
3. Establish critical limits;
4. Monitor each CCP;
5. Establish corrective action to be undertaken when a critical limit deviation occurs;
6. Establish a record keeping system; and
7. Establish verification procedures.

By carefully identifying potential sources of contamination throughout the production process and requiring continuous monitoring, extensive recordkeeping, and verification that control measures are in place, a strong HACCP program ensures a high degree of food safety. As a final measure of food safety assurance, FDA conducts inspections of firms and food products to confirm that HACCP principles are being appropriately applied. I must emphasize that all imported food products are subject to targeted, random FDA inspection when offered for import at U.S. ports of entry, and all seafood exporters to the United States must meet the same Good Manufacturing Practices and maintain the same HACCP plans that a domestic producer must meet and maintain for the same fish. Thus, any claim that FDA subjects domestic seafood to more stringent requirements than it does imported product, or that the FDA approach does not afford U.S. seafood producers a "level playing field" vis-à-vis overseas producers, is simply false.

HACCP requires any problems to be identified and eliminated or mitigated at their source. For imported seafood, that means problems must be fixed thousands of miles from the U.S. border. Importers are required to take steps to verify that their imported products are obtained from foreign processors that fully comply with the Seafood HACCP Regulation. Again, this requirement makes sure that the safety of imported seafood is equivalent to the safety of seafood harvested or processed domestically. And, it is in the best interest of domestic processors to ensure that all of their raw material supplies—from overseas and domestic—are safe and wholesome.

No regulatory system is perfect, and in a complex supply chain there is always room for improvement. For my company and my competitors across the nation, however, food safety

outcomes under the aegis of FDA speak for themselves. The FDA regulatory structure and approach has helped the seafood industry provide millions of meals *almost every day* without incident.

In terms of detection, the FDA PREDICT (“Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting”) system allows the agency to focus in on high-risk food imports while expediting entry for non-violative shipments. When a foodborne illness is detected with respect to a domestic or overseas product, the FDA approach gives our industry and the food industry in general the ability to identify and isolate the problem in the supply chain quickly and precisely. When that is not sufficient, the FDA has a wide range of enforcement options to use in correcting the problem, from collaborative work with the company involved, targeted detention of specific food lots, and narrow regulatory alerts; to 100 percent importer-financed testing and inspection requirements at the border, broad-based mandatory recalls, and civil and criminal punishments that can – and in recent memory have – caused whole companies to shutter their doors. The Food Safety Modernization Act – which of course had its start in this very Committee and which was enacted into law with wide bipartisan support – has substantially enhanced FDA’s enforcement tools, making a good system even better.

As someone with decades of first-hand experience in the American seafood industry, I can honestly say that both the regulator and the regulated industry are doing a better job than ever before. That is to the credit of the FDA inspectors across the country and at our ports; to the credit of hundreds of thousands of fishermen, and processing and distribution workers who keep food safety top of mind; and, yes, to the credit of Congress and in particular this Committee for establishing the legislative framework necessary to keep pace with a complex and growing value chain.

2008 FARM Bill Transfers Catfish, and Only Catfish, Oversight from FDA to USDA

Despite this record, in a side deal, Congress in 2008 transferred the responsibility for food safety regulation for catfish from the FDA to the Food Safety and Inspection Service within the USDA. The decision in the 2008 Farm Bill to create a catfish inspection program within FSIS was made behind closed doors and without either debate or findings by Congress as to the need for a change. It is a testament to how poorly-thought out the program was that FSIS delayed publication of a proposed rule until 2011 – nearly three years after the 2008 Farm Bill was passed – and then delayed its final rule until December 2015. If, as announced, FSIS fully implements the program on September 1, 2017, it will have taken almost nine years for the Federal Government to put into place a program its supporters characterize as a food safety emergency.

The program subjects all fish of the Order Siluriformes to continual inspection at any point during the processing of the fish by a FSIS inspector. Further, this would require countries exporting catfish — which equal about 3 percent of all seafood imports — to demonstrate equivalence to U.S. standards. This equivalency process takes on average 5-7 years to achieve.

This program would stop all foreign catfish from coming into the country until that level was achieved. That would mean less fish available to my customers.

USDA Risk Assessment Calls Catfish Low Risk Food

Now if catfish was a high risk fish, this would be understandable, yet the CDC and USDA have cited catfish as a low-risk food. According to the CDC, less than 2 people per year get sick from catfish – meaning you are more likely to get struck by lightning than get sick from catfish (310 people are struck by lightning each year).

Now because of a provision slipped into the Farm Bill (without debate and consideration of the House of Representative's position), one type of fish—catfish (and any fish categorized as a member of the Order siluriformes) has been moved to USDA office of FSIS for inspection. This change was not based on the fact that catfish and its cousins were posing a food safety risk—it was created by supporters of a few domestic catfish suppliers who knew that the USDA regulatory system would effectively block its imported competition (a Vietnamese species known as pangasius) at the border. This program is based solely on the fact that the regulatory differences between USDA and FDA make the product more difficult to import, not that it makes the product safer.

USDA Catfish Program is a Blatant Trade Barrier

Any nation can establish a food safety program different than other nations' programs. However, the United States has been a leader in holding other nations accountable for ensuring that the food safety systems are risk-based, as we have committed to in our treaty agreements. We do so not only in the interest of food safety and public health, but also to ensure that American farm exports are not disadvantaged in emerging markets.

The USDA catfish program meets none of the basic trade obligations: It was not based on a risk assessment; the USDA admits its catfish inspection program will not improve food safety; it is not the least trade restrictive means to achieve its goals; and it is a disguised (if not very well disguised) trade barrier.

The emerging markets to which American farmers seek to export their products are some of the nations that sell us their fish. They have made it clear that they will retaliate against American products, including likely American farm exports, when they win the trade dispute. Why Congress is sacrificing the exports interests of soy, beef, apples, and other farmed products on the altar of catfish is a puzzle to me.

Two Seafood Regulators in Same Facility: Doing the Job USDA Admits FDA Did Well Before

In all practicality, by moving this one type of fish over to a separate regulator for inspection, my business now has to deal with two separate regulators to inspect the products we sell to restaurants, grocery stores, and hospitals. The creation USDA Catfish Inspection Program means that we have one system and process for tuna, tilapia, shrimp, lobster (I could go on, we sell over 100 species) and a completely different system just for catfish. This program is so absurd that it requires my company to have an inspector on site at any time we open a larger box of catfish and place the product in smaller packages for our customers.

FDA-FSIS Memorandum of Understanding Fails to Address Regulatory Duplication

Supporters of this nonsensical program point to an MOU that FDA and FSIS signed in May 2014, and claim that this document addresses the duplication I just explained. Nothing could be further from the truth.

This MOU – MOU 225-14-0009 – commits FDA and FSIS to generate a list of facilities that process both catfish and other seafood. That is unhelpful for two reasons. First, the two agencies were already supposed to compile this list under a previous FDA-FSIS MOU. MOU 225-99-2001 directs each agency “to develop, maintain, and annually update a list of dual jurisdiction establishments (hereinafter “DJE”), that is, establishments that prepare, pack, hold, or otherwise handle both foods regulated by FSIS and foods regulated by FDA.” The new MOU adds nothing to that.

Second, and more importantly, these MOUs do nothing to reduce the burden and cost created by the USDA program in the first place. For the half-dozen or so seafood facilities in the U.S. processing only catfish, this MOU may have some value. But my company and the vast majority of seafood processors around the nation will still have two sets of regulations to meet, and two sets of regulators to contend with. The hassle and expense of USDA inspection remains. Having people in federal agencies generate a blizzard of paper simply to document that fact can only be regarded as a concrete solution here in Washington, D.C.

GAO Calls USDA Program Waste of Taxpayer Dollars

This program is nothing more than a special interest driven boondoggle that reveals a costly tale of misused tax dollars and protectionism. From USDA’s own estimates this program will cost \$14 million dollars to inspect one type of fish, where there is a world renowned system already inspecting seafood. Moreover, the creation of this program erects a trade barrier. To be blunt, this is a scam, and the Government Accountability Office has even called this program out 10 times since 2011 for waste and duplication.

USDA Catfish Program Eliminates More Than 1.3 Billion Meals

Pangasius, the fish targeted by proponents of the USDA program provides about 1.3 billion meals each year for American families. These are meals that the average person can afford. The

impression from many outside of Washington is that people here eat lobster and caviar, while they are asked to sacrifice. This program feeds that impression. As the U.S. government and public health officials are calling on people to eat more seafood, is it right for Congress to prop up a program that will cause such a massive market disruption and increase prices for families?

Without the supply of imported fish to complement the significant amount of domestic catfish we buy, we could not meet our customers' needs. Lower sales would mean we would be forced to cut our workforce.

Opportunity for Congress to Fix this Problem for Small Business

FDA's system is a universally recognized system to inspect seafood. For almost 20 years, it has proven its ability to minimize food safety risks, as well as its flexibility to be effectively applied in nearly all types and sizes of processing facilities. This system has reduced outbreaks of foodborne illness attributed to fish consumption in the U.S., and according to the CDC, the HACCP principles mandated to ensure safe and sanitary processing of fish is one of the leading potential factors behind this positive trend. As such, when Congress enacted FSMA, it adopted an approach using preventive controls, which is modeled on the Seafood HACCP system.

This begs to ask, if HACCP is good enough to be used as the backbone to the largest Food Safety Law in my lifetime, why isn't it good enough for catfish? There is no answer to that. My next question is, how can Congress fix this issue?

There is currently a Resolution which would return the oversight of catfish back to the Food and Drug Administration—S.J. Res 28. For many of us who wish that Washington would reduce the red tape and waste of tax dollars—this makes sense.

The USDA program is a complete waste of tax dollars. Our government is already squeezing job-creating small businesses, and this program is a needless, costly and duplicative regulation that burdens my company and all other seafood companies. Americans have concluded that the bureaucrats do not care about average people. Ending this program and its bloated USDA payroll will show that Congress is listening and responding to their concerns. It is my hope and the hope of others on this panel that Congress bring this bill up for a vote this week.

Last Sunday night, even Speaker Ryan, in an interview on *60 Minutes*, called for elimination of wasteful and unnecessary regulations. It is time to move from promises to small business to action for small businesses.

Mr. PITTS. The chair thanks the gentlelady.

Mr. Farrell, you are recognized, 5 minutes for your summary.

STATEMENT OF BART FARRELL

Mr. FARRELL. Mr. Chairman and subcommittee members, my name is Bart Farrell. I am the director of food and beverage for the Clyde's Restaurant Group. We are a local, privately owned company with 14 restaurants in Washington, D.C., Maryland, and northern Virginia. We employ 2,300 people, and hopefully you have enjoyed a meal at the Old Ebbitt Grill, the Hamilton, or the 1789 in Georgetown.

I am speaking today from both the Clyde's perspective but also as a leader of more than 100 local chefs who have expressed support for eliminating the USDA catfish program. We do so because the program threatens an important new fishery that can help save the Chesapeake Bay.

Several years ago, our supplier, aptly named Congressional Seafood, introduced us to the Chesapeake Bay wild blue catfish. It is relatively inexpensive as seafood items go, but with a scary backstory.

These fish were introduced into the James River in the 1970s as a sport fish for recreational fishermen. Unfortunately, these are apex predators with no known predators of their own. They are taking over the Chesapeake Bay and beyond. According to NOAA, these fish now account for a staggering 75 percent of the biomass in the James and Rappahannock Rivers and are increasing in population in many of the rivers and tributaries in the bay. They are consuming the bay's native fisheries, including rockfish, also known as striped bass, blue crabs, white perch, shad, and herring.

According to the Chesapeake Bay Foundation, one of the primary ways to reduce the population of these blue catfish and ensure the survival of the native fisheries is to establish and grow a commercial fishery for blue catfish. And that is what our suppliers and others have started to do.

These fish are becoming more and more popular at Clyde's and other restaurants. Our staff are educated on this evasive species, and our customers enjoy eating a quality, good-tasting fish and have a sense of civic pride in doing their part to help save the bay.

Let me briefly explain how this tasty fish gets from water to your plate around here. Watermen in the Chesapeake Bay region, North Carolina, or Delaware catch the fish. Processors cut the fish into fillets that chefs like. Distributors send the fish to retailers or restaurants. And consumers order the fish at restaurants or buy at shops and take home to cook. Each of these steps is essential to getting the fish to market. A break in any step will eliminate the market.

I am going to share an example of this market from one company. In the past 2 years, Murray L. Nixon Fishery of Edenton, North Carolina, alone has bought an estimated 2.5 million pounds of catfish with an estimated value of \$1 million to the watermen. These numbers have increased over the past 5 years due to the increase of the blue catfish in their area. The catfish processing at Murray L. Nixon Fishery allows this small business to keep a local

full-time staff of cutters working and, in that way, support local labor. That, in turn, keeps watermen working.

The USDA catfish program is requiring our suppliers to follow regulations of both the USDA for only catfish and FDA for all other seafood that they process. While wild blue catfish is good business, it will not justify the significant expense of capital and ongoing costs associated with meeting USDA's different regulatory requirements. As a result, many processors and distributors have indicated that they will leave the wild blue catfish business unless regulation of catfish is returned to the FDA.

Such a rational business decision will mean the supply chain between local watermen and restaurants will be broken. The results will be watermen losing the opportunity to be employed throughout the year, restaurants and stores lose the ability to sell delicious fish, and, sadly, the Chesapeake Bay and rivers will continue to be plagued by this invasive species. Who knows how far these fish will spread?

Attached to my written testimony is a letter signed by more than 120 outraged chefs urging Congress to eliminate the USDA program. We want to encourage the House to take up the Senate bill before you leave and rid us all of this wasteful and burdensome program.

As someone who has spent many hours fishing and hunting on the Chesapeake Bay, I trust you will do your part to ensure that the bay stays relevant and healthy with all of its native species for generations to come. A failure to act will say much about Congress' lack of commitment to save the bay, a true national treasure.

Thank you.

[The prepared statement of Mr. Farrell follows:]

*Statement of Bart Farrell
Director, Food and Beverage
Clyde's Restaurant Group*

*Statement before the Energy & Commerce Health Subcommittee
"Waste and Duplication in the USDA Catfish Inspection Program"
United States House of Representatives
Washington, D.C.
December 7, 2016*

Mr. Chairman and Subcommittee members, my name is Bart Farrell, and I am the Director of Food and Beverages for the Clyde's Restaurant Group. The Clyde's Restaurant Group is a local, privately-owned company with 14 restaurants in Washington, D.C., Maryland and Northern Virginia. We are 2,300 employees strong and provide hundreds of thousands of memorable dining experiences for people from all over the world every year. No doubt many of you have dined in one of our restaurants and may know somebody that has worked at a Clyde's Restaurant during our 53 years in business. Besides the Clyde's brand, we also operate the Old Ebbitt Grill, The Hamilton, and the 1789 Restaurant in Georgetown.

I am speaking today from both a Clyde's perspective, but also as a leader of the more than 100 local chefs who have expressed support for eliminating the USDA catfish program, because it threatens an important new fishery that can help save the Chesapeake Bay.

Clyde's Supports Local Processors and Fishing Communities

Clyde's is a proud supporter and customer of oyster harvesters, watermen, fishermen and livestock producers from Maryland, Delaware, Virginia and North Carolina. Five of our largest vendors for food and supplies operate their businesses in the state of Maryland. Congressional Seafood, based in Jessup, MD, is our seafood supplier and has been for many years.

Wild Blue Catfish Are Destroying the Chesapeake Bay

Several years ago Congressional Seafood introduced us to the Chesapeake Bay Wild Blue Catfish as a new menu item. It is relatively inexpensive as seafood items go but with an alarming back story. These fish were introduced into the James River in the 1970s as a sport fish for recreational fishermen. Unfortunately, these are apex predators ... they sit at the top of the food chain in the Bay with no known predators of their own. According to NOAA, these fish have taken over and now account for a staggering 75% of the biomass in the James and Rappahannock Rivers, and are increasing in many of the other tributary rivers in the area, thus doing significant

harm to the Chesapeake Bay's ecosystem.¹ They are consuming the Bay's native fisheries (rockfish/striped bass, blue crabs, white perch, shad, herring, menhaden, etc.). According to the Chesapeake Bay Foundation, one of the primary ways to reduce the population of these blue catfish and ensuring the survival of the native fisheries is to establish and grow a commercial fishery for the blue catfish.

Clyde's, Other Restaurants, and Retailers Seek to Market Wild Blue Catfish

Several companies are leading the way at growing this new fishery. These fish are becoming more and more popular at Clyde's and other restaurants throughout the region. Stores like Whole Foods, Wegmans and Safeway have successfully created a market for blue catfish. Our staff and customers are educated on this invasive species and not only enjoy eating a quality, good tasting fish but also having a sense of civic pride in doing their part to help save the Bay!

The Wild Blue Catfish Supply Chain, From Water to Table

To briefly explain how wild blue catfish gets to you as a consumer at Clyde's: Watermen in the Chesapeake or in North Carolina or Delaware catch the fish. Processors cut the fish into forms that chefs like. Distributors send the fish to retailers or restaurants. Consumer order the fish at meals away from home or buy at shops to take home and cook. Each of these steps is essential to getting the fish to the market. A break in any step will eliminate the market.

I am going to share an example from one company. In the past two years Murray L. Nixon Fishery out of Edenton, North Carolina alone has bought an estimated 2.5 million pounds of catfish with an estimated value of \$1 million from watermen. These numbers have increased over the past five years due to the increase of the blue catfish in their area. This company calculates that in 2015 there were 591 commercial waterman who landed catfish and approximately 100 dealers with employees who handled catfish in North Carolina.

The catfish processing at Murray L. Nixon Fishery allows this small business to keep a local fulltime staff of cutters working and in that way support local labor, despite the net restrictions, species limits, and seasonal availability that apply to other fish and that otherwise would limit the need for fulltime staff.

Our supplier, Chesapeake Seafood, provides a similar service to Clyde's.

USDA Catfish Program Impact on Our Supply Chain

The USDA catfish program will require our suppliers to follow regulations of both USDA (for catfish) and FDA (for all other seafood that they process). While wild blue catfish is a good

¹ See NOAA's fact sheet called, "Invasive Catfish," at <http://www.chesapeakebay.noaa.gov/fish-facts/invasive-catfish>.

business, it will not justify the significant expense of capital and ongoing costs associated with meeting USDA's different regulatory requirements. As a result, many processors and distributors have indicated that they will leave the wild blue catfish business unless regulation of catfish is returned to FDA. Such a rational business decision will mean the supply chain between local waterman and the restaurants will be broken. The result:

1. Watermen lose the opportunity to be employed fully through the year;
2. Restaurants lose the opportunity sell a new and delicious fish; and
3. Chesapeake Bay and rivers in North Carolina, Virginia, Maryland and Delaware all suffer from the unfished, invasive species of wild blue catfish.

More than 100 chefs, from nationally-known to locally-owned restaurants, signed a letter to Congressional leaders urging them eliminate the USDA catfish program and keep seafood safety at FDA.² We remain hopeful the House of Representatives will take the opportunity to vote on the Senate-passed S.J Res 28, which would do just that. As someone who has spent many hours enjoying the Chesapeake Bay and all of its wonders, I trust you will do your part to ensure that the Bay stays relevant and healthy with all of its native species for generations to come. A failure to act will say much about Congress' commitment to the Bay.

² I have attached that letter.

Chefs Supporting the Chesapeake Bay

We are chefs from the District of Columbia, Maryland, Virginia, Delaware and central Pennsylvania. We represent a diverse group of restaurants and foodservice facilities. We speak with one voice when it comes to supporting a healthy and balanced ecosystem in the Chesapeake Bay. We ask that you help us preserve the Bay and support the watermen and communities that depend on it.

Some facts of which you should be aware:

- Wild blue catfish are an invasive species, now found in the Chesapeake Bay and most of its tributaries. Some tributaries have a biomass of these fish at greater than 70%.
- Wild blue catfish can live up to 20 years and grow to over 100 pounds in size. Their footprint is spreading throughout the Chesapeake Bay and beyond.
- Wild blue catfish are apex predators with no known predator of their own. They eat anything and everything before them and now pose the single greatest threat to the Bay's ecosystem by consuming native species such as rockfish, shad, perch, and blue crabs.
- Conservation groups and state natural resource departments are deeply concerned about the serious and negative impacts of wild blue catfish on the Bay's ecosystem.
- Watermen, at the urging of state agencies, are now catching wild blue catfish and reducing the fish's impact on the Bay.
- Seafood companies in the District of Columbia, Maryland, Virginia, Delaware and central Pennsylvania support their restaurant and grocery store customers by processing wild blue catfish.
- These local seafood companies have created a market for these abundant and relatively inexpensive fish. Restaurants and grocery stores throughout the region have had great success marketing this fish to their customers.
- Watermen and the Bay communities in which they live are benefitting from fishing year round, as a result of the harvest of wild blue catfish.
- The USDA Catfish Inspection Program will require seafood companies that supply wild blue catfish to adhere to USDA regulation for catfish and FDA oversight for all other seafood.
- Seafood companies have stated that they will stop processing wild blue catfish if they are subject to regulation by two, separate food safety agencies. Seafood companies view this a burden and will not commit the additional financial resources to comply with yet another government agency.
- The Government Accountability Office has deemed the USDA Catfish Inspection Program as duplicative and wasteful.
- If seafood companies will not process the fish, the chain of providing wild catfish from the Chesapeake and its tributaries to our regional restaurants and grocery stores will be broken.
- The Chesapeake Bay and its watersheds, our customers, the watermen that harvest these fish and their communities will all lose.

Eliminating the USDA catfish program is good for our customers and the American taxpayer.
 Eliminating the USDA catfish program is good for the Bay watermen and their communities.
 Eliminating the USDA catfish program is good environmental stewardship for the Chesapeake Bay and its watershed.

We urge you to take the steps necessary to eliminate the USDA catfish program and ensure that the harvest of wild blue catfish continues. Please restore ALL seafood inspections back in the capable hands of the FDA.

Respectfully,

Brian Stickel
Corporate Chef
Clyde's Restaurant Group
Washington DC

Salvatore Ferro
Executive Chef
Old Ebbitt Grill
Washington DC

José Andrés
President
Jose Andres ThinkFoodGroup
Washington, DC

Greg Haley
Chef de Cuisine
Amuse Restaurant
Virginia Museum of Fine Arts
Richmond, Virginia

Jacques Haeringer
Chef
L'Auberge Chez Francois
Great Falls, Virginia

Austin Ginsberg
Executive Chef
Pearl Dive Oyster Palace
Washington, DC

Robert Meltzer
Head Chef
Jaleo Bethesda
Bethesda, Maryland

Russ Ventimiglia
Executive Chef
Clyde's at Chevy Chase
Chevy Chase, Maryland

Jeff Eng
Executive Chef
Tower Oaks Lodge
Rockville, Maryland

Jozef Valko
Proprietor
Dal Grano
McLean, Virginia

Daniel Ahn
Executive Chef
Clyde's at Tysons Corner
Vienna, Virginia

Zach Smith
Executive Chef
The Hamilton
Washington, DC

Harper McClure
Chef De Cuisine
Brabo by Robert Wiedmaier
Brabo Tasting Room
Alexandria, Virginia

Peter Laufer
Executive Chef
Willard Intercontinental
Washington, DC

Rodolfo Guzman
Head Chef
Jaleo DC
Washington, DC

Jeff Black
Owner
Republic / Blacks Bar & Grill /
Blacksalt Fish Market /
Black Market Bistro
Washington DC

Kyle Bailey
Executive Chef
Sixth Engine
Washington, DC

Jeffrey Gaetjen
Chef
Blacksalt
Bethesda, Maryland

Michael Gallo
Chef
Jam Bistro
Rehoboth Beach, Delaware

Greg Cahill
Owner
Whitlows on Wilson
Arlington, Virginia

Domenick Torlucci
Head Chef
Jaleo Arlington
Arlington, Virginia

Shannon Shaffer
Executive Chef
Design Cuisine
Arlington, Virginia

Matthew Kern
Chef
Salt Air
Rehoboth Beach, Delaware

Caroline Ross
Co-Founder
Riverbend Bistro
Alexandria, Virginia

Robert McGowan
Executive Chef
Clyde's at Mark Center
Alexandria, Virginia

Brinn Sinnott
Executive Chef
Fiola Mare Restaurant
Washington, DC

Chris Osborn
Vice President, Kitchen
Operations
Great American Restaurants
Falls Church, Virginia

James Barrett
Director of Food & Beverage
Westin
Annapolis, Maryland

Michael Costa
Head Chef
Zaytinya
Washington, DC

Ramon Martinez
Executive Chef
Jaleo
Jose Andres ThinkFoodGroup

Omar Rodgriguez
Head Chef
China Chilcano
Washington, DC

Karen Orlando
Owner
Mexicali Blues Restaurant & Bar
Arlington, Virginia

Koji Terrano
Nikkei Chef
Jose Andres Think FoodGroup
Washington, DC

Jawad Laouaouda and Tania
Leach
Owner
Bon Vivant Cafe + Farm Market
Alexandria, Virginia

Samuel Kim
Executive Chef
**1789 Restaurant, The Tombs,
and F. Scotts**
Washington, DC

Paul D. Dongarra
President and Chef
Table Field Catering
Catonsville, Maryland

Colin King
Head Chef
Oyamel
Washington, DC

Brett Arnold
Executive Chef and Owner
Smokin' Hot Bar and Grille
Glenwood, Maryland

Mark Kirwan
Owner
Samuel Beckett's Irish Gastro Pub
Shirlington, Virginia

Joe Godleski
President, The Butcher & The Baker
Tom & Terry's Market
Ocean View, Delaware

Todd Reynolds
Executive Chef
Fountain Head Country Club
Hagerstown, Maryland

Brian Kosack
Executive Chef
Clyde's at Gallery Place
Washington, DC

Henry Romanowski
Executive Chef
Eastport Yacht Club
Annapolis, Maryland

Joseph Harran
Executive Chef
Mythology Restaurant
Washington DC

Josh Hermias
Head Chef
Minibar by Jose Andres
Washington, DC

Charisse Dickens
Head Chef, Research and
Development
Jose Andres ThinkFoodGroup
Washington, DC

Rick Billings
Director, Research and
Development
Jose Andres ThinkFoodGroup
Washington, DC

Carlos Jimenez
Chef/Owner
Las Tres Regiones
Fairfax, Virginia

William Walls
Chef/Owner
Stoney's Bar & Grill
Washington, DC

Sean Wheaton
Chef, Research and
Development
Jose Andres Think Food Group
Washington, DC

Robert Wiedmaier
President
RW Restaurant Group
Washington, DC

Ruben Garcia
Creative Director
Jose Andres ThinkFoodGroup
Washington, DC

Theary So
Chef
Hank's Oyster Bar
Washington, DC

Danny McFadden
Managing Partner
**The Celtic House Irish Pub &
Restaurant**
Arlington, Virginia

Josh Whigham
Chef, Research and
Development
Jose Andres ThinkFoodGroup
Washington, DC

Anthony Harris
Owner
Bullfeathers
Washington, DC

Rodolfo Guzman
Head Chef
Jaleo DC
Washington, DC

Thomas Stack
Chef/Owner
**Irish Channel Restaurant &
Pub**
Washington, DC

Keith Holsey
Executive Chef
Portalli's
Ellicott City, Maryland

John Mooney
Chef/Owner
Bidwell Restaurant
Washington, DC

Donagh Gilhooly
Partner
Exiles Bar D.C.
Washington, DC

David Morrin
Regional Manager
O'Sullivan's Irish Pubs
Arlington, Virginia

Richard Mackey
Owner
Mackey's Public House
Washington, DC

Patrick Carroll Executive Chef Clyde's at Reston Reston, Virginia	Terri Cutrino Special Projects Chef Jose Andres ThinkFoodGroup Washington, DC	Kurt Peters Executive Chef Azure Restaurant Annapolis, Maryland
Patrick T Fanning Corporate Chef/Partner Cambridge Eateries Cambridge, Maryland	Chad Wells Corporate Chef Victoria Restaurant Group Columbia, Maryland	Scott Walker Executive Chef Bluestone Restaurant Timonium, Maryland
Margo Medina Pastry Sous Chef, Research and Development Jose Andres ThinkFoodGroup Washington, DC	John Critchley Corporate Chef Brine Restaurant Group Fairfax, Virginia	Jennifer Carroll Chef/Owner Requin Fairfax, Virginia
Bryan Voltaggio Chef/Owner Volt / Family Meal / Range / Aggio Washington, DC	Chad Gauss Chef/Owner The Food Market Hampden, Maryland	Tyler Skinner Executive Chef Iron Bridge Wine Company Columbia, Maryland
Chef Joe Corporate Chef Founding Farmers Washington, DC	Rodney Scruggs Executive Chef Occidental Washington, DC	Rey Eugenio Executive Chef Points South Latin Kitchen Baltimore, Maryland
Jeremiah Langhorn Chef/Owner The Dabney Washington, DC	Daniel Garcia General Manager Clarendon Grill Arlington, Virginia	William Morris Executive Chef Vermillion Alexandria, Virginia
Xavier Deshayes Executive Chef Ronald Reagan Building Washington, DC	Joe Edwardson Owner Joe Squared Baltimore, Maryland	Mike Isabella Owner Graffiato / G by Mike Isabella / Yona / Isabella Eatery / Kapnos / Pepita / Kapnos Taverna Washington, DC
Scott Drewno Corporate Chef The Source by Wolfgang Puck Washington, DC	John Shields Owner / Author Gertrude's Baltimore, Maryland	Jason Ambrose Owner Salt / 1857 Tavern Baltimore, Maryland

Ben Friedman and Fiona Lewis Co-Owners District Fish Wife Washington, DC	Wilbur Cox Executive Chef Elkridge Country Club Baltimore, Maryland	Zach Mills Executive Chef Wit & Wisdom Baltimore, Maryland
Bobby Jones Owner The Point Crabhouse Annapolis, Maryland	Andrew Market Executive Chef Beuchert's Saloon Washington, DC	Kristopher Sandholm Executive Chef Bo Brooks Baltimore, Maryland
Jeff Buben Owner Vidalia / Woodward Table Washington, DC	Ellen Kasov Co Owner Equinox Washington, DC	Dimitri Moshovitis Owner Cava Restaurant Group Washington, DC
Joe Raffa Executive Chef Think Food Group Washington, DC	John Snedden Owner Rockland's BBQ Arlington, Virginia	Chris Constantino Chef Owner Offalgood San Francisco, California
Ryan James Chef/Owner Mother's Cantina Ocean City, Maryland	Travis Wright Chef/Owner The Shark in OC Ocean City, Maryland	Jody Wright Owner Culture Authentic Eatery Ocean City, Maryland
Eric Yeager Head of Academic Planning Stratford University Baltimore, Maryland	Jeff Mahin Chef / Owner Summer House / Stella Barra Bethesda, Maryland	Brian McComas Owner Ryleigh's Oyster Bar Baltimore, Maryland
Josh Brown Chef/Owner Fox's Den / Vida Taco Bar / Level Small Plate Lounge Annapolis, Maryland	Patrick Russell Owner Koopers / Slainte Baltimore, Maryland	David Pow Owner Soul Restaurant Annapolis, Maryland
Patrick Hudson Owner The Local Oyster Baltimore, Maryland	Michael Stavlas Owner Hellas Restaurant Glen Burnie, Maryland	Spike Mendelsohn Owner Bearnaise / We the Pizza / Good Stuff Eatery Washington, DC
Adam Stein Executive Chef Red's Table Reston, Virginia	Adam Snyder Executive Chef Alewife Baltimore, Maryland	Bart Farrell Director, Food and Beverage Clyde's Restaurant Group Washington, DC

Will Artley
Executive Chef
Nonna's Kitchen
Alexandria, Virginia

Mr. PITTS. The chair thanks the gentleman and now recognizes Mr. Conrad, 5 minutes for summary.

STATEMENT OF JUSTIN CONRAD

Mr. CONRAD. Mr. Chairman and members of the subcommittee, my name is Justin Conrad. I am the president of Libby Hill Seafood Restaurants and Bay Hill Seafood Sales, both based in Greensboro, North Carolina. I am a proud member of the National Restaurant Association, an organization my father, Ken Conrad, proudly served as chairman.

My grandfather started Libby Hill in 1953. Our third-generation company is the kind of small business that politicians like to talk about when they say they want to grow the economy. We employ roughly 150 people in North Carolina.

The FDA's HACCP system works for our seafood distribution and restaurant businesses. Through the years, my family has served millions of meals. We have never had a food safety incident.

So if we have never had a problem and FDA is our regulator, what exact problem was Congress trying to solve when it shifted regulation of catfish from FDA to USDA in 2008? I can tell you this: It was not about food safety.

The catfish program is a caricature of all things that upset the average American about Washington. It wastes taxpayer dollars. USDA will spend \$14 million to inspect fish FDA effectively inspected for \$700,000. It has been cited as a waste by the GAO 10 times since 2011. This program does not improve food safety. Catfish, both imported and domestic, is a low-risk food.

Our suppliers, though, must now have one food safety system to meet FDA's regulation for pollock, flounder, shrimp, and other seafood items they provide and a second system for USDA. How can Congress claim that requiring us to have two regulatory systems to oversee the same plant is not duplicative or a burden to small business?

The catfish program requires my suppliers to gain USDA inspectors' blessing for their operating schedule 2 weeks in advance. Think about that. They cannot process fish without Federal approval of a private company's work schedule and having an inspector there. They need special dispensation to work over the weekend. Restaurants do not work on a Monday-through-Friday schedule.

How is our economy supposed to grow when a private company must seek Federal Government approval for its operating schedule 336 hours in advance? Those of us who believe in a free market relish competition. By contrast, crony capitalists seek to use rules to prevent competition. The USDA program is one such of those programs. It will eliminate all imported competition and most domestic competition. How can Congress favor a program that destroys small business in favor of two to three large companies that can afford the capital cost of USDA regulation?

This catfish program will only increase the cost of food for American families. Pangasius today is the sixth most popular seafood item Americans enjoy. It represents about 29 percent of value white fish that restaurants and retailers offer. Basic economics say if you eliminate 29 percent of a supply, prices will rise sharply.

How can Congress tell an American family that it established a program that will not improve their health but it will cost them more when they try to enjoy a fish meal at Libby Hill restaurants?

There is an increasing concern that the catfish program will set a dangerous precedent of moving other seafood species from FDA to USDA. Catfish farmers have publicly stated tilapia should be subject to this burden. I heard from a colleague that USDA investigation and enforcement agents came to their office on Monday and warned them they must register with the USDA for their tilapia imports. This is a company that does not import or process catfish, and yet they have USDA agents flashing their badges and telling them to register with the USDA for tilapia.

I also understand that some shrimp companies have already requested to be added to the program. This will destroy the shrimp industry in North Carolina. I have personally been told by members of the shrimping community in North Carolina that, rather than be saddled by additional regulations from a new government agency, they would opt to close their doors.

How does this help local seafood markets, restaurants, and workers who depend on these products to support their families? Unless the House acts now to reverse this awful policy, some Members of Congress will work to remove FDA from seafood altogether.

A tip of the hat to the Senate for passing S.J. Resolution 28 and to many of you for recognizing the opportunity to save small business from the onus of another regulatory burden. It is my sincerest hope that you can persuade House leadership to bring this resolution to a vote before you go home for Christmas.

Thank you.

[The prepared statement of Mr. Conrad follows:]

*Statement of Justin Conrad
President
Libby Hill Seafood Restaurants, Inc.
Statement before the Energy & Commerce Health Subcommittee
“Waste and Duplication in the USDA Catfish Inspection Program”
United States House of Representatives
Washington, D.C.
December 7, 2016*

Mr. Chairman and members of the Subcommittee, my name is Justin Conrad and I am the President of Libby Hill Seafood Restaurants, Inc. (Libby Hill) and Bay Hill Seafood Sales, LLC, both based in North Carolina. I am a proud member of the National Restaurant Association, an organization that my father, Ken Conrad, proudly served as Chairman. I thank you for holding this hearing and appreciate the opportunity to present my views on this important topic.

Libby Hill is a small restaurant chain that has been in my family for 3 generations. It is the kind of small businesses that politicians like to talk about when they talk with voters about growing the economy. We hire and source locally when we can and also provide great seafood from around the world to our hundreds of thousands of guests each year. Our motto is “We bring the Coast to you”. We provide meals to the average hard working American family.

Our combined companies currently employ roughly 150 workers in North Carolina.

FDA’s HACCP system works for our seafood distribution and restaurants business. My family has served millions of meals to Carolinians and others travelling through our neighborhood ... and we have never had a food safety incident associated with seafood. So, if we have never had a problem, and FDA is our regulator, what exact problem was Congress trying to solve when it shifted regulation of catfish from FDA to USDA in 2008? I can tell you this, it was not about food safety.

This catfish program is a caricature of all the things that upset the average American about Washington, D.C.:

1. It wastes taxpayer dollars: The Government Accountability Office has 10 times called the USDA program a waste of tax dollars and at high risk for abuse. GAO even put out a report stating Catfish Regulation Should not be Assigned to USDA. Why even have a GAO if Congress blows off their recommendations 10 times?
2. It increases the government cost of doing business 20 times over: USDA has told Congress (repeatedly), has told the Office of Management and Budget, and told GAO that the USDA catfish program will cost \$14 million per year. According to USDA, FDA spends \$700,000 for catfish oversight. How can Congress tell the American taxpayer it is acceptable for USDA to spend 20 times what it costs FDA to do the same job?

3. It does not improve food safety: USDA, through its own risk-assessment, admits that the effectiveness of the USDA catfish program is “unknown.” The Centers for Disease Control and other public health agencies state that catfish (both imported and domestic) is a “low risk fish.” USDA also admits that no one has gotten sick from salmonellosis (the USDA’s focus) since introduction of FDA HACCP in 1997. Again, what problem was Congress fixing by creating the USDA Office of Catfish Inspection?
4. It requires two regulators in the same plant: FDA regulates all seafood, but for catfish. USDA regulates all beef, pork, poultry, and only catfish among seafood. Our suppliers must have a food safety system to meet FDA’s federal regulation for the pollock, flounder, shrimp and other seafood items we serve to our customers. Our suppliers must also have a USDA employee at our facility whenever we process catfish. How can Congress or anyone else claim that requiring us to have two regulatory systems to oversee the same plant is not duplicative?
5. It destroys economic freedom: The USDA rule requires my suppliers to gain a USDA inspectors’ blessing for our operating schedule two weeks in advance (that is 336 hours in advance). Chefs in the Carolinas often call their suppliers for a catfish order 6 hours in advance. How is our economy going to grow when a private company must seek federal government approval for its operating schedule 336 hours in advance – and what does that level of regulation do to the small businesses that are responsible for job growth across the nation?
6. It will create a de fact barrier to a fish American enjoy: Let’s be honest. The USDA catfish program is designed as a trade barrier. It was promoted by narrow special interest that wanted to protect themselves from competition. If Congress really believed USDA were a better food safety regulator, why shift only catfish from FDA to USDA?
7. It does not create a level playing field for imported and domestic fish: Federal regulations have always required our company to treat domestic and imported seafood the same under FDA’s HACCP program. Congress had enough confidence in FDA’s seafood HACCP program that it became the foundation of the Food Safety Modernization Act Preventative Controls measures. For more than 20 years, all Libby Hill’s suppliers, whether local or imports, have been required to follow the same rules. Nothing has changed.
8. It reduces competition: Those of us who believe in a free market relish competition. By contrast, crony capitalists seek to use rules to prevent competition. The USDA program will eliminate all imported competition and most domestic competition. The Committee may have already heard from catfish producers (both wild and farmed) who oppose this program as a costly, unnecessary burden. How can Congress favor a program that

destroys small business in favor of 2-3 large companies that can afford the capital costs of USDA regulation?

9. It will increase food costs for the American family: Pangasius is today the sixth-most popular seafood item Americans enjoy. It represents about 29% of all the value white fish that restaurants and retailers offer. Basic economics say that if you eliminate 29% of a supply, prices will rise sharply. How can Congress tell the American family that it established a program that will not improve their health, but will cost them more when they try to enjoy a fish meal at the local restaurant?
10. It will likely expand to other seafood items: Finally, there is growing concern that the USDA catfish program would set a dangerous precedent of moving inspection of other fisheries from FDA to USDA. Catfish farmers have publicly stated that tilapia should be subject to this burden. We understand that some shrimp companies have already requested to be added to the program, as a means to avoid competition. Expanding this harmful program will hurt more American small businesses. I can tell you that it will destroy the shrimp industry in N.C. But the temptation to help the crony capitalists is very strong. Unless the House acts now to reverse this awful policy, I would not be surprised if Congress attempts to expand the USDA program in coming years.

Distributing safe, healthy seafood and serving delicious, affordable seafood meals is what our family business has done for decades. Keeping the unnecessary USDA program out of our facilities and off our plates saves consumers money. A tip of the hat to the Senate for passing S.J. Res. 28, and another to many of you in this Committee for recognizing the opportunity to save small business the onus of another regulatory burden. It is my sincerest hope that you can persuade House Leadership to bring this to a vote before you go home for Christmas.

Thank you for the opportunity to share these views today.

Mr. PITTS. The chair thanks the gentleman and now recognizes Dr. Otwell, 5 minutes for his summary.

STATEMENT OF STEVE OTWELL

Mr. OTWELL. Chairman Pitt and members of the subcommittee, I thank you for the opportunity to share my views on what I consider an unnecessary USDA catfish inspection program.

My name is Dr. Steve Otwell. I am an emeritus professor from the Food Science and Human Nutrition Department at the University of Florida. I retired there in the year 2014 after serving 23 years at the university, working on all aspects of seafood safety and quality both through research and training. During this time, I served on three National Academy of Sciences committees which advised congressional decisions on programs for seafood safety in our Nation.

I currently in my retirement am director of something known as the Seafood HACCP Alliance, which now includes a cadre of over 400 qualified instructors working in the field to advance FDA's proven HACCP approach for seafood safety.

As someone who has been on the front line of seafood safety, I can attest that the USDA regulation of catfish is unnecessary and, from a public health perspective, is an unjustified use of government resources.

It is a fact that farm-raised catfish from both domestic and international sources do not pose a significant or unique food safety burden that warrants additional or different Federal regulation. A review of documented illnesses in the United States reveal that fish, including catfish, is one the safest sources of muscle protein consumed in the United States and catfish is one of the safest fish selections.

Foodborne illnesses reported to the Centers for Disease Control since 1998 show that only one confirmed outbreak has been associated with the catfish product, and this was not a processing error. That is one outbreak out of 19,000 food outbreaks that have been reported over 17 years. That is a 0.005 percent occurrence of outbreaks over almost two decades.

In addition, the CDC has found that the outbreaks of foodborne illnesses attributable to fish consumed in the United States has significantly declined. Sixty-five outbreaks occurred in the years 1998 through 2004, whereas there were only 32 outbreaks during the years 2005 and 2012. The CDC report cited that HACCP principles mandated by FDA are the primary reason for this pattern. This was the same period when HACCP became implemented in the United States and, likewise, the same period when catfish consumption in the United States began to escalate.

The prevailing concern for imported catfish has been misuse of antibiotics. While the use of any unapproved drugs is indeed unacceptable, this challenge is not unique to imported catfish. FDA regulation and education efforts, aligned with the State authorities and cooperating nations, have made a significant impact in reducing the use of unapproved drugs over the last decade. And this trend will indeed continue to increase with the growing dependence on farm-raised product.

The preventative controls structure of FDA's HACCP program has indeed recently been used as a model for many rules under the Food Safety Modernization Act. Likewise, the U.S. Department of Agriculture used the FDA HACCP protocol in modeling some of their approaches.

In addition, since 1995, the Seafood HACCP Alliance education and training program has maintained one of the most highly recognized and copied seafood safety education programs in the world. This training program is certified by the Association of Food and Drug Officials, which represents the food safety authorities in every State of our Nation.

To date, over 45,000 seafood inspectors, plant workers, and quality assurance managers have been trained through this program through every State, every U.S. territory, and all nations exporting seafood to the United States. Training included over 90 percent of the catfish processing operations in the United States.

Concluding, the FDA's HACCP program has a long and impressive record of keeping Americans and the seafood we love safe. Changing regulations for the sake of changing, without an actual food safety benefit, unnecessarily fractures the system, and, ironically, it makes the products less safe. The cost of food safety man-hours and focus required to comply with two separate regulations by separate Federal authorities in one facility can have unintended yet very real consequences that we should not ignore.

Thank you for your time.

[The prepared statement of Mr. Otwell follows:]

Statement of Dr. W. Steven Otwell

Emeritus Professor, University of Florida
Director, Seafood HACCP Alliance

“Waste and Duplication in the USDA Catfish Inspection Program”
Energy & Commerce Health Subcommittee
United States House of Representatives
Washington, DC

December 7, 2016

Mr. Chairman, Ranking Member Green, and distinguished members of the Subcommittee, thank you for the opportunity to share my views on the unnecessary “Catfish Inspection Program” being implemented by the USDA.

My name is Steve Otwell, Emeritus Professor from the Food Science and Human Nutrition Department at the University of Florida from which I retired in 2014 after 32+ years of research, training and extension services addressing all aspects of seafood and aquaculture product quality and safety. The accompanying vita provides some condensed credentials based on my education and experience with commercial, regulatory and academic sectors across our nation and about the world. In particular, I served on three National Academy of Science Committees that prepared reports to help direct Congressional responses to assure seafood safety in our nation. Currently, I remain in ‘active’ retirement directing the Seafood HACCP Alliance which includes a cadre of over 400 qualified instructors advancing proven HACCP approaches and mandates for seafood safety for all seafood and aquaculture products destined for commerce in the United States.

I would like to address two points here today to demonstrate that having catfish and catfish products inspected by the USDA Food Safety and Inspection Service (FSIS) is unjustified and an illogical use of government resources. First, catfish itself is a low-risk fish and any additional regulatory oversight by a separate agency is unjustified. Second, FDA’s Seafood HACCP program is a robust science based regulatory program which has had a positive impact on the safety of seafood consumed by consumers in the United States (U.S.) for over the past 20 years.

There is no real, documented evidence that farm-raised catfish, from domestic or international sources, poses a significant food safety burden that warrants additional and duplicative federal regulations. Based on documented illnesses from consumption in the U.S. through the past 40 years, ‘fish’ remains the safest source of muscle protein eaten in the U.S. (combination of reports from the nation’s National Academy of Sciences and Centers for Disease Control and Prevention (CDC) reports can substantiate). Likewise, various species of catfish (all

Siluriformes) are one of the safest fish selections amongst all fish eaten in the U.S. regardless of source.

Catfish and other *Siluriforme* fish pose no significant food safety risk for the U.S. consumer. A review of foodborne illness outbreaks reported to the CDC since 1998 shows only one confirmed outbreak associated with catfish. That is one outbreak out of over 19,000 reported outbreaks during that 17-year period. CDC's in-depth annual report of foodborne disease outbreaks reported in 2014¹ reviews 864 reported outbreaks and over 13,000 associated-illnesses. The top five pathogen-food category pairs associated with the most outbreak illnesses were:

- Seeded vegetables, such as cucumbers or tomatoes (357 *Salmonella* illnesses)
- Chicken (227 *Salmonella* illnesses)
- Turkey (184 *Staphylococcus aureus* enterotoxin illnesses)
- Dairy (144 *Campylobacter* illnesses)
- Sprouts (115 *Salmonella* illnesses)

Notably absent from the list is seafood in general and more specifically catfish or other *siluriformes*.²

According to these recent data compiled by the CDC, outbreaks of foodborne illness attributed to fish consumption in the U.S. have declined significantly, from an average of 65 per year from 1998-2004, to 32 per year from 2005-2012. The trend appears to continue decreasing. The CDC specifically cited HACCP principles mandated by FDA to ensure safe and sanitary processing of fish as one of the leading potential factors behind the trend.³

FDA employees over 50 seafood safety experts who are dedicated to establishing policy and conducting research to ensure the safety of the seafood consumed by the U.S. consumer. They know and understand hazards associated with seafood products. These experts have established a food safety, risk-based inspectional priority for imported seafood products. The following are

¹ Centers for Disease Control and Prevention (CDC). Surveillance for Foodborne Disease Outbreaks, United States, 2014, Annual Report. Atlanta, Georgia: US Department of Health and Human Services, CDC, 2016.

² CDC ranked finfish as the top two pathogen-food category pairs for the most outbreaks – however these illnesses (i.e., ciguatera and scombroid toxin) are associated with specific wild-harvested species and never with catfish or other *siluriformes*.

³ Presentation by Sarah Bennett, CDC Division Foodborne, Waterborne and Environmental Diseases during conference arranged by the FL Sea Grant Program in Baltimore in August 2014, "Workshop: Implications for Future Considerations in Support of the Nation's Seafood Commerce." Presentations posted at Florida Sea Grant website, <https://www.flseagrant.org/seafood/haccp/> in listed items under 'Seafood HACCP' to find the conference proceedings).

the top ten “high-risk” potential products ranked in order based on severity of health consequences:⁴

- Refrigerated seafood products packed in oxygen limiting packaging or reduced oxygen packaged (ROP)
- Raw (fresh and fresh frozen) molluscan shellfish from uncertified shippers
- Ready-to-eat fish or fishery products using any of the following processes:
 - cooking or pasteurization process (e.g., cooked shrimp, crabmeat, cooked lobster, cooked crayfish, pasteurized crabmeat, surimi-based analogs, etc.)
 - hot or cold smoking process
- Seafood mixes: Combination of seafood products either all raw or a mixture of raw and cooked product
- Scombrototoxin-forming (histamine-forming) species
- Aquacultured seafood
- Ready-to-eat fish or fishery products that have not undergone a heat treatment (such as caviar, urchin roe, or raw fish intended for sashimi/sushi) that are meant to be consumed raw.
- Salt-cured, and/or air-dried, un-eviscerated fish, such as Kapchunka, or bloaters
- Acidified and low acid canned foods (LACF)
- Food Intolerance Substances (FITs)

The five highest priority items represent true food safety risks associated with severe foodborne illness implications. **The prominent concern associated with imported ‘catfish’ has been the detection of unapproved antibiotics, but this issue is not a direct food safety problem in terms of resulting illnesses, but rather it is a perceived risk. Additionally it is not unique to imported, farm-raised catfish, or even fish in general.** The USDA efforts to reduce agricultural dependence on antibiotics also remains a challenge for beef, poultry and other commodities in the U.S. addressing the suspicion that the use of antibiotics for agricultural purposes enhances antimicrobial resistance. FDA efforts, aligned with State authorities and cooperative nations, have made a significant impact to reduce occurrence of the use of unapproved aquaculture drugs through the past ten years. FDA’s screening and educational efforts have contributed to positive responses across the aquaculture world.

While screening is important, educational efforts will have the greatest impact long-term on eliminating the use of unapproved drugs. Aquaculture experts within FDA and the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) continue outreach for foreign aquaculture operations. Controls and alternative approaches which are the basis of the U.S. government’s capacity building efforts need to be built into the production process. This is the essential embodiment of the saying “give a man a fish he eats for a day, teach a man to fish he eats for a lifetime.” One-hundred percent inspection and end-product testing to see if an unapproved drug can be found will never promote best practices. Behaviors will not be changed unless there is

⁴ FDA’s Import Seafood Products Compliance Program 7303.844 located at <http://www.fda.gov/Food/ComplianceEnforcement/FoodCompliancePrograms/ucm071496.htm>

understanding of a better preventive controls. FDA's Seafood HACCP regulations provide these preventive controls.

The proven positive value and impact of FDA's mandated Seafood HACCP regulations, initiated in 1996, calls to question the need for a new regulatory scheme solely to oversee the production of catfish and other *siluriforme* fish. The proven impact of the FDA seafood HACCP program has resulted in specific exemptions for seafood processing from the recent, historical Food Safety Modernization Acts (FSMA) regulations just initiated in 2015. The FDA mandate for HACCP controls in domestic and international seafood operations has proven to be an effective and recommended approach. Many nations and other commodities have adopted food safety control programs using the FDA HACCP approach as a model, including USDA's HACCP for meat and poultry products.

Since 1995, Seafood HACCP Alliance Education and Training Program (the Alliance) has maintained one of the most highly recognized and copied seafood safety education programs in the world. It has involved every State, every U.S. Territory, and every nation exporting seafood to the U.S. The program is certified by the Association of Food and Drug Officials (AFDO), the 100+ year professional organization for all food safety authorities in our nation. To date over 45,000 seafood inspectors, plant workers and QA/QC managers have been trained in the U.S. and abroad. Thousands continue to be trained each year. This successful program has also become a model nationally and internationally of workforce training for safe food processing, and is being emulated by other food sectors as they seek to implement the wide-ranging regulations mandated by the Food Safety Modernization Act.

The Seafood Alliance training materials were and continue to be developed in cooperation with FDA to ensure that the teachings represent accurate interpretations of FDA's regulatory and food safety policy expectations. This training does not focus on how to comply with FSIS expectations for meeting their HACCP regulatory requirements. This is by the choice of FSIS who declined the Alliance's invitation to adapt this existing, effective training for catfish processors.

A cadre of 400 trainers is now available to continue training in every seafood-producing nation in the world. The U.S. government through FDA, JIFSAN, and Asia-Pacific Economic Cooperation (APEC) have sponsored Alliance Train the Trainer workshops globally – all focusing on HACCP and FDA's regulatory program. While other speakers have talked about the unnecessary duplication of inspectional oversight in processing facilities, I also want to point out the unnecessary duplication of training efforts that will be necessary to ensure catfish processors in the U.S. and abroad understand their new regulatory obligations under FSIS. If we find this duplication confusing here in the United States, imagine the confusion around the globe for trainers to explain, "sorry this U.S.-FDA sanctioned course which I'm offering does not apply to one of the fish that you are processing; you will need to seek that training elsewhere."

Finally, in conclusion, **changing regulations for the sake of changing without real food safety benefits will further reduce public access to affordable, healthful seafood selections.** This situation will also impact retail and restaurant commerce as processors and distributors of “catfish” and other seafood products struggle to maintain and comply with two separate regulations by two separate federal agencies. The danger is that firms will elect to avoid this struggle by eliminating “catfish” from their offerings, thus reducing access to this affordable, healthful fish. **Currently, every pound of domestic farm-raised catfish has a market; No domestic catfish goes unsold.** The domestic catfish producer's argument is price! Their prices have been historically influenced more by consumer demand and preference than competition. A historical review of Federal and State-based support programs (largely USDA funds) to boost value and market share for domestic, farm-raised catfish will reflect this situation.

Mr. PITTS. The chair thanks the gentleman.

That concludes the opening statements. We will now go to questioning. I will recognize myself for 5 minutes for that purpose.

Let me just ask all of you a couple of questions, and we will start with Ms. Gorton.

Was this USDA program put in place because of a food safety issue?

Ms. GORTON. Mr. Chairman, no, in my opinion, it was not in place because of any food safety issue.

Mr. PITTS. Mr. Farrell, your opinion?

Mr. FARRELL. No, it was not.

Mr. PITTS. Mr. Conrad?

Mr. CONRAD. Mr. Chairman, no, it was not.

Mr. PITTS. Dr. Otwell?

Mr. OTWELL. No, it was not, sir.

Mr. PITTS. All right.

Again, I will do a question to all of you. How does the USDA food safety inspection program impact the catfish market and the prices for consumers and your costs of doing business?

Ms. Gorton?

Ms. GORTON. Well, effectively, it is working to eliminate my ability to process fresh catfish, because I am not able to schedule the inspection in a way that meets our customers' order patterns. And so it is effectively eliminating domestic catfish and imported catfish from our line of products that we're able to offer. And we saw some of the Nation's largest retailers, many of whom are based in the South, who want this product.

Mr. PITTS. Mr. Farrell?

Mr. FARRELL. Well, for us, it would only apply to the wild catfish. And we would be forced to stop selling it because our local seafood suppliers don't want to have to deal with two government agencies. They only want to have to deal with the FDA.

Mr. PITTS. Mr. Conrad?

Mr. CONRAD. Thank you, Mr. Chairman. Our restaurants are family-style restaurants, and we serve blue-collar workers and working-class families. And the access to low-cost protein is vitally important to restaurants like ours. And any time you eliminate that low-cost protein and drive consumers to other proteins, it adversely affects our consumers and our customers.

Mr. PITTS. Dr. Otwell?

Mr. OTWELL. The regulation will confuse selection and limit access to a resource that is preferred and has health benefits.

Mr. PITTS. Dr. Otwell, if the FDA was in charge of catfish inspection, would they have been able to stop the imported shipments that Mr. Harper mentioned?

Mr. OTWELL. They were aware of these. In fact, some of the information that directed some of the USDA scrutiny was based on prior work of the Food and Drug Administration. Their targeting methods of suspect product gives you some route for scrutiny.

So the point is the FDA program, by being science-based and focused on reasonably likely things to occur, as they follow in their legislation, gave us enough alert to problematic areas. And USDA used that information to help them as well.

Mr. PITTS. Mr. Conrad, you work with catfish suppliers, right?

Mr. CONRAD. Yes, sir.

Mr. PITTS. What has been their experience with the program? What has their experience been like? How has it impacted their business?

Mr. CONRAD. Mr. Chairman, we work with both imported and domestic catfish producers. And I can tell you, it is a poorly kept secret that the catfish industry itself is somewhat divided on this issue, if you will.

Mr. PITTS. There are rumors that this program could be expanded to include shrimp. I think you mentioned that. What would happen to your business if shrimp were regulated by the USDA?

Mr. CONRAD. We actually source quite a bit of domestic shrimp from the Gulf of Mexico. However, in the United States, a large percentage of the shrimp consumed is imported shrimp. So if you see that increased cost go to the shrimp market as well, you could see a substantial cost increase of the domestic product. That would make it extremely hard for us to continue offering those products to our consumers.

Mr. PITTS. Ms. Gorton, what is your response to that question?

Ms. GORTON. So, at a time where food prices are rising, and particularly seafood prices, at the same time we are asking American consumers to consume more seafood. If farm-raised products like shrimp or tilapia or farm-raised salmon were to fall under USDA regulation, our costs would increase dramatically. It would severely impact my business in absolutely detrimental ways.

Mr. PITTS. My time has expired. The chair now recognizes the ranking member, Mr. Green, 5 minutes for questions.

Mr. GREEN. Thank you, Mr. Chairman.

And thank our panel for being here.

We heard at FDA that catfish is a low-risk commodity, a view I think the panel shares. I think it is noteworthy to highlight that Ms. Gorton stated in her testimony that you are more likely to be struck by lightning than become sick from eating catfish.

However, I want to hear from more of the group about the safety profile of catfish and if there are unique characteristics that would require the product to be regulated differently.

Mr. Otwell, your testimony highlighted that catfish is a low-risk product. Can you further explain on how you came to this conclusion?

Mr. OTWELL. I base this conclusion on the evidence that there haven't been any reports of illnesses associated with the consumption of this product, the dramatic historical increase in consumption over the last two decades, and there is no evidence that this is causing problems.

The prevailing concern which there is evidence for, that there is some misuse of antibiotics, or drugs, if you will, in this product and other aquaculture products, does not impose an immediate food safety risk. The primary concern that that is introducing is the concern for the—you may have heard the term increasing microbial resistance in the environment by using excessive antibiotics. This, again, is not unique to catfish or aquaculture as a whole; it is prolific throughout our whole use of foods and medications.

So the point is FDA is aware of that, they have focused on it. And it goes back to the 2 or 4 percent number that is thrown out

about their inspection. They are targeting that specific concern, and that is why we are aware of it in this room today.

Mr. GREEN. OK.

Ms. Gorton, given that your business is experienced in processing over 100 types of seafood products, are you aware of any safety issues unique to catfish that would necessitate this extra regulatory system?

Ms. GORTON. No, Congressman, I am not. And, in fact, we have been processing both domestic and imported catfish for years and have had no food safety concerns or violations.

Mr. GREEN. Let me go to the safety of the imports. As we have heard in testimony from various witnesses, catfish is a low-risk fish. Salmonella is the primary food safety hazard associated with catfish. We have also heard that the volume of seafood imports has increased substantially and that catfish accounts for about 4 percent of the seafood imports.

I think we all agree that safety is important of the food supply. However, the CDC reports that, despite the increased risk of imported seafood, the U.S. experienced a decrease in outbreaks of foodborne illnesses related to fish consumption.

Going back to Mr. Otwell, if you are familiar with the Nation's seafood inspection programs, to what can we attribute the decline of foodborne illnesses related to fish consumption in America? In your opinion, does FDA's longstanding risk-based program play a role in that decrease?

Mr. OTWELL. The Centers for Disease Control—that was a long question.

Mr. GREEN. Yes.

Mr. OTWELL. I will try to get some of it. But what I heard is—the Centers for Disease Control is probably the best authority of keeping responsible data to reflect that the illnesses from consumption of fish in the United States have dramatically increased since the implementation of HACCP. That is the strongest endorsement for the FDA HACCP program.

I don't know if that answers your question. It was a long question. Was there another point I should speak to?

Mr. GREEN. Well, does the FDA's longstanding risk-based program play a role in this decrease?

Mr. OTWELL. Absolutely. You can point to one dramatic thing, and a previous GAO report also discovered this. The increased awareness that HACCP has brought and the communication, not only between companies but between countries, of dealing with the prevailing issues and the possible controls to prevent the problem, as opposed to the approach that USDA has, to catch the problem. Prevention is a far more cost-effective approach.

Mr. GREEN. OK.

On the panel, as business owners, you would be the first line of defense if someone becomes ill from being served by you, and you have the confidence that the catfish you purchase is safe to sell and serve your customers. And you are satisfied with the FDA alone doing the inspection instead of the Department of Agriculture. Is that true?

Mr. FARRELL. That is very true. We have a tremendous responsibility to our customers and to our staff to provide safe meals, and

if we thought for a New York second there was a problem with any product, whether it is seafood or otherwise, we wouldn't serve it.

Mr. GREEN. Well, you are the canary in the coal mine, because—

Mr. FARRELL. Unfortunately.

Mr. GREEN [continuing]. Your customers, I am sure, will tell you.

Mr. Chairman, I yield back my time.

Mr. PITTS. The chair thanks the gentleman and now recognizes the vice chairman, Mr. Guthrie, 5 minutes for questions.

Mr. GUTHRIE. Thank you, Mr. Chairman.

Ms. Gorton, in your testimony, you note that the USDA FSIS will require countries that export catfish to establish equivalence standards. What do countries have to do to establish equivalency?

Ms. GORTON. My understanding of that, Congressman, is that they need to meet USDA protocol, which is based on meat and poultry packing in the United States.

My further understanding is that even countries such as Canada, one of our closest trading partners with whom we share a border, has taken 5, 6, 7 years to reach equivalency. So, effectively, if this rule is not repealed, we are going to be looking at a significant period of time with potentially not having access to this critical, low-cost product.

Mr. GUTHRIE. So, obviously, this would impact global trade?

Ms. GORTON. Yes.

Mr. GUTHRIE. And so can you explain how this does not meet basic trade obligations? And what would happen if one of these countries decided to go to the WTO?

Ms. GORTON. A lawyer is probably better able to answer that question than I am. However, because we do deal with a number of exporters from whom we import, they have made their position clear, in that they would seek to bring forth a WTO case. And I also understand that there have been a fair amount of opinions that they would be successful with that.

The concern then becomes what would they do to retaliate, and that is where our farmed products here in the U.S. would potentially come under fire.

Mr. GUTHRIE. So it would definitely affect global trade. Thanks. Thank you for that.

Ms. GORTON. Yes, Congressman.

Mr. GUTHRIE. Dr. Otwell, advocates of the program claim a 100 percent inspection system is better. Can you explain why this claim is false and why the inspection programs do not ensure quality?

Mr. OTWELL. The term "100 percent inspection" is based on the fact that you would have an inspector on site at all times or some equivalent thereof. And it gives the implication that you are going to visualize all the problems that are occurring. That is the best way you can police something, is to see it happen and prevent it, to catch it, if you will.

The prevailing concern, as we have noted here today, is the illegal use of antibiotics. That is the only problem we have been able to speak to. That is not something you can see and catch with 100 percent surveillance. It requires analysis and sampling, as the gentleman had been pointing out here earlier. And FDA, very much aware of the cost and burden in time of sampling, have come up

with a targeted approach that is cost-effective based on science and suspect product. You can't do 100 percent sampling. That is a false implication.

Mr. GUTHRIE. Thank you very much.

And that completes my questions. I yield back my time.

Mr. PITTS. The chair thanks the gentleman and now recognizes the gentleman from Virginia, Mr. Griffith, 5 minutes for questions.

Mr. GRIFFITH. Thank you very much, Mr. Chairman. I do appreciate it. And I appreciate your service to our country and your leadership and mentoring as we have gone through these committee processes on how to do things right since I got here in Congress some time ago. But do appreciate it very, very much.

OK. Mr. Conrad, you indicated that your business would be affected if USDA took over shrimp. And I implied, but I want to make sure I was making the right connection, that you would buy your shrimp from foreign sources because they would be able to undercut the American market, although it is fairly small, they would be able to undercut the American market, and you are currently buying American shrimp. Is that what I understood?

Mr. CONRAD. No, sir. I—

Mr. GRIFFITH. All right. I got it wrong. You can't tell me that Libby Hill would stop selling shrimp.

Mr. CONRAD. No, sir, absolutely not.

Mr. GRIFFITH. So—

Mr. CONRAD. The price would have to be passed on to our consumers, Congressman. And I think that is where we are with catfish right now. Consumers are going to be paying the bill, in my opinion, for a problem that didn't exist, sir.

Mr. GRIFFITH. OK.

Mr. CONRAD. And I think that would be continued should the USDA move into shrimp as well.

Mr. GRIFFITH. Now, let's talk about a little tilapia.

Mr. CONRAD. Yes, sir.

Mr. GRIFFITH. You said that somebody from the USDA exceeded their authority. And, serving on the Energy and Commerce Committee, this is not shocking, that an agency would overstep their authority. We see that all the time in lots of areas, unfortunately.

But you are saying that you got an oral report—and we are not stating it as definitive fact, but that you got an oral report that somebody who raises tilapia in your region had the USDA visit them and say you are going to have to register, even though all they raise is tilapia?

Mr. CONRAD. No, sir. It was a company that does not currently import catfish but is in the tilapia business, not necessarily in my region, but was visited by a USDA inspector.

Mr. GRIFFITH. OK. But they are a business that currently imports tilapia, or buys American, or does both foreign and American tilapia?

Mr. CONRAD. I am not sure about the American part, but they are in the tilapia business internationally.

Mr. GRIFFITH. All right. Because that would be a concern, as you may be aware. Although they don't sell to Libby Hill, I have a large tilapia indoor facility in my district that ships to the Northeast live fish. So I have to keep an eye on that.

Ms. Gorton, I have to ask, because I once worked at McDonald's many, many years ago, back in the 1970s, were you the providers of our Filet-O-Fish sandwich? Because I know that there was a Gorton's company that provided all our fish at that time.

Ms. GORTON. No, Congressman, but to clear up any confusion, my great-great-grandfather started what is now Gorton's of Gloucester, who provides McDonald's with their sandwiches. And my grandfather left that business in 1928 and started our company.

Mr. GRIFFITH. OK. So it is a family connection but not the same company.

Ms. GORTON. Exactly.

Mr. GRIFFITH. All right. I do appreciate that.

And you indicated it would be really hard for you all. Is it just that it would force a lot of folks out of the catfish market, as Mr. Conrad has said?

Ms. GORTON. Yes, sir. And just as he also shared, it would force us to pass along a price increase to consumers, who really are already paying high prices for all seafood and just can't afford it. And so they are going to look at alternative proteins, and I, for one, Congressman, don't want to be eating bugs in 20 years. So we are really committed to seafood.

Mr. GRIFFITH. I can appreciate that very much.

Well, I thank you all for being here.

And, obviously, Mr. Farrell, I read your testimony and asked questions earlier off of that. And that affects why you all seem to buy a lot from North Carolina. It is probably fish being caught in Virginia and other places and the Chesapeake Bay. And so we want to make sure that that wild-caught catfish, particularly the blue catfish, is still available for your restaurants, because it helps the bay and it helps put money in the pockets of Virginia businesses.

Mr. FARRELL. And can I just say that a lot of the fish that we are buying is actually from the Chesapeake Bay region.

Mr. GRIFFITH. That is what I suspected, yes, sir.

Well, I appreciate it very much.

And, again, Mr. Chairman, it is with some sadness that I yield back for the last time to you, Mr. Chairman.

Mr. PITTS. The chair thanks the gentleman.

Thank you, all the members, for your kind comments.

That concludes the questions of members present. We will have some followup questions. Other members may have written questions. We will send them to you. We ask that you please respond.

Thank you very much for coming in. It has been very, very informative.

I remind members that they have 10 business days to submit questions for the record. I ask that members submit their questions by the close of business on Wednesday, December 21.

Excellent hearing for our final one. I think it is time to go to lunch. Thank you.

Without objection, the hearing is adjourned.

[Whereupon, at 11:56 a.m., the subcommittee was adjourned.]

[Material submitted for inclusion in the record follows:]

PREPARED STATEMENT OF HON. FRED UPTON

Today's hearing is a valuable opportunity to hear more about the USDA Catfish Inspection Program. The Energy and Commerce Committee on a bipartisan basis, along with the nonpartisan government watchdog, the General Accountability Office, have warned about the harm, waste, and duplication of the USDA Catfish Inspection Program. Rather than improve our country's food safety, the program will further fracture our food safety inspection programs. In addition, the USDA catfish program will harm businesses and will increase prices for consumers and ultimately harm the catfish market.

That is why the Senate voted overwhelmingly under the Congressional Review Act to reject the USDA Catfish Inspection Program. I appreciate our witnesses for being here and for Health Subcommittee Chairman Pitts holding this hearing today so we can more closely examine this important issue.

Before I yield the remainder of my time, I want to take a moment to recognize Mr. Pitts, the subcommittee chairman of the past six years, who is retiring at the end of this Congress. Joe Pitts has been a leader for some of the committee's greatest accomplishments: reforming how Medicare pays America's physicians, improving the safety of our nation's drug supply chain, advancing dozens of bills to improve our nation's public health, and helping shepherd through the 21st Century Cures Act that will land shortly on President Obama's desk.

Joe, as a chairman your accomplishments and contributions are tremendous. You have been an unwavering and outstanding partner during your tenure as chairman, particularly as we journeyed down the path to Cures. The roundtables, the hearings, the markups, you were here pushing every step of the way and I cannot thank you enough. You have been a strong, gracious, and remarkable leader for this committee, leading one of the most productive subcommittees on Capitol Hill. Thank you for your tireless efforts and your friendship. I wish you nothing but the best to you and Ginny in this next chapter.

FRED UPTON, MICHIGAN
CHAIRMAN

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

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

June 22, 2016

The Honorable Paul Ryan
Speaker
H-232 U.S. Capitol Building
United States House of Representatives
Washington, DC 20515

The Honorable Nancy Pelosi
Minority Leader
H-204 U.S. Capitol Building
United States House of Representatives
Washington, DC 20515

The Honorable Kevin McCarthy
House Majority Leader
H-107 U.S. Capitol Building
United States House of Representatives
Washington, DC 20515

The Honorable Steny Hoyer
Minority Whip
H-148 U.S. Capitol Building
United States House of Representatives
Washington, DC 20515

Dear Speaker Ryan, Minority Leader Pelosi, Majority Leader McCarthy, and Minority Whip Hoyer:

We are writing to request that the House consider S.J.Res. 28 on the floor prior to adjourning for the July 4th recess. If enacted, S.J.Res. 28 would transfer jurisdiction over catfish back to the regulatory authority responsible for overseeing other types of seafood, the Food and Drug Administration (FDA), ending an unnecessary and duplicative program at the U.S. Department of Agriculture (USDA).

The USDA catfish program was created when it was added to the 2008 Farm Bill behind closed doors. This catfish language was not in either the House or Senate Farm Bill, and was never subject to a hearing or public consideration, prior to the Farm Bill conferees adding the language. Quite simply, the House never supported the establishment of this program. The House Agriculture Committee itself 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. A vote on S.J.Res. 28 would allow the House of Representatives to reaffirm its established position on this issue.

Letter to Speaker Ryan, Minority Leader Pelosi, Majority Leader McCarthy, and Minority Whip Hoyer
Page 2

There is no justifiable reason for USDA to oversee catfish, while FDA regulates all other seafood. This leaves American seafood companies in the untenable and illogical position of accommodating two sets of federal inspectors overseeing the same facility: one set of inspectors for catfish and another for all other seafood. Both USDA and GAO agree that there is no food safety justification for this regulatory divide.¹ FDA currently regulates all seafood safely under the Hazard Analysis Critical Control Points (HACCP) system which proactively identifies and addresses food safety risks. In fact, in the Food Safety Modernization Act, we used the seafood HACCP system as a model and expanded the HACCP requirements to all food under FDA's jurisdiction.²

Additionally, the USDA catfish program will cost American taxpayers an exorbitant amount, with nothing to show for it. According to GAO, the new USDA catfish program would be 20 times more expensive than FDA's regulation of catfish and "would likely not enhance the safety of catfish but would duplicate FDA and NMFS inspections at a cost to taxpayers."³

Charged with overseeing over 80 percent of the food Americans eat, including all other seafood, we have long entrusted FDA to be the primary regulator of our food supply. FDA has the scientific expertise and regulatory experience to oversee the entirety of the seafood market. According to David Acheson, the Former Chief Medical Officer of both USDA and FDA, "The House now has the opportunity to vote to get rid of this program and hopefully a better perspective on what is real food safety and what is political mischief."⁴

The USDA catfish program is a prime example of duplicative government regulation. The program adds unnecessary burdens to companies, wastes tax payer dollars, and does not enhance the safety of the U.S. catfish supply. Therefore, we ask that you take up the bipartisan S.J.Res. 28 on the House floor as soon as possible to ensure that the food safety system is not further fragmented by splitting seafood jurisdiction between FDA and USDA.

¹ United States Government Accountability Office Report. "Seafood Safety - Responsibility for Inspecting Catfish Should Not be Assigned to USDA", May 2012 (GAO-12-411). <http://www.gao.gov/assets/600/590777.pdf>. USDA, Food Safety and Inspection Service, *DRAFT Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection of Catfish*. December 2010 (on line at: http://www.fsis.usda.gov/wps/wcm/connect/80a428f3-43fb-4421-b97d-885909e5a228/Catfish_Risk_Assess_July2012.pdf?MOD=AJPERES).

² See Public Law 111-353 § 103, available at <https://www.congress.gov/111/plaws/publ353/PLAW-111publ353.pdf>

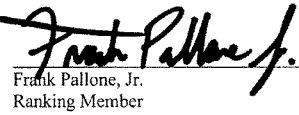
³ GAO-12-411 at pages 19-21.

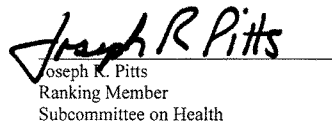
⁴ David Acheson, *Catfish Regulation -- A Perfect Example Of Wasted Resources In The US Government*, FORBES, June 6, 2016, available at <http://www.forbes.com/sites/davidacheson/2016/06/06/catfish-regulation-a-perfect-example-of-wasted-resources-in-the-us-government/print/>

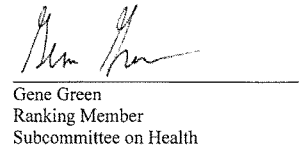
Letter to Speaker Ryan, Minority Leader Pelosi, Majority Leader McCarthy, and Minority Whip Hoyer
Page 3

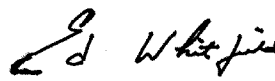
Sincerely,

 Fred Upton
Chairman

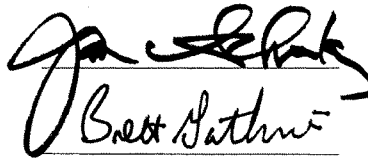
 Frank Pallone, Jr.
Ranking Member

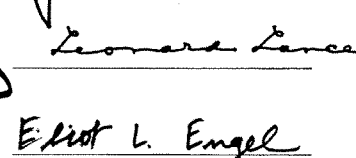
 Joseph R. Pitts
Ranking Member
Subcommittee on Health

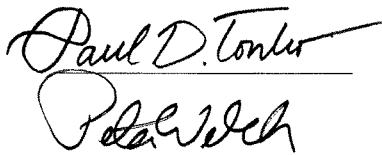
 Gene Green
Ranking Member
Subcommittee on Health

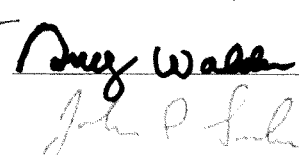
 Ed Whitfield

 Jim Iliis

 Jon Schuk
Brett Guthrie

 Leonard Lance
Eliot L. Engel

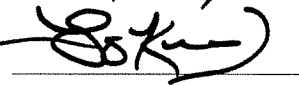
 Paul D. Tonko
Peter Welch

 Doug Walcott
John P. Loefer

 Keith Hays

 Bobby L. Felt

 Mark E. Amodeo

 Bob Kline

Letter to Speaker Ryan, Minority Leader Pelosi, Majority Leader McCarthy, and Minority Whip
Hoyer
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P. Murphy

Rand Elms

Larry Bucsho

Cliff Collins

Kevin Cramer

Jim Fox

Dave Loebsack

Kathy Castor

Mike Doyle

Jeff Pomeroy

Richard Hudson

Tim Murphy

Susan Brooks

David B. McTeer

La M. Bilal

Ron E. Fetter

FRED UPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

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

Majority (2013-2015)
Minority (2013-2015)

September 9, 2014

The Honorable Shaun Donovan
Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Dear Director Donovan:

We write regarding the significant, bipartisan policy concerns we share regarding the U.S. Department of Agriculture (USDA) final rulemaking currently under review by the Office of Information and Regulatory Affairs (OIRA) to establish a new catfish inspection program (RIN 0583-AD36).

There is no logical basis for USDA to oversee catfish, while the Food and Drug Administration (FDA) regulates all other seafood. This leaves American seafood companies in the untenable and illogical position of accommodating two sets of federal inspectors overseeing the same facility: one set of inspectors for catfish and another for all other seafood. Both USDA and GAO agree that there is no food safety justification for this regulatory divide.¹

Additionally, the USDA program has cost American taxpayers an exorbitant amount, with nothing to show for their investment. According to the GAO, the new USDA catfish program would be 20 times more expensive than FDA's regulation of catfish and "would likely not enhance the safety of catfish but would duplicate FDA and NMFS inspections at a cost to taxpayers."² Despite the fact that the catfish program was established in the 2008 Farm Bill, USDA has yet to inspect a single fish, despite having invested \$20 million to set up this program.³

¹ United States Government Accountability Office Report, "Seafood Safety - Responsibility for Inspecting Catfish Should Not be Assigned to USDA", May 2012 (GAO-12-411), <http://www.gao.gov/assets/600/590777.pdf>. USDA, Food Safety and Inspection Service, *DRAFT Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection of Catfish*, December 2010 (on line at: http://www.fsis.usda.gov/wps/wcm/connect/80a428f3-43fb-4421-b97d-885909e5a228/Catfish_Risk_Assess_July2012.pdf?MOD=AJPERES).

² GAO-12-411 at pages 19-21.


³ Ron Nixon, *New Catfish Inspections Are Posing a Problem for a Pacific Trade Pact*, N.Y. TIMES, November 13,

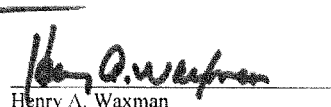
Letter to Director Donovan
Page 2

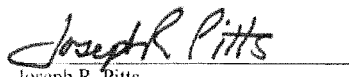
Currently, FDA is charged with overseeing over 80% of the food Americans eat. The agency has the scientific expertise and regulatory experience to oversee the entirety of the seafood market.

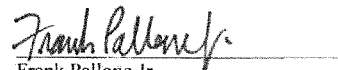
We ask that you take these significant, bipartisan concerns into account in your review of the USDA catfish inspection program final rule and ensure that the food safety system is not further fragmented by splitting seafood jurisdiction between FDA and USDA.

Sincerely,


Fred Upton
Chairman


Henry A. Waxman
Ranking Member


Joseph R. Pitts
Chairman
Subcommittee on Health


Frank Pallone Jr.
Ranking Member
Subcommittee on Health

FRED OPTON, MICHIGAN
CHAIRMAN

HENRY A. WAXMAN, CALIFORNIA
RANKING MEMBER

ONE HUNDRED THIRTEENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON ENERGY AND COMMERCE

2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Monday 1200-225 POC
Monday 1200-120-6115

November 26, 2013

The Honorable Frank Lucas
Chairman
Committee on Agriculture
United States House of Representatives
1301 Longworth House Office Building
Washington, D.C. 20515

The Honorable Collin Peterson
Ranking Member
Committee on Agriculture
United States House of Representatives
1305 Longworth House Office Building
Washington, D.C. 20515

Dear Chairman Lucas and Ranking Member Peterson:

As you continue your conference negotiations on the Farm Bill, we write to you to stress the importance of preserving the repeal of the U.S. Department of Agriculture's (USDA) catfish inspection program that was included in the House-passed bill, H.R. 2642, the Federal Agriculture Reform and Risk Management Act of 2013. As Chairman and Ranking Member of the House Committee on Energy and Commerce, we are concerned about the continued existence of this unnecessary and duplicative program at the USDA. We believe jurisdiction over catfish should be transferred back to the regulatory authority responsible for overseeing other types of seafood, the Food and Drug Administration (FDA).

There is no logical basis for USDA to oversee only catfish, while FDA regulates all other seafood. This leaves American seafood companies in the untenable and illogical position of accommodating two sets of federal inspectors overseeing their facilities: one set of inspectors for catfish and another for all other seafood. Both USDA and GAO agree that there is no food safety justification for this regulatory divide.¹ Additionally, the USDA program has cost American taxpayers an exorbitant amount, with nothing to show for their investment. Despite the fact that the catfish program was established in the 2008 Farm Bill, USDA has yet to inspect a single fish, despite having invested \$20 million to set up this program.²

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² Ron Nixon, *New Catfish Inspections Are Posing a Problem for a Pacific Trade Pact*, N.Y. TIMES, November 13, 2013, http://www.nytimes.com/2013/11/14/us/politics/second-catfish-inspection-program-by-us-complicates-pacific-trade-pact.html?_r=0


Letter to Chairman Lucas and Ranking Member Peterson
Page 2

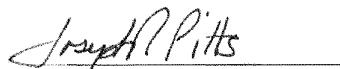
Charged with overseeing over 80% of the food Americans eat, we have long entrusted FDA to be the primary regulator of our food supply. FDA also has the scientific expertise and regulatory experience to oversee the entirety of the seafood market.

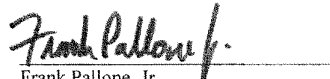
We share the goal of ensuring a safe and reliable source of seafood for all Americans. We believe the best way to achieve this goal is to transfer jurisdiction of catfish to its rightful place, under the oversight of the FDA.

Sincerely,


Fred Upton
Chairman


Henry A. Waxman
Ranking Member


Joseph R. Pitts
Chairman
Subcommittee on Health


Frank Pallone, Jr.
Ranking Member
Subcommittee on Health