

## UNITED STATES DEPARTMENT OF AGRICULTURE

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## PROPOSED RULE FOR MANDATORY INSPECTION

## OF CATFISH AND CATFISH PRODUCTS

+ + + + +

May 24, 2011

9:00 a.m.

USDA South Building  
Jefferson Auditorium  
1400 Independence Avenue, S.W.  
Washington, D.C.

## MODERATOR:

GREG DiNAPOLI  
Office of Public Affairs and Consumer Education  
Food Safety and Inspection Service

## FSIS:

CHARLES WILLIAMS  
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Office of Policy and Program Development  
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## PUBLIC COMMENT:

SENATOR MARK PRYOR, Arkansas  
CONGRESSMAN MICHAEL ROSS, Arkansas  
CHRIS WALDROP, Consumer Federation of America  
MATTHEW FASS, Maritime Products International  
JOHN GURLEY, Arent Fox LLP  
LISA WEDDIG, National Fisheries Institute  
TRACEY GONZALEZ, Grunfeld, Desiderio, Lebowitz,  
Silverman & Klestadt, LLP  
MICHAEL HANSEN, Consumers Union  
SENATOR THAD COCHRAN, Mississippi  
CONGRESSMAN BENNIE THOMPSON, Mississippi  
JOEY LOWERY, Catfish Farmers of America  
BUTCH WILSON, Catfish Farmers of America  
DR. CAROLE ENGLE, University of Arkansas  
CARL CUSTER, Custer, LLC  
JESSICA WASSERMAN, Wasserman & Associates  
DR. JOE BLAIR, HACCP Consulting Group  
MITT WALKER, Alabama Catfish Producers  
PATTY LOVERA, Food and Water Watch  
DR. ART MILLER, Exponent

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1 P-R-O-C-E-E-D-I-N-G-S

2 (9:07 a.m.)

3 MR. DiNAPOLI: Good morning, everyone. My  
4 name is Greg DiNapoli with the Office of Public  
5 Affairs and Consumer Education here at FSIS and your  
6 Moderator for today.

7 Welcome to all of those who are  
8 participating by phone.

9 This is the first of two public meetings  
10 being held to take your comments on the proposed  
11 rule for mandatory inspection of catfish and catfish  
12 products which published on February 24 of this  
13 year. The comment period closes on June 24th.

14 The second meeting will be held Thursday of  
15 this week in Stoneville, Mississippi, and  
16 transcripts from today's meeting will be available  
17 on the FSIS website approximately 30 days after the  
18 meeting.

19 You will notice on the Agenda, we do not  
20 have any break times. So please step out as needed,  
21 and our staff in the foyer will direct you to  
22 restroom facilities and to the cafeteria.

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1           We apologize, but food is not permitted in  
2 the auditorium. Bottled water, soda, drinks are  
3 allowed, but we ask that you take your trash with  
4 you.

5           Some of you did get a visitor's badge. So  
6 the visitor's badge will allow you to kind of come  
7 and go to the cafeteria, but if you do not have a  
8 visitor's badge, please let us know and we can  
9 escort you to the cafeteria so you do not have a  
10 problem getting in and out of the cafeteria.

11           The purpose of our meeting today is to  
12 accept public comments on the proposed rule.

13           Before we begin the public comment period,  
14 Mr. Charles Williams, from FSIS, will provide a  
15 brief overview of the proposed rule.

16           Mr. Williams is the Deputy Director for the  
17 Policy Issuances Division in the Office of Policy  
18 and Program Development. His role in the Office of  
19 Policy includes team leader of policy documents,  
20 drafting Agency regulations and directives, as well  
21 as a researcher, writer, and analyst for policy.

22           So at this time, I ask for Mr. Chuck

1 Williams to come up and present.

2 MR. WILLIAMS: Okay. Thanks, Greg. Good  
3 morning, ladies and gentlemen.

4 I'm here just to give an overview of the  
5 proposed rule, and it was developed in response to  
6 amendments to the Federal Meat Inspection Act  
7 (FMIA) which were made by the Food Conservation and  
8 Energy Act of 2008, known as the 2008 Farm Bill.

9 The Farm Bill amended the FMIA to make  
10 catfish, as defined by the Secretary, amenable to  
11 the Act and therefore subject to FSIS inspection.

12 The amendments of the FMIA also included  
13 making ante-mortem provisions and post-mortem  
14 provisions of the Act inapplicable to catfish, and  
15 the provisions for custom slaughter and processing  
16 also do not apply to catfish. Also, humane  
17 slaughter provisions do not apply to catfish.

18 The regulations for catfish must account  
19 for the conditions under which catfish are raised  
20 and transported to the processing establishment, and  
21 that's a relatively new feature for FSIS, the first  
22 direct authority that we have over pre-harvest

1 conditions.

2           Also, countries whose catfish products are  
3 imported must be operating equivalent systems of  
4 inspection that are equivalent to those of the  
5 United States, and also must comply with regulations  
6 for imported products that are administered by FSIS,  
7 and that includes regulations for the countries to  
8 be listed in our regulations as eligible for the  
9 importation of their products.

10           Next.

11           As I stated and as the Act provides, the  
12 definition of catfish is to be determined by the  
13 Secretary, and in the regulations in the proposed  
14 rule, we provide for a definition of catfish. It's  
15 the threshold question for determining what fish  
16 FSIS inspects, and we are requesting comment on the  
17 definition of catfish.

18           We are offering two definitions. One, fish  
19 belonging to the family *Ictalurus* which include the  
20 North American varieties of catfish which are sold  
21 commercially, and then a broader definition, one  
22 that encompasses the order Siluriformes, which

1 includes, in addition to the Ictaluridae, the  
2 catfish that are raised commercially, the fish that  
3 are raised commercially in the family Pangasiidae  
4 and Clariidae, and many fish in these families are  
5 imported into the United States.

6           There will be a new subchapter in the FSIS  
7 regulations, Subchapter F, and in these regulations,  
8 there is extensive cross-referencing to the meat  
9 inspection regulations. There are going to be, of  
10 course, some proposed requirements that are new to  
11 the catfish products industry, most notably the  
12 requirement for continuous inspection of catfish.  
13 We will be carrying out the provisions of the  
14 regulations under the authority of Section 606 of  
15 the Act, 21 U.S.C. 606, and this requires continuous  
16 inspection of catfish processing in establishments,  
17 in official establishments that process catfish.

18           There will be also mandatory Sanitation  
19 Standard Operating Procedures (SSOPs) and also  
20 mandatory Hazard Analysis Critical Control Point  
21 (HACCP) Plans, that the industry already is required  
22 to have under FDA regulations.

1           There will be, as I stated, narrow  
2 regulations based on FMIA provisions for ante-  
3 mortem, post-mortem and custom slaughter. Those are  
4 excluded by the amendments of the Act from applying  
5 to catfish.

6           Key features of the proposed rule include,  
7 in addition to FSIS inspection based on 21 U.S.C.  
8 606, pre-harvest provisions. We are proposing that  
9 catfish be raised under conditions where the  
10 producers will be monitoring the conditions to  
11 ensure that the catfish that emerge from the ponds  
12 will not be adulterated, and similarly, we are  
13 proposing a general requirement that fish be  
14 transported to the processing plant under conditions  
15 that will not result in the delivery of dead, dying,  
16 diseased, or otherwise adulterated catfish to the  
17 processing plants.

18           We are also proposing, as I said, mandatory  
19 Sanitation Standard Operating Procedures and the  
20 requirement for the catfish establishments to adhere  
21 to our other regulations which apply to other  
22 amenable species.

1           We'll also be enforcing requirements on  
2 imported catfish that will be similar to those that  
3 we enforce with respect to meat and meat food  
4 products.

5           The pre-harvest standards are somewhat  
6 general at this point. We expect that as we proceed  
7 in the implementation of the program, we will  
8 acquire additional information that may result in  
9 the promulgation of performance standards affecting  
10 pre-harvest and transportation and, of course, we  
11 will also be looking for comments on the present  
12 proposal to help us in that area.

13           In addition to the requirements for  
14 continuous inspection and the general pre-harvest  
15 regulations that we are proposing, we are also  
16 proposing that the labeling requirements that  
17 currently apply to meat and meat food products also  
18 apply to catfish, that is the products would have to  
19 be labeled with the product name, the brand name,  
20 the statement of ingredients, place of manufacture,  
21 et cetera.

22           And something new, as with our other

1 products, the catfish products would be required to  
2 be labeled with the official inspection legend. We  
3 are, for the moment, proposing that the official  
4 inspection legend be the same one that we use on  
5 meat products, but the exact design is open for  
6 comment.

7           There's also going to be a requirement for  
8 safe-handling labeling of products that are not  
9 ready-to-eat. We currently require, for meat and  
10 meat food products that are not ready-to-eat, a  
11 safe-handling label that instructs consumers to keep  
12 hot foods hot and cold foods cold, and separate raw  
13 from cooked and clean utensils and food contact  
14 surfaces and, in general, observe the necessary  
15 instructions for maintaining safe food.

16           We also are going to require that catfish  
17 processing control for retained water, that on the  
18 label, any water that is retained from processing  
19 should be listed by percentage in excess of net  
20 weight. That's what we do for meat and poultry  
21 products, and we will be insisting that the net  
22 weight labeling be 100 percent net weight, that is

1 it will be deglazed net weight to average 100  
2 percent of net weight after thawing, in the case of  
3 say frozen catfish fillets.

4 And we will be using as our technical  
5 reference NIST Handbook 133, Chapter 2, Section 2.6,  
6 and this is available free for downloading from  
7 [nist.gov](http://nist.gov).

8 We will also be applying the same nutrition  
9 labeling requirements that we apply to meat and meat  
10 food products, and these are similar to FDA's, some  
11 slight differences.

12 The expected impacts of the rule, we have  
13 discussed those in the context of the requirements  
14 of Executive Order 12866. The catfish rule was  
15 designated as economically significant, and for that  
16 reason, we are required to provide a benefit cost  
17 analysis, and what we have provided in the case of  
18 this rule is a break-even analysis which focuses on  
19 the potential benefits from controlling for  
20 *Salmonella* as the target pathogen, and the choice of  
21 that pathogen was determined in our risk assessment  
22 process.

1           The risk assessment is required because not  
2 only is the rule economically significant under E.O.  
3 12866, but it's considered to be a major rule under  
4 the Office of Risk Assessment and Cost Benefit  
5 Analysis Act and for regulations affecting health  
6 and safety, they're promulgated by USDA agencies.  
7 The regulations have to be, if they are determined  
8 to be major under that Act, they have to be  
9 supported by risk assessment.

10           And part of the economic analysis includes  
11 analysis of the effect of the rule on small  
12 entities, and we've made a preliminary determination  
13 that there will not be a significant effect on a  
14 substantial number of small entities, but this is  
15 based on taking into consideration the whole  
16 population, if you will, of entities, including  
17 processing plants and farms and transporters and so  
18 on.

19           So with that, I'll just thank you for  
20 coming and for choosing to participate in this  
21 public meeting and for providing us with comments  
22 and assisting us in carrying forward this proposed

1 rule process.

2 MR. DiNAPOLI: Thank you, Chuck. We'd like  
3 to acknowledge Senator Mark Pryor. If Mark Pryor  
4 would like to come and say a few words, we'd be  
5 happy to welcome the Senator.

6 SENATOR PRYOR: Well, thank you for the  
7 opportunity for me to provide these comments on the  
8 catfish inspection rule. I know you're considering  
9 options for defining how and when catfish will be  
10 inspected. As you work to determine the parameters  
11 of catfish inspections, I want to discuss why I  
12 believe a broad definition is a safer option.

13 Congress transferred inspection of catfish  
14 from the FDA to the USDA in the 2008 Farm Bill and  
15 for good reason. The current FDA process only  
16 inspects a tiny percentage of all imported catfish.  
17 However, over the past few years, there have been  
18 several drug and chemical violations in even these  
19 small batches that have been tested.

20 Americans eat more than 200 million pounds  
21 of catfish each year. So just imagine how many  
22 dangerous chemicals unsuspecting consumers have

1 eaten.

2           Clearly, I think we can do better by  
3 applying the rules equally to all catfish sold in  
4 the United States.

5           Consumers need confidence that every  
6 catfish sold in a grocery store or purchased --

7           OPERATOR: Excuse me, gentlemen. Your line  
8 is cutting out.

9           SENATOR PRYOR: -- is safe to eat. A  
10 consistent inspection program is paramount to  
11 achieving consumer confidence.

12           The GAO recently released a report that  
13 found the FDA's current seafood inspection program  
14 limited and acknowledged that the seafood inspection  
15 program needs to be strengthened.

16           In contrast, the USDA has a great track  
17 record on food safety, and I'd like to see that  
18 continue. I have confidence in USDA's ability to  
19 create a program that operates similarly to the  
20 inspection process for the beef and poultry  
21 industries and which is consistent with our  
22 international trade obligations which is important.

1 A broad USDA program means that inspectors will be  
2 on-site and that they will require corrective action  
3 for any safety problems identified.

4           The American catfish farmers believe that  
5 applying the rules consistently for domestic and  
6 imported catfish will result in fewer contaminants  
7 and better public health. I agree, and I urge USDA  
8 to adopt the broad definition for catfish and  
9 implement the final rule as soon as possible. Thank  
10 you.

11           MR. DiNAPOLI: Thank you, Senator.

12           First off, we'd like to start with  
13 Congressman Michael Ross as well from the State of  
14 Arkansas. Congressman.

15           CONGRESSMAN ROSS: Well, thank you for the  
16 opportunity to be here today, to provide comments on  
17 the catfish inspection rule. It's good to see my  
18 colleague and dear friend, Senator Mark Pryor here,  
19 to lend his support as well.

20           As you work to determine whether all or  
21 only some of the catfish consumed in the United  
22

1 States should be inspected by USDA, I urge you to  
2 support the broader option. It is important that  
3 USDA include all catfish that are raised and  
4 imported for consumption.

5 American consumers need confidence that  
6 every catfish sold in a grocery store or prepared in  
7 a restaurant is safe to eat. A consistent  
8 inspection program is essential to achieve consumer  
9 confidence.

10 In the 2008 Farm Bill, Congress voted to  
11 move inspection of catfish and related species, both  
12 imported and domestic, from the FDA to USDA to  
13 ensure they meet the same tough standards and  
14 protections as beef and poultry.

15 Congress left no ambiguity in the  
16 legislative language of the 2008 Farm Bill.  
17 Congressional intent is clear. Congressional intent  
18 is for all catfish and related species, domestic and  
19 imported, to be inspected to meet the highest USDA  
20 standards, and I emphasize, all catfish and related  
21 species.

22 Enacting a broad rule for the inspection of

1 catfish and related species will ensure the health  
2 and safety of American consumers.

3 A narrow rule would provide fewer  
4 inspections and could lead to more contaminated fish  
5 being introduced into the American food supply.

6 USDA has a great track record on food  
7 safety. I have confidence in their ability to  
8 create a program that operates similar to beef and  
9 poultry, which is consistent with our international  
10 trade obligations.

11 The GAO recently released a report that  
12 found FDA's current seafood inspection program  
13 "limited" and acknowledged that the seafood  
14 inspection program needs to be strengthened.

15 I agree, and that's why I urge USDA to  
16 adopt the broad definition for catfish and implement  
17 a final rule as soon as possible. Thank you.

18 MR. DiNAPOLI: Thank you, Congressman.

19 As we continue our public comment period,  
20 each speaker should keep his or her comments to  
21 roughly four to five minutes.

22 I have a list of those wishing to make

1 public comments. When I call your name, I ask that  
2 you come to the mic in the middle of the room to  
3 make those comments, and my apologies in advance if  
4 I mispronounce your name or your affiliation. If  
5 you could then, when you get to the podium, repeat  
6 your name and your affiliation, whom you're with,  
7 for the record; that would be appreciated.

8           We'd first like to start off with Chris  
9 Waldrop from Consumer Federation of America.

10           MR. WALDROP: Hello. My name is Chris  
11 Waldrop. I'm Director of Food Policy at Consumer  
12 Federation of America. CFA is a non-profit consumer  
13 advocacy organization founded in 1968 to advance the  
14 consumer interest through research, education, and  
15 advocacy.

16           Consumers expect the food they eat to be  
17 safe and expect imported food to meet the same  
18 standards for safety as they expect for domestic  
19 foods. CFA supports FSIS' proposed regulatory  
20 oversight of catfish because it will provide  
21 consumers with better assurance that imported and  
22 domestic catfish are meeting the same standards for

1 safety.

2           It is especially important because much of  
3 the catfish consumers eat is purchased in  
4 restaurants and other places where country of origin  
5 labeling is not required. So consumers at that  
6 point cannot differentiate between domestic or  
7 imported catfish.

8           To assure the broadest protection for  
9 consumers, FSIS should define catfish in the  
10 broadest terms possible to assure that all catfish  
11 species are covered as the representatives from  
12 Congress both indicated. It makes no sense for  
13 consumers to have some catfish regulated one way and  
14 other catfish regulated another.

15           Consumer groups have reviewed FDA import  
16 records regarding catfish and found that catfish  
17 coming into this country have been found to have  
18 unsafe animal drug residues, pathogens, unsafe food  
19 additives, and unsanitary conditions.

20           Since FDA inspects only a small percentage  
21 of imported fish that enters the United States, an  
22 inspection system as outlined in FSIS' proposed rule

1 that requires imported catfish to meet the same  
2 safety standards as domestic catfish would benefit  
3 consumers. Thank you.

4 MR. DiNAPOLI: Thank you, Chris.

5 Operator, we'd like to go to the phone.

6 Can you hear me?

7 OPERATOR: Yes, I can, sir.

8 MR. DiNAPOLI: Okay. Thank you.

9 Matthew Fass with Maritime Products  
10 International.

11 OPERATOR: Okay. One moment. Sir, your  
12 line is open.

13 MR. FASS: Okay. Thank you. My name is  
14 Matthew Fass, and I'm President of Maritime Products  
15 International, a family owned and operated company  
16 based in Virginia, engaged in the seafood industry  
17 for four generations, over 100 years. We are a  
18 focused direct importer and exporter and distributor  
19 of frozen seafood items from all over the world for  
20 U.S. distribution.

21 We are an extremely hands-on company  
22 working on the ground with production facilities and

1 farming operations on the ground all over the world,  
2 and we work to distribute product across the  
3 spectrum of U.S. customers including retailers,  
4 restaurants and value added processors. We work  
5 every day with producers, farmers, customers,  
6 regulatory agencies, inspection agencies, and other  
7 stakeholders in the global food supply chain.

8 I know there are time constraints on  
9 comments today. So I'll refrain from going into the  
10 type of detail I otherwise would on a variety of  
11 technical issues. The proposed rule is lengthy, and  
12 I am sure this is not the forum for addressing all  
13 detailed technical issues.

14 However, I would like to start with an  
15 overall comment that some may not want to hear in a  
16 forum like this, but with the personal issue we have  
17 on this issue, it would simply be negligent of me  
18 not to mention it.

19 It is extremely discouraging that we are  
20 even here today talking about a proposed regulation  
21 that picks out one particular species of seafood  
22 items from a full category, literally ripping it

1 away from one regulatory umbrella to place it under  
2 a new regulatory system, literally splitting a  
3 single category of food between two distinct  
4 regulatory authorities.

5           If the reality of the situation is that FDA  
6 regulatory oversight was severely lacking, and we're  
7 dealing with products with serious health and safety  
8 concerns, it would be an extremely different story,  
9 as our industry would have nothing if it does not  
10 have a foundation in safe and healthy products with  
11 strong regulatory oversight.

12           I believe this is exactly what has been in  
13 place with seafood and catfish in particular with  
14 FDA oversight, and although seafood in general has  
15 an exemplary track record regarding safety, to the  
16 extent that problems can exist as they can with any  
17 meat production from anywhere in the world, FDA  
18 possesses a number of ways to quickly act  
19 effectively to address an issue.

20           I therefore cannot help but look at this  
21 situation as almost the epitome of exactly the type  
22 of legislation or regulatory change that we're

1 trying to avoid these days, a regulation predicted  
2 to cost a significant amount of money, and it  
3 appears to be entirely redundant and otherwise  
4 unnecessary on the face of a fully functioning  
5 system.

6           It is worth mentioning that even USDA in  
7 its own initial work on this catfish project has  
8 specifically noted through its own random sampling  
9 that catfish represents a low risk food item in  
10 terms of health and safety issues, whether it's  
11 imported or produced domestically, direct evidence  
12 of a currently well-functioning regulatory system.

13           Rather than driven by facts, this issue has  
14 been driven by perception based more often on  
15 lobbying and, in my opinion, a brazen attempt by  
16 some narrow special interest and pure protectionism,  
17 sometimes laced with the most inappropriate and  
18 offensive tactics.

19           The key is that there is no support to  
20 claim that there is a need to spend tens of millions  
21 and eventually hundreds of millions to rip out a  
22 single species of seafood for a new regulatory

1 scheme.

2           I feel that it's appropriate to make this  
3 comment at this forum because I know it was not USDA  
4 who requested this oversight, but rather USDA has  
5 been tasked to do this by Congress and is doing the  
6 absolute best that it can. I simply think it is  
7 important for USDA and other stakeholders who may be  
8 listening to this forum to understand the background  
9 and perspective because there's only an  
10 understanding of full context that we have the best  
11 chance to arrive at the most appropriate final and  
12 functioning solutions.

13           Having said this, I would make two more  
14 specific comments on the current regulations. The  
15 first is to emphasize that I believe it must be an  
16 extremely unique situation for USDA in this  
17 particular situation. All possible subject products  
18 that are being imported are ones that are well  
19 entrenched with customers and markets already over  
20 the United States. In other words, this is not a  
21 proposal to regulate a potentially new food item  
22 that some only hope to bring to market across the

1 country. These are products that are here and being  
2 relied upon now by restaurants, institutions,  
3 supermarkets, processors and consumers all across  
4 the country and under the umbrella of a strong  
5 regulatory and private quality control oversight.

6 I believe history would show that it is  
7 extremely unlikely for the USDA to begin regulatory  
8 oversight in a situation like this without literally  
9 years of negotiations between regulatory authorities  
10 and potentially significant interruption in the flow  
11 of imported product. This is not due to the USDA  
12 system being better or worse or more challenging  
13 than the current FDA system, but rather it is  
14 related to country-to-country negotiations and  
15 agreements that must be in place between USDA and  
16 its foreign equivalents before the USDA can even  
17 begin the process, individual, foreign farm, and  
18 facility approvals.

19 I believe there are numerous examples of  
20 multiple years of negotiations, sometimes with no  
21 ultimate resolution during which time it is simply  
22 impossible for product to enter the United States.

1 In fact, I believe it's for this very reason those  
2 wanting to change the USDA have pushed for a new  
3 regulation.

4 I would simply ask the question whether in  
5 any of these other cases, USDA was working on  
6 product that was already well established with  
7 imports to the United States, with numerous national  
8 markets, utilizing strong safety protocols already  
9 in place.

10 The idea of supply chain disruption while  
11 trying to segue from one regulatory body to another,  
12 unless for absolutely legitimate food safety issues,  
13 would be devastating except for a few companies who  
14 may be hoping for a chance of monopolizing this  
15 market.

16 My second comment relates to the question  
17 posed by USDA whether *Pangasius* should be included  
18 within the definition of catfish. To this, I would  
19 say no, it should not be included in the definition.  
20 As one following the life of this product from its  
21 inception to customer plates, I would emphasize that  
22 it's worth remembering that *Pangasius* cannot be

1 imported or sold weekly in this country as catfish.  
2 It's just as simple as that. Ictaluridae is the  
3 only family of fish that is considered catfish in  
4 the United States, and as such, it is hard to  
5 understand how regulation specifically referring in  
6 its own language to catfish could include other  
7 species that simply cannot be considered as catfish  
8 under any U.S. definition.

9           It is easy for me to understand why the  
10 persons behind wanting this regulatory change have  
11 wanted to lobby for the inclusion of *Pangasius*.  
12 *Pangasius* has been a well-received product not only  
13 in the United States' markets but the 80 countries,  
14 over 80 countries around the world. It is a good  
15 quality, mild white meat fish, and it along with  
16 dozens of other species, including tilapia, pollock,  
17 cod, haddock, many others, compete at some level  
18 with domestic catfish for menu and supermarket  
19 slots.

20           While I can understand the desire of those  
21 lobbying for its inclusion to try to go after any  
22 opportunity to stop the flow of perceived

1 competition, I can only hope that from a regulatory  
2 and policy perspective, decision makers will not  
3 give into this effort and include products that  
4 cannot even be marketed under the same name and is  
5 an entirely different product.

6           In closing, I cannot emphasize, for us,  
7 that the key issue is not tweaking the current  
8 proposed regulations or even just the definition of  
9 catfish. It is continuing to believe that at some  
10 point logic and reason will prevail and decision  
11 makers will realize we have reached this point, not  
12 because of a regulatory system that is broken or  
13 products coming into this country that are unsafe,  
14 and in fact, we have a system currently working very  
15 well.

16           We are here based on some of the narrowest  
17 bunch of politics that still we are trying to get  
18 beyond. I know some will say that perceptions  
19 simply take over at some point, and we need to make  
20 sure we have the greatest consumer confidence  
21 possible, but I would suggest that when it comes to  
22 addressing perception, we need to take the exact

1 opposite tack, and at what point do we stop  
2 pretending and truly act serious about letting facts  
3 and honesty prevail over misconceptions and  
4 expensive politics that more often than not lead to  
5 unnecessary regulations, unintended consequences,  
6 and hurts our image and relations with others in the  
7 world. Thank you for your time.

8 MR. DiNAPOLI: Thank you, Matthew.

9 Next is John Gurley from Arent Fox.

10 MR. GURLEY: Good morning. Can everybody  
11 hear me?

12 Good morning. My name is John Gurley of  
13 the law firm, Arent Fox. Our firm represents the  
14 China Chamber of Commerce for import and export of  
15 food stuffs, native produce and animal byproducts  
16 which includes the major Chinese exporters of  
17 catfish to the United States.

18 In my remarks today, I will focus on five  
19 important issues. First, I want to emphasize that  
20 there are no significant health and safety issues  
21 related to imports of Chinese catfish. Like any  
22 product, domestic or imported, there have been

1 occasional minor issues, but the record of Chinese  
2 catfish is every bit as good as that of our American  
3 friends.

4           The notice issued by the USDA on  
5 February 24, 2011, confirms this fact when it states  
6 as follows: "Sparse information on the distribution  
7 of microbial contamination and chemical residues on  
8 catfish limit our ability to make strong statements  
9 about the baseline risks." This is another way of  
10 saying there's no real health and safety issues  
11 associated with imported catfish.

12           We all know that change in jurisdiction  
13 from FDA to the USDA was not warranted for health  
14 and safety reasons. It is Washington at its worst.  
15 An unneeded regulation designed to protect a select  
16 group of U.S. producers from legitimate competition.  
17 The losers are, of course, U.S. consumers and with  
18 an unnecessary and expensive new regulatory system,  
19 the American taxpayers. The GAO has estimated  
20 transferring jurisdiction to the USDA will cost  
21 taxpayers \$30 million just for 2011-2012.

22           This is at a time when USDA is under

1 enormous budget pressures and we understand is  
2 facing furloughs in the very program that will  
3 undertake the equivalence analysis.

4           A big issue in this case is the definition  
5 of catfish. I understand the position of the  
6 Vietnamese. They want to be excluded from any USDA  
7 regulation. We all do. But if *Pangasius* is  
8 excluded from the definition, then this new and  
9 expensive regulation would effectively target  
10 imports from a single country, China, a whole new  
11 regulatory regime for a single type of fish from a  
12 single country.

13           Surely, this would be unprecedented. Such  
14 a regulation would clearly violate WTO and would  
15 diminish America's standing with its trading  
16 partners.

17           Ictaluridae and *Pangasius* are both fish of  
18 the order Siluriformes. They should be treated the  
19 same. So while we sympathize with our Vietnamese  
20 colleagues, we think that if final regulations ever  
21 are issued, which we hope they are not, the  
22 definition of catfish should cover *Pangasius* as

1 well.

2           Timing issues. Catfish has been imported  
3 safely from China under the auspices of the FDA for  
4 a decade. So any draft regulation must take into  
5 account that there is no real rush to issue final  
6 regulations or set tight and unrealistic deadlines.

7           The key issue for the Chinese is fairness.  
8 USDA's past record in equivalence cases is  
9 instructive. For foreign countries' inspection  
10 regime to be deemed equivalent can take many, many  
11 years.

12           We note with interest that in a case  
13 involving Australia several years ago, when the  
14 original period for Australia to come into  
15 compliance expired, USDA correctly extended the time  
16 period until equivalence was demonstrated.  
17 Australia was treated fairly in that case.

18           China expects the same fair treatment for  
19 its catfish producers.

20           If there are final regulations, the Chinese  
21 exporters must be accorded at least five years to  
22 come into compliance, with extensions as necessary,

1 as they were with the Australians.

2           The Chinese already have some experience  
3 with USDA equivalence proceedings. A few years ago,  
4 after dutifully doing all they could to demonstrate  
5 that their inspection regime was equivalent, in  
6 respect to certain poultry products, Chinese poultry  
7 was still barred from the U.S. market due to  
8 Congress' refusal to allocate funds for inspections.  
9 In effect, the U.S. Government barred Chinese  
10 poultry even though China met all USDA requirements.  
11 As you know, China filed a WTO case against the  
12 United States, which the U.S. is trying to settle as  
13 we meet here today.

14           Do the U.S. and USDA really need another  
15 WTO case?

16           Finally, some perspective. Imports of  
17 Chinese catfish in the last year were about \$40  
18 million. We estimate that the Chinese's share of  
19 the total U.S. catfish market is well less than 5  
20 percent.

21           In contrast, the United States exported  
22 almost \$20 billion, and I will repeat, \$20 billion

1 in agricultural goods to China in the last year.  
2 Put another way, imported Chinese catfish represents  
3 just under 0.2 percent of U.S. exports of  
4 agricultural goods to China.

5 I leave you today with a single question.  
6 Why in the world would the U.S. Government  
7 jeopardize huge agricultural exports to China with  
8 the imposition of unfair regulations against Chinese  
9 catfish?

10 We are confident that the USDA will not  
11 take that risk.

12 Thank you for taking the time to listen to  
13 the views of my client.

14 MR. DiNAPOLI: Thank you, John.

15 Next is Lisa Weddig with the National  
16 Fisheries Institute.

17 MS. WEDDIG: Good morning. Thank you for  
18 allowing the National Fisheries Institute to provide  
19 these comments.

20 I'm Lisa Weddig. I'm the Director of  
21 Regulatory and Technical Affairs for NFI.

22 For more than 65 years, the National

1 Fisheries Institute has been the nation's leading  
2 advocacy organization for the seafood industry. Our  
3 member companies represent every element of the  
4 industry from fishing vessels at sea to importers,  
5 from processors to retailers and national seafood  
6 restaurant chains.

7 NFI and its members support and promote  
8 sound science-based public policy.

9 The notice for this public meeting  
10 requested comments on two specific areas, the scope  
11 of the proposed regulation with regards to the  
12 definition of catfish and the transition phases and  
13 their duration.

14 Catfish has been clearly defined under the  
15 U.S. law since 2002. That year, Congress amended  
16 the Federal Food, Drug and Cosmetic Act to define  
17 catfish as fish classified within the family  
18 Ictaluridae. Species of fish that were formerly  
19 marketed as catfish in the United States, species  
20 such as *Pangasius hypophthalmus* and *Pangasius*  
21 *bocourti* are now marketed by names such as swai or  
22 basa. Consumers just do not associate these fish

1 with catfish.

2           Implementing this new regulatory system for  
3 catfish, regardless of how the fish will be defined,  
4 will be a challenge for the industry, the Agency,  
5 and for our foreign trading partners, not because  
6 mandatory HACCP regulations in place under the Food  
7 and Drug Administration are inadequate, but because  
8 of the complete paradigm shift in regulations and  
9 Government oversight.

10           We just cannot comprehend how FSIS will be  
11 able to complete the equivalency assessment of a  
12 foreign government's inspection system for catfish  
13 prior to the Agency completing the implementation of  
14 the inspection program in the United States.

15           The implementation process must allow time  
16 for foreign authorities to work with FSIS to achieve  
17 equivalence recognition, whether it takes 3, 5, 7  
18 years or longer.

19           We caution the Agency to take great care in  
20 determining the scope of the definition and  
21 implementation for a final rule.

22           The seafood industry in the United States

1 that will be impacted by these regulations is much  
2 broader than the domestic industry processing  
3 domestic catfish. Catfish and other species are  
4 further processed in many states. To name a few,  
5 Florida, Georgia, Illinois, Idaho, Wisconsin,  
6 Massachusetts, Rhode Island, New Hampshire,  
7 Washington, Virginia. All these states are beyond  
8 the traditional catfish states.

9 All seafood processors will be impacted by  
10 the shift in regulatory oversight of catfish.

11 We're, in fact, puzzled why FSIS did not  
12 conduct outreach more broadly than meetings in  
13 Mississippi and Washington, D.C., given this  
14 national impact.

15 We thank you for this opportunity to share  
16 our views on the inspection of catfish at FSIS.  
17 Thank you.

18 MR. DiNAPOLI: Thank you, Lisa.

19 Next is Tracey Gonzalez with Grunfeld,  
20 Desiderio, Lebowitz, Silverman and Klestadt.

21 MS. GONZALEZ: Good morning. My name is  
22 Tracey Gonzalez. I'm an attorney at Grunfeld,

1 Desiderio in New York. We represent the Vietnam  
2 Association of Seafood Exporters and Producers, also  
3 known as VASEP. We're here today to urge the FDA,  
4 or I'm sorry, the USDA to define catfish in the same  
5 manner as the FDA has defined this term for the past  
6 10 years.

7           For FDA purposes, catfish are limited only  
8 to fish in the family Ictaluridae. They do not  
9 include all fish of the order Siluriformes. The  
10 USDA should adopt an identical definition. To do so  
11 would be in keeping not only with the FDA's  
12 longstanding definition, but with clear  
13 Congressional intent and public perceptions of the  
14 different fish species.

15           USDA has failed to enumerate any specific  
16 reasons for expanding the definition of catfish  
17 under the proposed inspection program.

18           VASEP is a non-governmental organization of  
19 Vietnamese seafood producers and exporters  
20 established in 1998. Seafood exports by VASEP  
21 members represent 80 percent of total seafood  
22 exports of Vietnam. The fish exported by VASEP

1 members include basa, swai, and tra, which are all  
2 subspecies of *Pangasius*. *Pangasius* is a separate  
3 and distinct species from Ictaluridae. *Pangasius* is  
4 marketed and sold in 80 countries around the world  
5 and Vietnam's *Pangasius* industry has grown  
6 exponentially over the past 10 years in order to  
7 keep up with demand. Totaling less than 35,000  
8 metric tons in 2003, Vietnam's *Pangasius* exports now  
9 exceed 600,000 metric tons annually. About 12  
10 percent of this volume ends up in the U.S. market.

11           The ability of the seafood industry to  
12 export *Pangasius* is critically important for the  
13 overall economic health of Vietnam.

14           USDA is considering two different  
15 definitions of the term catfish. The first would be  
16 consistent with the definition of catfish currently  
17 used by the FDA and U.S. Customs and Border  
18 Protection, which encompasses only those fish  
19 belonging to the family Ictaluridae. The second  
20 would broaden the scope of catfish to include all  
21 fish of the order Siluriformes.

22           The distinction is an important one.

1 Defining catfish as Siluriformes would mean that  
2 *Pangasius* would be subject to the USDA's new  
3 inspection rules even though for FDA and Customs  
4 purposes, these same fish are not catfish.

5           This change is unnecessary and, in our  
6 opinion, contrary to law. It defies well-known  
7 principles of statutory construction. It would  
8 cause confusion among exporters, importers, U.S.  
9 distributors, and retailers, and it may possibly be  
10 contrary to United States international obligations  
11 which could potentially lead to retaliation against  
12 U.S. exports by our trading partners.

13           FDA law, which is codified at 21 U.S.C.  
14 321(d), states that, "Notwithstanding any other  
15 provision of law, for purposes of the Federal Food,  
16 Drug and Cosmetic Act (a) the term catfish may only  
17 be considered to be a common or usual name or part  
18 thereof for fish classified within the family  
19 Ictaluridae and (b) only labeling or advertising for  
20 fish classified within that family may include the  
21 term catfish."

22           The phrase notwithstanding, any other

1 provision of law makes clear that Congress intended  
2 for this definition to be the only definition of  
3 catfish. Indeed, the FD&C Act is the only federal  
4 statute with such a definition.

5           The USDA's proposed rule would create a new  
6 definition which is both prohibited by the statutory  
7 language of 21 U.S.C. 321(d) and contrary to the  
8 existing definition. That definition has been in  
9 effect for nearly 10 years.

10           In addition, the proposed change in the  
11 definition of catfish would override and directly  
12 contradict all previous FDA guidance on this issue.

13           In a guidance for industry publication  
14 dated December 2002, FDA stated, "In accordance with  
15 a new Section 403(t) of the Act, importers, domestic  
16 distributors, and sellers of fish from families  
17 other than Ictaluridae, who previously used the term  
18 catfish in labeling or on the label as part of the  
19 common or usual name of the fish, may no longer use  
20 that term, either when the fish are offered for  
21 import into the United States or distributed or sold  
22 in interstate commerce within the United States.

1 Other names must be used."

2           As recently as March 18, 2011, FDA  
3 reiterated this definition of catfish in an import  
4 alert which indicated that non-Ictaluridae fish that  
5 is labeled as catfish may be subject to refusal of  
6 admission because FDA considers it misbranded.

7           In light of FDA's existing definition,  
8 USDA's proposal to change the definition of catfish  
9 to include all fish of the order Siluriformes would  
10 create confusion and uncertainty among exporters who  
11 would not know whether their products are or are not  
12 catfish. A *Pangasius* exporter or U.S. importer who  
13 declares that it is shipping catfish for USDA  
14 purposes would be in violation of FDA regulations  
15 concerning this branding.

16           The anticipated conflict between USDA and  
17 FDA terminology would also extend to Customs. The  
18 harmonized tariff schedule of the United States  
19 designates separate tariff provisions for *Pangasius*  
20 and other Siluriformes.

21           No foreign exporters should be placed in  
22 the position of being forced to ignore one American

1 Agency's regulations in order to comply with  
2 another's. U.S. regulations are confusing and  
3 difficult to understand even when they are  
4 internally consistent. It is simply unfair for our  
5 Government to create an obvious inconsistency where  
6 there is no reason to do so.

7           In fact, by creating this inconsistency,  
8 USDA's proposal to categorize *Pangasius* as catfish  
9 would be contrary to basic principles of statutory  
10 construction. In the United States, an agency  
11 action is considered arbitrary when the agency  
12 offers insufficient reasons for treating similar  
13 situations differently. There's ample case law  
14 supporting the proposition that two inconsistent  
15 definitions cannot stand unless there is a  
16 reasonable explanation for the discrepancy.

17           In this case, USDA proposes to interpret  
18 the term catfish as including non-Ictaluridae fish  
19 such as *Pangasius*, a definition that is totally  
20 inconsistent with FDA's interpretation, without any  
21 reasonable explanation for its decision.

22           Although FDA and USDA are separate

1 entities, the regulations overlap in many respects.  
2 The USDA definition of catfish that conflicts with  
3 FDA's definition will create an inconsistency in the  
4 law and create confusion as to which Agency's  
5 regulations should apply.

6           Moreover, defining catfish differently from  
7 the longstanding FDA definition may be contrary to  
8 our international trade obligations.

9           In an opinion commissioned by fish  
10 importers, trade expert James Baucus, the Chief  
11 Judge of the World Trade Organization's appellate  
12 body from 1996 through 2003, concluded that the  
13 United States would likely lose if Vietnam  
14 challenged the USDA's proposed definition of catfish  
15 before the WTO, precisely because FDA regulations  
16 are already effective.

17           Baucus warned that international trade  
18 judges would conclude that the only reason for the  
19 change in regulation was protectionism, an  
20 unreasonable explanation under the principles set  
21 forth by the WTO.

22           If a WTO panel ruled against the United

1 States, Vietnam would be allowed to retaliate.  
2 Senator Max Baucus is on record noting that the  
3 Vietnamese could block imports of U.S. beef in  
4 response.

5           Commenting on the proposed change of  
6 definition, Senator Baucus told reporters for  
7 *Congress Daily*, "If we expect other countries to  
8 follow the rules and drop these restrictions on U.S.  
9 agricultural products, including Montana beef, it is  
10 critical that we play by the rules and do not block  
11 imports for arbitrary or unscientific reasons."

12           This sentiment was echoed in March 2011  
13 when U.S. Senators John McCain of Arizona and Tom  
14 Coburn of Oklahoma introduced legislation that would  
15 rescind the measure transferring regulation of  
16 catfish from FDA to the USDA. In a statement issued  
17 on March 7, 2011, Senator McCain stated, "Not only  
18 is the catfish provision offensive to our principles  
19 of free trade, it flagrantly disregards our  
20 bilateral trade agreement and relationship with  
21 Vietnam."

22           MR. DiNAPOLI: Tracey, I'm sorry. If you

1 could try to wrap up as soon as you can.

2 MS. GONZALEZ: Sure. The FDA already  
3 monitors, tests, and certifies the safety of seafood  
4 imported into the United States. FDA programs  
5 include HACCP and the Good Manufacturing Practices  
6 regulations. In addition, FDA issues regular  
7 reports to Congress concerning food safety. There  
8 has been no showing in any of the underlying  
9 legislative materials, Agency proceedings or FDA  
10 reports, that Vietnamese *Pangasius* is in need of the  
11 type of control or oversight imposed by the draft  
12 USDA regulations.

13 MR. DiNAPOLI: Thank you.

14 Michael Hansen, Consumers Union.

15 I'd just remind everyone if you could keep  
16 your comments to roughly five minutes, we'd  
17 appreciate it. Thank you.

18 MR. HANSEN: Yes. My name is Michael  
19 Hansen. I'm a Senior Scientist at Consumers Union.  
20 We're the publisher of *Consumer Reports*. Consumers  
21 Union welcomes the opportunity to comment on FSIS'  
22 new proposal to require continuous inspection of

1 catfish and catfish products.

2           We're glad that FSIS will mandate  
3 inspection of catfish. We believe that FSIS is  
4 better suited than the FDA to ensure the safety of  
5 domestic and imported catfish as FSIS does a more  
6 comprehensive review of food safety systems.

7           We have concerns about the potential safety  
8 of catfish and catfish products being imported into  
9 the U.S., especially from Vietnam. Vietnam allows  
10 38 drugs to be used in aquaculture while the U.S.  
11 allows only 6. We believe FDA should define catfish  
12 to include all fish in the order Siluriformes and  
13 not just restrict the definition of catfish to those  
14 in the family Ictaluridae.

15           So, first, FSIS does stronger food safety  
16 review than FDA. FDA is supposed to ensure the  
17 safety of imported seafood primarily by enforcing  
18 HACCP regulations.

19           However, according to GAO, in 2010, FDA  
20 visited only 5 of 801 fish processing facilities in  
21 Vietnam. The foreign inspections FDA does perform  
22 usually involve reviewing the processors' HACCP

1 plans and other records to ensure that the  
2 processors have considered drug residues as a hazard  
3 and taken appropriate action.

4           FDA inspectors do not visit fish farms to  
5 evaluate drug use or controls, nor do they evaluate  
6 the capability, competence, and quality control of  
7 laboratories used to sample seafood from fish farms  
8 to see if the fish farm is using unapproved drugs  
9 because such fish farms are not considered  
10 processors and so not covered by FDA's HACCP  
11 regulations.

12           In contrast, FSIS regulations only allow a  
13 foreign country to export to the U.S. after FSIS has  
14 determined that the exporting country has a food  
15 safety system equivalent to that in the U.S. FSIS  
16 not only reviews documents provided by foreign  
17 governments to ensure that HACCP programs are being  
18 implemented, but they also conduct on-site  
19 evaluations of the government's inspections of  
20 processing facilities and the government's audits of  
21 laboratories and controls over, among other things,  
22 drug residue, sanitation, and animal disease.

1           We also feel that imported catfish may be  
2 more hazardous than domestic catfish.

3           The current FDA regulatory scheme is not  
4 adequate to prevent residues of illegal drugs in  
5 imported catfish. The vast bulk of imported catfish  
6 come from Vietnam.

7           According to GAO, FDA officials determine  
8 that Vietnam permits 38 drugs to be used while the  
9 U.S. only permits 6. Furthermore, all Vietnamese  
10 processing facilities' HACCP plans stated that if a  
11 drug unapproved by the European Union is found in a  
12 seafood product, that product should be diverted to  
13 another market. FDA officials concluded this HACCP  
14 plan requirement would result in such products being  
15 imported into the U.S.

16           The FDA then asked Vietnam to test 100  
17 percent of seafood products destined for the U.S.  
18 for unapproved drugs, such as nitrofurans and  
19 chlorine phenol. The Vietnamese government  
20 responded that it performed 100 percent testing only  
21 for products intended for countries with which it  
22 had a bilateral agreement, of which the U.S. was not

1 one. The FDA has not gone forward with getting that  
2 bilateral agreement.

3 FDA also prioritized the testing of all  
4 catfish and catfish-related species for nitrofurans,  
5 and yet between the years 2006 and 2009, FDA did not  
6 analyze any catfish samples for nitrofurans. Also  
7 in 2009, the FDA reported it collected drug residue  
8 testing on only one-tenth of one percent of all  
9 imported seafood products.

10 We'd also note that FDA's testing is so  
11 limited, they often do not test for drugs that are  
12 illegal to use in U.S. aquaculture but are permitted  
13 in Vietnam. For example, Vietnam permits the use of  
14 neomycin in aquaculture. In 2010, the EU detected  
15 excessive levels of neomycin in imported catfish  
16 from Vietnam. Since FDA doesn't include neomycin in  
17 its sampling program, it cannot say that catfish  
18 imported from Vietnam do not contain neomycin  
19 residues.

20 Finally, as for the definition of catfish,  
21 we believe USDA should define catfish to be any fish  
22 in the order Siluriformes. We point out that that

1 order contains 36 families. Taxonomists and  
2 biologists in general refer to the Siluriformes  
3 collectively as catfishes. We feel that USDA should  
4 follow established scientific practice that defines  
5 catfishes as all fish of the order Siluriformes.

6           If you restrict catfish only to the family  
7 Ictaluridae, then FSIS would not be able to require  
8 inspection of some of the catfishes from Vietnam,  
9 such as species within the family Pangasiidae, which  
10 is also known as the giant catfishes, and/or species  
11 in the Clariidae.

12           We'd also point out that if you use only  
13 the definition of Ictaluridae, that only covers 70  
14 percent of catfish consumed in the U.S. and only  
15 covers 20 to 25 percent of catfish that are imported  
16 from foreign countries.

17           We think that the large catfish raised in  
18 Vietnam are similar in appearance and habits to  
19 other catfish and can be farmed in a similar manner.  
20 So for both taxonomic and safety reasons, USDA  
21 should include all catfish, particularly the catfish  
22 in Pangasiidae as well as smaller ones, in its

1 definition to protect consumer safety. Thank you.

2 MR. DiNAPOLI: Thank you, Michael.

3 At this moment, I'd like to welcome Senator  
4 Thad Cochran of Mississippi, if he would like to get  
5 up to the podium and make some comments to the  
6 audience. Senator.

7 SENATOR COCHRAN: My statement is in the  
8 form of testimony for a hearing. I appreciate the  
9 opportunity to appear before the Department of  
10 Agriculture to comment on the proposed catfish  
11 inspection rule.

12 I'm here to support our nation's catfish  
13 industry and to urge the Department to adopt the  
14 broader option of inspection, so that all catfish  
15 consumed in this country will be subjected to  
16 inspection by the United States Department of  
17 Agriculture.

18 With nearly a third of all catfish consumed  
19 in the United States imported from foreign sources,  
20 it is important to health and safety interests that  
21 we provide the necessary tools and resources to  
22 ensure that these imports meet the same quality

1 standards as domestic products.

2           While we owe that assurance to American  
3 consumers, the current inspection system for catfish  
4 does not meet that responsibility.

5           The Government Accountability Office  
6 recently released a report on the current FDA  
7 seafood inspection policy, which characterized its  
8 effectiveness as limited and in dire need of  
9 strengthening. Only two percent of imported catfish  
10 is currently inspected in the United States.

11           The Food Safety and Inspection Service has  
12 the authority to provide a much stronger system that  
13 has proven its success. With a stringent, robust  
14 inspection system already in place, for beef,  
15 poultry, and other products, I believe a similar  
16 inspection program for catfish could be implemented  
17 while remaining compliant with our international  
18 trade commitments.

19           The two options that USDA issued in the  
20 proposed rule would bring significantly different  
21 food safety results. The broader option, which I  
22 urge you to support, would subject all consumed

1 catfish to the same inspection standards. The  
2 narrower option would exempt a large majority of  
3 imported catfish from meeting these requirements.  
4 Even with a limited inspection of the current  
5 system, there were health and safety violations  
6 found in 482 shipments of imported catfish products  
7 between 2002 and August of 2010.

8 Fish farming environments in countries like  
9 China, Vietnam, and Taiwan are far less controlled  
10 and are exposed to a number of chemicals that are  
11 banned in the United States.

12 Allowing contaminated products to enter our  
13 country's food supply, without being properly  
14 inspected, would not only weaken consumer  
15 confidence, it would impose a significant public  
16 health risk.

17 Our country enjoys the safest, most  
18 abundant, and affordable food supply in the world.  
19 Americans must be able to trust that the food they  
20 purchase in restaurants and at the grocery stores is  
21 of the highest quality.

22 I hope when you review the comments from

1 the public on this issue, the Department of  
2 Agriculture will chose to adopt the broader  
3 definition of the proposed catfish inspection rule  
4 to ensure the safety of our food supply.

5 Thank you again for the opportunity to  
6 share my views with you.

7 MR. DiNAPOLI: Thank you, Senator.

8 Congressman Bennie Thompson of Mississippi,  
9 if you'd like to come forward.

10 CONGRESSMAN THOMPSON: Thank you for the  
11 opportunity to provide comments on the catfish  
12 inspection rule.

13 As you're to determine whether all or some  
14 of the catfish consumed in this country should be  
15 inspected by USDA, I urge you to support the broader  
16 option.

17 Roughly a third of all catfish consumed in  
18 the United States comes from overseas. This foreign  
19 fish is produced by an industry that loosely  
20 attempts to control rates of contamination.

21 Between 2002 and August 2012, the FDA,  
22 which has authority over catfish inspection and

1 regulation, found health and safety violations in  
2 482 shipments of imported catfish products including  
3 *Salmonella* and carcinogens.

4 Three countries are responsible for 72  
5 percent of these violations, China 39.4 percent,  
6 Vietnam 20.7 percent, and Thailand, 11.8 percent.  
7 However, the FDA inspected only 0.1 percent of all  
8 seafood imported in the U.S. for banned drugs in  
9 2009.

10 From 2006 to 2009, the latest years for  
11 which data is available, the FDA violated its own  
12 guidelines and did not test any catfish samples for  
13 dangerous nitrofurans antibiotics which the U.S.  
14 bans for use in agricultural products according to  
15 the Government Accountability Office.

16 In November 2009, the Alabama Department of  
17 Agriculture and the industries examined catfish and  
18 related fish imported from five Asian countries and  
19 discovered that one out of every three of those  
20 imported fish tested positive for harmful antibiotic  
21 drugs that are banned for use in fish in the United  
22 States because of potential health and safety

1 dangers to consumers. Those imported fish from  
2 China, Vietnam, Cambodia, Indonesia, and Thailand  
3 would have landed on Alabama dinner plates if state  
4 authorities had not intervened.

5 Congress voted to fix this problem in the  
6 2008 Farm Bill by shifting regulation of catfish  
7 products from the FDA to the USDA, but 22 months  
8 later, this regulation which could help protect the  
9 American consumer has been marred in bureaucracy.  
10 OMB has delayed the rule indefinitely, and USTR is  
11 now weighing in with concerns of how food safety  
12 standards may antagonize some trading partners.

13 Trade should never trump food safety. With  
14 this Administration's emphasis on food safety, the  
15 broadest possible definition of this rule would be  
16 most beneficial to protecting the health and safety  
17 of American consumers.

18 The broad definition covers all catfish and  
19 catfish-related species, while the narrow definition  
20 sought by opponents seeking to water down the  
21 protections would cover only U.S. and Chinese  
22 catfish, leaving American consumers vulnerable to

1 contamination and pathogens that could be found in  
2 other imported Asian catfish relatives.

3           In addition to the safety of Americans, the  
4 rule will have tremendous impact on jobs in my home  
5 state of Mississippi. Mississippi represents 78  
6 percent of the catfish production in the United  
7 States.

8           Unfortunately, our acreage and production  
9 numbers are down, and so are the jobs associated  
10 with production. Catfish acreage in Mississippi has  
11 fallen 40 percent since it hit an all-time high of  
12 113,000 acres in 2002. In previous years,  
13 Mississippi had over 16,000 people working in the  
14 catfish industry, but that number is currently down  
15 to less than 10,000 employees.

16           Even though our industry is facing  
17 challenges, they remain extremely committed to  
18 providing a safe product for the American consumer.

19           The entire debate surrounding this catfish  
20 rule hinges on one brutal fact. If the foreign fish  
21 is as safe as fish grown domestically, there would  
22 be no need for concern from foreign producers. If

1 the foreign fish was grown using safe techniques, it  
2 would pass the inspection tests with flying colors.

3           However, the trade interest groups who have  
4 injected themselves into this debate are fully aware  
5 that foreign fish is inferior to fish grown  
6 domestically.

7           I respectfully urge USDA to swiftly  
8 finalize a definition that will help secure our  
9 nation's food supply. It is important that USDA  
10 include all catfish that are raised and imported for  
11 consumption. Consumers need confidence that every  
12 catfish sold in a grocery store, or purchased at a  
13 favorite restaurant, is safe to eat. A consistent  
14 inspection program is paramount to achieving  
15 consumer confidence.

16           USDA has a great track record on food  
17 safety. I have confidence in their ability to  
18 create a program that operates similar to beef and  
19 poultry, which is consistent with our international  
20 trade obligations.

21           I agree and urge USDA to adopt the broad  
22 definition for catfish and implement a final rule as

1 soon as possible. Thank you.

2 MR. DiNAPOLI: Thank you, Congressman.

3 Next is Joey Lowery from Catfish Farmers of  
4 America.

5 MR. LOWERY: Good morning. My name is Joey  
6 Lowery. I currently chair the Board of the Catfish  
7 Farmers of America. I'm a recent past president of  
8 CFA.

9 The Catfish Farmers of America has more  
10 than 600 members in 35 states. Our membership  
11 includes farmers, processors, scientists, financial  
12 institutions, vendors, and others.

13 I've been raising catfish for going on 26  
14 years on my farm in Newport, Arkansas. I appreciate  
15 the opportunity to speak this morning.

16 From my point of view, the proposed  
17 regulation before you represents a health and safety  
18 issue, pure and simple. Our number one priority,  
19 like yours, is the health and safety of the American  
20 consumers.

21 We're not just supporting this change in  
22 regulations because it imposes stronger safety

1 standards on imported fish; it also requires those  
2 same strong standards for our U.S. farm-raised  
3 catfish.

4           We're not asking imported catfish to be  
5 treated any differently than our own catfish. We  
6 want all catfish to be as safe as possible for the  
7 American consumer to enjoy.

8           The Government Accountability Office this  
9 April confirmed in the strongest possible way the  
10 need for the broadest and most rapid implementation  
11 of this regulation. When it comes to protecting  
12 consumers, the GAO concluded that the existing  
13 federal program to inspect imported seafood is so  
14 limited that it is insufficient and ineffective.

15           We feel that without regulation, our  
16 industry is vulnerable to a food safety incident,  
17 whether from long-term exposure to a carcinogen or  
18 short-term exposure to a pathogen, a tragedy we  
19 would all like to avoid.

20           In 2009 the FDA tested about .1 percent of  
21 all imported seafood product for drug residues, this  
22 according to the GAO, but for catfish, the numbers

1 are even more shocking. Even though the FDA's  
2 import sampling program states that it prioritizes  
3 the testing of all catfish and catfish-related  
4 species for residues of nitrofurans, during fiscal  
5 years 2006 through 2009, the FDA did not analyze a  
6 single imported catfish sample for nitrofurans.

7 Now, this is an antibiotic that has been  
8 banned for use in agricultural products by the U.S.  
9 and other countries, but which is still commonly  
10 used in Asia in catfish farming.

11 The GAO concluded that because of FDA's  
12 limited sampling, some of the more than 156,000  
13 metric tons of catfish imports that entered the  
14 United States during those three years could easily  
15 have contained residues of nitrofurans. That is  
16 shocking. That is unacceptable.

17 This is precisely why the Catfish Farmers  
18 of America supports turning over catfish inspections  
19 and regulation to your Agency.

20 Consumer confidence in safe and healthy  
21 seafood is critical to both the domestic and  
22 imported catfish industries. Experience shows that

1 if there's a food safety incident, consumer  
2 confidence for the entire product category, no  
3 matter the source of the product, is damaged. It  
4 often takes years for the consumption level of the  
5 product to rebound.

6 For the sake of consumer health, first and  
7 foremost, and also the health of an important job  
8 creating domestic and import industry, it is  
9 critical that FSIS begin regulating catfish.

10 Our industry is already suffering from high  
11 fuel costs, high feed costs, and now a lot of  
12 farmers are fighting 75-year floods. We cannot  
13 afford an outbreak of illness from catfish from  
14 anywhere.

15 Because farm-raised catfish are a protein  
16 source with a risk profile similar to meat, most  
17 consumers naturally assume seafood is inspected  
18 under the same guidelines as meat, eggs, and  
19 poultry, which are subject to USDA's FSIS  
20 inspection. If there is an incident, consumers will  
21 be outraged to learn how seafood is, in fact,  
22 regulated.

1           The Catfish Farmers of America support FSIS  
2 inspection in order to assure the consumer the  
3 safest and healthiest catfish, both domestic and  
4 imported.

5           We are not opposed to imports. We only  
6 oppose unhealthy imports. How anyone can argue  
7 against that is beyond us. We have a right to set  
8 standards of quality and safety on any product being  
9 marketed in this country, especially our food  
10 supply. This is a public health issue.

11           Why should any company that is not  
12 providing the same level of protection as domestic  
13 companies be selling food to the American consumers?  
14 It's that simple.

15           Economics and trade are very important but  
16 cannot be allowed to trump food safety.

17           I also want to emphasize that I and my  
18 fellow U.S. catfish farmers support the broadest  
19 definition possible for FSIS catfish inspections.  
20 There's a good rationale within the standard  
21 classification system used by FSIS biologists to  
22 describe and define catfish more broadly than

1 Ictaluridae.

2           America's classic catfish commonly known as  
3 a channel catfish is a member of the order  
4 Siluriformes. The Asian catfish, *Pangasius*,  
5 sometimes called basa, tra, and swai, are also  
6 members of the order Siluriformes and are grown on  
7 farms for export. Chinese farmers also raise  
8 American catfish, the Ictaluridae, on farms for  
9 export.

10           From our perspective, our farm-raised  
11 catfish and catfish-like species should be covered  
12 for food safety regulation; whether domestic or  
13 imported, and from whatever source country, the same  
14 food safety label should be required. If something  
15 less than all the farm-raised catfish are covered,  
16 this will lead to a disruption in the food safety  
17 protection we seek.

18           If catfish from Country A is inspected, but  
19 catfish from Country B is not inspected for food  
20 safety, confusion would reign in the marketplace.  
21 Consumers cannot be expected to understand why USDA  
22 was inspecting just some catfish while leaving other

1 catfish to chance.

2           In fact, if import volumes remain at  
3 current levels and the narrow definition of catfish  
4 is implemented, only 9 percent of all imported  
5 catfish and catfish-like species would be inspected  
6 and regulated by USDA.

7           Look at this practically. Consumers do not  
8 distinguish between catfish based on its source. If  
9 there's an outbreak of sickness from any catfish,  
10 consumption of all catfish will go down regardless  
11 of its point of origin. Consumers would not  
12 understand why some catfish were regulated and not  
13 others, and there would be severe criticism of the  
14 regulatory agencies.

15           We're not asking that imported fish be  
16 treated differently than U.S. farm-raised. We're  
17 only asking the Federal government to ensure that  
18 it's as safe. We don't believe trading safety for  
19 commerce is ever a bargain. We believe safety and  
20 quality should be the test for good public policy  
21 and good business.

22           It was made a law for a reason. Americans

1 are trying to eat healthier and are more safety  
2 conscious than ever before about what they feed  
3 their families. Consumption of seafood is growing.  
4 We encourage you to ensure that American consumers  
5 are getting the healthiest and safest catfish  
6 possible when they go to the grocery shelves or sit  
7 down to dinner at a restaurant.

8           This regulation was approved by a  
9 bipartisan vote of Congress nearly three years ago.  
10 Consumers shouldn't have to wait any longer for  
11 these protections.

12           We're asking you to take immediate action  
13 to avoid any terrible misfortune for a single U.S.  
14 consumer or for our industry. Thank you very much.

15           MR. DiNAPOLI: Thank you, Joey.

16           Next is Butch Wilson from Catfish Farmers  
17 of America.

18           MR. WILSON: Good morning. My name is  
19 Butch Wilson, and I currently serve as President of  
20 the Catfish Farmers of America. I've been in the  
21 catfish farming business for 26 years in Dallas  
22 County, Alabama.

1 I'm here to talk to you about the  
2 importance of ensuring health, safety, and quality  
3 of catfish on American grocery shelves, in our  
4 restaurants, and in our school cafeterias.

5 U.S. catfish growers are committed to  
6 health, safety, and image of our product. The  
7 U.S. farm-raised catfish are rated as one of the  
8 cleanest, healthiest, and most environmentally  
9 friendly fish products in the world by various  
10 consumer, seafood, and environmental groups,  
11 including the Audubon Society, the Environmental  
12 Defense Fund, and the Food and Water Watch. This is  
13 because we have invested in ensuring this high  
14 standard for our food safety and quality and have  
15 made it a priority of our business model.

16 Today, I and other U.S. farmers worry that  
17 the hundreds of thousands of tons of imported  
18 catfish and catfish-like species that are entering  
19 the U.S. markets are not raised in safe and healthy  
20 conditions and could pose health risks and undermine  
21 the American consumers' confidence in catfish. We  
22 know that any supply, whether domestic or foreign,

1 can destroy consumer confidence in our product with  
2 just one safety incident.

3 I want to share with you a few facts  
4 regarding imported catfish and catfish-like species  
5 and why now, more than ever, the American consumer  
6 and the American farmer need a broad definition of  
7 catfish to be included in the final rule.

8 In 2003 imported catfish and catfish-like  
9 species made up only 4 percent of all frozen catfish  
10 filets in the U.S. By 2009, imports accounted for  
11 57 percent of all frozen catfish filets sold in the  
12 U.S.

13 Imported catfish and catfish-like species  
14 have been found to contain harmful chemicals and  
15 drugs that are banned in food production in the U.S.

16 From August 2009 through July 2010,  
17 48 shipments of imported catfish were refused by FDA  
18 with over 2/3 of the refusals coming from Vietnam  
19 and China. In this year alone, from January to  
20 April, there's been 12 cases discovered of drugs and  
21 vet drug residues.

22 In addition, in my home state of Alabama,

1 the State Department of Agriculture lab tests  
2 returned the following results: 2005, 21 catfish  
3 samples from Vietnam, 19 positive for banned  
4 antibiotics, 3 for carcinogens. 2007, 129 catfish  
5 samples from China, 64 positive for banned  
6 antibiotics, 27 for carcinogens. 2009, 34 catfish  
7 from various Asian countries, 14 positive for banned  
8 antibiotics.

9           We recognize that the U.S. farmers would  
10 also be subject to additional regulations as a  
11 result of the new rule. We will be subject to even  
12 more checks and inspection standards when FSIS  
13 assumes control of catfish inspections and  
14 regulations. It will take more time, work, and  
15 expense for U.S. catfish farmers. However, these  
16 extra hurdles the U.S. industry is willing to take  
17 are well worth the cost of ensuring the health of  
18 the consumer and the image of the future of our  
19 industry.

20           That is why we have worked so hard these  
21 last several years to support FSIS taking over  
22 inspection and regulation of all catfish, domestic

1 and imported. We have faith in your systems. USDA  
2 inspectors will be on site at catfish operations in  
3 greater numbers than existing voluntary FDA and NOAA  
4 seafood inspection programs. The USDA will monitor  
5 catfish farms for health and safety hazards because  
6 food safety experts generally believe many hazards  
7 can be introduced to the food chain during  
8 production. The FDA nor NOAA has this authority.

9           The USDA has prior label approvals assuring  
10 that the catfish is properly represented on the  
11 label before it can be shipped to the marketplace.  
12 The FDA can find labeling deficiencies or  
13 mislabeling only after the product has reached the  
14 marketplace. It can take months before FDA  
15 discovers problems and takes action.

16           And perhaps most important for consumers,  
17 USDA will apply the same strong system of ensuring  
18 meat and poultry products are safe to the catfish  
19 industry. This equivalent system has been in  
20 operation for years, and other countries operate  
21 similar programs.

22           The USDA inspection approves the food

1 safety systems used by exporting countries and  
2 monitors the systems and the businesses in the  
3 exporting nation on a continuing basis.

4 Here USDA re-inspects the product after it  
5 is imported, examining more than twice the  
6 proportion that FDA inspects.

7 Currently USDA regulates and certifies the  
8 quality of meat, poultry, and dairy products but not  
9 fish. Fish comes under the authority of the FDA,  
10 which has far less rigorous inspection standards  
11 than USDA and FSIS.

12 We want USDA approval so that every catfish  
13 product imported into America meets the same  
14 rigorous standards for quality and safety as our  
15 farm-raised catfish.

16 I urge you to enact the provision of the  
17 2008 Farm Bill, approved by Congress, which will  
18 ensure that all catfish and catfish-like products  
19 from all sources, domestic and imported, meet the  
20 health and safety standards that Americans have come  
21 to expect from USDA, and that includes meat,  
22 poultry, eggs, and dairy products.

1           The rule needs to be broader and more  
2 comprehensive to cover all catfish and catfish-like  
3 species, domestic and imported. The original rule  
4 promulgated by the USDA FSIS was absolutely correct.  
5 It provided for a broad definition that would  
6 include all types of catfish, domestic and imported.  
7 USDA needs to give the same peace of mind to  
8 American consumers of catfish as it gives the  
9 consumers of imported meat and poultry. Consumers  
10 shouldn't have to play roulette when it comes to the  
11 safety of our food. Thank you for your  
12 consideration.

13           MR. DiNAPOLI: Thank you, Butch.

14           Next is Carole Engle, University of  
15 Arkansas.

16           DR. ENGLE: Good morning. My name is  
17 Dr. Carole Engle, and I serve as Chair and Director  
18 of the Aquaculture Fishery Center at the University  
19 of Arkansas at Pine Bluff. I've worked in the  
20 economics and marketing of aquaculture for more than  
21 30 years and have worked in 19 countries on all  
22 major continents, including Vietnam and China, where

1 I specifically visited farms that raised catfish for  
2 export to the United States.

3 In Vietnam, I visited farms in Can Tho and  
4 the Hau River and Ben Tre Province on the Tien Giang  
5 River.

6 Catfish are raised in cages and net pens in  
7 the rivers and also in what the Vietnamese  
8 mistakenly call ponds. These should really be  
9 referred to as raceways due to the frequent water  
10 exchange from the river. River water is used for  
11 all phases of life in the Mekong due to the high  
12 population density and the limited land. It also  
13 serves as the primary waste disposal system for the  
14 region, all waste, whether from human sewage, farm  
15 runoff or discharges from factories, slaughterhouses  
16 and cities, enter the river untreated. This same  
17 river water then flows through these earthen  
18 raceways where the fish are raised.

19 Since fish take up substances quickly from  
20 the water, any noxious substances, whether heavy  
21 metals or antibiotics in the water, will be absorbed  
22 into the fish flesh. There are numerous scientific

1 studies that document this.

2           Waste from one fish farm then contribute to  
3 the pollution to farms downstream that are flushing  
4 water from the same river through their raceways.  
5 Fish raised in these raceways are subjected  
6 continuously to whatever contaminants, chemicals,  
7 drugs, diesel, herbicides, or diseases are in the  
8 river water.

9           And the U.S. farmer use well water that has  
10 been filtered through rock and sand as it percolates  
11 down into the ground water aquifers.

12           In addition to the lack of protection of  
13 the water supply from adulterants in Vietnam, there  
14 is ample evidence of misuse of chemicals,  
15 antibiotics, and banned substances. I have heard  
16 Vietnamese scientists present survey data listing  
17 use of a wide range of chemicals that are not  
18 approved in the U.S. and have read a number of  
19 studies publishing similar information.

20           While visiting a farm in Vietnam, farmers  
21 denied using chemicals in spite of the presence of a  
22 shed storing them on the farm and shut the door when

1 I looked in.

2 Vietnamese fish are transported to  
3 processing plants in boats that are really floating  
4 cages, continuously exposing fish to chemicals and  
5 adulterants present in the river during transport.

6 I also observed dead fish taken into the  
7 plant and processed for sale. U.S. processors  
8 discard fish that are dead upon arrival and farms  
9 are not paid for such fish.

10 Temperatures inside the plant also were  
11 higher than allowed by U.S. standards.

12 In addition to adulteration of product,  
13 conference speakers have discussed the continued  
14 fraudulent mislabeling of Vietnamese basa, tra, and  
15 swai under many different names.

16 In China, I visited farms in Jiangsu and  
17 Hubei Provinces. Catfish are raised in surface  
18 waters from the Yangtze River conveyed through  
19 irrigation canals to ponds. The ponds in China are  
20 managed as static systems with yields similar to  
21 those in the U.S., but government subsidies for  
22 catfish production allow Chinese farmers to export

1 to the U.S. at low prices. My own cost analyses  
2 show that catfish production in China is not  
3 profitable without these subsidies.

4 In terms of food safety, the continuing  
5 discoveries of adulterated food products in China  
6 demonstrate the lack of an effective system to  
7 establish and maintain adequate food safety  
8 standards.

9 My own observations in China support this.  
10 I was invited to tour a factory that manufactured  
11 pharmaceuticals for livestock feeds. There were  
12 clearly labeled bottles of enrofloxacin and  
13 ciprofloxacin labeled for fish production. These  
14 are some of our antibiotics of last resort that we  
15 use to treat anthrax in the U.S. I asked for some  
16 samples of drugs sold to fish farmers and was given  
17 amoxicillin that we use for malaria, and  
18 nitrofurans, another antibiotic banned in the U.S.  
19 for use in livestock feeds.

20 The reason for zero tolerance of these  
21 antibiotics in livestock feeds is because their  
22 indiscriminate use will lead to development of

1 bacterial resistance in humans. This is already  
2 happening in Vietnam as documented by various  
3 scientific studies. There is no excuse for allowing  
4 such practices to also harm people in the United  
5 States.

6           The catfish inspection rule is a fairly  
7 simple issue in spite of the attempts to compound  
8 it. The U.S. is a world leader. As such, it should  
9 set the highest standards for food safety in the  
10 world, both to protect its own citizens and to set  
11 an example for the rest of the world. The sad  
12 reality is that we have lowered food safety  
13 standards in this country, especially for imports,  
14 than do many other countries as documented in the  
15 recent GAO report.

16           The catfish inspection rule sets a standard  
17 that will protect our food supply and then requires  
18 that imported product meet that same standard. Why  
19 would we hold our domestic industry to one standard  
20 while subjecting consumers to the risks from  
21 imported product that continues to be adulterated?

22           The broad definition is supported by sound

1 science. The official designation of catfish by the  
2 American Fisheries Society includes fish of both  
3 Pangasiidae and Ictaluridae families.

4 Our own marketing surveys at the University  
5 report continue confusion and fear of consumers over  
6 what catfish they are eating. This is exacerbated  
7 by continued fraud in mislabeling.

8 Based on my direct observations of farming  
9 operations overseas, my research of the scientific  
10 literature, and our own studies on seafood, I urge  
11 you to enact the broadest possible definition to  
12 include all catfish under the rule and to fully  
13 implement this program as quickly as possible.  
14 Thank you for this opportunity to speak here this  
15 morning.

16 MR. DiNAPOLI: Thank you, Carole.

17 Next is Carl Custer.

18 MR. CUSTER: My name is Carl Custer. I'm a  
19 food microbiologist. I worked for FSIS for 35 years  
20 at both bench and desk. I'm here to comment on the  
21 risk assessment and some aspects of the public  
22 health issues surrounding catfish.

1           For the public risk assessment, one simple,  
2 easy answer to the validity is that the August 2010  
3 version of the risk assessment was accepted by the  
4 *Journal of Food Protection* last November and was  
5 published in March of this year. As you know, the  
6 *Journal of Food Protection* is the premier food  
7 safety journal and it is a peer-reviewed journal.  
8 FSIS published a longer version of the risk  
9 assessment on their website in December of 2010.

10           In addition to it being accepted by a peer-  
11 reviewed journal, FSIS invited four experts to  
12 comment on that risk assessment, and those comments  
13 and the responses to their comments are up on the  
14 web and substantiate the validity of that risk  
15 assessment.

16           In addition, there were 25 organizations  
17 that contributed to the risk assessment, and they  
18 included universities, Federal and state agencies,  
19 and the American Association for the Advancement of  
20 Science.

21           The bad thing about having such a large  
22 committee writing a risk assessment is that some of

1 the boldness of the statements' conclusions will be  
2 watered down. As an example, and it was quoted  
3 previously, "However, limited information in the  
4 distribution of the microbial contamination and  
5 chemical residues in catfish limit our ability to  
6 make strong statements about the baseline."

7           There is always uncertainty in a risk  
8 assessment, which to the non-expert can be  
9 misinterpreted. A good risk assessment, such as  
10 this one, acknowledges and quantifies those  
11 uncertainties.

12           For example, in the risk assessment's  
13 summary, FSIS estimated, this risk assessment  
14 predicts that if the FSIS has a Siluriformes catfish  
15 inspection program fully operational within a two  
16 year timeframe, then between 230 and 2,077  
17 Salmonellosis cases might be prevented per year  
18 depending on whether the program is -- or 90 percent  
19 effective. If only Ictaluridae, the prediction is  
20 between 176 and 1,586 Salmonellosis cases prevented  
21 per year.

22           Now I'm going to switch to some of the

1 hazards about catfish and some of my opinions.

2           Catfish is a muscle food. It's different  
3 from the other things that FDA inspects. A muscle  
4 food, such as beef, poultry, and fish, have more  
5 hazards than fruits and vegetables that are  
6 inspected by FDA. Muscle foods are more perishable  
7 and more likely to contain zoonotic pathogens. The  
8 technical term for that is nasty bugs.

9           Additionally, residues are more likely to  
10 permeate the product unlike fruits and vegetables.  
11 Thus meat and poultry require more intensive  
12 regulatory oversight. The same I believe is true  
13 for fish and catfish and particularly aquaculture  
14 fish. FSIS employees and management are familiar  
15 with the risks of muscle foods and the issues with  
16 their regulatory oversight.

17           Catfish hazards, of course, start with the  
18 growers, and that's no different from other animal-  
19 based foods such as poultry and beef. Lack of  
20 toxins, pesticides, and pathogens are associated  
21 with the feed and growing environment.

22           Slaughter and processing can introduce new

1 hazards, but again like poultry, most of the hazards  
2 come in with the animals. Slaughter and processing  
3 should reduce those hazards.

4           The catfish risk assessment focused on  
5 *Salmonella* because of FSIS' experience and data  
6 showing that regulatory oversight can reduce  
7 *Salmonella* in poultry. *Salmonella* is also one of  
8 the leading food-borne zoonotic agents. The risk  
9 assessment addressed other bacterial pathogens and  
10 chemical hazards, but it focused on *Salmonella*.

11           In addition to *Salmonella*, there is the  
12 concern about chemical residues, and these were  
13 listed both in the GAO Report and the Economic  
14 Research Service Reports of January and April this  
15 year, and since they've already been mentioned, I  
16 will not mention it except for one thing about the  
17 GAO Report that the Consumers Union commented on,  
18 and that is the inspections involve FDA inspector  
19 reviewing records. They generally do not visit  
20 farms nor check the quality control or laboratories  
21 that analyze seafood.

22           Now, in my experience of years of auditing

1 domestic meat and poultry plants, paper reviews are  
2 inadequate. I have seen many well-written HACCP  
3 programs that on inspection of the operation were  
4 poorly implemented by undertrained or unsupervised  
5 workers.

6 Another factor, in the March 2011 *Journal*  
7 paper, FSIS cited three papers from the antibiotic  
8 resistant *Salmonella* in farm-raised catfish in  
9 China, Malaysia, and Thailand. Antibiotic resistant  
10 bacteria in farm-raised fish are the subject of a  
11 recently accepted paper by the American Society for  
12 Microbiology for publication in *Applied and*  
13 *Environmental Microbiology*. The paper is "Impact of  
14 Medicated Feed on the Development of Antimicrobial  
15 Resistant Bacteria in Integrated Pig, Fish Farms in  
16 Vietnam." The primary author is with the Veterinary  
17 Hygiene Department, National Institute of Veterinary  
18 Research, Hanoi, Vietnam.

19 A couple of sentences from the abstract and  
20 introduction support the need for better regulatory  
21 oversight of fish and fish products originating from  
22 this area. From the abstract: "Integrated

1 livestock fish aquaculture utilizes animal excreta,  
2 urine, and feed leftovers as pond fertilizers to  
3 enhance growth of plankton and other microorganisms  
4 eaten by the fish. However, antimicrobial-resistant  
5 bacteria may be transferred and develop in the pond  
6 due to selective pressure from antimicrobials  
7 present in animal feed, urine, and feces." That's  
8 Microecology 101.

9           From the introduction, two sentences, use  
10 of animal manure as fertilizers of aquaculture ponds  
11 is practiced widely in Southeast Asia. Livestock  
12 manure is disposed off into fishponds, and release  
13 of nutrients support the growth of photosynthetic  
14 organisms. Pigs are mainly fed commercial feed  
15 often containing antimicrobials added as growth  
16 promoters to improve feed conversion rate and to  
17 control and prevent diseases.

18           Manure, urine, and surplus feed are  
19 continuously discharged into the fish ponds. Now,  
20 this was written by a Vietnamese official.

21           MR. DiNAPOLI: Carl, I'm sorry. If you  
22 could wrap up.

1 MR. CUSTER: I am wrapping up right now.  
2 The information in this paper, in the April 2011 GAO  
3 Report, the January 2011 Economic Research Service  
4 Report offer additional support for FSIS inspection  
5 of catfish and catfish products.

6 In conclusion, the FSIS risk assessment is  
7 valid and supports catfish inspection coming under  
8 FSIS. Thank you.

9 MR. DiNAPOLI: Thank you, Carl.

10 Next is Jessica Wasserman from Wasserman  
11 and Associates.

12 MS. WASSERMAN: Good morning. I'm an  
13 attorney with over 20 years of experience in  
14 international trade law, and I'd just like to take  
15 this opportunity to show why the FSIS catfish rule  
16 is in accordance with international trade rules.

17 As you know, in the interagency process for  
18 this rule, FSIS has come under criticism for its  
19 risk assessment, specifically that the risk  
20 assessment would not meet WTO requirements and would  
21 make the U.S. vulnerable to a WTO dispute settlement  
22 challenge.

1           But stepping back and looking at the WTO  
2 Sanitary and Phytosanitary Agreement and the Codex,  
3 which the SPS incorporates, this is just not the  
4 case.

5           First FSIS conducted a science-based risk  
6 assessment as we have heard previously, and this is  
7 what is required by SPS. FSIS' risk assessment was  
8 science-based. FSIS is experienced in conducting  
9 risk assessments. It has a specialized division of  
10 risk assessment within its Office of Public Health  
11 Science (OPHS). The goal of OPHS is to provide  
12 expert scientific analysis, advice, data, and  
13 recommendations on all matters involving public  
14 health and science that are of concern to FSIS. The  
15 division has conducted hundreds of risk assessments,  
16 and a quick look the website shows that risk  
17 assessments for Avian Influenza, BSE, *E. coli*,  
18 *Salmonella*, *Listeria*, and more have been conducted  
19 over the years.

20           The risk assessment that FSIS conducted for  
21 this specific rule was a 106-page peer-reviewed risk  
22 assessment. It was drafted by dozens of experts as

1 has been reviewed in previous testimony.

2 I think it's safe to conclude that the FSIS  
3 risk assessment was science-based as required by  
4 international agreements.

5 There has been some criticism that's  
6 related to the uncertainty that's in the risk  
7 assessment, but this does not make the risk  
8 assessment invalid under WTO. International  
9 agreements recognize that there's some uncertainty  
10 always in risk assessment and that there's often not  
11 enough data, but that does not mean that a measure  
12 is not allowed. When there's uncertainty, the risk  
13 assessment needs to be transparent and quantify the  
14 uncertainty. Those are the requirements under SPS  
15 and Codex, and FSIS did those.

16 In addition, SPS specifically allowed for  
17 provisional measures if there is uncertainty.  
18 Article 5.7 of SPS states that in cases where  
19 relevant scientific evidence is insufficient, a  
20 member may provisionally adopt sanitary measures on  
21 the basis of available pertinent information, and  
22 that pertinent information can include measures

1 taken by other countries. So even if the risk  
2 assessment is uncertain, provisional measures are  
3 allowed under SPS.

4           And in this case, other countries have  
5 taken measures. The recent GAO Report, I won't go  
6 through that, pointed out some of these. SPS allows  
7 that members shall seek to obtain the additional  
8 information necessary for a more objective  
9 assessment of risk and review the sanitary measure  
10 accordingly within a reasonable period of time.

11           In other words, in this case, the sooner  
12 the FSIS implements the final rule and begins  
13 inspecting and collecting data, this would put it  
14 even more in accord with the SPS. The Codex also  
15 states that precaution is an inherent element of  
16 risk analysis. In other words, uncertainty does not  
17 invalidate a risk assessment either under U.S.  
18 practice or under international law as set out in  
19 SPS and Codex.

20           In fact, FSIS should be applauded for  
21 transparently and clearly presenting the uncertainty  
22 in its risk assessment. Under international

1 standards in Codex, transparency is a touchstone of  
2 risk assessment best practices.

3           The assumption that the U.S. would be  
4 challenged in the WTO over this risk assessment is  
5 highly speculative. It's mere speculation that the  
6 U.S. would be challenged in WTO for this risk  
7 assessment. WTO challenges are relatively rare.  
8 Challenges to measures to protect human health and  
9 life must meet a very high bar, and WTO even  
10 recognizes that members may introduce or maintain  
11 sanitary or phytosanitary measures which result in a  
12 higher level of sanitary protection than would be  
13 achieved by measures based on the relevant  
14 international standards and circumstances including  
15 provisional measures.

16           There is no precedent in which mere  
17 speculation about a WTO challenge trumped a U.S.  
18 regulation addressing human health and risk to human  
19 life.

20           In addition to the challenge of the risk  
21 assessment, equivalency as applied by FSIS has also  
22 been questioned in the interagency process, and

1 again we find that this is unfounded for the  
2 following reasons.

3           First, the mandate under the Federal Meat  
4 Inspection Act, which is the statute at issue that  
5 the reg is in accordance with, includes that FSIS  
6 conducts an equivalency determination. It would be  
7 a violation of the statute for FSIS to substitute a  
8 risk assessment for the equivalency determination,  
9 and nonetheless, FSIS did conduct a risk assessment.

10           Second, the equivalency is an established  
11 international practice. The EU reviews foreign  
12 government structures, food safety legislation, the  
13 foreign country's fish farm inspection program, and  
14 visits farms to ensure that imported seafood  
15 products come from countries with seafood safety  
16 systems equivalent to that of the EU.

17           In other words, the U.S. uses an approach,  
18 whether or not they call it equivalency, that is  
19 very similar to that used by FSIS. So equivalency  
20 is not unknown or unusual in international trade law  
21 practice. In fact, equivalency guidelines are even  
22 included in Codex.

1           So to answer the question as to why the  
2 risk assessment has become a football in the  
3 controversy over this regulation, with all due  
4 respect, FSIS is the science agency, and its science  
5 should not be second-guessed. Other agencies, such  
6 as USTR or OMB, don't have this expertise and should  
7 not interject politics into risk assessment.

8           In closing, we'd like to remind you of what  
9 is at stake here and quote from Codex. The Codex  
10 Alimentarius Commission has been supported in its  
11 work by the now universally accepted maxim that  
12 people have a right to expect their food to be safe,  
13 of good quality, and suitable for consumption.  
14 Food-borne illnesses are at best unpleasant. At  
15 worst, they can be fatal, but there are other  
16 consequences. Outbreaks of food-borne illness can  
17 damage trade and tourism and can lead to loss of  
18 earnings, unemployment, and litigation. Poor  
19 quality food can destroy the commercial credibility  
20 of suppliers, both nationally and internationally.

21           In other words, the FSIS rule is completely  
22 in accord with international agreements upon careful

1 review of the WTO, the SPS, and Codex. Thank you.

2 MR. DiNAPOLI: Thank you, Jessica.

3 Next is Joe Blair with the HACCP Consulting  
4 Group.

5 DR. BLAIR: I'm Dr. Joe Blair, Senior Vice  
6 President of the HACCP Consulting Group and here  
7 representing the Catfish Farmers of America.

8 I worked in a variety of supervisory and  
9 staff managerial positions in FSIS for 31 years.  
10 Four of those years were in the international  
11 programs. I'm now consulting in private practice.  
12 Considering FSIS and consulting combined, I have  
13 witnessed operations in more than 2,000 different  
14 plants in the U.S. and 10 other countries.

15 As a consultant, I worked extensively with  
16 Chile helping that country qualify for FSIS  
17 equivalency in meat and poultry. I have reviewed  
18 many farm plants on the FSIS equivalency list. I am  
19 convinced that virtually all of the plants which  
20 were actively exporting meat and/or poultry to the  
21 U.S. would compare favorably with the top 25 percent  
22 of U.S. meat and/or poultry plants.

1           This is a testament to the effectiveness of  
2 the FSIS equivalency program.

3           I've been following closely the debate  
4 about the food safety regulation in catfish, and  
5 I've become increasingly aware that many, and even  
6 some involved in the process, do not have a clear  
7 understanding of how the FSIS equivalency process  
8 operates and how it differs from the FDA regulations  
9 on imported seafood.

10           In order to understand the consequences of  
11 meeting the regulatory responsibility for catfish to  
12 FSIS, it is important to understand the FSIS  
13 equivalency process. My comments are in an effort  
14 to do this.

15           It also is recognized that FDA is in the  
16 process of implementing the new Food Safety  
17 Modernization Act and improvements in their system  
18 are expected. However, at this time, it is my view  
19 that the FSIS equivalency approach is the better one  
20 for regulating food safety.

21           FSIS is urged to implement an equivalent  
22 system for the importation of catfish similar to

1 what now exists for meat and poultry.

2           The equivalency system in FSIS is a  
3 government-to-government program designed to ensure  
4 that all plants designated as equivalent will  
5 operate under a continuous HACCP food safety system.

6           Some of the important elements of the  
7 equivalency process include a very detailed review  
8 of each country's legal authority and regulatory  
9 structure including laws, regulations, directives,  
10 and other instructions to the industry and/or  
11 inspection staff.

12           The inspection program is staffed with  
13 individuals who are paid from public or publicly  
14 managed funds. This is to avoid any conflict of  
15 interest or the appearance thereof.

16           The country has an effective enforcement  
17 system. The inspection program has competent,  
18 scientific, technical, and laboratory support  
19 utilizing international recognized methods and  
20 standards.

21           The review also includes one or more in-  
22 country FSIS audits involving visits to various

1 plants, laboratories, headquarters, and field  
2 offices. Based on favorable results of the in-  
3 country audit and review of regulatory documents  
4 submitted by the country, FSIS publishes a proposed  
5 regulation announcing their intent to approve the  
6 country to export to the U.S. After the appropriate  
7 comment period, FSIS may publish a final rule  
8 allowing the country to export to the U.S.

9           The initial process of establishing  
10 equivalency for a given country's system is quite  
11 detailed and may cover a span of several months to  
12 several years. Once equivalency is established,  
13 vital, periodic on-site assessments are conducted by  
14 FSIS personnel to ensure effective and consistent  
15 implementation, management, and oversight of the  
16 country's inspection program.

17           Each shipment of meat or poultry products  
18 to the U.S. is accompanied by a certificate issued  
19 by the regulatory agency certifying that the product  
20 has met all of the relevant equivalency standards.  
21 FSIS import inspectors review the documentation on  
22 all shipments of product received into the U.S. and

1 conducts a limited visual inspection of each lot  
2 offered for import.

3           A more detailed and systematic organoleptic  
4 examination with possible laboratory sampling is  
5 made of some lots. Enough lots of imported product  
6 are subjected to this more detailed examination in  
7 order to provide further verification of the proper  
8 operation of the exporting country's inspection  
9 system. This examination is driven by the automated  
10 import inspection system, and the intensity can  
11 increase or decrease dependent upon the level of  
12 compliance and/or risk.

13           Individual plants or the entire country's  
14 authorization to export to the U.S. can be halted if  
15 the equivalency standards are not met.

16           Equivalency is an established international  
17 practice required by the WTO. U.S. conducts  
18 equivalency reviews in other countries, and the U.S.  
19 is also subject to equivalency reviews by other  
20 countries.

21           The recent GAO Report has been quoted quite  
22 frequently already today, and I'll not go back and

1 repeat some of that, but the problems found by GAO  
2 have been adequately documented.

3           Consequently, because of the problems  
4 outlined by GAO, seafood containing residues of  
5 drugs not approved for use in the U.S. may be  
6 entering U.S. commerce. Further, the FDA's sampling  
7 program is ineffectively implemented.

8           I agree with the comments made by the two  
9 Senators and two Congressmen this morning, and it  
10 gives credence to the argument that the Federal  
11 government needs to do more to protect American  
12 consumers.

13           As a former Government employee, and now a  
14 private consultant in the area of international food  
15 safety regulation, I agree with both the Senators  
16 and Congressmen, and I'm dismayed to see the delay  
17 and confusion surrounding implementation of  
18 equivalence for catfish.

19           From the perspective of food safety, this  
20 is not an overly complex issue. It is time to get  
21 with it.

22           Thank you for the opportunity of offering

1 input to this important topic.

2 MR. DiNAPOLI: Thank you, Joe.

3 Next is Mitt Walker from the Alabama  
4 Farmers Federation.

5 MR. WALKER: Good morning. My name is Mitt  
6 Walker. I serve as Director of the Alabama Catfish  
7 Producers, which is a division of the Alabama  
8 Farmers Federation. I want to thank you for the  
9 opportunity to provide our comments relative to the  
10 proposed rule.

11 The Alabama Catfish Producers represents  
12 Alabama's 200 catfish farmers who produce more than  
13 130 million pounds of catfish annually. The catfish  
14 industry has an economic impact of nearly \$500  
15 million on the State of Alabama annually, with much  
16 of that impact occurring in the state's most  
17 economically depressed area, the Black Belt, located  
18 in West Central Alabama.

19 This organization is providing comments  
20 based first and foremost in the interest of  
21 protecting the American consumer. The domestic  
22 catfish industry takes great pride in providing a

1 safe, wholesome, and nutritious product. We welcome  
2 USDA inspection as a means of further bolstering the  
3 safety of domestically produced catfish. However,  
4 it's equally important to require these same  
5 standards for foreign producers and processors, all  
6 in the effort to provide the consuming public a  
7 greater level of safety from food-borne illnesses  
8 and exposure to contaminants.

9           American catfish farmers spent the last  
10 half century developing an industry through sound  
11 and sustainable farming practices and investing  
12 millions upon millions of dollars in marketing and  
13 infrastructure.

14           We continue to be concerned that imported  
15 catfish may cause a large-scale food-borne illness  
16 outbreak causing our domestic industry to crumble  
17 due to an unfairly tarnished reputation because of  
18 the lack of enforcement of food safety standards for  
19 imported catfish products.

20           The proposed rule refers to antibiotic and  
21 drug residues being within acceptable tolerances.  
22 However, residues of carcinogens and antibiotics

1 that are prohibited continue to be found in imported  
2 catfish. We believe the rule should specifically  
3 include language specifying zero tolerance for  
4 malachite green, crystal violet, enrofloxacin,  
5 ciprofloxacin, and other antimicrobials that are  
6 prohibited for use in the United States and should  
7 include language regarding disposition of fish and  
8 lots of fish in which residues of these substances  
9 or evidence of their use are found.

10           The Alabama Catfish Producers believe the  
11 definition of catfish in the context of food safety  
12 must be consistent with the approach to product  
13 definition for other animal groups regulated by  
14 FSIS. For example, poultry is defined broadly as  
15 any domesticated fowl and includes, among other  
16 chickens, turkeys, geese, and pigeons. Broadly  
17 defining a product group is essential for the  
18 proposed rule to be effective.

19           Consumers purchasing any product assumed to  
20 be catfish should have faith that the product safety  
21 is assured under the Act.

22           Therefore, to maintain consistency of

1 approach in defining product groups, all fish in the  
2 order Siluriformes should be considered as the  
3 amenable product of inspection. Broadly defining  
4 catfish as members of the order Siluriformes is  
5 consistent with the current science of fish taxonomy  
6 as you've heard earlier today.

7           As a result of extensive mislabeling of  
8 seafood and the resultant consumer confusion over  
9 product identity at retail, the goal of the proposed  
10 rule can only be realized by defining catfish in a  
11 way that prevents in all cases the possibility of  
12 consequences to human health related to food safety.  
13 When consumers purchase any product labeled as  
14 catfish, whether labeled correctly or fraudulently,  
15 although there is an expectation that the product is  
16 catfish, accordingly, the intent of the rule is  
17 possible only when catfish is defined using the same  
18 broad approach for other animals regulated by FSIS.  
19 That is, catfish should be defined only as a member  
20 of the order Siluriformes.

21           By broadly defining catfish, all catfish in  
22 commerce in the United States will be subject to an

1 equivalent assurance of quality and safety,  
2 providing maximum protection of the health and  
3 welfare of consumers.

4           Domestic and foreign entities should be  
5 subjected to the same timeframe for implementation  
6 of the rule as well, and this timeframe should be as  
7 short as possible in the interest of public safety.  
8 The total phase 3, phase 4, should be no more than  
9 one year. FSIS has been planning to implement this  
10 program for more than three years. So ample time  
11 has been provided for affected parties to prepare  
12 for rule implementation.

13           We appreciate the opportunity to comment on  
14 this long-awaited rule. It's our sincere hope that  
15 the safety of the American consumer will not be  
16 sacrificed to protect trade interest as the final  
17 rule is written. It is imperative that a broad  
18 definition be applied to accomplish the Food Safety  
19 and Inspection Service's mission of ensuring that  
20 the nation's commercial supply of meat, poultry, and  
21 egg products is safe, wholesome, and correctly  
22 labeled and packaged. Thank you for your attention.

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1 MR. DiNAPOLI: Thank you, Mitt.

2 Next is Roger Barlow with The Catfish  
3 Institute.

4 He's not here.

5 Patty Lovera from Food and Water Watch.

6 MS. LOVERA: Good morning. My name is  
7 Patty Lovera, and I work with a consumer group  
8 called Food and Water Watch. We're a non-profit  
9 consumer advocacy organization based here in D.C.

10 So I'm here today to say that we're  
11 supportive of USDA's FSIS developing this catfish  
12 inspection program for many of the reasons that  
13 we've heard about this morning. We think that FSIS  
14 has an inspection program with a lot more rigor that  
15 can be much more protective of consumers than the  
16 current way that catfish and other fish are being  
17 dealt with by FDA and NOAA.

18 The import issue is especially important.  
19 Consumers are increasingly becoming aware of where  
20 their food comes from, and the news that they're  
21 getting about imports isn't good, and as they learn  
22 more and as they read more headlines, they're

1 looking for more protection than the current system  
2 is giving them, which is why we think it's important  
3 to get this rule underway and get this inspection  
4 program going.

5           We've heard a lot about the GAO Report.  
6 We, too, are concerned about what that revealed  
7 about FDA's program, and for years, we've been  
8 concerned about FDA's lack of testing and lack of  
9 inspection, the low rates that they achieve for  
10 imported food.

11           So we're very interested in this inspection  
12 program moving forward, and we're very interested in  
13 making sure that the same standards are being  
14 applied for domestic production or imports.

15           So as far as the proposed rule that we're  
16 commenting on, we support the broader definition for  
17 catfish, using the order Siluriformes, to make sure  
18 that what consumers run into in the marketplace, if  
19 they run into it being marketed as catfish, we've  
20 heard a lot about that there is mislabeling. There  
21 has been a lot of concerns about the way that word  
22 is used. We think the most protective way to deal

1 with that is to go with the broader definition so  
2 that consumers have some assurance that those  
3 products have been inspected by the USDA.

4 I know there's been years of back and forth  
5 about this, but that back and forth and these  
6 definitional fights are coming because we do have a  
7 lot of chaos in the marketplace when it comes to  
8 this fish. There has been a lot of mislabeling. So  
9 we think one way to start to clear through that  
10 process is to get the broad definition that gets  
11 more product inspected no matter where it's from.

12 So we've heard a lot about a lot of  
13 different pieces of the rule, and we'll offer some  
14 more specific comments in writing about the specific  
15 questions that were asked about post-mortem  
16 procedures and how to deal with wild-caught fish. I  
17 will say that we think it's important that that  
18 identity of wild-caught catfish be maintained  
19 because we're all so very interested in country of  
20 origin labeling requirements that require that fish  
21 disclose whether they are farm-raised or wild-  
22 caught. We supported the rules and still do for a

1 long time. We think that's an important distinction  
2 for consumers. So we'll submit more in writing on  
3 that particular piece.

4           But the final thing I'll raise this morning  
5 is just we've heard a lot about the WTO. I think  
6 this is becoming a sad routine that we go through  
7 when we talk about imported food, that we see  
8 threats of a WTO challenge being waved around before  
9 anything even happens, but for consumers and for our  
10 members and supporters, they are looking to their  
11 elected officials in this country, which is the  
12 Congress, to protect them from unsafe food, to set  
13 up protective programs, and that's what Congress  
14 started to do in the 2008 Farm Bill.

15           So when Congress said to set up this  
16 program, that's what USDA has to go by, and we think  
17 that the way to do that is to make sure it's fairly  
18 applied, and it's done quickly, and the way to make  
19 sure that it's fairly applied is to use that broader  
20 definition of catfish so more product is subject to  
21 inspection. Thank you.

22           MR. DiNAPOLI: Thank you, Patty.

1           Next is Art Miller.

2           DR. MILLER: Good morning. My name is Art  
3 Miller with Exponent. I'm a principal scientist  
4 there. The Catfish Farmers of America retained my  
5 firm to evaluate risks associated with consumption  
6 of catfish as part of their food safety system.

7           Based upon its review and risk profile of  
8 current domestic and exported practices in catfish  
9 aquaculture and processing, Exponent concludes the  
10 following: Regarding overall federal regulation and  
11 inspection, first, freshwater aquaculture requires  
12 an inspection and food safety system that differs  
13 from marine wild-caught seafood programs because  
14 hazards, their sources and interventions differ  
15 significantly.

16           Second, consumers cannot differentiate, as  
17 it's been stated earlier, among various catfish  
18 species. Therefore, a broader taxonomic definition  
19 of catfish to include order Siluriformes fin fish  
20 will provide the greatest level of consumer  
21 protection, by including products with similar  
22 characteristics and potential hazards.

1           Regarding hazard exposure, major hazards of  
2 concern for aquaculture fin fish include  
3 environmental chemicals, antimicrobial drug  
4 residues, and pathogenic microorganisms. These may  
5 arise during growing or processing.

6           Chemical contaminants have been found more  
7 frequently in imported catfish, specifically  
8 persistent organic pollutants such as DDT, PCBs, and  
9 organochlorine pesticides.

10           Antimicrobials. FDA surveillance testing  
11 shows the presence of illegal antimicrobials in  
12 imported catfish. Therapeutic or prophylactic use  
13 of such agents can maintain fish health in  
14 contaminated water and crowded ponds and cages.  
15 Antimicrobials commonly present in imported catfish  
16 include malachite green and gentian violet, both  
17 carcinogens and fluoroquinolones, a class of human  
18 antibiotics which authorities worldwide consider at  
19 risk of losing its effectiveness. All are illegal  
20 for use in aquaculture in the U.S., and Exponent has  
21 found no instance where FDA found an illegal drug in  
22 domestic aquaculture fin fish.

1           *Salmonella* is the most significant acute  
2 hazard associated with catfish and the second most  
3 common violation found in imported fishery and  
4 seafood products. This microbial hazard has been  
5 detected on both domestic and imported products.  
6 Comparative surveys find it more frequently on  
7 imported products, however.

8           Regarding interventions, minimizing  
9 consumer exposure must focus on prevention of  
10 contamination across the entire food chain since  
11 typically there is no post-harvest treatment of  
12 fresh or frozen fish to eliminate hazards. The  
13 requirement for a contiguous producer, processor,  
14 distributor, food safety systems, across the entire  
15 supply and distribution chain is axiomatic, but  
16 Exponent envisions the following verification  
17 entities as additional safeguards for aquaculture  
18 fin fish.

19           First, the Global Food Safety Initiative is  
20 a non-governmental program promoted by retailers to  
21 require food producers to meet stringent  
22 requirements for control and production in achieving

1 a high level of safety. Requirement of  
2 participation in this program would require a  
3 greater verification of the safety of aquaculture  
4 products.

5           Second, FSIS' inspection program directs  
6 greater regulatory resources than does FDA to define  
7 performance standards for microbial hazards, to  
8 conduct active surveillance, and to evaluate each  
9 establishment's progress towards achieving  
10 acceptable performance levels.

11           Safety cannot be inspected into a product  
12 at a domestic processing establishment or at the  
13 port of entry. Rather, the combination of effective  
14 federal and private sector controls will minimize  
15 hazards from entering all points of the food chain,  
16 thus ensuring that Americans continue to receive  
17 safe and nutritious foods.

18           Thank you for your time.

19           MR. DiNAPOLI: Thank you, Art. I believe  
20 that's the last of our public commenters.

21           We thank you for coming today. We  
22 appreciate your time and your comments. Additional

1 information can be found on the FSIS website, and  
2 the transcript from today's meeting will be  
3 available on our website in approximately 30 days.

4           Again, the second public meeting will be  
5 this Thursday in Stoneville, Mississippi, May 26th,  
6 and again, the comment period closes on June 24th.

7           We appreciate you coming. Have a great  
8 day.

9           (Whereupon, at 11:18 a.m., the meeting in  
10 the above-entitled matter was adjourned.)

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C-E-R-T-I-F-I-C-A-T-E

This is to certify that the attached proceedings in

the matter of:

UNITED STATES DEPARTMENT OF AGRICULTURE

PROPOSED RULE FOR MANDATORY INSPECTION

OF CATFISH AND CATFISH PRODUCTS

Washington, D.C.

May 24, 2011

were held as herein appears, and that this is the  
original transcription thereof for the files of the  
United States Department of Agriculture, Food Safety  
and Inspection Service.

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VICTOR LINDSAY

Court Reporter