October 7, 2014

The Honorable Shaun Donovan
Director
Office of Management and Budget
725 17th Street, N.W.
Washington, D.C. 20503

Transmitted via facsimile: (202) 395-3888

Dear Director Donovan:

We are writing to request that you expedite your review of the U.S. Department of Agriculture's (USDA) draft final rule on the inspection of catfish and catfish products. More than six years have passed since the Food, Conservation, and Energy Act of 2008 (Farm Bill) assigned regulatory responsibility for catfish to the USDA's Food Safety and Inspection Service (FSIS). It is vital for implementation to begin as soon as possible to ensure that catfish products distributed in the United States are safe, wholesome, and free of unapproved drugs and potentially harmful contaminants.

There is a strong logical basis for this regulatory shift. In 2013, Americans consumed more than 305 million pounds of catfish. Approximately 78 percent was imported, with about 95 percent of this amount coming from Vietnam. According to the Food and Drug Administration (FDA), aquaculture producers face unique production problems not encountered in wild-caught fisheries, and often rely on chemicals and new animal drugs to overcome issues associated with high density farming and poor on-farm hygiene. A wide range of chemicals is used to control or prevent specific diseases, to improve water quality conditions, and to manage pest or stress problems. Relatively few new animal drugs have been approved for aquaculture in the U.S. (As of 2011, the FDA had approved 7, compared to 32 approved for use in Vietnam). As a result, aquaculture growers, particularly in developing countries, may use unapproved new animal drugs or general purpose chemicals that are not permitted for use in an attempt to prevent or control fungal, viral, or bacterial problems.

There is clear scientific evidence that the residues of these chemicals used in aquaculture can remain in the edible portion of the fish through harvesting, processing, and consumption. The FDA has determined that the potential immediate and long-range human health consequences may include hypersensitivity reactions, toxicity-related reactions, potential carcinogenic and mutagenic effects, and increasing prevalence of antibiotic-resistant microorganisms. Despite these known risks to public safety, the FDA's performance with regard to testing imported catfish for residues of unapproved chemicals has been insufficient to ensure that the catfish consumers are eating is safe and not adulterated.

In a 2011 report, the Government Accountability Office (GAO) found that the FDA imported seafood sampling program, which supplements its oversight program, was limited. In particular, the sampling program did not generally test for drugs that some countries and the European Union (EU) have approved for use in aquaculture, despite the fact that many of those drugs remain unapproved in the United States. Moreover, only a small share of imported seafood is tested. For example, GAO determined that in fiscal year 2009, FDA tested about 0.1 percent of all imported seafood products for drug residues. Specifically regarding catfish during fiscal years 2006 through 2009, GAO found that the FDA did not analyze a single catfish sample for nitrofurans, which is a class of antibacterial drug commonly used in foreign aquaculture that has been banned by the FDA because of its carcinogenic effects and potential risk to public health.

The need for better catfish oversight is clear, and moving responsibility under the U.S. Department of Agriculture's Food Safety and Inspection Service (FSIS) provides the best opportunity for improvement. Based on requirements of the Federal Meat Inspection Act (FMIA), FSIS places a greater responsibility on the foreign countries that want to export products derived from the list of amenable species under the Act, which now includes catfish. More specifically, foreign countries wishing to export such products to the United States must prove that their systems for food safety are at least equivalent to that of the United States. In addition, FSIS conducts drug residue sampling, microbiological sampling, packaging and labeling checks, among other things at U.S. ports of entry to ensure foreign food safety systems are operating effectively. While FDA generally tests about .1 percent of seafood imports, FSIS inspects every shipment of meat and poultry that enters the country.

According to its proposed rule, FSIS intends to apply to catfish and catfish products provisions of the FMIA that currently apply to meat, poultry and egg products. Therefore, domestic catfish processing plants would be subject to continuous inspection by FSIS personnel; foreign countries wishing to export catfish to the U.S. would have to obtain equivalence agreements with FSIS; and imported catfish shipments would be subject to the various drug sampling and labeling checks at U.S. ports of entry referenced above. Although FSIS chose to focus its catfish risk assessment on salmonella as the primary food safety hazard in catfish, it is important to note that FSIS has also conducted a quantitative risk assessment on the potential public health outcomes associated with chemical contaminants. We consider the findings, which were not specifically mentioned in the proposed rule, to be deeply concerning. For instance, when FSIS assessed the impact of applying its new program compared to the current FDA regulatory regime, it would result in the reduction of roughly 175,000 cancers, 91,800,000 exposures to antimicrobials, and 23,280,000 exposures to heavy metal that constitute a health risk. The volume of catfish imports has more than doubled since the time this assessment was conducted, therefore the potential health impact of applying USDA catfish inspection is far greater today.

Despite the health risks consumers are currently facing, we continue to hear arguments against USDA catfish inspection which we simply find to be false or misleading at best. With regard to concerns about the potential burden it would place on U.S. seafood companies, the proposed rule specifically states that FSIS inspectors will only be in domestic catfish processing facilities – not seafood import facilities, distribution facilities, wholesale or retail establishments. Initial estimates by the USDA indicated that only 22 plants across the entire

United States would be in the domestic inspection program, and the program would only employ 45 domestic inspectors altogether. Therefore, it would be physically impossible for FSIS inspectors to somehow create new and additional burdens for the thousands of U.S. seafood establishments. It is also important to keep in mind that the domestic catfish industry generally supports USDA's proposed regulations.

Concerns have also been expressed about potential duplication of federal responsibilities and inefficient use of tax dollars. However, we find there to be no logical explanation for such concerns. A provision in the Agricultural Act of 2014 requires FSIS and the FDA to develop a Memorandum of Understanding (MOU) to enhance interagency coordination and clarify jurisdictional issues in order to avoid duplication. FSIS and FDA completed the MOU and believe it will ensure that inspection oversight will be non-duplicative, and that requirements for domestic and foreign catfish products will be met in accordance with the intent of Congress. Given the total number of catfish processors in the U.S. and the existing MOU between FSIS and FDA, there is no justification for the argument that American seafood companies would have two different inspectors in their facilities at the same time.

The regulatory shift to FSIS should alleviate pressure on the FDA and allow it to better execute its regulatory responsibilities for all other seafood. It is quite obvious that the amount FDA spends annually (estimated to be around $700,000) on catfish is insufficient to ensure the 300 million-plus pounds consumed each year is safe. Thus freeing up FDA resources by moving catfish inspection to an agency more equipped to handle it is a win for all parties. Congress did not intend for the catfish mandate to result in additional spending, and FSIS is expected to fulfil its new responsibilities within the discretionary spending levels annually approved by Congress. Moreover, the FSIS program could actually lead to a reduction in federal spending when you consider the health care savings associated with preventing 175,000 lifetime cancers. Any federal resources that have been spent thus far in setting up the program should be reflective of the Department's management of funds rather than the program's ability to enhance consumer safety.

Regarding the potential impact on international trade, FSIS already imposes equivalence requirements on all foreign countries currently exporting meat, poultry and egg products to the U.S. In addition, food safety equivalence is a concept that was introduced by the World Trade Organization's (WTO) Agreement of the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The agreement actually regards equivalence as a way to encourage the development of international food safety standards for harmonization between members and the facilitation of trade. Furthermore, the SPS Agreement explicitly affirms the right of each government to choose its level of protection; including a 'zero risk' level if it so chooses.

We do not think it is unfair to ask of other countries to comply with safety standards that are equivalent to what is required of our domestic producers, and we disagree with the argument that such requirements were intended or will result in unfair trade restrictions. The European Union, which is the world's largest importer of catfish, already applies similar sanitary measures for equivalence, and has existing arrangements with major catfish exporters such as Vietnam and Thailand. Given the fact that Vietnam currently complies with the EU's imported seafood requirements, which GAO has found to be far more rigorous than the practices currently carried out by the FDA, we feel that Vietnam should be able to come into FSIS compliance with relative ease. However, until FSIS implements those new requirements, U.S. consumers will continue to

be subject to inferior products. For instance, a 2011 GAO report on seafood safety revealed that a 2008 inspection of Vietnam's drug residues control program indicated that all seafood products found to be containing drugs unapproved by the EU were to be diverted to another market. Since the U.S. is one of Vietnam's top catfish export markets, second only to the EU, it is quite possible that those shipments are being diverted to the U.S.

In closing, there is ample information to suggest that USDA catfish inspection has the potential to significantly improve consumer safety, without negatively impacting U.S. seafood companies, international trade, or the regulatory responsibilities of federal agencies. With respect to catfish and catfish products, the consumer is not in a position to know the conditions under which catfish are raised or processed, and they are unable to fully evaluate the potential hazards posed by the products they consume. American consumers deserve a higher degree of trust in what they are eating, but USDA has yet to meet its obligations under federal law. We would greatly appreciate your willingness to expedite the review of USDA's draft final rule on catfish.

Should you have any questions regarding our letter, please contact Tony Corbo at Food & Water Watch at (202) 683-2449.

Thank you for your consideration.

Sincerely,

Center for Foodborne Illness Research & Prevention

Consumer Federation of America

Food & Water Watch

National Consumers League

United Food & Commercial Workers International Union