June 24, 2011

Docket Clerk
U.S. Department of Agriculture
FSIS, Room 2-2127
George Washington Carver Center
5601 Sunnyside Ave.
Beltsville, MD 20705

Re: Docket No. FSIS-2008-0031; Mandatory Inspection of Catfish and Catfish Products; 76 *Fed. Reg.* 10434 (Feb. 24, 2011)

Dear Sir/Madam:

The American Meat Institute (AMI) is the nation's oldest and largest meat packing and processing industry trade association. AMI members slaughter and process more than 90 percent of the nation's beef, pork, lamb, and veal and nearly 75 percent of the turkey produced in the United States. Exports are a key component to growth and profitability in the meat industry and for that reason AMI members and the meat industry have a vested interest in ensuring that any inspection program implemented by the Food Safety and Inspection Service (FSIS or the agency) does not adversely affect the meat industry's export opportunities.

The rule under consideration could be viewed by some nations as an unjustified barrier affecting their exports of catfish to the U.S. Specifically, the proposed rule and its preamble raise the specter of retaliation by at least two important and growing export markets for meat and poultry products, China and Vietnam. Driven by these concerns, AMI submits the following comments encouraging the agency to craft the rule such that it does not trigger retaliatory measures by important trading partners.

The Scope of the Catfish Inspection Program Should be Narrowly Construed to Avoid Retaliation

The 2008 Farm Bill left to the discretion of the Secretary of Agriculture how "catfish" is defined for purposes of the new inspection program. The proposed rule provides a definition of "catfish" that largely mirrors the definition of meat in existing regulations. The proposal, however, does not articulate how broadly or narrowly FSIS interprets the meaning of the word "catfish," which in turn has a

direct bearing on the scope of the FSIS inspection program and whether some companies will be subject to the program. Rather FSIS outlines two options the agency is considering and invites comment on those options.

Specifically, in the preamble the agency offers that, after a review of the legislative and regulatory history and the scientific taxonomic classification system, it has identified two options for defining "catfish." The agency could follow the definition adopted by Congress in the 2002 Farm Bill that defines "catfish" as "only fish of the Ictaluridae family for marketing and labeling purposes under the FD&C Act," which is the definition used by the Food and Drug Administration in its seafood program.[1] This approach would narrow the scope and exclude, for example, fish from the family Pangasiidae, which is produced in Vietnam and in several other countries.

FSIS identified the other option to be a definition based on its review of the taxonomy and applicable scientific order, which would "include all fish of the order Siluriformes."[2] This approach would expand significantly the scope of the fish deemed to be catfish for purposes of inspection.

AMI supports the first option for several reasons. First, given AMI's concerns that this program will be viewed as a non-tariff trade barrier by countries such as China and Vietnam, the more limited definition could lessen the potentially adverse impact in the event one or more countries seek to retaliate in some fashion.

Second, the more narrow definition would strengthen the U.S. position that the program is not a non-tariff trade barrier. Congress decided in the 2002 Farm Bill that Pangasiidae could not be labeled as "catfish" a labeling prohibition that remains in effect because the Congress has not repealed it. FSIS adoption of the more narrow application in option one is consistent with that Congressional determination. Moreover, including only fish from the Ictaluridae family would help demonstrate that the United States government is consistent in its view as to what are "catfish" and that establishing this program was not intended to serve as a non-tariff trade barrier.

Conversely, expanding the inspection program's scope beyond the Ictaluridae family to include, for example, Pangasiidae as "catfish" for purposes of this inspection program would strengthen the argument that other countries could make that this program is nothing more than a barrier to trade because, although the U.S. would consider Pangasiidae to be catfish and require it to be inspected both domestically and abroad, the Pangasiidae could not bear labeling identifying it as

[1] 76 *Fed. Reg.* at 10436.
[2] *Id.* FSIS recognized that this is the definition used by FDA before the 2002 Farm Bill and would be a definition based on taxonomy.

catfish when offered for sale in the U.S.[3] Anyone, including Vietnam and China, could legitimately question how the U.S. could justify such an intellectually inconsistent position, as well as a position that could be viewed as contrary to the national treatment provision, the most-favored nation provision, and possibly other provisions of the General Agreement on Tariffs and Trade and the WTO Agreement on Technical Barriers to Trade (TBT).

Adoption of the position that catfish includes fish only from the Ictaluridae family does not threaten public health or create added safety problems. The preamble states that the Food and Drug Administration and the Centers for Disease Control and Prevention "consider commercially raised catfish to be a low risk food."[4] Pangasiidae and other fish would remain part of the FDA Seafood Inspection Program and still be subject to the same safeguards as all other fish under the seafood HACCP regulations and other requirements of the Federal Food, Drug, and Cosmetic Act.[5]

Because the Risk Assessment is Flawed and Acting on it may be Inconsistent with WTO Principles the Rule Should not Move Forward without Additional Risk Analyses

The United States has often opposed foreign sanitary and phytosanitary measures that have the effect of limiting imports of U.S. farm and food products. Indeed, the WTO Uruguay Round agreement on sanitary and phytosanitary measures (SPS) establishes important rules and disciplines on the use of SPS measures so that they may not be used as disguised import restrictions.

In that regard, the SPS Agreement contains a number of provisions that may be applicable in the case of catfish. Fundamentally, WTO member countries *"have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided that such measures are not inconsistent with the provisions of this Agreement.*"[6] Such provisions include:

Article 5.1 -- *Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.*

[3] This paradox raises a question as to whether such a circumstance would be inconsistent with the Federal Meat Inspection Act's prohibition on false and misleading labeling and the agency's duty to prevent such occurrences. See 21 U.S.C. 607 and 610.
[4] 76 *Fed. Reg*. at 10438.
[5] Indeed, the preamble discusses the regulatory regimen applicable to imported fish and fish products. 76 *Fed. Reg*. at 10437.
[6] Article 2.1 of the SPS Agreement

Unfortunately, the risk assessment conducted by FSIS appears to fall well short of the requirements set by the SPS agreement. Indeed, FSIS raises doubt about the adequacy of its risk assessment based on the following statements made by the agency.

- "However, limited information on the distribution of microbial contamination and chemical residues on catfish limit our ability to make strong statements about the baseline risk. Furthermore, the lack of experience with implementing continuous inspection programs in the context of aquaculture makes estimating the impact of such a program on risk difficult."[7]
- "There is substantial uncertainty regarding the actual effectiveness of an FSIS catfish inspection program."[8]
- "Sparse information limits [USDA's] ability to make strong statements about the baseline risk."[9]
- "The true effectiveness of FSIS inspection for reducing catfish-associated human illnesses is unknown."[10]
- "…the rate at which FSIS inspection will achieve its ultimate reductions is unknown."[11]

These statements lead to the conclusion that the risk assessment conducted by FSIS is of dubious value because of the dearth of available data. Indeed, because of data limitations, the risk assessment focused on exposure to *Salmonella* not because of a known problem associated with that pathogen and catfish, but rather because "…a broad hazard identification study identified *Salmonella* as a potential concern in catfish."[12] (Emphasis added) Indeed, *Salmonella* was chosen as the proxy for all pathogens because, according to the study, "…the general burden of illness from this pathogen in the U.S. remains a concern and there is evidence that at least one outbreak of human salmonellosis may have been related to catfish consumption."[13] (Emphasis added)

In short, the risk assessors had virtually no documented evidence of a pathogen-related problem associated with catfish on which to base their risk analysis but because a risk assessment is required by law, the risk assessors chose to use poultry as the proxy in the analysis of the possible effectiveness of an FSIS continuous inspection program for *Salmonella* control. Such an approach does not

[7] *DRAFT Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish*, p. 9, December 2010, http://www.fsis.usda.gov/PDF/Catfish_Risk_Assess_Dec2010.pdf
[8] *Id*. at 11
[9] 76 *Fed. Reg*. at 10436
[10] *DRAFT Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish*, p. 40, December 2010, http://www.fsis.usda.gov/PDF/Catfish_Risk_Assess_Dec2010.pdf
[11] *Id*.
[12] 76 *Fed. Reg*. at 10440
[13] *Id*.

satisfy the provisions of Article 5.1 above and likely will not withstand scrutiny if this rule is challenged in a WTO setting. For that reason, the agency should not move forward with a final rule until a complete and defensible risk assessment is completed. To do otherwise invites a challenge and the likely retaliation that would stem from that challenge.

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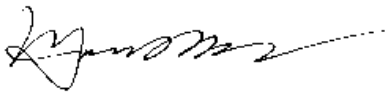
For the foregoing reasons AMI respectfully suggests that the agency not pursue a final rule until a more comprehensive risk assessment is completed. Moreover, in any final rule the agency should limit the scope of the inspection program to catfish from the Ictaluridae family. Such an approach is consistent with earlier congressional action and will help limit the threats of retaliation from other countries. If you have any questions regarding these comments or anything else regarding this matter, please contact me at 202 587 4229 or mdopp@meatami.com.

Respectfully submitted,



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