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PUBLIC INTEREST COMMENTS

BRIDGING THE GAP BETWEEN ACADEMIC IDEAS AND REAL WORLD PROBLEMS

PUBLIC INTEREST COMMENT ON *MANDATORY INSPECTION OF CATFISH AND CATFISH PRODUCTS*

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Richard Wiliams
Director of Policy Research

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The Regulatory Studies Program (RSP) of the Mercatus Center at George Mason University is dedicated to advancing knowledge of the impact of regulation on society. As part of its mission, RSP conducts careful and independent analyses employing contemporary economic scholarship to assess rulemaking proposals from the perspective of the public interest. Thus, this comment in response to the Food Safety and Inspection Services (FSIS) of the U.S. Department of Agriculture (USDA) Notice of Proposed Rulemaking does not represent the views of any particular affected party or special interest group but is designed to assist the USDA as it seeks to address issues associated with the regulation of catfish.

Based on a requirement arising from the Food, Conservation, and Energy Act (Farm Bill) of 2008, FSIS is proposing to define "catfish" for the purposes of continuous inspection under the Federal Meat Inspection Act (FMIA). This rule, henceforth referred to as "the catfish rule," has been ascertained to be an economically significant rule, with benefits or costs greater than $100 million in any year. This comment is intended to provide an in-depth evaluation of the both the analysis and the rule beyond the score provided by the Mercatus Regulatory Report Card (attached as Appendix B to this comment).

The Mercatus Regulatory Report Card, henceforth referred to as "the Report Card," is a tool that evaluates the quality and use of RIAs of proposed economically significant rulemakings published by federal agencies since January 2008. The Report Card identifies key issues and best practices in the regulatory process and highlights issues with specific regulations. It evaluates the quality of regulatory analysis and its use in decisions, but does not evaluate whether the proposed rule is economically efficient, fair, or otherwise good public policy. The Report Card assesses whether the RIA and preamble to the proposed rule make a reasonable effort to cover the major elements of regulatory analysis, but does not evaluate the quality of the underlying science used by the agency. However, for public interest comments such as this one, an examination will be made of the depth and the quality of the underlying science and the regulatory decision.

The catfish rule received a Report Card score of 25 out of 60 or, on a scale of 100, a grade of 42.[1] The best analysis thus far evaluated in the Mercatus Center's Report Card project received a score of 48 out of 60 possible points; the catfish regulation scores well below this level. This suggests that the analysis is done quite poorly in terms of the quality and use.

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[1] To see how scoring works, see the Mercatus Center at George Mason University website: http://mercatus.org/content/regulatory-report-card-faq#howdoestheregulatoryreportcardwork.

The comments in this rule will generally follow the outline of the report card, with substantial additional observations and analysis.

I. OPENESS

1. How easily were the RIA, the proposed rule, and any supplementary materials found online?
2. How verifiable are the data used in the analysis?
3. How verifiable are the models and assumptions used in the analysis?
4. Was the analysis comprehensible to an informed layperson?

First, as noted on the Report Card, FSIS did make their analyses easy to find and FSIS received a perfect 5 out of 5. The regulation was easy to find on regulations.gov and on the USDA website.

However, on the issue of data's being verifiable (Item 2 in the Report Card), FSIS received a 2 out of 5. Some of the data is based on "expert opinion," although FSIS does not identify the experts or how they made their judgments. For example, for parameter estimates to estimate the time and temperature parameters necessary to control pathogens for baking and frying catfish, FSIS utilized "expert opinion and review of several on-line cooking recommendations." What experts; where are they from; what websites?[2]

The Report Card notes that the risk assessment is "technical" but an expert could follow it.[3] In fact, the risk assessment appears to be an accumulation of a great deal of statistics, microbiology, and risk modeling, although this science appears to mask basic facts about the most likely current risks associated with catfish and any likely impact of continuous inspection (discussed further below). In response to a peer review, FSIS defended its use of probabilistic risk assessments in the risk assessment: "Probabilistic risk-assessment approaches are widely used throughout the international risk-assessment community, especially in the area of food safety."[4] Probabilistic estimates combine point data and distributions to generate distributions. However, if the data going into them is poor, the resulting distributions will not have much of a basis in reality. (See Appendix A to this comment for more explanation).

II. ANALYSIS

5. How well does the analysis identify the desired outcomes and demonstrate that the regulation will achieve them?
6. How well does the analysis identify and demonstrate the existence of a market failure or other systemic problem the regulation is supposed to solve?
7. How well does the analysis assess the effectiveness of alternative approaches?
8. How well does the analysis assess costs and benefits?

Need for Regulatory Action

FSIS cites in the RIA that the need for regulatory action lies in a provision of the Food, Conservation, and Energy Act of 2008 (Farm Bill) that makes catfish subject to continuous inspection under the FMIA.[5]

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[2] Risk Assessment Division, Food Safety and Inspection Service, United States Department of Agriculture, Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish, December, 2010, 25. (hereafter referred to as "Risk Assessment").
[3] Mercatus Center at George Mason University website, "Catfish Inspection Proposed Rule," 8 June 2011, http://mercatus.org/reportcards/catfish-inspection.
[4] Risk Assessment Division, Office of Public Health Science, Food Safety and Inspection Service, United States Department of Agriculture, DRAFT Peer Review Comments and Responses to a Draft Risk Assessment of the Public Health Effect of an FSIS Catfish Inspection Program, March 2011, 20, http://www.fsis.usda.gov/PDF/Catfish_RA_Peer_Review_March2011.pdf.
[5] *Food, Conservation, and Energy Act of 2008*, Public Law 110–246, 122 U.S. *Statutes at Large* 923 (2008).

Although a legal requirement does mean that regulatory agencies must regulate, the economic analysis is not the best place to recite a legal requirement. More properly, that should lie in other parts of the preamble. The economic analysis should be able to cite evidence of a large systemic problem, normally a failure of markets, that is not likely to be resolved in the near future either by normal market processes or by other levels of government, i.e., state or local. Section 1 of Executive Order 12866 requires this.[6] In fact, the analysis received a zero on this item in the Report Card.[7]

This part, the need for regulatory action, as well as other parts of the analysis, must be factual because it will inform the executive, Congress, and stakeholders as to whether or not regulatory action is necessary, as well as to identify the nature and cause of the problem the regulation is supposed to solve. Even where Congress has established a legal requirement for regulation, it is not customary—and in fact likely—to be an exceedingly rare case, that Congress or any other governmental body has performed an economic analysis of need for and likely consequences of regulatory action. The Office of Information and Regulatory Affairs (OIRA) has often reminded executive branch agencies that it is their interpretation of economic executive orders that RIA's should have this information:

> "You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost. Such information may be useful to Congress under the Regulatory Right-to-Know Act."[8]

In this case in particular, when there is a requirement in a bill as large as the Farm Bill, an analysis of this type is necessary to ensure that social resources are not expended in a manner that distorts the efficient use of societal resources. By doing a proper analysis, USDA can advise others as to whether there is, in fact, a problem to be solved and—if there is a problem—whether changes in law could provide more effective or efficient remedies. Laws can be changed.

In this case, the need for regulatory action appears to be zero based on two facts:

1) All catfish, both domestic and imported, are now under the FDA's seafood HACCP program and most domestic processors, 18 out of 23, are under additional intense inspection from the National Marine Fisheries Service (NMFS) under the Department of Commerce. These programs are fairly extensive and cover most of what FSIS intends to cover.
2) There is no significant risk associated with catfish from Salmonella and the case has not been made for any other hazard.[9] FSIS was right to consider Salmonella as no other hazard seems to have manifested itself as a problem for catfish and Centers for Disease Control and Prevention (CDC) has recently noted that, "Salmonella infection should be targeted because it has not declined significantly in more than a decade."[10]

[6] EO 12866 states, "Each agency shall identify the problem it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem; see http://www.whitehouse.gov/sites/default/files/omb/inforeg/eo12866.pdf.
[7] Mercatus Center at George Mason University website, "Catfish Inspection Proposed Rule."
[8] OMB Circular A-4: 17, http://www.whitehouse.gov/omb/circulars_a004_a-4.
[9] To see how risk for food borne disease is estimated, see Appendix A to this comment.
[10] Centers for Disease Control and Prevention, "Vital Signs: Incidence and Trends of Infection with Pathogens Transmitted Commonly Through Food --- Foodborne Diseases Active Surveillance Network, 10 U.S. Sites, 1996-2010," June 10, 2011, http://www.cdc.gov/mmwr/preview/mmwrhtml/mm60e0607a1.htm?s_cid=mm60e0607a1_w.

There are two possible ways to estimate food borne disease risk, epidemiologically and through modeling. As the risk assessment notes, epidemiologically, there has been only one possible outbreak of human Salmonellosis associated with catfish in the past 20 years.[11] That outbreak occurred in 1991, with 10 cases of Salmonella Hadar—primarily associated with turkey—at a restaurant in New Jersey.[12] Catfish has also not been identified in case-control studies of Salmonellosis.[13] Nevertheless, FSIS goes on to calculate, using mathematical modeling, that based on one possible outbreak, there must be two outbreaks for every 1,160 Salmonellosis cases from catfish, producing an estimated number of 2,400 annual human illnesses. The preamble identifies six other outbreaks where the linkage to catfish appears even weaker than the "possible" outbreak in New Jersey.[14] As with so much in this risk assessment, these estimates appear to be mostly conjecture. If not conjecture, FSIS suggests in its PRIA that it is also addressing "perceived concerns with the safety and quality of raw agricultural products."[15]

USDA points out that catfish are already regulated by both the Department of Commerce and the Food and Drug Administration (FDA). FDA instituted the very first government-run Hazard Analysis Critical Control Point systems for all seafood (fish and shellfish) products in the mid-1990s. FDA stated in its final rule that "the ultimate goal of these regulations should be the improved safety of fish and fishery products—a reduction in the actual number of seafood-related illnesses."[16] In its rule, FDA used "experts" to assess how likely it was that the seafood HACCP program was effective. For all types of seafood, FDA estimated that of the estimated 200 annual cases of Salmonella non-typhi, between 150 and 100 cases would be averted. This would leave—again for all types of seafood—only 50 to 100 annual cases of Salmonella if FDA's HACCP program was as effective as claimed. Thus, USDA claims that the number of Salmonella cases from catfish alone is 10 times the level estimated by FDA for all fish. FDA reported that Salmonella had been present in cooked ready-to-eat fish, smoked fish, and molluscan shellfish.

FSIS examined other possible hazards such as chemicals and other pathogens. For chemicals, FSIS cited the "'possibility' of illegal drugs or other chemicals" and found that "catfish may not frequently harbor" them.[17] Citation of presence/absence data or action levels[18] are not a sufficient indicator of risk, only of the possibility of risk. Action levels are established primarily based on "achievability, or in FDA terms, "unavoidability" rather than risk. Therefore, the presence of any toxin of any kind says nothing about risk; it must be accompanied by an estimation of the dose and potency (dose/response) of the compound. That is, it's not whether you consume a toxin, only how much and how sensitive you are to it.

FSIS's risk assessment that only looks at hazards is outdated, and FSIS should consider risk/benefit models such as the FDA draft risk assessment for seafood.[19] This analysis includes the negative risk from

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[11] Risk Assessment, 36.

[12] Centers for Disease Control and Prevention, "Investigation Announcement: Multistate Outbreak of Salmonella Hadar Infections Associated with Turkey Burgers," April 4, 2011, http://www.cdc.gov/salmonella/hadar0411/040411/index.html.

[13] Risk Assessment, 36.

[14] Docket No. FSIS-2008-0031: 10440.

[15] RIA, 76.

[16] U.S. Food and Drug Administration, "Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products," 60 FR 665095, December 18, 1995, 65174, http://www.fda.gov/food/foodsafety/productspecificinformation/seafood/seafoodhaccp/ucm111304.htm.

[17] Docket No. FSIS 20089-0031: 10439.

[18] Action levels are limits at or above which FDA will take legal action to remove products from the market, see U.S. Food and Drug Administration, "Guidance for Industry: Action Levels for Poisonous or Deleterious Substances in Human Food and Animal Feed," August 2000, http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ChemicalContaminantsandPesticides/ucm077969.htm.

[19] U.S. Food and Drug Administration, Draft Risk & Benefit Assessment Report, Draft Summary of Published Research, Peer Review Report, January 15, 2009, http://www.fda.gov/Food/FoodSafety/ProductSpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/ucm088758.htm.

methyl mercury hazards as well as the benefits of omega-3 fatty acids that improve IQ and reduces cardiovascular disease. Any effect of the catfish rule on the consumption of catfish will have the effect of reducing both hazardous components, e.g., Salmonella, and beneficial components, e.g., omega-3 fatty acids. This point was also made in the peer review of the catfish risk assessment.[20] Risk/benefit models can be used to compare all risks, e.g., chemical, physical and biological, to all benefits, e.g., nutritional.

Further, most of the risk assessment is based on results from poultry for which FSIS has a great deal of data. However, nowhere is it explained in the assessment how land-based animals have any relationship whatsoever with water-based fish in predicting risks. Absent some compelling explanation, this entire exercise should be stricken.

FSIS estimates through modeling that the lower and upper bound numbers of cases of s\Salmonellosis associated with catfish are 100 and 6,200. However, given that there have been no confirmed cases; the lower bound must be considered to be zero, particularly as all catfish are heated before being consumed.

The risk assessment made a number of assumptions about their risk parameters that are problematical:

a. FSIS had no data on the concentration and distribution of Salmonella on catfish; they were assumed to be the same as poultry.[21]
b. Prevalence data for raw fish was based on one study of only 220 fish that found five samples that tested positive, and this prevalence rate was extended to imported catfish.[22]
c. The growth rate (assumed to be between a 10 and 40-percent increase) was also taken from chickens.[23]
d. The time and temperature parameters were based on "expert opinion" and on-line cooking recommendations.[24]

It is noteworthy that FSIS used PERT distributions for cooking distributions. PERT distributions are "used exclusively for modeling expert estimates, where one is given the expert's minimum, most likely and maximum guesses."[25] These distributions are shaped by those three data points. The shape of the distribution is, therefore, extremely dependent on the most likely value, in particular, whether it is close to the minimum or maximum, which is just an expert's estimate. FSIS does not explain why the cooking parameters they generate do not show most likely estimates very close to the minimum needed to kill Salmonella. As FSIS notes, the cooking temperature parameter is the most sensitive parameter in the risk assessment. As FSIS correctly notes, catfish is most likely to be either baked or fried (99 percent).[26] Heating Salmonella cells to a core temperature of 145F destroys these cells.[27] FSIS recommends elsewhere that, depending on the method of cooking and the size of the fish, this generally means cooking fish anywhere from two to 15 minutes. For fish under one-inch thick, 10 minutes is usually more than enough time to kill any Salmonella bacteria. Given the fact that no outbreaks have been associated with catfish for 20 years, isn't it likely that catfish is cooked sufficiently to destroy Salmonella?

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[20] Risk Assessment Division, Office of Public Health Science Food Safety and Inspection Service, United States Department of Agriculture, DRAFT Peer Review Comments and Responses to a Draft Risk Assessment of the Public Health Effect of an FSIS Catfish Inspection Program, March 2011, 32-34. http://www.fsis.usda.gov/PDF/Catfish_RA_Peer_Review_March2011.pdf.
[21] Risk Assessment, 21.
[22] Ibid., 20.
[23] Ibid., 25.
[24] Ibid., 25.
[25] Vose Software website, "Pert Modeling," 2007, http://www.vosesoftware.com/ModelRiskHelp/index.htm#Distributions/Continuous_distributions/PERT_distribution.htm.
[26] Risk Assessment, 17.
[27] Askville by Amazon website, "What Temperature and for How Long Does it Take to Kill Salmonella and Other Common Household Bacteria?" 2006, http://askville.amazon.com/temperaturelongkillsalmonellacommonhouseholdbacteria/AnswerViewer.do?requestId=1829676.

FSIS has limited data on the number of contaminated servings per year (one short study found a contamination rate of 2.3 percent[28]) that enumerate the number of Salmonella.[29] For enumeration, FSIS inexplicably assumed that the distribution of number of Salmonella is exactly the same distribution as is found in poultry (actually, slightly less by way of a "default" assumption).[30] There is no justification given for this assumption, and it seems implausible that catfish have any more relationship to chickens than they do to elephants. Although there is no reason given for this assumed relationship, FSIS goes on to say it may be more plausible than comparing enumeration to hogs or cattle.[31] This seems to be a matter of FSIS knowing something about the animals it currently regulates but knowing almost nothing about the catfish it intends to regulate.

In fact, a more likely vehicle for contamination of catfish would not be industry processing but rather retail or consumer mishandling such as through cross-contamination. FSIS acknowledges that this is a possibility in catfish-filleting operations at the manufacturing level but not in the retail or consumer setting.[32] Retail handling is exempt from this proposed rule.

When zero demonstrated risk and two agencies that have only recently put together intensive programs for seafood are examined together, it is unlikely that catfish presents any significant risk to anyone.

Alternatives

In the Regulatory Report Card, the agency received a 2 out of 5 on the section that addresses, "How well does the analysis assess the effectiveness of the solution?"[33] Basically, the scorers report that the range of options is entirely too narrow. There were two sets of options presented in this rule: first, whether an inspector needed to be in the processing plant throughout each shift or whether the inspector should visit an establishment each day; [34] and second, two options for the scope of the rule based on a definition of catfish. The two possible definitions to establish whether imported catfish are covered are: the order Siluriformes—which would include imported fish; versus one family within Siluriformes, Ictaluridae—domestic only. The risk assessment "estimates" that, based on exposure alone—as rates of contaminated servings and effectiveness are assumed to be the same—the expanded definition would prevent about 29 percent more illnesses.[35]

According to the RIA, the Siluriformes order contains two other families, Pangasidae and Claridae that are cheaper than Ictaluridae and are raised in overseas farms and exported to the United States. This means that, for those consumers that purchase these products, they may be paying a lower price for the imported fish. The very fact that imported fish are considered as a part of the inspection program, with most of the cost imposed on them (coupled with, apparently, zero risk) gives the appearance that this is a regulation whose actual purpose is protection of domestic competitors, not protection of public health. This fact seems to be buttressed by FSIS's report that sales of domestic catfish have dropped by around 13 percent since 2007 while imports have increased by about the same amount.[36] However, at least part of

[28] Risk Assessment, 20.
[29] The purpose of enumeration is to get a count of the number of bacteria per serving or per gram. Without this information, it is impossible to estimate the dose that people ultimately get. Of course, cooking reduces the dose.
[30] Risk Assessment, 21 and 22.
[31] Ibid., 21.
[32] Ibid., 40.
[33] Mercatus Center at George Mason University website, "Catfish Inspection Proposed Rule,"
[34] Preliminary Regulatory Impact Analysis of Catfish Rule, 32-33. (Hereafter referred to as RIA.)
[35] Risk Assessment, 34.
[36] RIA, 50.

this problem is that domestic costs have increased for domestic catfish as a result of increased demand for catfish feed as farmers sell more corn for biofuels.[37]

Under the provisions of the proposed catfish rule, FSIS is proposing mandatory Sanitation Standard Operating Procedures (SSOPs) and Hazard Analysis Critical Control Point (HACCP) plans. SSOPs are plans to ensure that the plant is essentially a sanitary plant for processing. HACCP is a system of processing controls to ensure that processes are monitored and corrected when there is a chance that hazards may enter the system. Given that these requirements already exist under FDA's HACCP plan, it is unclear whether FSIS plans some new activity. Table 2 in the RIA does not show any significant difference between the FDA plan and the FSIS plan. In fact, Table 2 fails to note that FDA also has SSOP requirements. FSIS assumes in its RIA that "many catfish and catfish products processing establishments would need to re-write their existing HACCP plans to be compliant with FSIS HACCP plans."[38] Given that all other seafood, juice and, eventually, all other products except meat and poultry and egg products are likely be subject to FDA's oversight of their mandated HACCP plans under the Food Safety Modernization Act,[39] FSIS should explain the deficiency in HACCP plans now required by FDA. In particular, given that FDA oversees seafood products that are actually risky, e.g., shellfish from the Gulf of Mexico, FDA could undoubtedly benefit from FSIS insight into the best manner in which to prepare a HACCP plan. For example, FSIS technical experts might have an excellent explanation for why four to six critical control points are necessary for catfish products.[40] FSIS is also proposing to do more sampling, the costs of which should be justified at the margin by the benefits of this sampling. To be specific, FSIS should state precisely how much sampling will be required, what those samples are expected to reveal in terms of contaminated product and how likely any sampling program is to prevent illnesses.

FSIS is also proposing to require new labels that would say "inspected and passed" on catfish products. Presumably, the only people who would benefit from this would be catfish consumers. Is there any evidence that consumers are not satisfied with the current levels of safety associated with catfish? Is there any notion that consumers would be willing to pay for this information, much less the entire program? If the RIA had done a better job of identifying the problem the regulation is supposed to solve, and the problem's root cause, FSIS might have answers to those questions.

FSIS is also considering employing technological means to identify the species of fish such as DNA sequencing based on "the interest of the catfish products industry and consumers."[41] If such interest exists, FSIS should provide evidence of that interest. For example, are consumers actually concerned about knowing the species identity of catfish? If producers are interested, why are they interested?

Effectiveness of FSIS's Program

FSIS uses a lot of text to try to speculate about how effective the FSIS inspection program is likely to be and how long it might take to get to peak effectiveness while acknowledging that "substantial uncertainty remains about the level of effectiveness that can be achieved by FSIS inspection."[42] However, there is zero discussion of a mechanism for how such an inspection might actually reduce the number of Salmonella in catfish other than to note, "The role of daily FSIS inspection of catfish processing

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[37] Scott Stiles, "Historical High in 2007 Catfish Feed Costs: Situation, Outlook," *Delta Farm Press,* April 11, 2008, http://deltafarmpress.com/historical-high-2007-catfish-feed-costs-situation-outlook.
[38] RIA, 64.
[39] U.S. Food and Drug Administration, "Food Safety Modernization Act," June 13, 2011, http://www.fda.gov/food/foodsafety/fsma/default.htm.
[40] RIA, 74.
[41] Docket No. FSIS – 2008-0031: 10446.
[42] Risk Assessment, 33.

establishments in reducing potential contamination rates is expected to be important."[43] The mechanism for achieving such importance appears to be that FSIS inspectors will observe what is happening and will periodically test products and this will prevent 10 to 90 percent of all cases.[44]

Speculation such as "it is expected that testing data will show a progressively lower occurrence of pathogens…particularly if significant levels are found," is just wishful thinking.[45] In the absence of a mechanism and data that describes precisely what activities would take place during FSIS inspections that would lead to reductions in pathogens—in particular related to fish, not birds—a plausible assumption is that "FSIS inspection could be totally ineffective (0 percent peak effectiveness)."[46] There is no basis whatsoever for the assumption that the FSIS model will prevent a "plausible" "10 to 90 percent"[47] of all cases of samonellosis from catfish which would result in preventing between 230 and 2,077 cases per year.[48] In the uncertainty analysis, the lower bound figure is decreased to eight illnesses prevented per year.[49] One peer reviewer's comment on an earlier version of the draft risk assessment makes the point about the mechanism for how risk will be reduced,

> "In Section 2.5.1, I cannot be sure how the inspection program operates—in ways that influence the probability of a contaminated catfish reaching the table. The ratio of positive-to-negative detects is good information, but if the inspection program finds a contaminated fish, some number of other fish will need to be culled. The reader isn't told how this is done. Is the entire "catch" from which that contaminated fish was taken culled? Is it all catfish from that water body? If it is a Siluriformes but not an Ictaluridae, are all the Siluriformes members from that same catch or water body culled? It would be nice to provide this information and explain how this approach relates to the ways in which beef and poultry are culled (which is where the pre-and-post ratio of concentrations is obtained)."[50]

Distribution of Effects

Executive Order 12866 requires that agencies analyze distributive impacts and equity.[51] In Table 2, it appears as though most of the cost of this regulation will fall on our trading partners who must initiate an "equivalence" program to be eligible for trade with the United States. This aspect should be covered in the analysis of distribution of impacts as it may generate a serious trade challenge as a result of possibly being a non-tariff trade barrier.

It should discuss the fact that for those foreign firms who remain in business exporting to the United States, much of the cost will be passed onto domestic consumers. For foreign firms, the impact of having to be in compliance with "all of the inspection, building construction standards and other provisions of the FMIA and regulations" are likely to be prohibitive compared to domestic industries.[52] FSIS should provide interested parties a chance to comment on the costs to foreign producers, rather than "focusing only on the domestic costs and is asking for information of costs to foreign producers."[53] As the bulk of

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[43] Ibid., 41.
[44] Ibid., 11.
[45] Ibid., 41.
[46] Ibid., 43.
[47] Ibid., 40.
[48] Ibid., 65.
[49] Ibid., 63.
[50] Risk Assessment Division, Office of Public Health Science, Food Safety and Inspection Service, United States Department of Agriculture, DRAFT Peer Review Comments and Responses to a Draft Risk Assessment of the Public Health Effect of an FSIS Catfish Inspection Program, March 2011, 46. http://www.fsis.usda.gov/PDF/Catfish_RA_Peer_Review_March2011.pdf.
[51] Executive Order 12866, Section 1 (5).
[52] Docket No. FSIS-2008-0031,10448.
[53] RIA, 54.

costs appear to fall on foreign producers, this seems like a serious oversight for this PRIA. There certainly appears to be no basis for the assumption that "the flow of imported catfish would not change as a result of this rulemaking."[54] If the regulation does have the effect of excluding many foreign producers, it may also end up increasing prices for U.S. consumers.

Net Benefits

FSIS may have understated costs. In particular, there are likely to be large administrative costs in overseeing each firm's conversion as well as on-going costs dealing with USDA in-plant inspectors. This involves senior management time and it should be calculated. For example, FSIS is proposing that "FSIS approves operating schedules…for catfish processing establishments… to ensure that the Agency can maintain an inspector's presence."[55] Each official establishment is required to "submit a work schedule to the District Manager for approval."[56] Having on-site personnel "helping" to make these and other management decisions is a sea-change in operations. FSIS has also not provided cost estimates for testing—beyond the estimated $12 million[57] that taxpayers would pay, presumably every year—for FSIS testing. Industry testing costs may very possibly be large. It is incumbent on FSIS to estimate these costs and, rather than simply soliciting comments on the testing frequency and costs, should provide them for comment.[58]

Neither an option to define catfish differently nor having a once-daily inspection based on HACCP is likely to generate net benefits. There simply are not enough cases of Salmonellosis to prevent and the case has not been made for any other hazards. Cooking catfish may account almost exclusively for the non-existent risk, but it has also been supplemented with two extensive federal programs. This means that any costs that are incurred by this program represent a social loss. The additional costs will be paid by consumers and taxpayers.

III. USE

9. Does the proposed rule or the RIA present evidence that the agency used the analysis
10. Did the agency maximize net benefits or explain why it chose another alternative?
11. Does the proposed rule establish measures and goals that can be used to track the regulation's results in the future?
12. Did the agency indicate what data it will use to assess the regulation's performance in the future and establish provisions for doing so?

In the Report Card, the agency received a 1 out of 5 in answer to the question, "Did the agency maximize net benefits or explain why it chose another alternative?" In fact, the agency did not calculate net benefits in this rule.

There are two criteria that the president has instructed the executive branch to use when making regulatory decisions:

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[54] Ibid., 82.
[55] Docket No. FSIS-2008-0031: 10443.
[56] Executive Order 12866, Section 1 (5).
[57] RIA, 90.
[58] Ibid., 78.

(1) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective.

(2) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only (emphasis mine) upon a reasoned determination that the benefits of the intended regulation justify its costs.

If the analysis had been properly done, FSIS would have concluded that any costs are not justified by the likely benefits of this rule, so that the ideal approach would be to leave existing federal programs in place. However, presuming Congress does not wish to amend the Farm Bill, the next-best cost-effective alternative would be to put in place the minimum controls allowed by law and use the narrowest definition of catfish, i.e., the family Ictaluridae.

Summary

FSIS has not established a case for additional regulation. On the contrary, the risk assessment and benefit-cost analysis demonstrate that there is no need for additional regulation of catfish and any and all costs that are likely to be incurred by both foreign and domestic producers and passed on to U.S. consumers are not likely to be justified by the benefits. Further, it is unlikely that USDA could ever meet their threshold for the number of cases of Salmonella that need to be averted for this regulation to pay for itself. FSIS should revise both analyses to reflect actual risk and estimate the total costs for both domestic and foreign producers and put them out for comments. Revised analyses are likely to show that no option under the new provisions of the Farm Bill are likely to be cost-beneficial.

The case has been made elsewhere that regulation and inspection, the bulwark of federal intervention to control food borne disease for over 100 years, is most likely outdated, which may explain the lack of progress on Salmonella.[59] One reason is that it is becoming easier to trace foods that have caused food-safety problems back to the source. This has led to a greater incentive for private inspections. In fact, FSIS notes that 70 percent of "slaughtering and processing (catfish) establishments are subject to, at a minimum, an annual review by buyers or representative of buyers for the verification of processes used at the establishment."[60] This rule and the accompanying analysis draw attention to the fact that, as private food-safety incentives change, government's role should also change. This rule perpetuates the trajectory we have been on for over 100 years that increasingly is outdated and ineffective.

Risk for food borne pathogens can be estimated in two ways, from epidemiology—essentially reporting cases of food borne disease that comes from states to the CDC—and mathematical modeling. In the latter case, you begin with an underlying contamination rate that can result from catfish contamination in the water or after removal from the water. In the case of catfish, that would mean the percentage of catfish likely to be contaminated with Salmonella and within a contaminated catfish, what is the number (concentration) of Salmonella microbes in the fish (per gram or per serving). Obtaining the concentration of microbes is called "enumeration." With that information, you can model how much the Salmonella will reproduce itself and grow the concentration before the fish is cooked. Microbes will grow under the right conditions and at different rates, depending on water (activity), the right pH, and other conditions of the "host" food. The next step is to determine what will kill off the Salmonella, in this case, cooking. The

[59] Richard A. Williams, "A New Role for the FDA in Food Safety," (Working Paper, Mercatus Center at George Mason University, Arlington, VA, 2010),
http://mercatus.org/sites/default/files/publication/wp1069-a-new-role-for-the-fda.pdf.
[60] RIA, 45.

longer and hotter and more thorough the cooking process, the more likely it is that all of the Salmonella will die.

Finally, where there is remaining Salmonella, whether or not someone gets sick depends on the concentration of the microbes and who ingests it. This is estimated using potency values—essentially, for each dose of microbes that people ingest, how many are likely to get sick, and how sick, just an illness or death. Older people and children may be less resistant as are people whose immune status is weakened, e.g., by HIV.

The modeling that is done often will not just take a single value, e.g., everyone cooks their fish at the same temperature for the same length of time. Instead, they will use a distribution of values. If you use any distributions, you will need to multiply one distribution by another and this is why we have probabilistic modeling like "Monte Carlo analysis." This type of analysis takes random points on two distributions and multiplies them to produce a new distribution that has one multiplied by another.

The main problem with probabilistic modeling is that it can hide the assumptions that go into the numbers and distributions that are multiplied. Also, because you are multiplying, if your parameter values are conservative—meaning that you take a worst case scenario in terms of contributing to risk—then multiplying one conservative value by another leads to a severely conservative value and the reported risks will greatly exceed the true risk. So, for example, if you multiplied a value for the underlying percentage of catfish that are contaminated that are likely to be higher than the actual value by a concentration rate that is also higher than the true concentration rate, you would estimate very high initial exposure to Salmonella. This is simple multiplication. If the two real values are two and five, and you use four and 10 to multiply together, the result is 40, not 10. If you continue to compound this problem by multiplying the likely reduction in Salmonella due to cooking by a number that doesn't reflect real cooking times and temperatures (understates them) and the effect of cooking (understates it), you would begin to see exposures that would predict many more cases than actually occur. This is why it is important to compare these outputs with actual reported cases.

Actual reported cases are known as epidemiology and are the second way we estimate risk. They are not perfect either because sometimes individuals do not know what made them ill. Also, sometimes they do not visit the doctor or report their case. This is why there is usually some underreporting. However, it should be noted that more individuals think they have been made ill by seafood than is likely to be the case. This latter problem tends to offset somewhat the problem of underreporting of cases of seafood poisoning.

Appendix A

Estimating Risk from Food Borne Disease

Risk for food borne pathogens can be estimated in two ways, from epidemiology—essentially reporting cases of food borne disease that comes from states to the CDC—and mathematical modeling. In the latter case, you begin with an underlying contamination rate that can result from catfish contamination in the water or after removal from the water. In the case of catfish, that would mean the percentage of catfish likely to be contaminated with Salmonella and within a contaminated catfish, what is the number (concentration) of Salmonella microbes in the fish (per gram or per serving). Obtaining the concentration of microbes is called "enumeration." With that information, you can model how much the Salmonella will reproduce itself and grow the concentration before the fish is cooked. Microbes will grow under the right conditions and at different rates, depending on water (activity), the right pH, and other conditions of the "host" food. The next step is to determine what will kill off the Salmonella, in this case, cooking. The longer and hotter and more thorough the cooking process, the more likely it is that all of the Salmonella will die.

Finally, where there is remaining Salmonella, whether or not someone gets sick depends on the concentration of the microbes and who ingests it. This is estimated using potency values—essentially, for each dose of microbes that people ingest, how many are likely to get sick, and how sick, just an illness or death. Older people and children may be less resistant as are people whose immune status is weakened, e.g., by HIV.

The modeling that is done often will not just take a single value, e.g., everyone cooks their fish at the same temperature for the same length of time. Instead, they will use a distribution of values. If you use any distributions, you will need to multiply one distribution by another and this is why we have probabilistic modeling like "Monte Carlo analysis." This type of analysis takes random points on two distributions and multiplies them to produce a new distribution that has one multiplied by another.

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