APPENDIX A

EXECUTIVE ORDER 12866 - PRELIMINARY REGULATORY IMPACT ANALYSIS

Contents

I. Introduction..... 6
A. Current Regulatory Framework..... 6
B. Need for Regulatory Action…..... 9
C. Proposed Actions..... 10
1. Definition of Catfish..... 10
2. Appling the Requirements in the FMIA to Processing Establishments.. 12
3. Pre-harvest Provisions – Production and Transportation..... 13
4. Import Requirements..... 13
5. FSIS Inspection Provisions..... 14
6. Implementation/Phase-in..... 18
II. Farm-Raised Catfish and Catfish Products Baseline..... 23
A. Farm-Raised Catfish and Catfish Products Domestic Industry..... 23
1. Production and Prices..... 32
2. Catfish and Catfish Food Products Production per Capita, in the U.S. – Siluriformes..... 40
3. Processing, Cooking, and Inspection..... 41
4. Microbiological, Chemical, and Other Testing..... 44
5. Inspection..... 44
6. HACCP Plans and Third Party Audits..... 45
7. Refrigeration and Cooling in Processing Areas..... 46
8. Sanitation..... 47
9. Employee Training..... 48
B. Human Health Baseline – Catfish Associated Human Illness..... 48
III. Regulatory Alternatives..... 50
A. Status Quo..... 51
B. Proposed Alternative Inspection Systems..... 51
IV. Cost Analysis..... 54
A. Domestic Industries Compliance Costs..... 54
B. Sanitation Standard Operating Procedures Additional Domestic Costs... 56
1. Plan Development and Initial Implementation: Additional Costs..... 56
2. Sanitation SOPs Recordkeeping and Record Storage: Additional Costs. 57
3. Sanitation SOPs Ongoing Additional Implementation Costs..... 59
4. Sanitation SOPs Training: Additional Costs..... 61

C. Hazard Analysis and Critical Control Point (HACCP) Systems Additional Domestic Costs..... 63
1. HACCP Plan Development, Validation, and Reassessment Additional Costs..... 65
2. HACCP Training Additional Costs..... 68
3. HACCP Personnel Additional Costs..... 70
4. HACCP Recordkeeping and Record Storage Additional Costs..... 71
D. Pre-harvest – Production and Transportation Additional Costs..... 75
E. Microbiological, Chemical, and Other Testing Additional Domestic Costs..... 78
F. New Labels: Additional Costs..... 79
G. Provision of Government Office Space and Equipment Additional Costs.. 80
H. Re-inspection at Import Establishments Additional Costs..... 82
I. Additional Agency Costs..... 83
1. Training and Personnel Additional Costs..... 84
2. Develop Generic HACCP Models and Sanitation SOPs Models – Additional Costs..... 88
3. Re-inspection – Additional Costs..... 89
4. Microbiological, Chemical, and Other Testing – Additional Costs.... 90
5. Total FSIS Additional Implementation and Annual Costs..... 91
J. Total Additional Domestic Costs..... 91
V. Potential Benefits..... 97
A. Consequences of Illnesses..... 100
B. Potential Magnitude of Catfish-Related Illnesses..... 102
C. Break-even Analysis.....103
VI. Summary..... 106
VII. Effects on Small Entities to Regulatory Flexibility Act..... 108
References..... 110
Exhibits..... 113

Tables

Table 1. Key features of provisions of the proposed rule: mandatory inspection of catfish and catfish food products..... 19

Table 2. Overview Comparison of authority between FDA, NOAA, and FSIS for catfish and catfish food products..... 21

Table 3. Under scenario #1, Siluriformes catfish domestic supply chain: producers, slaughter/(primary) processors, further (secondary) processors-only, importers, loaders/haulers, and feed mills – projected number of domestic establishments affected by the proposed rule, under the Siluriformes definition of catfish, order Siluriformes and small domestic entities affected..... 27

Table 4. Under scenario #2, Ictaluridae catfish domestic supply chain: producers, slaughter/(primary) processors, further (secondary) processors-only, importers, loaders/haulers, and feed mills – projected number of domestic establishments affected by the proposed rule, under the Ictaluridae definition of catfish, family Ictaluridae and small domestic entities affected..... 31

Table 5. Domestic Ictaluridae catfish slaughter and processing establishments (primary processors), employees, and catfish products Processed, in 2007..... 37

Table 6. Sanitation SOP plan development additional domestic cost for scenarios #1 and #2..... 57

Table 7. Sanitation SOPs recordkeeping and record storage additional domestic costs for scenarios #1 and #2..... 59

Table 8. Sanitation SOPs training additional domestic costs for scenarios #1 and #2..... 62

Table 9. Summary of additional domestic costs for sanitation SOPs for scenarios #1 and #2..... 63

Table 10. HACCP additional domestic costs for plan development, validation and annual reassessment for scenarios #1 and #2..... 67

Table 11. Projected additional domestic cost of HACCP training for scenarios #1 and #2..... 69

Table 12. HACCP personnel additional domestic cost for scenarios #1 and #2..... 71

Table 13. HACCP additional domestic costs for recordkeeping and monitoring (certification) for scenarios #1 and #2..... 73

Table 14. Summary of additional domestic costs for HACCP requirements for scenarios #1 and #2..... 75

Table 15. Additional domestic cost of new labels for scenarios #1 and #2.. 80

Table 16. Inspection program training, personnel, and other costs for scenarios #1 and #2..... 88

Table 17. FSIS / Agency additional implementation and annual costs for scenarios #1 and #2..... 91

Table 18. Projected additional mean total domestic costs of the proposed measures for scenarios #1 and #2..... 96

Table 19. Testing prevalence of *Salmonella* spp. in raw Siluriformes catfish and catfish food products, 1979-2009..... 100

Table 20. Distribution of new human salmonellosis cases by severity..... 101

Table 21. Projected number of new human *Salmonella* spp. illnesses per year, for the baseline distribution - for one year of U.S. catfish consumption – for scenarios #1 and #2..... 103

Table 22. Projected additional mean annualized costs of FSIS catfish inspection for the proposed rule and reduction in illnesses needed for benefits to exceed additional costs for scenarios #1 and #2..... 106

Acronyms and Abbreviations

CDC	Centers for Disease Control and Prevention
ERS	Economic Research Service
FDA	United States Food and Drug Administration
FSIS	Food Safety and Inspection Service
FY	Fiscal Year
GAPs	Good Agricultural Practices
GaqP	Good Aquacultural Practices
GMP	Good Manufacturing Practices
cGMP	Current Good Manufacturing Practices
HACCP	Hazard Analysis, Critical Control Points
hr	hours
Kg	kilogram
lbs	pounds
NASS	National Agricultural Statistics Service
No.	number
NOAA	National Oceanic and Atmospheric Administration
NMFS	National Marine Fisheries Service
Pct	percent
QC	Quality Control
RFA	Regulatory Flexibility Analysis
SBREFA	Small Business Regulatory Enforcement Fairness Act-1996
SSOPs	Sanitation Standard Operating Procedures
US	United States
USDA	United States Department of Agriculture
wk	week
yr	year

I. Introduction

For purposes of this analysis, the proposed rule being considered by the Food Safety and Inspection Service (FSIS) has been designated by the Office of Management and Budget as significant and is being evaluated as required by Executive Order 12866.

A. Current Regulatory Framework

Catfish slaughtering and processing establishments, catfish and catfish products further processing establishments, exporters, and importers are subject to the Food & Drug Administration (FDA) seafood HACCP regulations in 9 CFR 123 and other requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA). FDA's regulations on current good manufacturing practices (cGMPs, in 21 CFR 110) also apply to these establishments. For catfish producers, FDA provides advice and assistance through its Good Aquaculture Practices Program (GAqPs). However, FDA does not provide a continuous inspection program.

About 18 of 23 slaughtering and processing catfish establishments have contracted for voluntary, fee-for-service inspection and certification programs administered by the National Marine Fisheries Service (NMFS), National Oceanographic

and Atmospheric Administration (NOAA), U.S. Department of Commerce.

NMFS administers three levels of seafood inspection programs under authority of the Agricultural Marketing Act (7 U.S.C. 1622, 1624) and regulations implementing that act (50 CFR 260). These are: (1) a resident inspection program, which provides continuous inspection to qualifying establishments; (2) an integrated quality assurance program, under which an establishment operates an NMFS-approved quality assurance system and assists NMFS personnel in carrying out U.S. grading or specification regulations; and (3) a HACCP-Quality Management Program (QMP), under which the establishment's quality program is enhanced to meet the ISO 9001 quality management standards.

An establishment that participates in the continuous inspection program must agree to prepare products using only wholesome raw materials and to correctly label inspected items. The establishment must also agree to prior label approval by NMFS and to furnish it with reports that it may request on processing, packaging, grading, laboratory analysis, and production of inspected products. The establishment must provide facilities to NMFS inspectors and agree to conditions under which inspection may be suspended or terminated (50 CFR 260.97).

The premises of the establishment must be free from conditions that may result in food contamination (50 CFR 260.98). Buildings and structures must be equipped with adequate lighting, ventilation, drains and gutters, and hot and cold water. Facilities must be of sound construction and capable of being thoroughly cleaned. Processing rooms must be so designed and constructed as to permit clean and orderly processing and operating conditions. Birds, dogs, cats, and other animals must be excluded from rooms where processed products are being prepared, handled, or stored. Insects and other pests must also be excluded. The use of chemical compounds, such as cleaning agents, insecticides, rodenticides, and bactericides must be limited to circumstances and conditions approved by NMFS (50 CFR 260.99).

An establishment participating in any of the inspection programs is expected to have organized food-safety management systems that provide for effective internal and external communications, management review, and resources adequate for maintaining a sound food safety program. This food safety program is implemented through a combination of operational prerequisite programs that document how food safety hazards are to be controlled and HACCP plans for each product processed by the establishment. HACCP plans must be validated.

The establishment is expected to document how it would control nonconforming products, handle recalls, and withdraw defective products from the market. All HACCP-related records must be available to NMFS inspectors.

The establishment must maintain documented Sanitation Standard Operating Procedures (Sanitation SOPs) and prerequisite programs. The programs must ensure the safety of processing water, prevent contamination of food-contact surfaces, and prevent cross-contamination generally in the establishment.

Through its sanitation program, the establishment must ensure adequate hand washing, hand sanitation, and toilet facilities for its employees; protection of edible products from adulteration; the proper labeling, use, and storage of toxic compounds. The program must ensure that pests are excluded from the establishment.

B. Need for Regulatory Action

Although catfish, like other fish, are subject to FDA regulations, the 2008 Farm Bill amended the Federal Meat Inspection Act (FMIA) to provide that "catfish, as defined by the Secretary," is an amenable species (21 U.S.C. 601 (w)(2)). Catfish and catfish products are therefore subject to continuous inspection under the FMIA, which FSIS administers. The 2008 Farm Bill (Sec. 11016) stipulates that the FMIA amendments are not to apply until USDA issues implementing regulations and that

final regulations to carry out the amendments must issue no later than 18 months after the date of enactment (June 18, 2008) of the legislation, or December 2009. Thus, this regulatory action is necessary to implement this statutory mandate.

C. Proposed Actions

The Food Safety and Inspection Service (FSIS) is proposing regulations requiring continuous inspection of catfish and catfish products. The regulations would require that catfish and catfish products produced and sold in commerce intended for use as human food are safe, wholesome, not adulterated, and properly marked, labeled, and packaged consistent with the FMIA.

Under the FMIA, FSIS intends to apply to catfish and catfish food products most provisions of the Act that now apply to meat and meat food products.

1. Definition of Catfish

The 2008 Farm Bill designated that the Secretary of the United States Department of Agriculture (USDA) is to determine the definition of catfish. The eventual decision regarding the definition of "catfish" would determine the scope of the FSIS inspection program. This FSIS analysis considered two possible definitions. One possible definition is catfish native to North America that belong to the family Ictaluridae. Another possible definition is all fish of the order Siluriformes. If catfish

are eventually defined as all fish of the order Siluriformes, FSIS would inspect domestically produced catfish and would re-inspect all imported catfish. If eventually defined as fish only of the family Ictaluridae, FSIS would inspect domestically produced catfish and would re-inspect approximately 20-25 percent of imported Siluriformes.

USDA is asking for public comments on the scope of the definition and would fully define and describe the term in the final rule.

Following is FSIS's projected costs and benefits of implementing the proposed catfish inspection system, under FSIS jurisdiction using the two different definitions. The first scenario (hereafter designated as scenario #1) would bring under the requirements of the FMIA and regulations implementing it a definition of "catfish" as any member of the order Siluriformes, including the family Ictaluridae, as well as other families and species, such as members of the family Pangasiidae -- basa, tra, swai -- and members of the Clariidae family that are commonly farm-raised in overseas locations and exported to the United States.

In addition, FSIS analyzed a definition of "catfish" as any member of the common farm-raised species of the North American family Ictaluridae -- channel catfish, blue catfish, and hybrid channel-blue catfish. This scenario (hereafter designated as

scenario #2) would be subject to the same proposed requirements as in scenario #1.

Other key features or provisions of the proposed rule for the mandatory inspection of catfish and catfish food products are summarized in Table 1 and outlined below:

2. Applying the Requirements in the FMIA to Processing Establishments

Under this proposal, FSIS would apply the requirements in the FMIA to the inspection of the processing of catfish and catfish food products, taking account of the conditions under which the catfish are raised and transported to the processing establishment (21 U.S.C. §606). NMFS's Seafood Inspection Program currently applies the requirements of 21 U.S.C. §608 in the facilities it inspects.

FSIS would apply the FMIA provisions for the destruction of condemned products and for the inspection and certification of products to be exported (21 U.S.C. 606). FSIS would also apply the sanitation regulations to, and would inspect the conditions of sanitation in, the processing establishments for catfish and catfish products (21 U.S.C. 608).

The FMIA, as amended, effectively prohibits the sale, transport, offer for sale or transportation, or receipt for transportation, in commerce, of any catfish or catfish product

intended for use as human food that has not been inspected and passed by FSIS (21 U.S.C. 610).

3. Pre-harvest Provisions – Production and Transportation

Under this proposal, FSIS would take account of the conditions under which the catfish are raised and transported to the processing establishment. Catfish for human food must have grown and lived under conditions that would not render them unsound, unwholesome, unhealthy, or otherwise unfit for human food. FSIS advises producers to monitor pond water and sediments for suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and industrial chemicals. FSIS would sample feed, fish, and pond water and sediments.

A vehicle used to transport catfish to a processing establishment would need to contain sufficient water and oxygen to ensure that the catfish that arrive at the establishment are not adulterated under proposed 9 CFR 531.1 and 21 U.S.C. 601(m)(5) in that they have died otherwise than by slaughter.

4. Import Requirements

With respect to products of foreign origin, the FMIA prohibits their importation if they are adulterated or misbranded, and unless they were produced under conditions that comply with all the inspection, building construction standards, and other provisions of the FMIA and regulations that are applicable to similar products in the United States. Imported

products must meet the inspection, sanitary, quality, species verification, and residue standards that apply to United States products.

5. FSIS Inspection Provisions

Under the FMIA, FSIS must appoint inspectors to examine and inspect all amenable species and their products that are intended for food. These provisions would apply with respect to catfish and catfish products inspection.

a. Access to Premises, Inventory, and Records

The Act requires persons engaged in business as meat brokers or wholesalers, or in the transportation, storage, or importation of any carcasses, parts or products of carcasses, of animals for human food to give authorized representatives of the Secretary access to their places of businesses. The representatives have the right to examine the facilities, inventory, and records of the businesses, and to take reasonable samples of their inventory upon payment of the fair market value for the samples.

b. Registration of Affected Businesses

Persons engaged in business as meat brokers, renderers, animal food manufacturers, wholesalers of carcasses, parts, or products of amenable species intended for human food or other purposes, and other types of business involving the handling of animal carcasses and parts must, when required by regulations,

register with the Department and hence FSIS (21 U.S.C. 643). In addition, producers must be registered with FSIS. Live-fish haulers may need to be registered with FSIS, if they are independent businesses.

c. State-Federal, Federal-State Cooperative Inspection Programs

The FMIA provides for FSIS cooperation with State agencies in the development and administration of State meat inspection programs that impose standards that are at least equal to those of the Federal program. In some cases, FSIS may provide advisory and technical assistance, as well as funding (up to 50 percent of the total cost of the program), to achieve this objective (21 U.S.C. 645(a)).

d. Exemptions for Retail or Restaurant Operations

With respect to the preparation of carcasses, parts, meat and meat food products of amenable species, including catfish, operations of types traditionally and usually conducted in retail outlet stores and restaurants are subject to exemption from Federal inspection (21 U.S.C. 645).

e. Billing Overtime and Holiday Inspection Services

The cost of the Federal meat inspection service – catfish and catfish products inspection service – is to be borne by the United States. The cost of overtime and holiday inspection is

charged to the recipient of the service under 7 U.S.C. 2219a (21 U.S.C. 695).

f. Mandatory Sanitation SOPs and HACCP Plans

FSIS is proposing regulations that would require catfish and catfish products slaughtering and processing establishments, and catfish and catfish products further processing food establishments to develop, validate, and implement Pathogen Reduction (PR) Hazard Analysis and Critical Control Point (HACCP) Systems and Sanitation Standard Operating Procedures (Sanitation SOPs). In addition, processing establishments would develop and continue pre-requisite programs for process control.

FSIS would inspect and verify catfish and catfish product establishments' compliance with food safety standards and related requirements. FSIS would structure inspection activities so inspection program personnel can focus on areas of greatest risk in the catfish and catfish product processing system within each establishment, on the ability of establishments to maintain a sanitary environment, and to ensure that catfish and catfish products leaving facilities are safe.

g. New Labels

The proposal would require new labels that have the official USDA inspection legend including the phrase "inspected and passed" on catfish and catfish product packages, and safe handling labels on packages of not ready-to-eat catfish and

catfish products, and raw catfish and catfish products. The proposal would require catfish and catfish products to bear labeling with the same features as for meat and meat food products, such as product name, brand name, ingredients, and place of manufacture. In addition, the proposal has retained water requirements for raw catfish and catfish products: 100-percent net weight and deglazed net weight to average 100 percent of net weight after thawing. Furthermore, the proposal has nutrition labeling requirements.

h. Ready-to-eat (RTE) Products

The proposal would make ready-to-eat (RTE) catfish and catfish products, such as cooked, and dried or smoked catfish products – subject to requirements for the control of *Listeria monocytogenes*.

i. Export Requirements

The proposal requires affixing of stamps and marking of products for exports. FSIS issues export certificates that are required for clearance of vessels and transportation to foreign destinations.

j. Government Office Space and Equipment Requirements

The proposal requires provision of Government office space and some equipment in each of the catfish and catfish products slaughter and processing establishments, and catfish and catfish products further processing food establishments.

k. Records Requirements

The proposal requires persons engaged in catfish- and catfish product-related businesses to keep records of transactions. These records include shippers' certificates, seals, permits, and guaranties of suppliers. In addition, the proposal requires records for Sanitation SOPs, HACCP plans, and processing records. Records are to be kept at the place of business or central headquarters, for a two-year retention period from when the transaction occurred.

6. Implementation/Phase-in

To provide for an orderly transition from FDA's regulatory program to FSIS's more intensive continuous inspection program, FSIS is proposing a phased-in approach to implementation of the final rule that establishes the new mandatory catfish inspection program. During the transition period, FSIS is seeking to provide establishments and foreign countries that would be subject to the final rule with the opportunity to train their personnel and to bring their operations into compliance with the new regulations. (Comments have been invited on the appropriate length and nature of the transition period.)

Table 1 shows the key features or provisions of the proposed rule for the mandatory inspection of catfish and catfish products, by FSIS.

Table 1. Key features or provisions of the proposed rule: mandatory inspection of catfish and catfish food products.

Key Features or Provisions of the Proposal	Scenarios	
	Scenario #1 includes:	**Scenario #2 includes:**
Determination of the definition of "catfish" that is done by the Secretary of the United States Department of Agriculture (USDA)	- Siluriformes definition - Farm-raised "catfish" - order Siluriformes - Members include the members of the family Ictaluridae, such as -- channel catfish, blue catfish, and flathead catfish --, as well as other species, such as catfish members of the family Pangasiidae -- basa, tra, swai -- and catfish members of the family Clariidae that are commonly farm-raised in overseas locations and exported to the United States.	-Ictaluridae definition - Farm-raised "catfish" - family Ictaluridae - Members include the common farm-raised North American species such as channel catfish, blue catfish, and hybrid channel-blue catfish.
Imports	Numerous families affected such as the family Ictaluridae, the family Pangasiidae, and the family Clariidae.	Only the family Ictaluridae affected.
The following key features or provisions of the proposal apply to both scenario #1 and scenario #2:		
Apply the requirements in the FMIA[a] to processing establishments		
Pre-harvest provisions – production and live transportation to processing establishments		
Import requirements		
FSIS inspection provisions		
Access to premises, inventory, and records		
Registration of affected businesses		
State-Federal, Federal-State Cooperative Inspection Programs		
Exemptions for retail outlets or restaurant operations		
Billing overtime and holiday inspection services		
Mandatory Sanitation SOPs and HACCP plans		
New labels		
Ready-to-eat (RTE) products requirements		
Export requirements		
Government office space and equipment		
Records requirements		
Implementation phase-in		

[a]FMIA - Federal Meat Inspection Act

FSIS compared (in Table 2) the overview authority between FDA, NOAA, and FSIS for catfish and catfish food products. With the proposal to require continuous inspection of catfish and catfish food products, FSIS would incur the costs of establishing a new program. The domestic catfish industry would have to make marginal changes to comply with the proposed requirements. A difference between the requirements of the three agencies is FSIS's requirement for Sanitation Standard Operating Procedures (SSOP). Further differences are FSIS's more expansive import inspection and more testing for detecting adulterants.

Table 2. Overview Comparison of authority between FDA, NOAA, and FSIS for catfish and catfish food products.

Agency / **Subject**	**Food and Drug Administration Division of Seafood Safety (DSS)**	**National Marine Fisheries Service Seafood Inspection Program (SIP)**	**Food Safety and Inspection Service Office of Catfish Inspection Programs (OCIP)**
(1) Statutory and Regulatory References	Food, Drug and Cosmetic Act; Public Health Service Act	Agriculture Marketing Act, 1946 established voluntary inspection and certification program. FD&C Act	Federal Meat And Inspection Act as applicable to the amenable species "catfish"
(2) Preapproval Before Grant or Mark of Inspection Given			Steps to become an FSIS inspected establishment: - Application by establishment - Regulations and requirement

(3) Hazard Analysis and Critical Control Point (HACCP)	The emphasis for FDA HACCP requirements which includes Hazard Analysis, HACCP plan, Corrective Actions, Verification, Records, Training, Sanitation control Procedures, Importer Verification etc.	Resident inspection HACCP program emphasis is on:
		- Critical Control Points
		- Critical Limits
		- Corrective Actions
			FSIS's HACCP program (proposed:
			- Hazard Analysis must be written and available to inspection personnel for validation
			- The HACCP plan should identify of food safety hazards such as:
			  - Physical
			  - Chemical
			  - Biological
			- Identify Critical Control Points (CCP)
			- Identify Critical Limits (CL)
			- Identify procedures and frequency
			- Include all Corrective Actions that have been developed in accordance with §417.3(a)
			- Provide for a recordkeeping system that documents the monitoring of CCP's
			- List verification procedures and frequency
			- Validate:
			  - CCPs are effective in controlling hazards
			  - Through reliable science and evidence that intervention is effective in establishment's setting

(4) Sanitation Standard Operating Procedures (SSOP)			SSOP must be written and available to inspection personnel: SSOP requirements proposed: - Development of SSOP - Implementation of SSOP - Maintenance of SSOP - Corrective Actions - Recordkeeping
(5) Domestic Inspection Sites and Frequency	Inspects at plant production and importation sites	SIP estimates they have approximately 2/3 of the domestic production under contract.	FSIS to provide continuous inspection. In performing inspection, it has authority to inspect:

	Inspection of facilities approximately every 1-3 years based on prioritization and risk Annual workplans outline the Agency's inspection goals Approximately 20 hours are currently allocated in the workplan for a single seafood HACCP inspection based on an overall average of previous seafood HACCP inspection times.	Monitors at plant and vessel processing sites	- At appropriate frequency as determined by the Agency based on its findings - Ponds - Transport to processor - Retail outlet establishments - Continuous - Slaughter and processing facilities - Import houses
(6) Inspection Methodology	Annual work plans outline the Agency's inspection goals Auditor chooses at least one production/ process based on product risk priorities, previous audit results, or product under production at the time.	Fee-for-Service discontinuous HACCP compliance monitoring is dependent on the level of contractual service. Resident inspection program provides continuous inspection to contracted Establishments. Weekly HACCP record reviews for specific contracts.	FSIS would inspect on a continuous basis to verify that all catfish and catfish products are: - Safe - Wholesome - Unadulterated - Properly labeled And, FSIS can take regulatory control to: - Condemn or retain catfish carcass parts or products
(7) Import Inspection	Inspect approximately 1% of imported seafood product including catfish and catfish products Evaluation of required written and implemented seafood HACCP controls for imported seafood		FSIS has a government to government relationship with our trading partners. Initial equivalence evaluations of foreign meat and poultry food regulatory systems are a prerequisite for trade. As a result, 100 percent of product would be inspected by the eligible countries and would be re-inspected at the U.S. border by FSIS.
(8) Microbial and Residue Sampling	Random, priority based sampling Based on the work-plan sampling "For Cause" sampling conducted Laboratory analysis - pathogens, chemical, particulate for import surveillance Targeted sampling assignments for products of concern for import surveillance		FSIS performs 3 types of sampling: 1. Regulatory verification and statistical sampling based on a scientific, risk based analysis throughout production process to ensure that establishment is controlling the process in accordance with its HACCP plan. 2. Statistically designed baseline sampling program for pathogens of concern 3. Statistically designed sampling program for chemical residues - Chemotherapeutic - Pesticide - Heavy metals

II. Farm-Raised Catfish and Catfish Products Baseline

A. Farm-Raised Catfish and Catfish Products Domestic Industry

Discussion throughout this section is focused on domestically raised Ictaluridae. The National Agriculture Statistics Service (NASS) of the Department of Agriculture (USDA) reports that there are approximately 1,300 Ictaluridae catfish farms in 16 states (USDA/NASS 2009). These Ictaluridae catfish farms are small entities that typically employ less than 20 persons. The majority of United States Ictaluridae catfish production ponds acreage and sales are in Mississippi, Arkansas, Alabama, and Louisiana. The combined production pond acreage of these 4 states makes up about 94% of all Ictaluridae catfish production ponds acreage. In 2007, total sales from these 4 states made up approximately 96% of all domestically raised Ictaluridae catfish sales.

Domestically raised Ictaluridae catfish is the leading aquaculture industry in the United States. Commercial Ictaluridae catfish production generates over 46% of the value of aquaculture production in the United States. From the first commercial production in ponds in the 1960s, Ictaluridae catfish production grew to reach annual sales of 660 million pounds (live weight) in 2003. However, U.S. catfish production dropped to annual sales of about 496 million pounds (live weight) in 2008. The most rapid growth occurred in the 1980s as new

technologies and markets developed rapidly. Moreover, the rapid growth of the U.S. Ictaluridae catfish industry in the 1980s and 1990s led to its becoming one of the most important agricultural activities in States such as Mississippi, Arkansas, and Alabama. In these States, the Ictaluridae catfish industry generates an economic impact of billions of dollars and is the primary source of economic activity and employment in a number of counties. For example, the domestic Ictaluridae catfish industry in Chicot County, Arkansas, alone, generated a total economic impact of $359 million, $20 million in total tax revenue, and 2,534 jobs (46% of all employment in the county) when all direct, indirect, and induced effects were accounted for (Kaliba and Engle, 2004). The overall impact of this domestic industry is even greater because it is concentrated in a region of the country that is characterized by low levels of economic development and high rates of unemployment.

The southern United States has a transportation and communications infrastructure that facilitates transportation of catfish feeds from feed mills to catfish farms, fingerlings from fingerling producers to food catfish production facilities, food catfish from production facilities to processing establishments, and miscellaneous equipment and supplies to catfish farms. For marketing purposes, the lower Mississippi River alluvial plain

is located within one trucking day (approximately 500 miles) of about one-third of the United States population.

Within the southern United States, the two major catfish-producing areas are 1) a relatively well-defined geographical area of the lower Mississippi River alluvial valley that includes northwest Mississippi, southeast Arkansas, and northeast Louisiana and 2) a less well-defined area of west-central Alabama and east-central Mississippi.

While Ictaluridae catfish production is concentrated in the Mississippi Delta region, there is Ictaluridae catfish produced in at least 16 states. Those states (other than Mississippi, Arkansas, Alabama, and Louisiana) with more than 500 acres of catfish production ponds acreage in 2009 were: California, North Carolina, Missouri, Georgia, Florida, and Kentucky.

For scenario #1 (Siluriformes Domestic Catfish Supply Chain) with the Siluriformes definition of catfish, FSIS projects that the proposal could affect 1,439, or 83 percent, of 1,724 domestic establishments that include Ictaluridae catfish producer farms, feed mills, live catfish haulers, processors, further processing food establishments, and importers (Table 3). The remaining 285, or 17 percent, of 1,724 would be those domestic establishments and importers that would be retail outlet operations that would be exempt from this proposed rule.

There are an estimated 1,300 commercial catfish producer farms in the United States that supply live Ictaluridae catfish to about 23 active catfish slaughtering and processing establishments in the United States (USDA NASS, 2009). A NASS survey found 18 catfish processors that can slaughter and process 2,000 pounds live weight or more per 8-hour shift (USDA NASS, 2008). FSIS solicits information on the number and location of active catfish slaughtering and whole catfish and catfish products processing establishments in the United States.

In addition, based on FDA inspection data (FDA, 2007), there are about 415 FDA inspected establishments in the United States that are registered to process (e.g., dressing, cutting portions, cooking, drying, or smoking) fish or seafood. Based on discussions with FDA catfish experts, about 190, or 46 percent of these FDA registered establishments are known to have further processed Siluriformes catfish and catfish products within the past several years. However, FSIS assumes that about 180 of these 415 establishments are retail outlet operations and thus they are exempt from FSIS catfish inspection. FSIS assumes that about 2 percent of these 415 or about 10 establishments do further processing-only (i.e., smoking or cooking) of Siluriformes catfish or catfish products. Furthermore, there are about 185 seafood wholesalers or brokers including importers / exporters (FDA, 2007) in the United States. Based on

discussions with catfish experts, FSIS assumes that about 80 wholesalers or brokers for these 185, or about 43 percent, would likely be affected because, after the implementation of the final rule, they might bear some additional costs, or some loss of business because they might import less Siluriformes catfish or catfish food products from one of the 15 countries that currently export Siluriformes catfish or catfish food products to the United States. The United States exports Ictaluridae catfish and catfish food products to about 12 countries.

Table 3. Under scenario #1, Siluriformes catfish domestic supply chain: producers, slaughter/(primary) processors, further (secondary) processors-only, wholesalers or brokers, loaders/haulers, and feed mills - projected number of domestic establishments affected by the proposed rule, under the Siluriformes definition of catfish, order Siluriformes and small domestic entities affected.

Catfish Supply Chain	Potential Number	Percent Affected	Projected Number Affected	Small[a] Entities Affected		Large[b] Entities Affected	
				Pct.	No.	Pct.	No.
Producers	1,300	100	1,300	100	1,300		
Feed Mills	15	100	15	100	15		
Loaders/Haulers	11	100	11	100	11		
Slaughter and Processors	23	100	23	83	19	17	4
Further Processors-only	190	5	10	100	10		
Wholesalers or Brokers, Importers and Exporters	185	43	80	100	80		
Totals	1,724		1,439		1,435		4

[a]Small means 500 or less full-time equivalent (FTE) employees
[b]Large means more than 500 full-time equivalent (FTE) employees
Source: National Agricultural Statistics Service (NASS), 2009

In addition, FSIS assumes that about 50 percent or 11 of the 23 domestic Siluriformes catfish and catfish products

processors contract with about 11 loading-and-hauling firms. These 11 firms capture and load the live catfish into their approximately 66 water-tanker trucks (using approximately 6 trucks per establishment), and then transport the catfish live to the processing establishments. The remaining 12 processing establishments run their own catching and hauling crews using approximately 5 trucks per establishment or a total of about 60 water-tankard trucks.

Commercial domestic Ictaluridae catfish are typically produced in controlled aquatic environments (e.g., ponds, and cages placed in lakes or rivers); seined harvested; transported or hauled alive in super-oxygenated water, sometimes water cooled in transit; and delivered live to a processing establishment often within several hours of being seined (Silva, 2001). In addition, Ictaluridae catfish can arrive at the processing establishment within an hour of where they are raised. Furthermore, the domestic Ictaluridae industry already has mandatory HACCP quality assurance programs. Further, a large share of the industry conducts third party audits of their catfish and catfish products processing practices.

Domestic and foreign raised Siluriformes catfish and catfish products constitute a growing share of total freshwater fish consumption in the U.S., according to the Economic Research Service (ERS, 2008). The Siluriformes catfish share is expected

to grow in response to increased consumer demand or preference for food safety and product innovation. Innovation in Siluriformes catfish products is reflected in the rate of new products entering the market place, including marinated products, breaded products, cooked, dried, or smoked products, shelf-stable products, canned and pouched cooked products, and refrigerated grocery products. Siluriformes catfish by-products include fish meals, and fertilizers. Based on FSIS discussions with industry experts, about 6 domestic Siluriformes catfish and catfish products slaughter and processing firms are vertically integrated with ownership of production and slaughter and processing facilities.[1] About 7 of the 23 establishments, or about 30 percent, are organized as cooperatives.[2]

In addition, based on FSIS discussions with catfish industry experts, Table 3 shows that nearly all of the affected Siluriformes firms or establishments are considered small entities that have 500 or less full-time-equivalent (FTE) employees.

For scenario #2 (Ictaluridae Domestic Catfish Supply Chain, Table 4), the Ictaluridae definition of catfish, the projection is the same as in Scenario #1 for the estimated 1,300 commercial domestic Ictaluridae catfish producer farms in the United States

[1] FSIS discussions with representatives of catfish trade organizations .
[2] Ibid

that supply live Ictaluridae catfish to about 23 active catfish slaughter and processing establishments in the United States (USDA NASS, 2009). Ictaluridae are the North American catfish that are raised in the United States. However, in scenario #2, the number of wholesalers or brokers, including importers, affected moves downward from an estimated 80 Siluriformes wholesalers to about 18 Ictaluridae wholesalers affected because the bulk of the imports are Siluriformes that are not of the family Ictaluridae. Furthermore, FSIS discussions with industry experts indicated that many of the Siluriformes processing-only or Siluriformes wholesalers distributor establishments would not be affected under the scenario #2 (Ictaluridae definition of catfish) because they could continue to utilize the relatively lower cost Siluriformes members of the Pangasiidae family -- basa, tra, swai -- and members of the Clariidae family catfish that are commonly farm-raised in overseas locations and exported to the United States, at a unit price below domestic Siluriformes catfish of the family Ictaluridae.

Table **4.** Under scenario #2, Ictaluridae catfish domestic supply chain: producers, slaughter/(primary) processors, further (secondary) processors-only, wholesalers or brokers, loaders/haulers, and feed mills - projected number of domestic establishments affected by the proposed rule, under the Ictaluridae definition of catfish, family Ictaluridae and small domestic entities affected.

Catfish Supply Chain	**Potential Number**	**Percent Affected**	**Projected Number Affected**	**Small[a] Entities Affected**		**Large[b] Entities Affected**	
				Pct.	**No.**	**Pct.**	**No.**
Producers	1,300	100	1,300	100	1,300		
Feed Mills	15	100	15	100	15		
Loaders/Haulers	11	100	11	100	11		
Slaughter and Processors	23	100	23	83	19	17	4
Further Processors-only	190	5	10	100	10		
Wholesalers or Brokers, Importers and Exporters	185	10	18	100	18		
Totals	1,724		1,377		1,373		4

[a]Small means 500 or less full-time equivalent (FTE) employees
[b]Large means more than 500 full-time equivalent (FTE) employees
Source: NASS, 2008

FDA's regulation at 21 CFR 123 requires that all seafood including Siluriformes catfish and catfish food products be processed under HACCP plans.

The baseline information of the Siluriformes catfish and catfish products industry supply chain is largely based on discussions with the FDA, U.S. National Marine Fisheries Services (NMFS), U.S. catfish trade organizations, and universities. In addition, FSIS collected baseline information by site visits and by discussions with industry and extension services experts.

To obtain a full analysis of both costs and benefits, FSIS solicits comments on the structure of the domestic and foreign

catfish supply chain, the number and type of establishments, wholesalers (including importers or distributors), and companies that would likely be affected under the Siluriformes definition of catfish, order Siluriformes of scenario #1, and the Ictaluridae definition of catfish, family Ictaluridae of scenario #2.

1. Production and Prices

According to the United States Department of Agriculture, National Agricultural Statistics Service (NASS, 2008), domestic Ictaluridae farm-raised catfish processed during September 2008 totaled 39.7 million pounds round weight (live weight), up 1 percent from September 2007. The average price paid to producers was 82.9 cents per pound for September 2008, up 0.2 cents from August 2008 and 13.2 cents above September 2007. Net pounds of processed Ictaluridae catfish sold during September 2008 totaled 17.9 million pounds, down 12 percent from the comparable month in 2007. The total end of the month inventory increased 8 percent from last month and was up 5 percent from a year ago. Sales of fresh catfish, at 6.51 million pounds, were down 13 percent from September 2007 and represented 36 percent of total sales. Frozen catfish sales, at 11.4 million pounds, were down 12 percent from September 2007 and accounted for the remaining 64 percent of total catfish sales. Sales of whole catfish represented 17 percent of the total catfish sold,

fillets accounted for 61 percent, and the remaining 22 percent were mostly steaks, nuggets, and value added products.

The September 2008 average price received by processors for domestic total fresh Ictaluridae catfish was $2.60 per pound, up 23 cents from September 2007. Prices for fresh whole catfish were $1.73 per pound, up 8 cents from September 2007. Prices for domestic fresh Ictaluridae fillets were up 30 cents from September 2007 at $3.33 per pound. Total frozen Ictaluridae catfish averaged $2.59 per pound, up 25 cents from September 2007. September 2008 prices for frozen whole dressed Ictaluridae catfish were up 14 cents at $2.26 per pound and frozen Ictaluridae fillets at $3.07 per pound were up 28 cents from September 2007. The 2006-2008 average prices were $0.83 per pound for frozen whole Ictaluridae catfish,[3] $1.14 per pound for frozen Ictaluridae catfish fillets,[4] and $0.402 per pound for frozen Ictaluridae catfish nuggets.[5]

Freshwater imports for consumption of Ictalurus, Pangasius, and other catfish of the order Siluriformes for 2007 totaled 84.5 million pounds, up 13 percent from the 75.0 million pounds imported in 2006.

In 2007, Siluriformes (Ictalurus and non-Ictalurus) imports were from China, Indonesia, Mexico, Thailand, and Vietnam. The

[3] Wholesale price. Source; Catfish Market Statistics, NASS, USDA.
[4] Wholesale price, Source: Catfish Monthly Summary, NASS, USDA.
[5] Wholesale price. Source: Catfish Market Statistics Annual, NASS, USDA.

Ictalurus imports totaled 1.32 million pounds, which were from China and Mexico.

In 2007, fresh boneless U.S. Ictaluridae catfish fillet exports totaled 62,900 pounds, with 56,100 pounds going to Canada and the rest going to Mexico, the Netherlands, and the Turks and Caicos Islands. Frozen, boneless catfish fillets, for the month of August 2008, totaled 12,000 pounds all going to the Netherlands. Import and export data are compiled by the U.S. Census Bureau.

In 2007, about 496.2 million pounds (live weight) of Ictaluridae catfish were processed, or packed for the consumer as domestically farm-raised catfish, or for use in the production of catfish products, down 12 percent from the 566.1 million pounds processed in 2006.[6] About 98 percent of domestic Ictaluridae farm-raised catfish were used in the production of catfish whole fish, fillets and nuggets products. Most of the remaining 2 percent produces organic fertilizer and fish meal that is an ingredient for pet foods and other animal foods. In 2007, Siluriformes catfish and catfish food products comprised 2.7 percent of all seafood consumed, in the United States.[7] In 2007, the 3.9 percent growth in consumption of Siluriformes catfish and catfish food products is attributable to increased

[6] U.S. Department of Agriculture, National Agricultural Statistics Service. Catfish, August 31, 2008.
[7] U.S. Department of Agriculture, National Agricultural Statistics Service, Agricultural Statistics. Various issues.

demand by consumers for catfish foods, ample supply of catfish and catfish food products, relative low prices to consumers, and the recognized safety of Siluriformes catfish and catfish products.

Most of the live domestic Ictaluridae catfish used in catfish and catfish food product processing establishments are relatively local to the processing establishments. Depending on the market prices for farm-raised catfish at the retail outlet level, catfish destined for the catfish and catfish product market can be graded and packed for catfish and catfish products export markets.

About 23 (and possibly more, especially seasonally in the summer months) establishments slaughtered and processed Ictaluridae catfish and catfish products in 2008, based on discussions with catfish trade associations and university extension service experts. About 20 establishments produced Ictaluridae catfish and catfish food products for the entire year. A total of 23 establishments had some Ictaluridae catfish slaughtering and catfish processing activities during 2008. Of the 23 establishments processing catfish and catfish food products, more than half the establishments added chemicals or ingredients, such as sodium tri-polyphosphate or breading materials, to one or more of their products. Most domestic

Ictaluridae establishments produced fresh and frozen catfish and catfish food products.

Domestic fresh Ictaluridae catfish and catfish food products accounted for about 83 percent of all Ictaluridae catfish and catfish food products marketed as finished product in 2007. Frozen Ictaluridae catfish and catfish products accounted for about 12 percent. Dried/smoked/cooked Ictaluridae catfish and catfish products accounted for about 5 percent.[8] These products are produced in domestic Ictaluridae slaughtering and processing establishments that are shown in Table 5, for 2007.

[8] U.S. Department of Agriculture, NASS. Catfish and Catfish Products Volume Database, FY 2007.

Table 5. Domestic Ictaluridae catfish slaughter and processing establishments (primary processors), employees, and catfish products Processed, in 2007.

Processing Establish-ments	State	Employees full-time equivalents (FTE)	Use, Weekly Live Weight Volume, in pounds	Capacity, Weekly Live Weight Volume, in pounds	Percent Utilitiza-tion of Capacity	Annualized Live Weight Volume, in millions of pounds (calculated)
1	OK	75	75,000	-	-	3.9
2	MS	>500	1,122,000	-	-	58.3
3	NC	100	125,000	-	-	6.5
4	MS	>500	1,122,000	-	-	58.3
5	MS	400	800,000	-	-	41.6
6	AR	75	75,000	-	-	3.9
7	TX	105	350,000	-	-	18.2
8	ID	NA	20,000	-	-	1.0
9	MS	150	200,000	-	-	10.4
10	LA	100	250,000	-	-	13.0
11	LA	250	500,000	-	-	26.0
12	AL	200	400,000	-	-	20.8
13	AR	75	100,000	-	-	5.2
14	MS	>500	1,120,000	-	-	58.2
15	MS	30	8,000	-	-	0.4
16	MS	100	150,000	-	-	7.8
17	MS	100	200,000	-	-	10.4
18	TX	28	25,000	-	-	1.3
19	MS	300	400,000	-	-	20.8
20	AL	200	350,000	-	-	18.2
21	AL	>500	1,500,000	-	-	78.0
22	MS	100	250,000	-	-	13.0
23	TX	30	20,000	-	-	1.0
Totals of Above		4,418	9,162,000	12,605,000	72.7	476.4

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.
Source: U.S. Catfish Trade Organizations, 2007.

About 23 Ictaluridae catfish slaughter and catfish products primary processing establishments employ a total of about 4,400 full-time-equivalent (FTE) persons or about an average of about 191 FTEs per establishment.[9,10] This level of employment compares

[9] Catfish trade organizations discussions, August, 2008.

to the approximately 166 FTEs per establishment in the meat and poultry industry which employs over 500,000 FTE persons in about 3,000 livestock slaughter and meat products primary processing establishments according to Dun and Bradstreet (2008). Of the 23 Ictaluridae establishments, 4 are large establishments that employ more than 500 FTE persons.

Domestic and foreign Siluriformes catfish and catfish products are used in the food service industries, institutional food settings, and restaurant trade. Most of the domestic Ictaluridae slaughtering and processing establishments produce Ictaluridae catfish and catfish products that are directly sold to domestic and foreign distributors and retailers. Several of the domestic Ictaluridae slaughtering and processing establishments import Siluriformes (Ictaluridae and non-Ictaluridae) catfish food products that are directly sold to domestic distributors and retailers.

FSIS asks for information on the number and location of processing-only (secondary processors) establishments that further process Siluriformes (Ictaluridae and non- Ictaluridae) catfish and catfish food products to produce value-added catfish

[10] For the purposes of the Regulatory Flexibility Act, firms that produce catfish or catfish products are classified as small if they employ 500 or fewer FTE employees, the standard established by the Small Business Administration for these types of firms. Based on 2008 discussions with individuals of the catfish trade organizations, 4 establishments employed more than 500 FTE employees.

and catfish food products for wholesale markets of domestic intrastate and interstate commerce, and exports.

Siluriformes (Ictaluridae and non-Ictaluridae) catfish and catfish food products include whole catfish, fillets, nuggets, steaks, and various products with or without non-catfish ingredients that are processed, breaded, and cooked into ready-to-eat (RTE) food products. Siluriformes catfish and catfish food products may be available in fresh/chilled, frozen, smoked, cooked, marinated, breaded, and dried forms. The volume and variety of Siluriformes catfish and catfish products and other finfish products have increased at the retail level in recent years (ERS, 2008).

In 2007, fresh/chilled Ictaluridae catfish and catfish food products accounted for less than half, or about 90.7 million pounds, of all, or about 252.4 million pounds, of Ictaluridae catfish and catfish food products marketed in the U.S. as finished product in 2007 (NASS, 2008). Frozen Ictaluridae catfish and catfish food products accounted for more than half, or about 161.7 million pounds, of the Ictaluridae sales. Marinated Ictaluridae catfish food products accounted for a small percent of Ictaluridae sales. Smoked, dried or other

Ictaluridae catfish food products accounted for an even smaller percent of Ictaluridae sales (NASS, 2008).[11]

According to discussions with the domestic Ictaluridae catfish industry representatives, the industry produced a total of about 496.2 million pounds (live weight) of domestic Ictaluridae catfish and catfish food products in 2007. About 5 slaughter and processing establishments produce less than 50 million pounds of Ictaluridae catfish and catfish food products annually, with an average of 22.0 million pounds of Ictaluridae catfish and catfish food products. About 18 slaughtering and processing establishments produce 50 million pounds or more, with an average output of 97.6 million pounds of Ictaluridae food products per year. These 18 establishments produced 71.3 percent of all domestic Ictaluridae catfish and catfish food products, in 2007.

2. Catfish and Catfish Food Products Production per Capita, in the U.S. – Siluriformes

According to the Economic Research Service (ERS, 2008), about 0.8 of one pound of Siluriformes (Ictaluridae and non-Ictaluridae) catfish and catfish food products are produced

[11] U.S. Department of Agriculture, NASS, Catfish Products Volume Database, FY 2007 Note: Calculation for pounds produced in 2000 based on the assumption that average catfish weighs about 5 pounds. The year 1997 was the last in which these production data were collected. Source: Agricultural Statistics 1990 and Agricultural Statistics 1998, U.S. Department of Agriculture, NASS. .

domestically and overseas annually for the general public, per capita. However, FSIS discussions with the domestic Ictaluridae catfish industry indicated that people that live in the southern United States eat more Siluriformes catfish and catfish food products per capita than those who reside in the northern and western areas. The U.S. consumer has numerous choices of finfish (e.g., tilapia, salmon, and others) that are substitutes for Siluriformes catfish and catfish food product. These seafood substitutes are widely available at retail markets. The consumption of Siluriformes catfish and catfish food products is about 7 percent of the total finfish market annually, in the U.S. (ERS, 2009).

3. Processing, Cooking, and Inspection

Domestic Ictaluridae catfish and catfish food products are processed by a mix of automated equipment and hand work that: moves the live catfish from receiving; hand sorts out non-catfish; washes the catfish; de-heads the catfish; sorts by sizes; performs evisceration, separation/fabrication of fillets and pieces/nuggets (non-fillets) from the shell (i.e., skeletal bones) of the catfish, and skin removal; hand trims fillets and nuggets to remove tags of skin and bones; conducts chilling by water bath; packages; and blast freezes (Silva, 2001). Fresh catfish and catfish products are chilled to a temperature not to exceed 45°F prior to additional processing.

The FDA regulations require that all Siluriformes catfish and catfish food products processed and distributed for consumption be chilled or frozen, or be shelf stable (cooked, smoked or dried) (FDA, 1994). In addition, processing areas need to be at 45 degrees or less (FDA, 1994).

Because of the diversity of the domestic Ictaluridae catfish and catfish food products industry, there are numerous "systems" by which Ictaluridae catfish production and Ictaluridae catfish and catfish food products processing are linked. Much of the Ictaluridae catfish and catfish food products industry has moved to the use of processing systems that minimize the period of time (and physiological stress in the catfish) between live catch and processing to control pathogen growth and ensure catfish quality. The domestic Ictaluridae catfish and catfish products industry uses some "in-line" facilities meaning systems in which all catfish presented for processing arrive directly from the growing-out ponds that are mostly co-located with the catfish and catfish food products processing establishment. FSIS discussions with Industry experts, however, have indicated that relatively few (estimated at 3-5) establishments slaughter and process catfish at in-line facilities.

A second type of domestic processing system is characterized by Ictaluridae catfish and catfish food product

slaughtering and processing establishments that are located in close proximity to a number of growing-out ponds, thereby minimizing the time the catfish are in transit. The grow-out ponds may be owned by the catfish products slaughtering and processing establishment. The slaughtering and processing establishments may be legally organized as a producer cooperative. The catfish slaughtering and catfish product processing establishment may also purchase catfish from a limited number of nearby suppliers under contract. FSIS discussions with Industry experts indicated that most of the catfish slaughtering and catfish product processing establishments are supplied by this system.

Under a third system, domestic Ictaluridae catfish slaughtering and catfish and catfish food product processing establishments purchase market-sized Ictaluridae catfish from a number of different sources, market intermediaries, or catfish and catfish products imports. The Ictaluridae catfish may vary greatly in age and other factors indicative of quality or stressed catfish (e.g., flavor, color and texture of flesh, or chemical residues). FSIS discussions with industry experts indicate that there are relatively few (estimated at 2) domestic establishments that slaughter and process Ictaluridae catfish and catfish food products using this system.

Regardless of the system, seasonal factors influence Siluriformes supply and demand conditions during the year. The U.S. summer grilling season has highest consumer demand for Siluriformes catfish fillets and steaks. Catfish and catfish food product processing establishments often modify their acquisition and marketing practices accordingly.

4. Microbiological, Chemical, and Other Testing

In the 18 high-volume domestic Ictaluridae catfish slaughter and processing establishments, the U.S. Department of Commerce, National Oceanic and Atmospheric Administration (NOAA) Fisheries, National Marine Fisheries Service (NMFS) tests catfish and catfish products for microbiological contaminants and chemical adulterants. In addition, establishments test, for off-flavors caused by algae, samples of catfish from production ponds before harvesting a production lot of catfish.

5. Inspection

FDA inspection program personnel conduct pre-operational sanitation inspections and monitor sanitary conditions of the establishment premises, facilities, and equipment during operations at every catfish and catfish product processing establishment, once or twice a year. However, NOAA/NMFS inspection program personnel conduct pre-operational sanitation inspections and monitor sanitary conditions of the processing establishment premises, facilities, and equipment continually

during operations at about 18 of 23 catfish and catfish food product establishments, daily. FDA and NOAA/NMFS inspection program personnel are responsible for observing the cleanliness, type, and wholesomeness of raw materials and finished products, the handling of ingredients, packaging, labeling, freezing, storing, and all other operations related to the processing and production of catfish and catfish products. In those establishments that contract for NOAA/NMFS services, inspection program personnel are required to be on duty whenever catfish and catfish food products are processed; or packaged; and catfish and catfish food products are received or shipped (Silva, 2001). According to FSIS discussions with industry experts, about 18 slaughtering and processing establishments annually pay the NMFS approximately $1.3 million for inspection services and certifications. These establishments provide office and locker space for NMFS inspection program personnel.

6. HACCP Plans and Third Party Audits

FSIS discussions with catfish experts of the catfish trade organizations found that about 16, or 70 percent, of the 23 slaughtering and processing establishments are subject to, at a minimum, an annual review by buyers or representatives of buyers for the verification of processes used at the establishment. The discussions also indicated that about 10, or 35 percent, of those 23 establishments were subject to certification,

verification, and endorsement from an independent, non-government organization, using a formal, specified and regular procedure of audit and review.

FSIS solicits more information on services and for third-party auditors by the private sector.

Furthermore, 23, or 100 percent, of the domestic slaughter and processing establishments have written HACCP plans, based on discussions with experts of the catfish trade organizations and universities that have catfish extension programs. HACCP programs, as practiced by the catfish and catfish products processing industry, address quality control for catfish and non-catfish ingredients, proper processing for fresh, frozen, and dried product, and finished product testing. A large share of catfish and catfish product processing establishments with HACCP programs or prerequisite programs likely maintain one or more logs to verify performance under these programs[12].

7. Refrigeration and Cooling in Processing Areas

Refrigeration and cooling in the processing area of the establishment significantly affect the conditions under which the growth of *Salmonella* spp. in catfish and catfish products can occur (Hui, 2001). FSIS, after discussions with catfish experts from trade organizations and universities, estimates

[12] Catfish trade organizations and universities. 2008. Discussions with catfish experts.

that about 60 percent of catfish and catfish products are processed under refrigeration and cooling at a temperature at 45°F or lower, while the remaining (40 percent) products are at between 45°and 59°F while in slaughtering and processing areas. There is no single temperature, but FSIS compliance guidance for maintaining sanitation of food-contact surfaces and utensils recommends minimum cleaning frequencies that increase with higher temperatures, with the cleaning frequencies increasing markedly with temperatures above 50°F to 55°F (See Sanitation Performance Standards Compliance Guide, 4-602.11 at http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/SanitationGuide.htm). Traditionally, to help control microbial growth, FSIS has expected room temperatures where raw product is handled to be below 50°F.

8. Sanitation

In addition to common sanitation practices, FSIS, after discussions with catfish industry experts, estimates that about 80 percent of the processing establishments conduct a mid-shift clean-up. In addition, FSIS projects based on discussions with industry experts that more than 80 percent of establishments conduct sanitation inspections of non-product contact zones once

per day before daily operations begin, before shift operations begin, or more than once per shift.

9. Employee Training

The FSIS discussions with a catfish industry expert indicated that some of the establishments have a formal food safety course that is provided by professional trainers to newly hired employees. Most of the establishments provide scheduled and unscheduled on-the-job food safety training for newly hired employees. Some of the establishments conduct formal refresher courses in food safety, largely by establishment personnel. All of the establishments conduct on-the-job food safety training. The expert representative, Juan Silva of Mississippi State University, also indicated that most of the establishments have at least one employee that has completed formal HACCP training (3-5 day course), with some having 1-3 employees that have completed such a training course.

B. Human Health Baseline - Catfish Associated Human Illness

Using the foodborne disease outbreaks data from the Centers for Disease Control and Prevention, FSIS identified 7 reported catfish-associated outbreaks with a total 66 reported illnesses from 1973 to 2007. A catfish foodborne disease outbreak is defined as the occurrence of 2 or more cases of a similar illness resulting from the ingestion of a common food of catfish. The last recorded catfish-associated outbreak was in

2007. Disease etiology was reported for 3 of the 7 outbreaks identified: 1 outbreak was due to Enterotoxigenic *E. coli*, ETEC O169:H41, with 41 cases in 2003; 1 was due to a chemical with 2 cases in 2000 but lack of further detail information about the chemical involved; and one was due to *Salmonella* Hadar with 10 cases in 1991. According to Wyatt *et al*., (1979) before FDA HACCP regulations were in effect, *Salmonella* spp. were found in 21% of aquaculture live catfish in 1979 and can be harbored within live catfish for 30 days after exposure to high levels (Ward, 1989).

An increased probability of illness is associated with consumption of a variety of anthropogenic chemicals such as pesticides, environmental contaminants, and drugs. Various chemicals have been detected in domestic and imported catfish and catfish products; these compounds represent a potential hazard to consumers.

Catfish and catfish products eaten by U.S. consumers are consumed cooked, often deep fried, and minimizing microbiological hazards. However, some catfish steaks or fillets eaten by U.S. consumers are consumed after being cooked by microwave, broiling, or grilling. Microwaving, broiling, and grilling likely have illness relative risks higher than that of deep frying because microwaving, broiling, or grilling may not

sufficiently heat all parts of the catfish steak or fillet in order to kill all pathogens.

The effect of uncertainty about the baseline level of illnesses or illness relative risks and the effect of the HACCP plans and Sanitation SOPs on the reduction in illnesses or illness relative risks is examined in the FSIS draft risk assessment (USDA FSIS, December 2010) and Benefits Analysis section, below.

III. Regulatory Alternatives

The alternative of no rulemaking is unavailable. The 2008 Farm Bill requires FSIS to issue regulations for mandatory inspection of catfish and catfish products. Consistent with Executive Order 12866 and OMB Circular A-4, two alternatives were considered: (1) A more intensive approach in which an inspector would be stationed in a processing plant throughout an operating shift; (2) A less intensive approach in which an inspector would visit an establishment each day. Under either approach, the inspector would verify Sanitation SOPs and HACCP systems following procedures as instructed by FSIS's automated system for assigning inspection procedures and would conduct microbiological, food chemistry, drug and other chemical residue sampling as directed or as necessary. Also, under either alternative, FSIS would conduct periodic verification of controls at producer locations. The more intensive approach

would also involve closer examination of incoming fish and outgoing product lots for adulteration or potential misbranding. The regulatory alternatives for the implementation of HACCP and related requirements to the catfish and catfish products industry follow:

A. Status Quo

Under the status quo, catfish and catfish product processing establishments would continue to be regulated by FDA and comply with HACCP-based, food safety management methods to control pathogens and prevent product contamination supplemented by the voluntary, fee-for-service inspection and certification programs administered by the NMFS. The use of such programs could continue to grow among well-managed firms. The emphasis on the use of client-driven food safety requirements and third party audits would ensure that the share of establishments with verified, effective food safety management practices would further increase over time. However, as previously stated, the alternative of no rulemaking is unavailable since the 2008 Farm Bill requires FSIS to issue regulations for mandatory inspection of catfish and catfish products.

B. Proposed Alternative Inspection Systems

Strictly in terms of implementing the FMIA with respect to catfish and catfish products, FSIS could take a prescriptive, command-and-control approach to inspection, as it has in the

past with meat and poultry and currently does with egg products. Command-and-control requirements specify, often in great detail, how an establishment is to achieve a particular food-safety objective. They may involve the use of specific techniques or processing parameters; the review and approval of equipment, establishment drawings and specifications; and the review and approval of particular process control programs. FSIS, however, rejected this command-and-control approach in 1996 with the adoption of the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) Systems final rule (61 FR 38806; Jul. 25, 1996). Moreover, command-and-control approaches are generally disfavored, and less burdensome, more flexible approaches are generally preferred, under Executive Order 12866 and OMB Circular A-4.

Thus, FSIS is proposing to adopt, as it has for meat and poultry, the somewhat less intensive, yet effective, approach to inspection that focuses on the verification of an establishment's food safety system, which consists of an establishment's HACCP plan, Sanitation SOPs, and prerequisite programs. As mentioned elsewhere in this document, the FSIS HACCP requirements for meat and poultry establishments are very similar to the FDA HACCP requirements for seafood processors (in 21 CFR 123).

FSIS's inspection approach is similar to that taken by NMFS in its voluntary continuous inspection program, discussed above, for seafood processing establishments. Catfish and catfish products processing establishments that are already enrolled in the NMFS voluntary program could transition with relatively few adjustments into the FSIS mandatory inspection program. Those that are not in the NMFS program would have to make somewhat greater adjustments, in the areas of sanitation programs, prior label approval, documentation, and recordkeeping.

As for products that are to be imported into the United States, under the FMIA and the regulations that FSIS is proposing, to be eligible to ship catfish and catfish products to the United States, foreign countries would have to have inspection systems for catfish and catfish products that FSIS finds to be equivalent to the United States system. Officials of those inspection systems would have to certify individual processing establishments and ensure that products exported to the United States meet FSIS requirements.

The evaluation of a country's inspection system to determine equivalence involves two steps:

- FSIS conducts a document review of an evaluation of the country's laws, regulations, and other written information.

- If FSIS preliminarily determines that the inspection system maintains standards equivalent to the requirements outlined in 9 CFR 327.2, a technical team would visit the country for an on-site review to evaluate the inspection system based on the information submitted to FSIS for the document review.

If the result of these two steps is a successful determination of equivalence, FSIS would begin rulemaking to add the country to the list of countries eligible to export meat, poultry and egg products to the United States.

IV. Cost Analysis

A. Domestic Industries Compliance Costs

The major additional domestic compliance costs include those associated with the development, validation, and implementation of mandatory sanitation SOPs and mandatory HACCP plans that are different from the existing regulatory framework previously discussed (Table 1 and 2). FSIS would limit this analysis to the domestic industry only. FSIS is focusing only on domestic costs and is asking for information on costs to foreign producers. The rule would affect about 23 domestic establishments that slaughter and (primary) process catfish and catfish food products (NASS, 2009). In addition, according to FSIS discussions with catfish industry and federal (FDA and

NMFA) experts that have data on such establishments, the rule would affect about 10 domestic food establishments that conduct further (secondary) processing, including repackaging of catfish and catfish food products. The compliance cost of several sanitation SOPs and HACCP measures rely on the projected mean time required to perform related operations, such as recordkeeping and certification procedures. The projections are based on the practices that are mostly not currently required. The projected frequencies, time requirements, and costs are based on information provided by FSIS's discussions with industry experts familiar with HACCP and sanitation SOPs systems and the domestic catfish and catfish food products industry.

The hourly wage rates used in the cost analysis are as follows: Quality Control (QC) manager--$34.41; Supervisors or QC technicians--$25.28; and production workers--$18.00. The compensation wage rates used in the analysis are based on those reported for employees at meat and poultry processing establishments in the PR/HACCP final rule. The rates are updated using the Employment Cost Index published by the Bureau of Labor Statistics (BLS, 2010). The compensation rates include 33 percent overhead for employee benefits.

B. Sanitation Standard Operating Procedures Additional Domestic Costs

The proposal requires that each establishment have a developed and implemented written sanitation standard operating procedures (SSOP) plan that is specific to its catfish and catfish food products operations. While establishments are now not required to have a SSOP plan, some establishments operate under SSOP plans. FSIS solicits comments on the proportion of catfish and catfish food products establishments that already have SSOP plans.

1. Plan Development and Initial Implementation: Additional Costs

It is assumed that a quality control manager develops the written plan for SSOPs. The average time required would be 8 hours to prepare the first plan for a production process (e.g., production of individual quick frozen (IQF) product) and 4 hours for the second plan, if needed. FSIS recognizes that the time required for plan development would be determined by the number of establishment production processes, the types of products produced, volume of production, the quality and source of the catfish stock, establishment conditions, and other factors. The one-time cost of plan development for the catfish and catfish food products industry is projected to be $5,093. The

annualized cost is projected to be $678 for a ten-year period at a 7 percent discount rate[13].

Table 6. Sanitation SOP plan development additional domestic cost[a] for scenarios #1 and #2.

No. of Processes	**No. of Establishments Affected**		**Time Hours**	**Wage Rate $/hr.**	**One-time First Year Cost**		**Annualized Total Cost**	
	Scenario				Scenario		Scenario	
	#1	#2			#1	#2	#1	#2
					$thousands			
1	4	4	8	34.41	1.1	1.1	-	-
2	10	10	8	34.41	2.8	2.8	-	-
2	9	9	4	34.41	1.2	1.2	-	-
Total	23	23			5.1	5.1	0.7	0.7

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

2. Sanitation SOPs Recordkeeping and Record Storage Additional Costs

The time requirements for recording are based on the time required to conduct two sets of sanitation observations per day, one for pre-operational sanitation procedures and one for operational sanitation. The observation and recording tasks associated with SSOPs recordkeeping are assumed to require an average of 15 minutes by a trained production employee. The quality control technician or establishment management equivalent reviews records compiled by the production employee. This review is projected to average 10 minutes per day.

[13] Unless stated otherwise, all present value and annualized calculations will be made using a discount rate of 7 percent over a ten-year period.

FSIS's discussions with experts indicated that about half of the establishments conduct sanitation inspections of product contact zones more than once per shift, and 10 percent conduct such inspections once per shift before shift operations begin. The other 40 percent of establishments conduct such inspection on a basis that is less frequent than that foreseen by the proposal. In addition, the discussions with industry experts indicate that about 30 percent of establishments conduct sanitation inspections on non-product contact zones more than once per shift and that 10 percent conduct such inspections once per shift before shift operations begin. The other 60 percent of establishments conduct such inspections on a basis that is less frequent. The amount of time such inspections require is not known. However, the level of effort in these activities might be indicated by the commitment of personnel resources. FSIS assumes for this analysis that about 60 percent of the establishments have a food safety manager, and that about 75 percent have two or more employees that work in a quality control department. Of the establishments with a quality control manager, FSIS assumes that about 85 percent of the establishments have at least 25 percent of that employee's time devoted to managing food safety activities. Based on these assumptions and expert opinions, FSIS estimates that between 62 percent and 45 percent of the establishments conduct Sanitation

SOPs recordkeeping in a manner that is consistent with the provisions of the proposal. For the purposes of this analysis, a compliance rate of 50 percent is used. Based on these estimates, the projected annual costs to the industry would be about $32,100.

Table 7. Sanitation SOPs recordkeeping and record storage additional domestic costs[a] for scenarios #1 and #2.

Establish-ments / Shifts	**Establish-ments Affected**		**Record-keeping Time Hours per day**	**Wage Rate $/hr.**	**Review Time Hours per day**	**Wage Rate $/hr.**	**Operating Days per year**	**Annual Total Cost**		**Annualized Total Cost**	
	Scenario							Scenario		Scenario	
	#1	#2						#1	#2	#1	#2
								$thousands			
One shift	8	8	.25	18.00	.17	25.28	260	-	-	-	-
Two shifts	4	4	.50	18.00	.17	25.28	260	-	-	-	-
Total	12	12						32	32	32	32

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

3. Sanitation SOPs Ongoing Additional Implementation Costs

Ongoing additional costs of increased cleaning frequency are associated with the sanitation SOPs because of relatively high room temperatures in the processing areas of some domestic processors. There is no single temperature, but FSIS compliance guidance for maintaining sanitation of food-contact surfaces and utensils recommends minimum cleaning frequencies that increase with higher temperatures, with the cleaning frequencies increasing markedly with temperatures above 50 °F to 55 °F (See

Sanitation Performance Standards Compliance Guide, 4-602.11 at http://www.fsis.usda.gov/Frame/FrameRedirect.asp?main=http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/SanitationGuide.htm). Traditionally, to help control microbial growth, FSIS has expected room temperatures where raw product is handled to be below 50 °F. In some processing areas of affected establishments, where there may be somewhat higher ambient temperatures, there would be minor additional sanitation operating costs of additional cleaning labor and cleaning compounds. These processing areas that are cleaned at a higher frequency would not necessarily require additional capital investment to upgrade refrigeration or cooling equipment. Also, these processing areas would not necessarily require associated additional recurring operating costs of electricity and maintenance to operate refrigeration or cooling equipment in order to lower the processing room temperature.

Because about 3 domestic establishments are projected to operate processing at air temperatures above 50 to 55 degrees Fahrenheit (F), these establishments would need additional cleaning of food contact surfaces each day. For this, additional labor for equipment cleaning and sanitation is projected to take 10 minutes per day billed at $18.00 per hour, or $3.00 (($18 / 60) x 10) for 10 minutes. FSIS projected that

these establishments would work 260 days per year for an annual cost of about $780 ($3.00 per day x 260 days). Furthermore, additional water, and cleaning and sanitizing materials are projected to cost $160 per year. Then, for each establishment this totals to $940 ($780 + $160) per year. Thus, for 3 establishments, this totals to $2,820 (3 x $940) per year. In addition, in the first year, FSIS projected that each of about 23 establishments would need to purchase about $130 of additional cleaning equipment such as new scrub brushes and water hoses. For all 23 establishments this would total about $3,000 (23 x $130).

FSIS asks for public comment and information on this issue and would include the additional data in the analysis for the final rule.

4. Sanitation SOPs Training Additional Costs

Based on FSIS's discussion with catfish experts, FSIS assumes that about 70 percent of the establishments' training programs are conducted at their establishment. These programs are either a formal food safety course conducted by establishment personnel or are a scheduled on-the-job food safety program, also conducted by establishment personnel. However, FSIS assumes that conducting a SSOPs intervention program is a new requirement and consequently training would be conducted at all establishments.

Training in Sanitation SOPs verification for catfish and catfish products processing establishments would likely take two hours for both a Quality Control (QC) technician and production worker for each shift at the establishment[14]. Training would be conducted once every three years, or in the first, fourth, seventh, and tenth year of the 10-year period of analysis. Training materials are obtained at no cost from the FSIS Center for Learning. The training cost per period is $2,511. When the costs of the 4 training periods are annualized over a ten-year period, the cost is $1,011.

Table 8. Sanitation SOPs training additional domestic costs* for scenarios #1 and #2.

Personnel	Establis-hments Affected		Shifts in Establi shment	Time Hour s	Wage Rate $/hour	Annual Total Cost per period[2]		Annualized Total Cost	
	Scenario					Scenario		Scenario	
	#1	#2				#1	#2	#1	#2
						Dollars			
Verification:									
QC Technician	17	17	1	2	25.28	860	860	-	-
	6	6	2	2	25.28	607	607	-	-
Sub-Total						1,467	1,467	-	-
Recordkeeping:									
Production Worker	17	17	1	2	18.00	612	612	-	-
	6	6	2	2	18.00	432	432	-	-
Sub-Total						1,044	1,044	-	-
Total	23	23				2,511	2,511	1,011	1,011

1. Training materials include video tapes, handouts, etc. used in training that would be obtained from the FSIS training center at no cost.
2. Assumes all establishments conduct training in the same time period. Training is conducted during the first, fourth, seventh, and tenth years of a ten-year time period.
3. Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

The summary of additional domestic costs for sanitation SOPs for scenarios #1 and #2 is in Table 9.

[14] Training time requirement is provided by the FSIS Training Center and based on time needed to complete video instruction.

Table 9. Summary of additional domestic costs[*] for sanitation SOPs for scenarios #1 and #2.

Measure	First year / One-time Cost		First year Cost		Annual Cost after first year		Annualized Total Cost	
	Scenario		Scenario		Scenario		Scenario	
	#1	#2	#1	#2	#1	#2	#1	#2
	$thousands							
Plan Development, validation and Reassessment	5	5	5	5			-	-
Training (years 1, 4, 7 & 10)			2	2			-	-
Additional Ongoing Implementation	3	3	6	6	3	3	-	-
Recordkeeping and Record Storage			32	32	32	32	-	-
Total	8	8	46	46	35	35	37	37

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

Total annual SSOPs average domestic costs are projected at about $45,000. First year average cost is projected at about $45,700. The annual average cost is about $37,200. The annual average recurring cost after the first year is about $37,200. The annualized average cost is about $37,200.

C. Hazard Analysis and Critical Control Point (HACCP) Systems Additional Domestic Costs

The proposal requires that each establishment have a developed, validated, and implemented written HACCP plan that is specific to each process being performed in the catfish and catfish food products establishment. While the establishment is already required to have a HACCP plan, this HACCP plan may not

be validated on products. FSIS asks for comments on the proportion of catfish and catfish products establishments that already have HACCP plans that are validated. FSIS compliant HACCP plans would have the required validation on products. However, for purposes of this analysis, FSIS assumes that many catfish and catfish products processing establishments would need to re-write their existing HACCP plans in order to be compliant with FSIS HACCP plans. Establishments need not prepare HACCP plans for processes for which the hazards, CCPs, critical limits, corrective actions, monitoring and verification procedures, and recordkeeping systems are similar. However, in order to have FSIS-compliant HACCP plans, the establishments may need to conduct validation on a product-by-product basis.

For purposes of this analysis, there would be two processes employed in catfish and catfish products production (fresh/frozen and breaded products). Fresh/frozen products include 4 primary categories: catfish fillets, whole catfish, catfish nuggets, and steak products. Breaded catfish products include three primary categories: breaded catfish fillets, breaded catfish nuggets, and breaded catfish steak products. In addition, there could be marinated products, individual quick frozen (IQF) products (e.g., fillets, steaks, and nuggets), cooked products, and smoked/dried products. Each HACCP plan would include identification of the processing steps that

present hazards; identification and description of the CCP for each identified hazard; specification of the critical limit that may not be exceeded at the CCP (and, if appropriate, a target limit); a description of the establishment monitoring procedures; a description of the corrective action to be taken if a critical limit is exceeded; a description of the records that would be generated and maintained regarding this CCP; and a description of the facility verification activities and the frequency at which they are to be conducted. Establishments would also be required to record observations when monitoring CCPs and to document any deviations and corrective actions. Such records are to be reviewed and certified by an employee not involved in recording observations.

1. HACCP Plan Development, Validation, and Reassessment Additional Costs

The proposal requires that the establishment review and analyze its processes. A HACCP-trained QC technician or other suitable personnel could perform the hazard analysis.

The discussions with industry experts indicate that some (assumed to be about 80 percent) catfish and catfish product establishments have a written HACCP plan; that a significant share of these plans designate slaughter, breading, marinating, and other processes as CCPs; and that a large share of these establishments maintain records to verify a number of HACCP

activities. Based on discussions with industry experts, FSIS assumes that about 75 percent of small establishments and about 90 percent of large establishments have a written HACCP plan. Based on these discussions, there would be 4 one-process establishments and 11 two-process establishments that would be required to develop a HACCP plan[15].

Upon completion of the hazard analysis and development of the HACCP plans, establishments are required to determine whether the HACCP plan is functioning as intended. During the initial validation period, establishments are to repeatedly test the adequacy of the CCPs, critical limits, monitoring and recordkeeping procedures, and corrective actions identified in the HACCP plan. Activities conducted by the establishment that are associated with validation include the calibration of process-monitoring instruments, direct observations of monitoring activities and corrective actions, and review of records.[16] The most critical aspect of the HACCP plan validation for catfish and catfish product processing establishments would be to ensure that the chilling process employed at the establishment achieves the required level of stopping bacteria growth to validate the adequacy of CCP critical limits.

[15] The number of one-process and two-process establishments in compliance with the HACCP establishment requirement is estimated. The number of affected establishments is estimated.
[16] 9 CFR 417.4

The projected one-time first-year cost of HACCP plan development and validation for a single process establishment is about $8,000. For a two-process establishment, the cost is projected at about $6,000 per process, or a total of about $12,000.[17] In addition, all 23 processing establishments are required to conduct an annual reassessment of their HACCP plan which is estimated at about $70 per process in plan. The total one-time first-year costs for plan development are projected to be about $98,000. The annual reassessment thereafter is about $1,050 for the industry.

Table 10. **H**ACCP additional domestic costs* for plan development, validation and annual reassessment for scenarios #1 and #2.

Process	**Establish-ments Affected**		**Cost Per Process in Plan**	**Annual Reassessment Cost after first year**		**One-time First-year Plan Development Total Cost**		**Annualized Total Costs**	
	Scenario			**Scenario**		**Scenario**		**Scenario**	
	#1	**#2**		**#1**	**#2**	**#1**	**#2**	**#1**	**#2**
			$thousands						
One process firms	4	4	8	0.6	0.6	32	32	-	-
Two process firms	11	11	6	1.1	1.1	66	66	-	-
Industry	15	15		1.7	1.7	98	98	14	14

* Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

The analysis does not include costs associated with taking a corrective action when routine monitoring of a CCP detects a deviation from an established critical limit.

[17] The estimated HACCP plan development costs are based on FSIS discussions with catfish industry experts.

2. HACCP Training Additional Costs

Each catfish and catfish products processing establishment, or further processing food establishment is projected to employ a quality control (QC) manager and a quality control(QC) technician to ensure compliance with the proposed measures. At a minimum, the quality control (QC) manager would have successfully completed a recognized HACCP training course of at least 3-5 days with an equivalent amount of time of training in the principles of HACCP, the application of these principles, and the development of a HACCP plan for catfish and catfish products. A QC technician would be responsible for day-to-day activities related to the HACCP plan implementation.

FSIS's industry discussions with experts indicate that HAACP-trained employees are likely found in a large share of catfish and catfish product establishments. Further, FSIS estimates that about 54 percent (18 of 33) of the establishments employ a food safety manager. Based on FSIS's discussions with catfish experts, FSIS estimates that about 75 percent of catfish and catfish product establishments have at least 2 or more employees that work in a quality control (QC) department and that 85 percent of the establishments have at least 1 employee that has completed a formal 3-5 day HACCP training course. For the purposes of this analysis, 35 percent of establishments would obtain training for a QC manager and QC technician for

each shift where processing operations are conducted. Of the 16 establishments in need of HACCP training, 12 establishments operate one shift and 4 operate two shifts. Training would be conducted on the first year of implementation and also the sixth year to account for attrition.

HACCP training course materials, including test materials, are available at no cost from the FSIS Center for Learning. The projected time required to complete the course is 40 hours. The course is self taught. The training material is the same as that used by FSIS to train its employees. FSIS assumes that this method of instruction would be used rather than hiring a consultant to teach the course at the work site or to send employees to an off-site location. Training costs per training period is projected at $47,700, with an annualized cost of $10,873.

Table 11. Projected additional domestic cost[a] of HACCP training for scenarios #1 and #2.

Size of Establish-ment/ Type of Employee	**Establish-ments Affected**		**No. of Employees**		**Train-ing Hours**	**Wage Rate $/hour**	**Total Costs per training period**		**Annualized Total Costs**	
	Scenario		Scenario				Scenario		Scenario	
	#1	#2	#1	#2			#1	#2	#1	#2
One shift:							$thousands			
QC Manager	2	2	16	16	40	34.41	22	22	-	-
QC Technician	3	3	16	16	40	25.28	16	16	-	-
Two shifts:										
QC Manager	3	3	4	4	40	34.41	6	6	-	-
QC Technician	3	3	4	4	40	25.28	4	4	-	-
TOTAL	11	11					48	48	11	11

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

3. HACCP Personnel Additional Cost

Personnel costs are associated with the activities of the QC manager who would be responsible for addressing and performing functions related to hazard analysis, plan development, plan validation, and review and assessment of critical limits and responses to deviations. These activities are projected to require 5 percent and 10 percent of the QC manager's time at one and two process facilities, respectively. The salary of QC managers is projected at $71,658, based on the hourly compensation rates used in the analysis. The personnel costs associated with HACCP implementation are based on the expert opinion that about 60 percent of establishments employ a food safety manager, which is the equivalent of a quality control manager. The broader quality control activities associated with HACCP plan validation, review, and related tasks may be performed at the corporate level, given the similarity of plans and processes at catfish and catfish product establishments. Based on these findings, the number of establishments that would not currently comply with the projected personnel time requirement related to hazard analysis, plan development, plan validation, and review and assessment of critical limits and responses to deviations are 5 one-process firms and 6 two-process firms. Based on these projections, the

projected annual personnel costs to the catfish and catfish products industry would be $79,200.

Table 12. HACCP personnel additional domestic cost[a] for scenarios #1 and #2.

Shift / Process	Establishments Affected		HACCP Employees		Percent of time	Annual Total Cost		Annualized Total Cost	
	Scenario		Scenario			Scenario		Scenario	
	1#	2#	1#	2#		1#	2#	1#	2#
One shift:						$thousands			
One Process	2	2	2	2	5	2	2	-	-
Two Processes	3	3	12	12	10	44	44	-	-
Two shifts:									
One process	3	3	6	6	5	11	11	-	-
Two processes	3	3	6	6	10	22	22	-	-
Total	11	11				79	79	79	79

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

4. HACCP Recordkeeping and Record Storage Additional Costs

The proposal requires facilities to record observations when monitoring CCPs and to document any deviations and corrective actions. The rule also requires that such records be certified by an employee not involved in recording observations. HACCP records include measurements taken during processing, deviations from CCPs, corrective actions, verification check results, and related information including the identity of the product, the product code or production lot, and the date of the recording.

Recordkeeping costs include the time it takes to make observations and record the results of those observations, plus the cost of certifying and maintaining records. Total

recordkeeping costs are the sum of the costs for three components: monitoring CCPs and recording findings, certifying records, and storing records. The monitoring and recording costs are described by the formula:

RC = O x CP x T/60 x WR x D where

RC = Monitoring and recording costs,

O = Number of industry operations requiring recordkeeping,

CP = Number of CCP's per HACCP plan,

T = Recording time in minutes per CCP,

WR = Wage rate for recording and monitoring, and

D = Days of operations during the year, in this case, 260.

The cost of certification is described by the formula:

C = S x CC x TC/60 x WC x D where,

C = Certification costs,

CC = Number of CCP's per plan,

S = Number of shifts,

TC = Time in minutes for certifying each CCP per shift, and

WC = Hourly wage rate for QC technician,

FSIS projects that 18 of the 33 establishments conduct recordkeeping and verification in varying degrees. FSIS considers the recordkeeping and verification practices at about 15 establishments to be conducted in a manner that would be found at official meat and poultry establishments. These establishments constitute 45 percent (15/33) of the industry.

The remaining 55 percent, or 18 establishments, are considered not to be in compliance with the recordkeeping and monitoring requirements for the purposes of the analysis, even though a significant recordkeeping and monitoring may be performed at these establishments.

Table 13. HACCP additional domestic costs[a] for recordkeeping and monitoring (certification) for scenarios #1 and #2.

Shift / Task /Process	Establish-ments Affected		HACCP Processes in Plans	CCPs per Plan	Time Per CCP Minutes	Wage Rate $/hr.	Operat-ing Days	Annual Total Cost		Annualized Total Cost	
	Scenario							Scenario		Scenario	
	#1	#2						#1	#2	#1	#2
One Shift:								$Thousands			
Recordkeeping:											
1 process	4	4	1	5	3	18.00	260	5	5	-	-
2 processes	11	11	2	5	3	18.00	260	26	26	-	-
Monitoring:											
1 process	4	4	1	5	1	25.28	260	2	2	-	-
2 processes	11	11	2	5	1	25.28	260	12	12	-	-
Sub-Total	15	15						45	45	-	-
Two shifts:											
Recordkeeping:											
1 process	1	1	1	5	3	18.00	260	1	1	-	-
2 processes	2	2	2	5	3	18.00	260	5	5	-	-
Monitoring:											
1 process	1	1	1	5	1	25.28	260	1	1	-	-
2 processes	2	2	2	5	1	25.28	260	2	2	-	-
Sub-total	3	3						9	9	-	-
Total	18	18						53	53	53	53

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

Other variables included the mean number of CCPs per plan and the mean amount of time for recording and reviewing records per CCP. The number of CCPs per catfish and catfish product processing establishment may vary considerably across the industry. The major variables affecting the number of CCPs at any individual establishment are the number and types of products produced, age of the establishment, whether or not the

establishment is an in-line processor, and the quality of the catfish stock. FSIS technical personnel suggest 4 to 6 CCPs per HACCP plan. Another expert suggests a minimum of 3 CCPs.[18] This source also states that it is important for processors to know the history of the catfish they receive, suggesting additional CCPs may be needed. Based on information obtained from industry experts and those familiar with catfish and catfish product processing, the number of CCPs is projected to be an average of 5 per establishment per process. Based on these factors, the projected annual cost of HACCP recordkeeping and monitoring is estimated to be $53,400. FSIS seeks comment on the number of additional CCPs anticipated, taking into account the variables listed above.

Recordkeeping storage costs were based on a national survey of storage costs showing an average annual cost of $8.40 per square foot in 1994, which was updated to $9.63 per square foot. Annual storage costs for HACCP records were assumed to be $60 per establishment for a total of $1,080 (18 x $60).

The total first-year additional cost of the proposed HACCP requirements for the catfish and catfish product industry is

[18] Personal communication with Catherine Viator, RTI. Reported in RTI International. 2002. "Pathogen reduction and Other Technological Changes in the Meat, Poultry, and Egg Industries." RTI Project no. 07182.017. 3040 Cornwallis Rd., P.O. Box 12194 Research Triangle Park, NC 27709-2194

projected to be $279,000. The total annual costs are projected to be $158,000.

Table 14. Summary of additional domestic costs[a] for HACCP requirements for scenarios #1 and #2.

Measure	First year / One-time Total Costs		First year Total Cost		Annual Total Cost after first year		Annualized Total Cost	
	Scenario		Scenario		Scenario		Scenario	
	#1	#2	#1	#2	#1	#2	#1	#2
	$thousands							
Plan development, validation, and reassessment	98	98	98	98	2	2	14	14
Training (years 1 & 6)	48	48	48	48			11	11
Personnel – HACCP			79	79	79	79	79	79
Recordkeeping and certification			53	53	53	53	53	53
Record Storage			1	1	1	1	1	1
Other Compliance	5	5	7	7	2	2	3	3
TOTAL	103	103	287	287	137	137	162	162

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

The total additional costs of SSOPs and HACCP for the catfish and catfish food product processing domestic industry are shown in Table 14. The first year and annual costs of these measures are $310,400 and $184,500, respectively.

D. Pre-harvest – Production and Transportation Additional Domestic Costs

Under this proposal, FSIS would take account of the conditions under which the catfish are raised and transported to the processing establishment. Catfish for human food must have

grown and lived under conditions that would not render them unsound, unwholesome, unhealthy, or otherwise unfit for human food.

The majority of the real and perceived concerns with the safety and quality of raw aquaculture products originate at the farm level. These concerns include pathogen contamination (e.g. *Salmonella*), chemical contamination, and misused or unapproved chemotherapeutic drugs.

Under scenario #1 of the proposal, FSIS assumes that catfish producers and haulers of live catfish to processing establishments would need to be included in SSOPs and HACCP plans of the receiving processing establishments. Furthermore, producers and haulers would likely need to put in place Good Aquaculture Practices (GAqPs) or Good Manufacturing Practices (GMPs).

In addition, FSIS projects that catfish producers would have additional laboratory testing costs to monitor pond water and sediment for suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and industrial chemicals. FSIS would sample feed, fish, and pond water and sediment.

FSIS solicits information on the costs to the catfish producers because of the proposal.

In addition, FSIS assumes that about 50 percent, or 11 of the 23 catfish and catfish products processors, contract with

about 11 loading-and-hauling firms. These 11 firms capture and load the live catfish into their approximately 66 water-tanker trucks (using approximately 6 trucks per establishment), and then transport alive the catfish to the processing establishments. The approximately 11 firms that run their 66 water-tankard trucks would likely need to upgrade about 50 percent of the 66 trucks, or an upgrade of about 33 trucks. The remaining 12 processing establishments run their own catching crews and hauling using approximately 5 trucks per establishment or a total of about 60 water-tankard trucks. After implementation of the final rule, FSIS assumes that 50 percent of these 11 contracted firms or approximately 5 firms would be affected because of additional HACCP plans, SSOPs, and Pre-requisite Program requirements for the transportation of the live catfish to the processing establishments.

For transportation of live catfish to the processing establishment, the proposal requires sufficient water and oxygen to ensure catfish are not adulterated. FSIS projects that haulers would have a one-time cost of approximately $1,800 per truck to purchase and install equipment on each of their 63 (30 + 33) trucks that would provide sufficient oxygen to ensure that catfish are not adulterated when they arrive at the slaughter and processing establishments. Many of these trucks already

have and use this equipment. FSIS assumes that about 126 trucks are used to haul catfish to the processing establishments.

FSIS projects that the one-time cost would be approximately $56,700 (63 x 900) for the additional equipment. Furthermore, FSIS projects that the operating cost annually for the oxygen injection and maintenance is 20 percent of the $900 cost of the equipment, or $180 per year per truck. If there are about 126 trucks, the projected annual cost would be $22,680 (126 x 180).

FSIS solicits information on the number of firms and trucks that would be affected by the proposed rule, and the compliance cost to trucker firms or processing firms.

E. Microbiological, Chemical, and Other Testing Additional Domestic Costs

The proposed rule requires additional microbiological, chemical, and other testing. In addition, FSIS projects that catfish producers would have additional laboratory testing costs to monitor pond water and sediment for suspended solids, organic matter, nutrients, heavy metals, pesticides, fertilizers, and industrial chemicals. FSIS would sample feed, fish, and pond water and sediment.

FSIS solicits information on the testing frequency and costs to the catfish and catfish processors and catfish producers because of the proposal. Then, FSIS would include these costs in the cost analysis with the final rule.

F. New Labels: Additional Domestic Costs

The proposed rule requires new label statements for all catfish and catfish products. Additionally, statements must be printed on the principal display panel of the product. To determine the cost of this proposed regulation on the industry, a labeling cost model developed by researchers at RTI was used to project costs (Muth, 2001). This model was originally developed for various consumer food products and was adapted for catfish and catfish products. The one-time cost is for the manufacturing of the flexographic printing plates with the required information of the official inspection legend, place of manufacture, 100-percent net weight, safe-handling labeling for products that are not ready-to-eat. These plates are assumed to have a useful life of at least 10 years. The printing of new catfish and catfish product labels is an additional cost because of this proposed rule.

For the scenario #1, based on the RTI analysis, FSIS projected that the one-time cost of the new labeling requirement for the processors is about $121,000, and annual recurring cost is about $18,000. For scenario #2, FSIS projected that the one-time cost of the new labeling requirement for the processors is about $102,000, and annual recurring cost is about $11,000. The lower label cost for scenario #2 is due to the lower volume of

labeled products. Some of the importers repackage product and would need to add additional labels.

Table 15. Additional domestic cost[*] of new labels for scenarios #1 and #2.

Type of label	Type of product	First year / One-time Cost		First-Year Cost (One-time Cost and Recurring Costs)		Annual Cost after first year		Annualized Total Cost	
		Scenario		Scenario		Scenario		Scenario	
		#1	#2	#1	#2	#1	#2	#1	#2
		$thousands							
Pre-printed	Fresh	75	71	-	-	-	-	-	-
	Frozen	13	8	-	-	-	-	-	-
Sticker	Fresh	16	11	-	-	-	-	-	-
	Frozen	17	12	-	-	-	-	-	-
Total		121	102	139	113	18	11	34	25

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

G. Provision of Government Office Space and Equipment Additional Costs

The proposal requires provision of Government office space and some equipment in each of the approximately 23 catfish and catfish products processing establishments, and in each of the approximately 10 catfish and catfish products further processing (processing-only) establishments. FSIS assumes that it would occupy the existing 18 NMFS offices of the 23 establishments that slaughter and process catfish and catfish products. However, FSIS would need new remodeled office space in about 15 establishments – about 5 establishments that slaughter and process catfish and catfish products, and about 10 that further process catfish and catfish products. FSIS assumes that it

would need at a minimum 150 (10 x 15) square feet of securable office space with at least one desk with a drawer that can be locked, a chair, and a locker to hang clothes. In addition, the Government office needs to have a telephone and telephone connection, and 110-120 volt 20 ampere electrical outlet. Furthermore, the office needs ventilation, heating, cooling, and lighting that meets OSHA standards for office space. Based on discussion with experts that construct office space, FSIS projects that this space would cost about $6 per square foot to remodel existing space, or $900 (6 x 150) per office. Furthermore, FSIS projects that it would cost about $200 to furnish the remodeled office space with a desk/table, chair, locker cabinet, and telephone. FSIS projects that the total one-time cost at $1,100 (900 + 200) per Government office that would be for exclusive use by FSIS. FSIS projects that the one-time cost to the approximately 15 establishments for additional Government offices would be about $16,500 (15 x 1,100). FSIS projects that the recurring costs would be about $40 per month for telephone service, electricity, heating, cooling, and other, or $480 (12 x 40) per year per office. FSIS projects that the recurring annual cost to the approximately 15 establishments for the additional Government offices would be about $7,200 (15 x 480).

H. Re-inspection at Import Establishments Additional Cost

For the purposes of this analysis, FSIS assumes that the flow of imported catfish would not change as a result of this rulemaking. Specifically, we assume that countries which currently export catfish to the U.S. processors would be able to obtain equivalency from USDA by the end of the proposed phase-in period. Thus, U.S. processors who rely on imported catfish would not face a shortage of catfish to process and would not need to switch products they process. FSIS recognizes that this assumption may not be realistic. If countries that currently export catfish to the U.S. processors are not able to obtain equivalency before the implementation date, U.S. processors who rely on imported catfish may face a shortage of fish to process or would need to switch products they process leading to higher costs and lower profits. If so, additional costs would be incurred and those costs would have to be considered in a full analysis. Comments are requested on these issues.

The proposal requires import inspection establishments to provide facilities space for the re-inspection of catfish and catfish food products that meet the same sanitation requirements for the re-inspection of meat and poultry products. This provision could apply to about 80 import establishments for scenario #1. For scenario #2, this provision could apply to about 18 importers who import Ictaluridae. To carry out this

task, FSIS randomly selects samples of imported catfish and catfish products and conducts various tasks including product examinations, net weight compliance checks, condition of the container, incubation of shelf-stable products, special examinations, and laboratory analyses.

The proposal does not result in any changes to the maintenance, operation, or physical requirements of inspection houses where re-inspection activities are conducted. FSIS experts conclude that all import establishments conducting meat and poultry re-inspection activities could apply and be granted authority to conduct catfish and catfish product re-inspection activities. Establishments would have to add a SSOPs plan to current written plans, but the costs of doing so are minimal. For scenario #1, FSIS projects that the recurring cost for about 80 importers after the first year is about $600 each year, after a first year cost of about $1,800. For scenario #2, FSIS projects that the recurring cost for about 18 importers after the first year is about $400 each year, after a first year cost of about $500.

FSIS solicits information on the costs to the import establishments because of the proposal.

I. Additional Agency Costs

There are a number of tasks that FSIS must undertake prior to and during the implementation of sanitation SOPs and HACCP

plans in the catfish and catfish product processing, further processing, and production supply chain industries. Costs currently incurred by FDA and NMFS would be incurred by FSIS, if the proposal is finalized. In addition, NMFS would not generate revenues by providing voluntary inspection services to catfish processors. be transferable to FSIS, and likely these revenues would no longer be available to NMFS. FSIS in this analysis uses a net agency cost, after considering projected net cost savings of FDA and NMFS because they would be displaced by FSIS inspection services that would be free to the industry, except for overtime and other fees such as for export certificates.

1. Training and Personnel Additional Costs

The SSOP, HACCP, and RTE training has not been targeted for catfish and catfish product inspectors. New training would need to be developed based on the rule, and the inspection policies to verify implementation of the rule would be outlined in a directive. All catfish and catfish product inspectors would need the training.

The long-term objective of FSIS is to establish an inspection system where inspection program personnel would be equally qualified to conduct inspection activities at meat or poultry establishments, or maybe catfish and catfish product processing establishments. To accomplish this objective, inspection program personnel would be cross-trained in meat,

poultry, and catfish and catfish product HACCP procedures and inspection tasks.

Training for FSIS inspection program personnel is based on the following assumptions. Inspection program personnel assigned to catfish and catfish product processing establishments, catfish and catfish products further processing food establishments, and catfish production establishments could require one week of training on SSOPs and one week of training on HACCP. They could complete training on the Performance Based Inspection System (PBIS) through computer-based training. They could then complete the Other Consumer Inspection training by computer-based training, completing the modules that are applicable to the procedures that need to be performed in the establishments in their assignment. As appropriate, inspection program personnel currently assigned to meat and poultry establishments could complete one week of training on catfish and catfish product processing. The total costs (including travel, lodging, per diem, and training program) for a one-week training program is $1,125. For scenario #1, FSIS anticipates that it could train 109 catfish and catfish product inspection program personnel for three weeks each, for a total of 327 training weeks at a one-time cost of $367,900 (109 x 3 x $1,125). The total number of training weeks provided to FSIS inspection program personnel is 377. Based on these

assumptions, the cost of training FSIS inspection program personnel is expected to be $424,125 (377 x $1,125). For scenario #2 with fewer importers and a smaller volume of products to inspect, fewer FSIS inspection program personnel and fewer training weeks would be needed. In this case, the training cost could be for about 10 percent fewer or about 340 training weeks for FSIS inspection program personnel for about $382,500. For both scenarios #1 and #2, replacement inspectors could be required during periods when inspectors at catfish and catfish product establishments are being trained. The cost of replacement inspectors is projected at about $1,279 per week based on discussions with an FSIS district office. Consequently, for scenario #1, the projected one-time cost of replacement inspectors is about $418,200 (327 x $1,279). For scenario #2, the projected one-time cost of replacement inspectors is about $371,000 (290 x $1,279). The projected total one-time cost of training inspectors at catfish and catfish product establishments and further processing food establishments is $842,400, for scenario #1. For scenario #2, FSIS projects about 10 percent less cost, or about $760,000.

The annual salaries for each inspector are $54,900 for a recurring cost of $329,400, for scenario #1, and $329,400, for scenario 2. One-time re-location costs are projected at $7,500 per employee for a total of $45,000. The training costs could

be the same as those identified above for a projected total of $20,250. The projected total one-time costs to FSIS for training related costs are $907,600, for scenario #1, and $818,000 for scenario #2. For scenario #1, FSIS projects that its testing and other costs (e.g., packing and shipping samples, analyzing these samples, recording results in the Agency's databases, and reporting results to the industry and the public) are about $12,018,900 per year (see Table 16). For scenario #2, FSIS projects that it's testing and other costs would be about $9,000,000 per year because of a smaller volume of product yet testing for species identification would increase for this scenario.

Table 16. Inspection program training, personnel, and other costs[*] for scenarios #1 and #2.

Type of Cost	First year / One-time costs		First year total costs (one-time and recurring costs)		Annual Costs after first year		Annualized Total Cost Annual Costs after first year	
	Scenario		Scenario		Scenario		Scenario	
	#1	#2	#1	#2	#1	#2	#1	#2
	$thousands							
Catfish and catfish products processing, further processing, exporters, and production establishments:								
Catfish inspection personnel			329	329	329	329	-	-
Training	424	382	424	382	86	77	-	-
Replacement Inspection	418	371	418	371				
Subtotal	842	753	1,171	415	415	415	-	-
Other Staff Costs:							-	-
Salary			2,838	2,838	2,838	2,838	-	-
Training	20	20	18	18	18	18	-	-
Relocation	45	45						
Testing and other costs			12,019	9,000	12,019	9,000	-	-
Subtotal	65	65	14,875	14,875			-	-
Total	908	818	15,290	15,290	14,958	14,958	14,958	14,958

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

2. Develop Generic HACCP Models and Sanitation SOPs Models – Additional Costs

FSIS plans to assist catfish and catfish food product primary processing establishments, and food establishments that further (secondary) process catfish and catfish food products with HACCP and sanitation SOPs implementation. A generic model, containing different process category examples for catfish and catfish food products, could be developed to assist catfish and catfish product establishments and catfish production

establishments in the preparation of their HACCP plans. The model is illustrative and could serve to minimize many obstacles to preparing a HACCP plan. As was the case with meat and poultry HACCP implementation, FSIS could also invite members of the private sector to participate in ongoing small establishment demonstration projects following promulgation of a final rule to show how HACCP systems can work under actual operating conditions. Based on FSIS's experience with assisting small meat and poultry establishments, the cost of FSIS activities to assist catfish and catfish product processing establishments, and further processing establishments with HACCP and Sanitation SOPs implementation is $125,000.

3. Re-inspection – Additional Costs

The proposal requires import inspection establishments to provide facilities for the re-inspection of catfish and catfish products that meet the same sanitation requirements for the re-inspection of meat and poultry products. This provision could apply to about 80 establishments. To carry out this task, FSIS randomly selects samples of imported meat and poultry products and conducts various tasks including product examinations, net weight compliance checks, condition of the container, incubation of shelf-stable products, special examinations, and laboratory analyses.

The proposal does not result in any changes to the maintenance, operation, or physical requirements of inspection houses where re-inspection activities are conducted. FSIS experts conclude that all import establishments conducting meat and poultry re-inspection activities could apply and be granted authority to conduct catfish and catfish product re-inspection activities. Some training may be required for FSIS inspection program personnel located at these facilities. These training needs could be addressed through current FSIS employee training programs.

4. Microbiological, Chemical, and Other Testing – Additional Costs

FSIS would conduct or purchase services to run microbiological, chemical, and other tests. FSIS would sample and test feed, fish, and pond water and sediment, for microbes, chemicals, and species determinations. FSIS projects that it would cost about $12,000,000 per year to collect, ship, and analyze these samples; recording results in the Agency's databases; and reporting results to the industry and the public). Under the proposed scenario #2, the Ictaluridae definition of catfish, FSIS would need to do relatively more test samples for speciation compared to scenario #1.

5. Total FSIS Additional Implementation and Annual Costs

For scenario #1, the projected total cost of FSIS additional implementation one-time first-year is $1,032,000, and annual cost of $15,302,000 per year, after the first year, are shown in Table 17. For scenario #2, the projected total cost of FSIS additional implementation one-time first-year is $944,000, and annual cost of $11,625,000 per year, after the first year, are shown below. Scenario #2 requires less FSIS resources because it has about 62 fewer importers and less volume of imported products to inspect than scenario #1.

Table 17. FSIS / Agency additional implementation and annual costs* for scenarios #1 and #2.

Tasks	One-Time First Year Total Costs		First Year Total Costs (One-time and Recurring Total Costs)		Annual Total Cost after first year		Annualized Total Costs	
	Scenario		Scenario		Scenario		Scenario	
	#1	#2	#1	#2	#1	#2	#1	#2
	$thousands							
Training-for catfish and catfish products processing, further processing, and catfish production; and salaries of support staff	842	753	3,784	3,100	2,942	2,350	-	-
Training and Inspection - other staff and inspection personnel	65	65	394	335	329	270	-	-
Generic HACCP Models	125	125	125	125			-	-
Re-inspection			12	5	12	5	-	-
Testing and Other			12,019	9,000	12,019	9,000	-	-
Total	1,032	944	16,334	12,565	15,302	11,625	15,438	11,749

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

J. Total Additional Domestic Costs

For scenario #1, the additional mean total first-year and one-time cost to the catfish and catfish food products domestic

supply chain industries of the proposed measures is projected at about $306,000. The first year cost is projected at about $543,000. For the catfish and catfish food product domestic industry, the additional mean annual cost is projected at $187,000. The projected additional mean estimated annualized cost is $240,000 (See Table 18). The projected lower bound (10th percentile) is $237,000, and the projected upper bound (90th percentile) is $243,000.[19] The present value of the mean cost, using a 7 percent discount rate over 10 years is projected at $1.7 million (Table 18).

For scenario #2, the additional mean total first-year and one-time cost to the catfish and catfish food products domestic supply chain industries of the proposed measures is projected at about $286,000. The first year cost is projected at about $516,000. For the catfish and catfish food product domestic industry, the additional mean annual cost is projected at $181,000. The projected additional mean estimated annualized cost is $230,000 (See Table 18). The projected lower bound (10th percentile) is $227,000, and the projected upper bound (90th percentile) is $233,000.[20] The present value of the mean cost,

[19] A stochastic simulation model was used to determine the distribution of values. Uncertainty analyses are conducted to estimate cost distributions for each of the alternatives for the proposed rule. The stochastic model uses @RISK (Version 4.5, Palisades Corp.) to examine the effects of uncertainty.

[20] A stochastic simulation model was used to determine the distribution of values. Uncertainty analyses are conducted to estimate cost distributions

using a 7 percent discount rate over 10 years is projected at $1.6 million (Table 18). The results of the uncertainty analysis of the costs are in the economic model in Exhibit A below.

For scenario #1, the projected additional mean total annualized cost to the catfish and catfish food products supply chain industries of the provisions of the proposal analyzed is about $0.0008 per pound ($240,000 / 285 million pounds, in 2007) of aggregate processed catfish and catfish food products.

For scenario #2, the projected additional mean total annualized cost to the catfish and catfish food products supply chain industries of the provisions of the proposal analyzed is about $0.0011 per pound ($230,000 / 204 million pounds, in 2007) of aggregate processed catfish and catfish food products.

The cost of the provisions to the catfish and catfish food products industry compares to a 2006-2008 average price of $0.83 per pound for frozen whole catfish,[21] $1.14 per pound for frozen catfish fillets,[22] and $0.402 per pound for frozen catfish nuggets.[23] These costs compare to an estimated cost of about 1 cent per pound of meat and poultry associated with the Pathogen

---

for each of the alternatives for the proposed rule. The stochastic model uses @RISK (Version 4.5, Palisades Corp.) to examine the effects of uncertainty.

[21] Wholesale price. Source: Catfish Market Statistics, NASS, USDA.

[22] Wholesale price. Source: Catfish Monthly Summary, NASS, USDA.

[23] Wholesale price. Source: Catfish Market Statistics Annual, NASS, USDA.

Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) rule of 1996 (Ollinger and Mueller, 2003).

For scenario #1, for the domestic industry and the government, the additional mean total first-year one-time cost to the catfish and catfish products supply chain industries and additional cost to the government of the proposed measures is projected at $1.3 million. The additional mean total first-year cost is projected at $15.4 million. Additional mean annual cost is projected at $14.0 million. The projected mean annualized cost is $14.2 million (See Table 18). The projected lower bound (10^{th} percentile) is $14.1 million. The projected upper bound (90^{th} percentile) is $14.3 million. The present value of the mean total cost, using a 7 percent discount rate over 10 years is projected at $100.0 million (Table 18).

For scenario #2, for the domestic industry and the government, the additional mean total first-year one-time cost to the catfish and catfish products supply chain industries and additional cost to the government of the proposed measures is projected at $1.2 million. The additional mean total first-year cost is projected at $11.8 million. Additional mean annual cost is projected at $10.5 million. The projected mean annualized cost is $10.6 million (See Table 18). The projected lower bound (10^{th} percentile) is $10.3 million. The projected upper bound (90^{th} percentile) is $10.9 million. The present value of the

mean total cost, using a 7 percent discount rate over 10 years is projected at $74.8 million (Table 18).

Table 18. Projected additional mean total domestic costs[a] of the proposed measures for scenarios #1 and #2.

New Measure	One-Time First Year Cost		First Year Total Costs (One-time and recurring costs)		Annual Total Cost after first year		Annualized Total Costs	
	Scenario		Scenario		Scenario		Scenario	
	#1	#2	#1	#2	#1	#2	#1	#2
Industries Costs[1 2 6]:	$thousands							
Sanitation SOPs	8	8	45	45	35	35	37	37
HACCP Plans - validated	103	103	287	287	137	137	162	162
Pre-harvest actions- for catfish producers			3	3	3	3	3	3
Pre-harvest actions- for live catfish haulers[7]	57	57	79	79	23	23	30	30
Labels	121	102	139	113	18	11	34	25
Government office space and equipment	16	16	24	24	7	7	9	9
Re-inspection at Import Establishments	1	0.1	2	0.5	1	0.4	1	0.5
Other- reduced payments			-36	-36	-36	-36	-36	-36
Sub-Total Industries Additional Compliance Costs (of the above)	306	286	543	516	187	181	240	230
Agency Costs:								
Additional Cost to FSIS Testing			65	56	65	56	65	56
Additional Costs to FSIS Inspection	1,032	944	16,334	12,565	15,302	11,625	15,438	11,749
Reduced Costs to FDA[3]			-160	-40	-160	-40	-160	-40
Reduced Costs to Commerce Dept NOAA NMFS[4 5]			-1,340	-1,340	-1,340	-1,340	-1,340	-1,340
Sub-Total Agency Additional Costs (of the above)	1,032	944	14,899	11,241	13,867	10,301	14,003	10,425
Total Costs (of the above)	1,338	1,230	15,442	11,757	14,054	10,482	14,243	10,656

[a] Numbers in the table are rounded. Therefore, a total may not equal the sum of its parts.

1. Only costs for the domestic market are considered.
2. Establishment wage rates (hourly) with benefits for 2008: $18 for production employee, $25.28 for supervisors or quality control (QC) tech, and $34.41 for QC manager.
3. FDA -$312 million FY 2008 budget for all food – estimated at $7.3 mil for all seafood program of estimated 4,900mil. lbs.; estimated at $0.0015 per pound of seafood inspected. For scenario #1, FSIS estimated 107 mil. lbs. of catfish and catfish products are inspected. For scenario #2, FSIS estimated 107 mil. lbs. of catfish and catfish products are inspected.
4. NOAA NMFS - $18 million FY 2008 budget for SIP of 2,100 million lbs. or about $0.009 per pound of seafood inspected; about $80 per hour inspection fee, $255 per hour fee for HACCP work. For scenario #1, FSIS estimated 156 mil. lbs. processed weight of catfish and catfish products are inspected. For scenario #2, FSIS estimated 156 mil. lbs. processed weight of catfish and catfish products are inspected.
5. In 2007, processed catfish and catfish products were 496 million lbs. live wt; 285 million lbs processed wt. for scenario #1.
6. Record storage estimated at $9.63 per square foot.
7. Estimate that about 50 percent of the live catfish haulers are independent firms.

V. Potential Benefits

If the series of regulatory changes proposed by FSIS improves the implementation of sanitation and HACCP plans, they could reduce the prevalence and levels of microbial pathogens and other contaminants in catfish and catfish products by reducing pathogen numbers and other contaminants at critical points during processing and by denying the opportunity for growth of those pathogens that are present. SSOPs and HACCP systems ensure process control through selected critical control points. The HACCP plan requires that the establishment manager, quality control manager, and others establish CCPs for every hazard identified in the hazard analysis and critical limits at each CCP; establish a plan to monitor those CCPs; determine how deviations from critical limits would be handled; and establish procedures for validating that the plan is being followed and that it is properly controlling the identified hazards.

The analysis of benefits anticipates that catfish and catfish products establishments would be in compliance with the requirements for Sanitation SOPs and HACCP according to the implementation schedule. Based on discussions with industry experts, FSIS believes that a significant share of the catfish and catfish products industry is already compliant with many of the individual proposed measures. Even though compliance rates for some HACCP related activities may be relatively high, the

performance of HACCP systems depends on how well all the elements are being performed.

The proposed SSOPs and HACCP mitigations are not specifically incorporated into the analysis, and therefore, their benefits cannot be quantified. Additional human health benefits are expected from the implementation of SSOPs and HACCP plans, as catfish and catfish products processing establishments improve refrigeration or cooling in processing areas, sanitation, processing, and packaging practices.

To illustrate potential benefits, FSIS has assessed the annual numbers of new *Salmonella* spp. illnesses that would need to be reduced for societal benefits to equal additional costs. This can be written as:

Reduction in new human Illnesses per year = Annualized additional cost of proposed rule/Cost per new human illness

The analysis of benefits anticipates that catfish and catfish product processing establishments would be in compliance with the requirements for HACCP Plan and Sanitation SOPs according to the implementation schedule. FSIS believes that a significant share of the domestic catfish and catfish products industry HACCP plans is already compliant with many of the proposed measures.

We chose *Salmonella* spp. to illustrate the potential benefits because the updated draft catfish risk assessment prepared by FSIS -- "Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish" (USDA FSIS, December 2010) -- identified *Salmonella* as a potential concern in catfish. However, the number of human illnesses associated with catfish and catfish products is relatively small compared to that associated with meat and poultry products.

Published literature reports that *Salmonella* spp. testing results show that a share of raw catfish and raw catfish food products tested positive for *Salmonella* spp. Table 19 shows the percentages of samples that tested positive for *Salmonella* spp. for catfish fillets, for 1979-2009. The percentage of positive samples during this period for fillets ranged from 2.3 to 48.6 percent. However, we note that some of these estimates are based on samples taken prior to full implementation of FDA's seafood HACCP regulations of 1994.

Table 19. **T**esting Prevalence[a] of *Salmonella* spp. in raw Siluriformes catfish and catfish food products, 1979-2009

Year of Study	Whole Fresh	Fresh Fillets	Frozen Fillets
1979 Lawrence E. Wyatt, et al	21%	48.6%[b]	
1998 (collected 1994-1995) McCaskey, T., et al		2.3%	
May 2003 through December 2004 Pal, Amit, Douglas L. Marshall. 2009.			42% of 60 samples
2009, Juan Silva, Mississippi State University.		30-40%	

[a] percent positive of sample tested

Sources:
- Lawrence E. Wyatt, et al. 1979. Occurrence and Control of Salmonella in Freshwater Catfish, Journal of Food Science. Volume 44, Issue 4, pages 1067-1073
- McCaskey, T., Hannah, T., Lovell, T., Silva, J., Fernandez, C., Flick, G. 1998. Safe and delicious study shows catfish is low risk for foodborne illness. Highlights of Agricultural Research 45 (4). Auburn University, Auburn, AL. http://www.ag.auburn.edu/aaes/communications/highlights/winter98/catfish.html
- Pal, Amit, Douglas L. Marshall. 2009. Comparison of cultured media for enrichment and isolation of Salmonella spp. from frozen Channel catfish and Vietnamese basa fillets. Food Microbiology. Volume 26, pages 317-319.
- Unpublished data from Juan Silva, Mississippi State University. Personal communication, November 25, 2009.

A. Consequences of Illnesses

Following the Economic Research Service (ERS, 2009), FSIS assumes 3 illness severity levels of salmonellosis. They are classified as: mild, does not visit a physician and lasts 1-3 days; moderate, visits a physician and lasts 2-12 days; or severe, which results in hospitalization and recovery and may last from 11-21 days. The CDC estimates that 8.1 percent of the *Salmonella* spp. cases in 1997 could have resulted in physician visits, and that 1.2 percent of *Salmonella* spp. cases led to

hospitalizations. Thus it is reasonable to conclude that the remaining 90.7 percent of gastrointestinal cases are mild and do not require a visit to a physician.

Table 20. Distribution of new human salmonellosis cases by severity

Type	**Percent of Cases**	**Severity**
Salmonellosis cases from Consumption of Catfish and Catfish Products (and from cross contamination to other food products that are consumed)	90.7	No physician visit (Mild)
	8.1	Physician visit (Moderate)
	1.2	Hospitalization (Severe)
Total	100	

Epidemiological evidence suggests that salmonellosis leads to both acute and chronic illnesses. The acute illness that accompanies salmonellosis generally causes gastrointestinal symptoms that can lead to lost productivity and medical expenses. Salmonellosis may result in acute or chronic arthritis. Arthritis is characterized by limited mobility, pain and suffering, productivity losses, and medical expenditures. Finally, salmonellosis can result in death, especially in the elderly, children, and people with compromised immune systems. FSIS projected the costs for each of the severity levels shown in Table 20.

The benefits from this proposed regulation are presented both in monetary and non-monetary terms. One way to measure the effects of foodborne illness is to use Quality Adjusted Life

Years (QALYs) or Quality Adjusted Life Days (QALDs). This method involves using a weighting system for determining how much less the utility of illness or death is to society or to the individual than the utility of good health.

This analysis uses the ERS estimates for medical costs associated with salmonellosis (updated to 2004 dollars)[24] (ERS, 2009) and the FDA weights for QALDs. The medical costs associated with arthritis are from Zorn & Klontz (1998). Applying the same methodology as FDA in projecting a monetary value for each QALD, using the value of a statistical life (VSL); and the value of a statistical life year (VSLY), FSIS projects a mean annualized cost of about $18,000 per new average case of salmonellosis (FDA, 2009).

B. Potential Magnitude of Catfish-Related Illnesses

As previously noted, CDC data shows that one outbreak was directly attributed to *Salmonella* Hadar with 10 cases in 1991. However, due to under reporting of illness and the difficulty in attributing illness to a particular vehicle, the actual number of illnesses associated with catfish may be larger.

FSIS conducted an illustrative assessment of the potential risk to human health of catfish consumption, using the example of Salmonella contamination. Table 21 shows the projected number of new human illnesses annually for the baseline

[24] FSIS uses the Medical Care Services CPI inflator to express figures in 2004 dollars.

scenarios #1 (catfish order Siluriformes) and #2 (catfish family Ictaluridae).

Table 21. Projected number of new human *Salmonella* spp. illnesses per year, for the baseline distribution - for one year of U.S. catfish consumption – for Scenarios #1 and #2

Whole Catfish and Catfish Products	Baseline Mean	Lower Bounds, 5th percentile	Upper Bounds, 95th percentile
Scenario #1	2,308	2,229	2,387
Scenario #2	1,764	1,695	1,833

The derivation and assumptions for the baseline data are described in the FSIS Draft Catfish Risk Assessment (USDA FSIS, December 2010). FSIS requests comments on the use of these assumptions in the FSIS draft risk assessment.

C. Break-even Analysis

USDA has conducted a breakeven analysis that shows the number of new illnesses from *Salmonella* spp. that would need to be prevented to ensure that benefits in terms of the dollar savings from reduced medical costs and deaths, and the value of Quality Adjusted Life Days (QALDs)(FDA, 2009) to exceed the additional costs. The analysis (Table 22) illustrates the minimum effectiveness required for positive net benefits for each scenario: scenario #1 (Siluriformes) and scenario #2 (Ictaluridae).

We note there may be benefits from reduced exposure to other pathogenic microorganisms and chemical residues in catfish and catfish food products not captured by these *Salmonella* spp. based estimate.

For the scenario #1, applying the proposed regulations to Siluriformes catfish and catfish food products, using the projected cost of an average case of *Salmonella* spp. of about $18,000, roughly 790 illnesses would need to be averted for benefits to exceed costs. If we assume the projected baseline human illnesses from the FSIS draft catfish risk assessment (USDA FSIS, December 2010) of about 2,300 new salmonellosis cases per year, then this is about 34 percent inspection effectiveness in reducing those new illnesses to where benefits exceed costs. This yields about 790 new illnesses avoided per year suggesting that the benefits may exceed costs under these assumptions (see Table 22).

For the scenario #2, applying the proposed regulations to Ictaluridae catfish and catfish food products, using the projected cost of an average case of *Salmonella* spp. of about $18,000, roughly 590 illnesses would need to be averted for benefits to exceed costs. If we assume the projected baseline human illnesses from the FSIS draft catfish risk assessment (USDA FSIS, December 2010) of about 1,764 new salmonellosis cases per year, then this is about 33 percent inspection

effectiveness in reducing those new illnesses to where benefits exceed costs. This yields about 590 new illnesses avoided per year suggesting that the benefits may exceed costs under these assumptions (see Table 22).

Table 22. Projected additional mean annualized costs of FSIS catfish inspection for the proposed rule and reduction in illnesses needed for benefits to exceed additional costs for scenarios #1 and #2

"Catfish" Definition	Projected Costs Annualized (at 7% discount rate) (in Millions)	Reduction in illnesses needed for benefits to exceed costs	Minimum effectiveness required based on FSIS RA mean illnesses baseline,
Siluriformes Scenario #1	$14.2	790 cases of salmonellosis avoided per year	34 percent (790 / 2,308)
Ictaluridae Scenario #2	$10.6	590 cases of salmonellosis avoided per year	33 percent (590 / 1,764)

VI. Summary

Summarizing the benefits, for scenario #1 and #2, the analysis anticipates that all catfish and catfish food product establishments would be in compliance with the requirements for SSOPs and HACCP by the end of the phased implementation outlined in the preamble of the proposed rule. From discussions with industry experts, FSIS believes that a significant share of the domestic catfish and catfish food products industry is compliant with many of the individual proposed measures; although because of differences between FDA and FSIS regulations, FSIS believes the industry would need time to make adjustments. Even though domestic compliance rates for HACCP related activities may be relatively high, the performance of HACCP systems depends on how well all the elements – hazard analysis, monitoring of CCPs and

critical limits, recordkeeping, verification -- are being performed.

Summarizing the additional costs, for scenario #1, the projected additional mean total one-time first-year cost to the Siluriformes catfish and catfish food products domestic supply chain industries and to FSIS of the proposed measures is about $1.3 million. The projected additional mean total first year cost, including the additional one-time cost and annual cost, to the Siluriformes catfish and catfish food products supply chain industries and to FSIS of the proposed measures is about $15.4 million. The projected additional mean annual costs after the first year to industry are about $240,000. The projected total annualized average cost to the Siluriformes catfish and catfish food products supply chain industries of the provisions of the proposal analyzed is about $0.0008 per pound of aggregate catfish and catfish food products.

Summarizing the additional costs, for scenario #2, the projected additional mean total one-time first-year cost to the Ictaluridae catfish and catfish food products domestic supply chain industries and to FSIS of the proposed measures is about $1.2 million. The projected additional mean total first year cost, including the additional one-time cost and annual cost, to the Ictaluridae catfish and catfish food products supply chain industries and to FSIS of the proposed measures is about $11.7

million. The projected additional mean annual costs after the first year to industry are about $230,000. The projected total annualized average cost to the Ictaluridae catfish and catfish food products domestic supply chain industries of the provisions of the proposal analyzed is about $0.0011 per pound of aggregate Ictaluridae catfish and catfish food products.

The cost to the catfish and catfish food products industry compares to a 2006-2008 average price of $0.83 per pound for frozen whole Ictaluridae catfish,[25] $1.14 per pound for frozen Ictaluridae catfish fillets,[26] and $0.402 per pound for frozen Ictaluridae catfish nuggets.[27] These costs compare to projected cost of about 1 cent per pound of meat and poultry associated with the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) rule of 1996 (Ollinger and Mueller, 2003).[28]

VII. Effects on Small Entities to Regulatory Flexibility Act

The Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), this proposed rule would not have a significant economic impact on a substantial number of small entities, under either scenarios, in the United States. While this action would affect a substantial number of small entities, the action would likely not have a

[25] Wholesale price. Source: Catfish Market Statistics, NASS, USDA.
[26] Wholesale price. Source: Catfish Monthly Summary, NASS, USDA.
[27] Wholesale price. Source: Catfish Market Statistics Annual, NASS, USDA.
[28] Ollinger, Michael and Valerie Mueller. 2003. "Managing for Safer Food: The Economics of Sanitation and Process Controls in Meat and Poultry Establishments." Agricultural Economics Report 817. Economic Research Service, U.S. Department of Agriculture. Washington, DC.

significant effect on these small entities in the United States, as indicated in this Initial Regulatory Flexibility Analysis (IRFA). The analysis is in Exhibit B below.

References

Alberini, A., N. Cropper, A. Krupnick and N.B. Simon, 2002. "Does the Value of a Statistical Life Vary with Age and Health Status? Evidence from the United States and Canada." Resources for the Future, Discussion Paper, pp.02-19, April.

Bureau of Labor Statistics, 2010. "Economic News Release: Employment Cost Index." http://www.bls.gov/news.release/eci.toc.htm.

Bush, J.W., M.M. Chen, and D.L. Patrick. 1973. "Health Status Index in Cost Effectiveness. Analysis of PKO Program." Berg, Robert L., ed., Health Status Indexes: Proceedings of a Conference conducted by Health Services Research, Tucson, AZ, October 1-4, 1972. Chicago: Hospital Research & Education Trust.

Centers for Disease Control and Prevention. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5414a2.htm

Consumer Price Index – All Urban Consumers, Medical Care Services, Bureau of Labor Statistics, 2004. http://www.bls.gov/cpi/

Curtis, P., North Carolina State University, Raleigh, NC. October 5, 2001. Personal communication with Catherine Viator, RTI.

Cutler, D.M. and E. Richardson. 1997. "Measuring the Health of the United States Population." Microeconomics, Brookings Paper, pp. 217-271.

Diener, A., B. O'Brien and A. Gafni. 1998. "Health Care Contingent Valuation Studies: A Review and Classification of Literature." Health Economics 7: pp. 313-326.

Economic Research Service, 2009. "Foodborne Illness Cost Calculator for *Salmonella*. http://www.ers.usda.gov/data/foodborneillness.

Economic Research Service, 2008. "Per Capita Consumption of Selected Food Products. http://www.ers.usda.gov/

Fisher, A., L. Chestnut and D. Violette. 1989. "The Value of Reducing Risks of Death: A Note on New Empirical Evidence," Journal of Policy Analysis and Management 8(1): pp.88-100.

FoodNet, Foodborne Diseases Active Surveillance Network, 2003. Emerging Infections Program, Report on Foodborne Pathogens.

Foreign Agricultural Service. 2007. "Catfish and Basa Imports Continue to Increase Despite Confirmed Antidumping", Market News, May 2007.
Foreign Agricultural Service. 2008 Data: U.S. trade data, U.S. Imports Trade data.

Frenzen, P. D., T.L. Riggs, J. C. Buzby, T. Breuer, T. Roberts, D. Voetsch, S. Reddy and the FoodNet Working Group. 1999. "*Salmonella* Cost Estimate Updated Using FoodNet Data." FoodReview, (22) 2: pp.10-15.

Garber, Alan M. and C. E. Phelps. 1997 "Economic Foundations of Cost-Effectiveness Analysis." Journal of Health Economics, vol. 16, pp. 1-31.

Glasshof, R., USDA/FSIS Technical Center, Omaha, NE. October 29, 2001. Personal communication with Catherine Viator, RTI.

Hirth, Richard A., M. Chernew, E. Miller, A. Fendrick, W. Weissert, 2000. "Willingness to Pay for a Quality-adjusted Life Year: In Search of a Standard." Health Economics. July-Sept vol. 20: pp.332-342.

Hirth, Richard A., M. Chernew and A. Fendrick, 2003. "What is the Price of Life and Why Doesn't It Increase at the Rate of Inflation?" Arch Intern Med, vol. 163, July 28.

Hui, Y.H., Pierson, M.D., Gorham, J.R.,(eds), 2001. Foodborne Disease Handbook. 2nd edition, vol.1 Bacterial Pathogens. Marcel Dekker, Inc., New York-Basel.

Kaplan, Robert M., J. Anderson and T. Ganiats, 1993. "The Quality of Well-Being Scale: Rationale for a Single Quality of Life Index." From Quality of Life Assessment: Key Issues in the 1990s. Stuart Walker and Rachel Rosser, eds. Kluwer Academic Publishers, 1993, pp. 65-94.

Kaliba, A. and C.R. Engle. 2004. "The economic impact of the catfish industry on Chicot County, Arkansas." Journal of Applied Aquaculture 15(1/2).

Mead, Paul S, L. Stutsker, V. Dietz, F. McCraig, J.S. Bresee, L. Shapiro, P.M. Griffin and R.V. Tauxe. 1999. "Food-Related Illness and Death in the United States." Emerging Infectious Diseases, vol. 5 (5), Sept-Oct, pp. 607-625.

Muth, M.K., E.C. Gledhill, and S.A. Karns. 2001. "FDA Labeling Cost Model." Prepared for the U.S. Department of Health and Human Services. Research Triangle Park, NC: RTI.

Ollinger, M. and V. Mueller. 2003. "Managing for Safer Food: The Economics of Sanitation and Process Controls in Meat and Poultry Establishments." Agricultural Economics Report 817. Economic Research Service, U.S. Department of Agriculture. Washington, DC.

Pasko, T. and B. Seidman. 2002. "Physician Characteristics and Distribution in the United States." 2002-2003 Edition. Chicago: American Medical Association.

Raybourne, R. B., K. Williams and T. Roberts. 2003. "Food Poisoning, Economic Implications." Encyclopedia of Food Sciences and Nutrition, Benjamin Caballero, ed. Academic Press, Elsevier Science Ltd. London, UK. pp. 2672-2682.

Silva, J. 2001. Processing Channel Catfish. South Regional Aquaculture Center, Publication 183.

Thompson, Glen T.D., D. DeRubeis, M. Hodge, C. Rajanayagam and R. D. Inman. 1995. "Post-*Salmonella* Reactive Arthritis: Late Clinical Sequelae in A Point Source Cohort." American Journal of Medicine, vol. 98 (January): pp.13-21.

U.S. Census Bureau. 2002. Statistical Abstract of the United States, pp. 413-416 and 436.

U.S. Census Bureau, Income, 2003.

U.S. Department of Agriculture. Food Safety and Inspection Service. Office of Public Health Science. December 2010. Draft Risk Assessment of the Potential Human Health Effect of Applying Continuous Inspection to Catfish. Washington, D.C.

U.S. Department of Agriculture. Economic Research Service. 2009. Cost Calculator for *Salmonella.*

U.S. Department of Agriculture /National Agricultural Statistics Service (USDA/NASS). 2008. Catfish 2007 Summary. <http://usda.mannlib.cornell.edu/reports/nassr/

U.S. Department of Agriculture /National Agricultural Statistics Service (USDA/NASS). 2009. Catfish January 2009 Reports.

U.S. Food & Drug Administration. 1994. Federal Register. 21 CFR Parts 123 and 1240: Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule.

U.S. International Trade Commission (USITC). 1999. "Industry and Trade Summary: Catfish." USITC Publication 3268.

Unnevehr, L.J. and H.H. Jensen. 1996. "HACCP as a Regulatory Innovation to Improve Food Safety in the Meat Industry." Amer. Jour. Agr. Econ. (78) August, pp. 764-769

Viscusi, W. Kip and Joseph Aldy. 2003. "The Value of a Statistical Life: A Critical Review of Market Estimates throughout the World." AEI-Brookings Joint Center for Regulatory Studies, January.

Voetsch, D., F. Angulo, S. Shallow, M. Farley, C. Hedberg, P. Cieslak and R.V. Tauxe and the Food Networking Group. 1998. "Estimate of the Burden of Illness Caused by Nontyphoidal *Salmonella* Infections in the United States from FoodNet." American Public Health Association 126th Annual Meeting, Washington, DC.

Ward, D. 1989. Microbiology of Aquaculture Products. Food Technology, Nov 82-86.

Wassenaar, J.D. and S.L. Thran. 2001. "Physician Socioeconomic Statistics." 2000-2002 Edition: Profiles for Detailed Specialties, Selected States and Practice Arrangements. Chicago: American Medical Association.

Wyatt, Lawrence. 1979. Occurrence and Control of *Salmonella* in Freshwater Catfish, Journal of Food Science. Volume 44, Issue 4, pages 1067-1073.

Williams, R.M. 1996. "The Costs of Visits to Emergency Departments." The New England Journal of Medicine, vol. 334(10): pp. 642-646.

Zorn, David J. and Karl Klontz. 1998. Appendix "The Value of Consumer Loss Relating to Foodborne Reactive Arthritis." 63FR 24254, May 1.

Exhibits

Exhibit A. Economic Model – Schedules of Costs for Scenarios

In the following two tables, the schedules of costs for each of the two scenarios for defining catfish are detailed by year. These are the costs projected for each of the components that are given in Tables 6 through 17 of the preliminary regulatory impact analysis (PRIA). The totals are summarized in Table 18 of the PRIA. The totals in these tables are the 10-year total without applying any discount for determining the present values. The determination of the present values at 7 percent over 10 years for each of these cost components was done in the economic model. In addition, the present values were annualized and reported in Table 18 of the PRIA.

Exhibit A. Table 1A. Schedule of Costs for Scenario #1:

Year	Sanitation SOP plan development cost	Sanitation SOP recordkeeping costs	Sanitation SOP training costs	Additional Sanitation SOP compliance costs	HACCP plan development and validation	HACCP annual reassessment	HACCP training costs	HACCP personnel costs	HACCP recordkeeping and monitoring costs
1	5,093	32,129	2,510	6,000	98,000	516	47,752	79,200	53,400
2		32,129		3,000		1,669		79,200	53,400
3		32,129		3,000		1,669		79,200	53,400
4		32,129	2,510	3,000		1,669		79,200	53,400
5		32,129		3,000		1,669		79,200	53,400
6		32,129		3,000		1,669	47,752	79,200	53,400
7		32,129	2,510	3,000		1,669		79,200	53,400
8		32,129		3,000		1,669		79,200	53,400
9		32,129		3,000		1,669		79,200	53,400
10		32,129	2,510	3,000		1,669		79,200	53,400
Totals	5,093	321,285	10,041	33,000	98,000	15,536	95,504	792,000	534,000

Exhibit A. Table 1A. Schedule of Costs for Scenario #1 (continued):

Year	HACCP records storage costs	Additional HACCP plan compliance costs	Additional Cost of Labels	Additional Micro & Residue Testing	Additional Cost of Government office space and equipment	Additional costs to producers	Additional costs to transporters/haulers	Additional costs to importers	Reduced Costs (payments) to Commerce Dept NOAA Fisheries
1	1,080	7,000	138,700	65,000	23,700	3,100	79,380	1,800	-36,400
2	1,080	2,000	17,700	65,000	7,200	3,100	22,680	600	-36,400
3	1,080	2,000	17,700	65,000	7,200	3,100	22,680	600	-36,400
4	1,080	2,000	17,700	65,000	7,200	3,100	22,680	600	-36,400
5	1,080	2,000	17,700	65,000	7,200	3,100	22,680	600	-36,400
6	1,080	2,000	17,700	65,000	7,200	3,100	22,680	600	-36,400
7	1,080	2,000	17,700	65,000	7,200	3,100	22,680	600	-36,400
8	1,080	2,000	17,700	65,000	7,200	3,100	22,680	600	-36,400
9	1,080	2,000	17,700	65,000	7,200	3,100	22,680	600	-36,400
10	1,080	2,000	17,700	65,000	7,200	3,100	22,680	600	-36,400
Totals	10,800	25,000	298,000	650,000	88,500	31,000	283,500	7,200	-364,000

Exhibit A. Table 1A. Schedule of Costs for Scenario #1 (continued):

Year	Reduced Costs to FDA	Reduced Costs to Commerce Dept NOAA Fisheries	Additional Costs to FSIS
1	-160,000	-1,340,000	16,334,000
2	-160,000	-1,340,000	15,302,000
3	-160,000	-1,340,000	15,302,000
4	-160,000	-1,340,000	15,302,000
5	-160,000	-1,340,000	15,302,000
6	-160,000	-1,340,000	15,302,000
7	-160,000	-1,340,000	15,302,000
8	-160,000	-1,340,000	15,302,000
9	-160,000	-1,340,000	15,302,000
10	-160,000	-1,340,000	15,302,000
Totals	-1,600,000	-13,400,000	154,052,000

Exhibit A. Table 2A. Schedule of Costs for Scenario #2:

Year	Sanitation SOP plan development cost	Sanitation SOP recordkeeping costs	Sanitation SOP training costs	Additional Sanitation SOP compliance costs	HACCP plan development and validation	HACCP annual reassessment	HACCP training costs	HACCP personnel costs	HACCP recordkeeping and monitoring costs
1	5,093	32,129	2,510	6,000	98,000	516	47,752	79,200	53,400
2		32,129		3,000		1,669		79,200	53,400
3		32,129		3,000		1,669		79,200	53,400
4		32,129	2,510	3,000		1,669		79,200	53,400
5		32,129		3,000		1,669		79,200	53,400
6		32,129		3,000		1,669	47,752	79,200	53,400
7		32,129	2,510	3,000		1,669		79,200	53,400
8		32,129		3,000		1,669		79,200	53,400
9		32,129		3,000		1,669		79,200	53,400
10		32,129	2,510	3,000		1,669		79,200	53,400
Totals	5,093	321,285	10,041	33,000	98,000	15,536	95,504	792,000	534,000

Exhibit A. Table 2A. Schedule of Costs for Scenario #2 (continued):

Year	HACCP records storage costs	Additional HACCP plan compliance costs	Additional Cost of Labels	Additional Micro & Residue Testing	Additional Cost of Government office space and equipment	Additional costs to producers	Additional costs to transporters/haulers	Additional net costs to importers	Reduced Costs (payments) to Commerce Dept NOAA Fisheries
1	1,080	7,000	112,700	56,000	23,700	3,100	79,380	1,100	-36,400
2	1,080	2,000	11,200	56,000	7,200	3,100	22,680	375	-36,400
3	1,080	2,000	11,200	56,000	7,200	3,100	22,680	375	-36,400
4	1,080	2,000	11,200	56,000	7,200	3,100	22,680	375	-36,400
5	1,080	2,000	11,200	56,000	7,200	3,100	22,680	375	-36,400
6	1,080	2,000	11,200	56,000	7,200	3,100	22,680	375	-36,400
7	1,080	2,000	11,200	56,000	7,200	3,100	22,680	375	-36,400
8	1,080	2,000	11,200	56,000	7,200	3,100	22,680	375	-36,400
9	1,080	2,000	11,200	56,000	7,200	3,100	22,680	375	-36,400
10	1,080	2,000	11,200	56,000	7,200	3,100	22,680	375	-36,400
Totals	10,800	25,000	213,500	56,000	88,500	31,000	283,500	4,475	-364,000

Exhibit A. Table 2A. Schedule of Costs for Scenario #2 (continued):

Year	Reduced Costs to FDA	Reduced Costs to Commerce Dept NOAA Fisheries	Additional Costs to FSIS
1	-40,000	-1,340,000	12,565,000
2	-40,000	-1,340,000	11,625,000
3	-40,000	-1,340,000	11,625,000
4	-40,000	-1,340,000	11,625,000
5	-40,000	-1,340,000	11,625,000
6	-40,000	-1,340,000	11,625,000
7	-40,000	-1,340,000	11,625,000
8	-40,000	-1,340,000	11,625,000
9	-40,000	-1,340,000	11,625,000
10	-40,000	-1,340,000	11,625,000
Totals	-400,000	-13,400,000	117,190,000

Exhibit B. Initial Regulatory Flexibility Analysis.

The Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), this proposed rule will not have a significant economic impact on a substantial number of small entities, under either scenarios, in the United States. While this action will affect a substantial number of small entities, the action will likely not have a significant effect on these small entities in the United States, as indicated in this initial regulatory flexibility analysis (IRFA).

FSIS considered two possible definitions for catfish: North American fish belonging to the family Ictaluridae, and all fish of the order Siluriformes. If catfish are defined as all fish of the order Siluriformes, FSIS will inspect domestic and imported catfish, including basa and swai. If defined as fish of the family Ictaluridae, FSIS will inspect virtually all domestically produced and about 20-25 percent of imported Siluriformes. USDA is asking for public comments on the scope of the definition and will fully define and describe the term in the final rule.

The IRFA, therefore, describes the affected small businesses under both scenarios: Scenario #1 (Siluriformes) and Scenario #2 (Ictaluridae.) Scenario #1 principally affects about 1,300 commercial catfish farms, 15 commercial catfish feed

mills, 11 commercial catfish loader/hauler (live-hauling) transporters, 23 catfish slaughter and primary processor establishments, 10 catfish further (secondary) processing-only establishments, and 80 catfish broker/importers for a total of 1,439 entities. Of these 1,439 entities, all but 4 large catfish slaughter and primary processors meet the Small Business Administration (SBA) size criteria for small businesses in the food manufacturing classification or other categories, in that they have 500 or fewer employees. See Tables 3 of Section II-A of the PRIA. Scenario #2 includes all the entities of scenario #1 except 62 of 80 importer entities. All of the importer entities are considered to be small because they have 500 or less full-time equivalent (FTE) employees. The 4 large catfish slaughter and processing entities are considered to be large because they have more than 500 FTE employees. The proposed action would affect a substantial number of small entities because the requirements would apply to all processing establishments in the catfish and catfish products industry that ship their products in interstate commerce and would to some extent pertain to fish-farming practices and live-haul transporters. However, the action would not have a significant effect on these small entities, as indicated in this IRFA.

As discussed in the Cost Analysis, Section V of the PRIA, the projected additional average total annualized cost to the

domestic catfish and catfish products supply chain industries of the provisions of the proposal analyzed is about $0.0008 per pound ($240,000 / 285 million pounds, in 2007) of aggregate domestic and imported processed catfish and catfish products for scenario #1. For scenario #2, the additional annualized total cost is about $0.0011 per pound ($230,000 / 204 million pounds, in 2007). The projected additional average cost ($0.0008 to $0.0011 per pound of processed catfish and catfish products) of compliance to the provisions of the proposal compares to a 2006-2008 average price of $0.83 per pound (round or live weight) for frozen unprocessed whole catfish,[29] $1.14 per pound for frozen processed catfish fillets,[30] and $0.40 per pound for frozen processed catfish nuggets.[31]

From the discussion in the Additional Agency Costs, Section I of the PRIA, NOAA / NMFS charges catfish processing entities about $0.009 per pound for its inspection service. Thus, for scenario #1, NOAA / NMFS inspection cost plus FSIS's projected additional inspection cost equals about $0.0098 (0.009 + 0.0008) per pound (processed weight) of domestic catfish products. For scenario #2, NOAA / NMFS inspection cost plus FSIS's projected

[29] Wholesale price. Source; Catfish Market Statistics, National Agricultural Statistics Service, USDA.
[30] Wholesale price. Source: Catfish Monthly Summary, National Agricultural Statistics Service, USDA.
[31] Wholesale price. Source: Catfish Market Statistics Annual, National Agricultural Statistics Service, USDA.

additional inspection cost equals about $0.01 (0.009 + 0.0011) per pound. However, under this proposal, FSIS will not charge the catfish and catfish products processing industry for ordinary inspection services. This is a cost savings of about $0.009 per pound of domestic catfish and catfish products for NOAA / NMFS inspection service to about 18 of the catfish processing entities that used NOAA inspection service, including about 14 that are small processing entities.

This projected additional average total cost of $0.0008 (scenario #1) to $0.0011 (scenario #2) per pound of catfish to processing entities for compliance to FSIS's HACCP and Sanitation SOPs (SSOPs) compares to an estimated total cost of about $0.01 per pound of meat and poultry associated with the Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP) rule of 1996 (Ollinger and Mueller, 2003). Therefore, if the projected additional total HACCP and SSOPs compliance cost is about $0.0008 per pound (scenario #1) or $0.0011 per pound (scenario #2) of processed catfish products to processing entities, then the additional compliance cost represents a relatively small proportion of the average sales prices of the fabricated catfish and catfish products that range from $0.40 per pound for nuggets to $1.14 per pound for frozen catfish fillets.

In Table 1B below, there are projected disaggregated mean total additional costs of the proposed measures for the affected 1,435 small entities of scenario #1 and 1,373 small entities of scenario #2. For scenario #1, the total additional annualized cost is about $204,400 for the 1,435 small entities or an additional average annualized cost of about $142 ($204,400 / 1,435) per small entity. This compares to an additional compliance cost of about $240,000 for both the 1,435 small and the 4 large entities – a total of 1,439 entities. This is an additional average cost of about $167 ($240,000 / 1,439) per entity (small and large).

For scenario #2, the total additional annualized cost is about $195,100 for the 1,373 small entities or an additional average annualized cost of about $142 ($195,100 / 1,373) per small entity. This compares to an additional compliance cost of about $230,000 for both the 1,373 small and the 4 large entities – a total of 1,377 entities. This is an additional average annualized cost of about $167 ($230,000 / 1,377) per entity (small and large).

When disaggregated by sector, Tables 2B (scenario #1) and 3B (scenario #2) below, there are 29 small entities of the total 33 processing (primary plus secondary) entities. Of the 29 small processing entities, 19 are small slaughter/primary processors and 10 are small secondary processing-only entities.

For the 19 small primary processors, the projected mean annualized total aggregated costs per entity affected, at a 7% discount rate over 10 years, is about $4,668 ($88,700 / 19). However, the estimated annual aggregated catfish and catfish products revenue of the 19 primary processing entities is about $463 million. Thus, the estimated annual aggregated catfish and catfish products revenue is about $24 million ($463 million / 19) per small primary processing entity. Therefore, the projected proportion of this additional cost to estimated revenue is relatively small at about 0.02 percent ($4,668 / $24 million) per slaughter/primary processing entity.

There are about 10 small secondary catfish and catfish products processing-only entities. For the 10 small secondary processors entities, the projected mean annualized total aggregated costs per entity affected, at a 7% discount rate over 10 years, is about $5,300 ($53,100 / 10). However, the estimated annual aggregated catfish and catfish products revenue of the 10 secondary processing entities is about $180 million. Thus, the estimated annual aggregated catfish and catfish products revenue is about $18 million ($180 million / 10) per small secondary processing entity. Therefore, the proportion of this projected additional cost to estimated revenue is relatively small at about 0.03 percent ($5,300 / $18 million) per secondary processing entity.

For the 1,300 small entities of the catfish producers the projected mean annualized total aggregated costs per entity affected, at a 7% discount rate over 10 years, is about $20 ($25,800 / 1,300). However, the estimated annual aggregated catfish revenue for the 1,300 catfish production entities is about $359.2 million. Thus, the estimated annual aggregated catfish revenue is about $300,000 ($359 million / 1,300) per small catfish-producer entity. Therefore, the proportion of this projected additional cost to estimated revenue is relatively small at about 0.007 percent ($20 / $300,000) per catfish-producer entity.

For the 15 small entities of the catfish feed mills, the projected mean annualized total aggregated costs per entity affected, at a 7% discount rate over 10 years, is about $20 ($300 / 15). However, the estimated annual aggregated catfish feed mill revenue for the 15 catfish feed mill entities is about $159.8 million. Thus, the estimated annual aggregated catfish-feed-mill revenue is about $11 million ($160 million / 15) per small catfish-feed-mill entity. Therefore, the proportion of this projected additional cost to estimated revenue is relatively small at about 0.0002 percent ($20 / $276,000) per catfish-feed-mill entity.

For the 11 small entities of commercial catfish loader-hauler (live-hauling) transporters, the projected mean

annualized total aggregated costs per entity affected, at a 7% discount rate over 10 years, is about $2,000 ($23,700 / 11). However, the estimated annual aggregated catfish loader-hauler revenue for the 11 commercial catfish live-hauling transporter entities is about $15 million. Thus, the estimated annual aggregated catfish live-hauling transporter revenue is about $1.4 million ($15 million / 11) per small catfish live-hauling transporter entity. Therefore, the proportion of this projected additional cost to estimated revenue is relatively small at about 0.15 percent ($2,000 / $1.4 million) per catfish live-hauling transporter entity.

For scenario #1, for the 80 small entities of commercial catfish broker/importers the projected mean annualized total aggregated costs per entity affected, at a 7% discount rate over 10 years, is about $160 ($12,800 / 80). However, the estimated annual aggregated catfish broker/importers revenue for the 80 commercial catfish broker/importers entities is about $160 million of catfish and catfish products. Thus, the estimated annual aggregated catfish and catfish products broker/importers revenue is about $2.0 million ($158 million / 80) per small catfish broker/importer entity. Therefore, the proportion of this projected additional cost to estimated revenue is relatively small at about 0.008 percent ($160 / $2.0 million) per catfish broker/importer entity.

For scenario #2, for the 18 small entities of commercial catfish broker/importers the projected mean annualized total aggregated costs per entity affected, at a 7% discount rate over 10 years, is about $194 ($3,500 / 18). However, the estimated annual aggregated catfish broker/importers revenue for the 18 commercial catfish broker/importers entities is about $36 million of catfish and catfish products. Thus, the estimated annual aggregated catfish and catfish products broker/importers revenue is about $2.0 million ($36 million / 18) per small catfish broker/importer entity. Therefore, the proportion of this projected additional cost to estimated revenue is relatively small at about 0.01 percent ($194 / $2.0 million) per catfish broker/importer entity.

Scenario #1 and scenario #2 will have an unknown effect on a substantial number of foreign small entities that export catfish and catfish products to the United States. Imported catfish and catfish products will have to be inspected under a foreign system that is equivalent to that of the United States and from establishments that the foreign inspection authority has certified as complying with United States requirements.

This proposed rule would directly and indirectly affect multiple sectors of the U.S. economy. These effects are likely on numerous small firms, jobs (i.e., employment) and on the government (i.e., local, state and federal). Some of the likely

affected (directly and indirectly) sectors, in addition to the types of entities already mentioned in Exhibit B, Table 2, include food service and restaurant firms, consumers, and government agencies.

FSIS is asking for more information on how this proposed action will affect domestic and foreign entities. Then, this information will be analyzed in the final regulatory impact analysis (FRIA) of the final rule.

Exhibit B. Table 1B. For 1,435 small domestic entities*: projected disaggregated additional mean total costs [a] of the proposed measures, under scenario #1 and for 1,373 small domestic entities under scenario #2.

New Measure	One-Time First Year Cost*		First Year Total Costs* (One-time and recurring costs)		Annual Total Cost* after first year		Annualized Total Costs*	
	Scenario		Scenario		Scenario		Scenario	
	#1	#2	#1	#2	#1	#2	#1	#2
Industries Costs:	$thousands							
Sanitation SOPs	6	5	33	31	27	26	28	27.6
HACCP Plans - validated	75	73	252	246	112	106	133	126.0
Pre-harvest actions- for catfish producers			3	3	3	3	3.0	3.0
Pre-harvest actions- for live catfish haulers	57	57	79	79	23	23	30.0	30.0
Labels	87	77	92	81	5	4	8.6	7.0
Government office space and equipment	16	16	24	24	7	7	9.0	9.0
Re-inspection at Import Establishments	1	0.1	2	0.5	1	0.4	0.8	0.5
Other- reduced payments			-8	-8	-8	-8	-8.0	-8.0
Total Small Entities Industries Additional Compliance Costs (of the above)	242	228.1	477	456.5	170	161.4	204.4	195.1

Exhibit B. Table 2B. For 1,435 small domestic entities*: estimated aggregated mean revenue and projected aggregated additional mean total costs [a] of the proposed measures, under scenario #1, by domestic private sectors and by affected domestic entities

(1) Description of the Catfish and Catfish Products Supply Chain Entities in the Private Sectors that will be Principally Affected by the Proposed Rule (NAICS Code**)	(2) Aggregated Additional Annualized Costs for all the Small Entities*** (Dollars)	(3) Projected Number of Affected Small Entities	(4) Projected Average Aggregated Annualized Costs per Small Entity (col. 2 divided by col. 3) (Dollars)	(5) Estimated Aggregated Annualized Revenue for all the Small Entities**** ($ Million)	(6) Estimated Average Aggregated Annualized Revenue per Small Entity (col. 5 divided by col. 3) ($ Million)	(7) Average-Cost-to-Revenue Ratio, in percent, Annualized, for Small Entities (col.4 divided by col. 6) (percent)
I. Catfish Producers - Farms & Ponds -(112511)	25,800	1,300	20	359	0.3	0.007
II. Catfish Feed Mills - (311119)	300	15	20	160	11	0.0002
III. Catfish Loaders/Haulers (Live-Haul) Transporters – Livestock Trucking -(4842202)	23,700	11	2,154	15	1.4	0.15
IV. Catfish Slaughter/Primary Processors – Food Manufacturing - (311712)	88,700	19	4,668	463	24	0.022
V. Catfish Secondary Processors-only – Food Manufacturing - (311711)	53,100	10	5,310	180	18	0.030
VI. Catfish Wholesalers, Brokers, Importers, Exporters - (424460)	12,800	80	160	158	2	0.008
Totals - Catfish Industry above	204,400	1,435	142	1,335	931,000	0.15

[a] Numbers in the table are rounded. Therefore a total may not equal the sum of its parts.

* Small means 500 or less full-time equivalent (FTE) employees (Small Business Administration (SBA) definition)
** North American Industry Classification System (NAICS) code, NAICS Association, 2002
*** Projected Additional Average Costs of the proposed FSIS Program by Private Sectors from Exhibit B. Table 1: Annualized at 7 percent discount over 10 years
**** Estimated Average Revenues - Annualized at 7 percent discount over 10 years
Source: Census of Agriculture 2009, National Agricultural Statistical Service (NASS), 2009, and catfish experts from the cooperative extension service and the catfish industry.

Exhibit B. Table 3B. For 1,373 small entities*: estimated aggregated mean revenue and projected aggregated additional mean total costs [a] of the proposed measures, under scenario #2, by domestic private sectors and by affected domestic entities

(1) Description of the Catfish and Catfish Products Supply Chain Entities in the Private Sectors that will be Principally Affected by the Proposed Rule (NAICS Code**)	(2) Aggregated Additional Annualized Costs for all the Small Entities*** (Dollars)	(3) Projected Number of Affected Small Entities	(4) Projected Average Aggregated Annualized Costs per Small Entity (col. 2 divided by col. 3) (Dollars)	(5) Estimated Aggregated Annualized Revenue for all the Small Entities**** ($ Million)	(6) Estimated Average Aggregated Annualized Revenue per Small Entity (col. 5 divided by col. 3) ($ Million)	(7) Average-Cost-to-Revenue Ratio, in percent, Annualized, for Small Entities (col. 4 divided by col. 6) (percent)
I. Catfish Producers - Farms & Ponds - (112511)	25,800	1,300	20	359.2	0.3	0.007
II. Catfish Feed Mills - (311119)	300	15	20	159.8	10.6	0.0002
III. Catfish Loaders/Haulers (Live-Haul) Transporters – Livestock Trucking - (4842202)	23,700	11	2,154	14.9	1.4	0.15
IV. Catfish Slaughter/Primary Processors – Food Manufacturing - (311712)	88,700	19	4,668	463.2	24.4	0.022
V. Catfish Secondary Processors-only – Food Manufacturing - (311711)	53,100	10	5,310	180.0	18.0	0.030
VI. Catfish Wholesalers, Brokers, Importers, Exporters - (424460)	3,500	18	194	36	2.0	0.001
Totals - Catfish Industry above	195,100	1,373	142	1,335.5	930,662	0.15

<This page is intentionally left blank>