

## **SUPPORTING STATEMENT JUSTIFICATION FOR CATFISH INSPECTION**

### **1. Circumstances Making Collection Of Information Necessary:**

This information collection requests new information collection burden hours that address the regulatory requirements in Catfish Inspection.

The Food Safety and Inspection Service (FSIS) has been delegated the authority to exercise the functions of the Secretary as provided in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 et seq.). This statute mandates that FSIS protect the public by verifying that meat and meat food products are safe, wholesome, not adulterated, and properly marked, labeled and packaged.

The Food, Conservation, and Energy Act of 2008 (Pub. L. 110-246), known as the 2008 Farm Bill, amended the FMIA to include “catfish, as defined by the Secretary” among the species amenable to the FMIA. Hence, FSIS is proposing regulations for the inspection of catfish. These proposed regulations will mirror the current FSIS meat regulations as far as is feasible.

FSIS is proposing establishing requirements applicable to catfish establishments designed to reduce the physical, chemical, and biological hazards on catfish products and reduce the incidence of foodborne illness associated with the consumption of those products. The regulations (1) require that each establishment develop and implement written sanitation standard operating procedures (Sanitation SOPs); (2) require catfish establishments to verify the adequacy of their process controls; and, (3) require each catfish establishment to develop and implement a system of preventive controls, known as Hazard Analysis and Critical Control Points (HACCP) system, designed to improve the safety of their products.

In addition, catfish establishments would have to meet labeling requirements for catfish product, including nutrition labeling. Producers (farms), haulers/loaders, wholesalers, brokers, importers and exporters of catfish products would have to register with FSIS. And any consignee who refuses to accept delivery of catfish product because it is potentially adulterated or misbranded would have to notify FSIS.

### **2. How, By Whom and Purpose Information Is To Be Used:**

The following is a discussion of the required information collection and recordkeeping activities.

### *Standard Operating Procedures (SOP) for Sanitation*

Official catfish establishments would have to develop, implement, and maintain, in a written plan, the establishment's Sanitation Standard Operating Procedures. Sanitation SOPs would have to describe all procedures that an establishment will conduct daily to prevent direct contamination or adulteration of product. SOPs would have to be revised, as needed, to keep them effective and current. When establishments take corrective actions, establishments would have to modify their SOPs, if necessary. Establishments would have to maintain daily records sufficient to document the implementation and monitoring of SOPs, including corrective actions taken. Records would have to be maintained for at least six months and made available to FSIS. FSIS does not review or approve the plans. In most cases, inspectors would review the records once a day.

### *HACCP*

Catfish establishments would have to develop and implement a written HACCP plan, keep relevant records, and reassess the HACCP plan annually or as needed (any modifications would have to be added to the existing HACCP plan). Only individuals trained in the seven HACCP principles may develop or modify and reassess an establishment's HACCP plan.

Catfish establishments would develop written HACCP plans that include: identification of the processing steps which present hazards; identification and description of the critical control point (CCP) for each identified hazard; specification of the critical limit which may not be exceeded at the CCP, and if appropriate, a target limit; description of the monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded; description of the records which will be generated and maintained regarding this CCP; and description of the establishment verification activities and the frequency at which they are to be conducted.

FSIS does not review or approve the plans. However, plans must be on file and available to FSIS program employees upon request.

Catfish establishments would keep records for measurements during slaughter and processing,

corrective actions, verification check results, and related activities that contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The information will be recorded at the time that it is observed, and the record will be signed by the operator or observer.

Lastly, catfish establishments may have prerequisite programs that are designed to provide the basic environmental and operating conditions necessary for the production of safe, wholesome food. Because of its prerequisite programs an establishment may decide that a food safety hazard is not reasonably likely to occur in its operations. The establishment would need to document this determination in its Hazard Analysis and include the procedures it employs to ensure that the program is working and that the hazard is not likely to occur. The prerequisite program and the laboratory results generated in auditing the program are to be available to FSIS upon request.

### *Labeling*

Catfish establishments would have to develop product labels to be approved by FSIS. To receive approval for such labels, establishments would complete OMB-approved FSIS Form 7234-1 (0583-0092). In addition to the form, respondents also submit duplicate copies of the labels. The establishment would maintain a copy of all the labeling used, along with product formulation and processing procedures. Respondents would use FSIS Form 8822-4 (which will be submitted to OMB for approval with the revision of the Marking, Labeling, and Packaging of Meat, Poultry, and Egg Products information collection (0583-0092)) to request reconsideration of a label application that the Agency has modified or rejected.

Previously approved labeling that contains changes such as holiday season designs, addition or deletion of coupons, UPC production codes, or recipe suggestions; newly assigned or revised establishment numbers; changes in the arrangement or language of directions for opening containers or serving the product; or the substitution of abbreviations for words or vice versa, does not need additional FSIS approval. Establishments would keep a copy of the labeling used, along with the product formulation and processing procedures on file.

FSIS would require nutrition labeling on the major cuts of single-ingredient, raw catfish products, either on their label or at their point-of-purchase, unless an exemption applies. If the manufacturer provides nutrition information on the label of individual packages of the major cuts of single-ingredient, raw meat or poultry products, the retailer is not required to provide the information at the point-of-purchase. However, if the manufacturer does not provide the nutrition information on the label of these

products, the retailer is required to provide the information at their point-of-purchase.

FSIS is estimating that all retailers would display point-of-purchase information for the major cuts of single-ingredient, raw catfish products, because this is an inexpensive means of providing nutrition information for multiple products and because manufacturers would not be required to include nutrition labels on the major cuts of single-ingredient, raw catfish products.

Consumers would use this information to make better informed nutrition choices when purchasing these meat and poultry products.

FSIS would require nutrition labels on all ground or chopped catfish products, with or without added seasonings, unless an exemption applies. As part of routine duties, inspection program personnel will review these labels or labeling materials.

Consumers will use this information to make better informed nutrition choices when purchasing these meat and poultry products.

#### *Registration and Notification*

Catfish producers (farms), wholesalers, brokers, haulers, loaders, importers and exporters would be required to register with FSIS by submitting FSIS Form 5020-2 and providing current and correct information to FSIS, including their name, the address of all locations at which they conduct the business that requires them to register, and all trade or business names under which they conduct these businesses. They would also be required to inform FSIS when information on the form needs to be updated.

### **3. Use Of Improved Information Technology:**

Under the Government Paperwork Elimination Act, the records may be maintained electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data. FSIS estimates that 60% of the recordkeeping will be done electronically.

### **4. Efforts To Identify Duplication:**

No office, USDA agency or any other Government agency requires information regarding pathogen reduction and HACCP systems for meat and poultry products. There is no available information that can be used or modified.

## **5. Methods To Minimize Burden On Small Business Entities:**

Data collected from small businesses are the same as for large ones. The information collections must apply to all businesses slaughtering and processing catfish products to ensure wholesome and unadulterated products. However, small businesses under FSIS inspection almost always are small or very small establishments. Therefore, because these small and very small establishments are low volume establishments the amount of microbiological testing is less than for higher volume establishments. Moreover, small and very small operations are usually less complex than larger operations and require less sophisticated HACCP plans to be developed and maintained. There are 1,705 small businesses.

## **6. Consequences If Information Were Collected Less Frequently:**

To conduct the information collections less frequently will reduce the effectiveness of the catfish inspection program.

## **7. Circumstances That Would Cause The Information Collection To Be Conducted In A Manner:**

- **requiring respondents to report information to the agency more often than quarterly;**
- **requiring respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;**
- **requiring respondents to submit more than an original and two copies of any document;**
- **requiring respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;**
- **in connection with a statistical survey, that is not designed to produce valid and reliable results that can be generalized to the universe of study;**
- **requiring the use of a statistical data classification that has not been reviewed and approved by OMB;**
- **that includes a pledge of confidentiality that is not supported by authority established in statute or**

regulation, that is not supported by disclosure and data security policies that are consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- requiring respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

To ensure that catfish establishments are producing wholesome and unadulterated product, FSIS requires the use of the internationally recognized food safety system—HACCP. In order to effectively monitor and verify official establishment's use of HACCP, the Agency must necessarily require daily information collection and recordkeeping by the industry. This information collection is consistent with all other guidelines listed above.

#### **8. Consultation With Persons Outside The Agency:**

In accordance with the Paperwork Reduction Act, FSIS embedded a 60-day notice in the proposed rule, published in the Federal Register (76 FR 10434; February 24, 2011), requesting comments regarding this information collection request.

#### **9. Payment or Gifts to Respondents:**

Respondents will not receive any gifts or payments.

#### **10. Confidentiality Provided To Respondents:**

No assurances other than routine protection provided under the Freedom of Information Act have been provided to respondents.

#### **11. Questions Of A Sensitive Nature:**

The applicants are not asked to furnish any information of a sensitive nature.

#### **12. Estimate of Burden**

A. The total burden estimate for the reporting and recordkeeping requirements associated with this information collection is 206,959.45 hours. The burden estimates are broken down into four categories described in the pages that follow.

Standard Operation Plans for Sanitation	34,009
HACCP	144,575.95
Labeling	27,998.5
Registration & Notification	376
Total	206,959.45

Standard Operation Procedures (SOPs) for Sanitation

*Development*

FSIS estimates that it will take an average of 5 hours to write a sanitation program for catfish establishments. The Agency estimates that there will be 213 new catfish establishments coming under inspection that will consequently have to develop and write their SOPs. There will be approximately 213 establishments that will spend an annual total of 1,065 hours developing their SOPs.

**SANITATION STANDARD OPERATING PROCEDURES (SOPs) - Plan Development**

Type of Establish- - Ment	No. of Respon- - dents	No. of Res- - ponses per Responde nt	Total Annual Response s	Time for Response in Mins.	Total Annual Time in Hours
All Estabs.	213	1	213	300	1,065

*Evaluation and Revision*

It will take 60 minutes for catfish establishments to reassess and modify a SOP. FSIS estimates that 213 establishments will respond three times annually for a total of 639 responses and 639 hours.

**SANITATION STANDARD OPERATING PROCEDURES (SOPs) -- Plan Evaluation and Revision**

Type of Establish- - Ment	No. of Respon- - dents	No. of Res- - ponses per Responde nt	Total Annual Response s	Time for Respons e in Mins.	Total Annual Time in Hours
All Estabs.	213	3	639	60	639



*Recordkeeping*

The burden of documenting the adherence to a SOP is based on three components; recording, reviewing, and storage. Recording encompasses conducting and inscribing the finding from an observation and filing of the document produced. This action is assumed to take 30 minutes per day. FSIS estimates that annually each of the 213 catfish establishments will perform recordkeeping duties 260 times with a total of 55,380 responses and 27,690 hours.

**SANITATION STANDARD OPERATING PROCEDURES (SOPs) -- Recording and filing**

Type of Establish - Ment	No. of Respon- dents	No. of Res- ponses per Respon- dent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Estabs.	213	260	55,380	30	27,690

*Record Review*

Review of the records generated is assumed to take 5 minutes per day for a catfish establishment (cf. §§416.14 and 416.15). The Agency estimates that each of the 213 establishments will annually review its SOP records 260 times for a total 55,380 responses and 4,615 hours.

**SANITATION STANDARD OPERATING PROCEDURES (SOPs) -- Record Review**

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responde-nt	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Estabs.	213	260	55,380	5	4,615

The burden estimate is 34,009 hours for Sanitation SOP information collection activities.

HACCP

*Plan Development*

The Agency estimates that 2 new catfish establishments will each spend 8,160 minutes once annually for a total of 272 hours developing their HACCP plans.

**HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM -- Plan Development**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Estabs.	2	1	2	8,160	272

*Reassessment*

FSIS estimates that every establishment will have to reassess its HACCP plan and CCPs 5 times a year. Establishments will spend an average of 1,500 minutes per reassessment. Reassessment of HACCP plans includes both analysis and the time it takes to actually modify their HACCP plan. The 213 catfish establishments will have annual total of 1,065 responses and 26,625 hours.

**HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM -- Plan Reassessment**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Estabs.	213	5	1,065	1,500	26,625

*Recordkeeping*

The Agency estimates that each of the 213 establishments would have to spend 5 minutes performing recordkeeping activities 2,387 times for an annual total of 508,431 responses and 42,369.25 hours.

**HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM -- Recordkeeping**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Estabs.	213	2,387	508,431	5	42,369.25

*Record review*

FSIS estimates that each of the 213 catfish establishments would have to spend 2 minutes reviewing their HACCP records 2,387 times a year for a total of 508,431 responses and 16,947.7 hours.

**HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM -- Record Review**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Estabs.	213	2,387	508,431	2	16,947.7

*Prerequisites*

The Agency estimates that 213 establishments will spend 24 hours once annually developing new prerequisite programs for a total of 213 annual responses and 5,112 hours. And 213 establishments will each spend 1 hour recordkeeping 250 times a year for an annual total of 53,250 responses and 53,250 hours. There will be a grand total of 53,463 responses and 58,362 hours for prerequisite programs.

**HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM - Prerequisite Programs**

Type of Establishment	Type of Collection	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
All	Prerequisite Program Development	213	1	213	24	5,112
All	Prerequisite Program	213	250	53,250	1	53,250

Type of Establishment	Type of Collection	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
	Recordkeeping					
All	Total	213	251	53,463		58,362

The burden estimate is 144,575.75 hours for HACCP information collection activities.

Labeling

The Agency estimates that, on average, it takes 75 minutes to develop, submit, and maintain recordkeeping of a label, including 15 minutes to complete FSIS Form 7234-1. FSIS estimates that each year, approximately 10 times per year, 213 catfish establishments will spend 75 minutes to develop, submit to FSIS, and maintain recordkeeping of labels, for a total of 2,130 responses and 2,662.5 hours.

**LABELING DEVELOPMENT, APPLICATION, & RECORDKEEPING  
(FSIS Form 7234-1)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All firms	213	10	2,130	75	2,662.5

FSIS estimates that, on average, it will take approximately 15 minutes to complete FSIS Form 8822-4 to request reconsideration of a label. The Agency estimates that each year, approximately twice per year, 2 catfish establishments will complete FSIS Form 8822-4 for a total of 4 responses and 1 hour.

**REQUESTS FOR LABEL RECONSIDERATION  
(FSIS Form 8822-4)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Ests.	2	2	4	15	1

FSIS estimates that it takes approximately 15 minutes to make changes to and comply with recordkeeping requirements associated with generically approved labeling. The Agency estimates that 100 catfish establishments will annually make 10 generically approved labeling changes for a total of 1,000 responses and 250 hours.

**GENERIC LABEL PREPARATION AND RECORDKEEPING**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Ests.	100	10	1,000	15	250

FSIS estimates that obtaining point-of-purchase materials and making them available for consumers will take an average of 10 minutes for 74,910 retail establishments for a total of 74,910 responses and 12,485 hours.

### **OBTAINING/DISPLAYING POINT OF PURCHASE MATERIALS**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Recurring Time Requirement in Hours
Retail ests.	74,910	1	74,910	10	12,485



FSIS estimates that one-time, first year development cost of nutrition labels for ground or chopped products will take an average of 6 hours. Labels developed at official establishments will be submitted to FSIS. The Agency estimates that 213 establishments would develop 5 labels and 255 grocery stores would develop 2 labels for a total of 1,575 responses and 9,450 hours.

**DEVELOPMENT OF NUTRITION LABELS FOR GROUND/CHOPPED PRODUCTS**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
Establishment	213	5	1,065	6	6,390
Grocery stores	255	2	510	6	3,060
Total	468		1,575	6	9,450

FSIS estimates that it will take 213 establishments 5 times a year and 255 grocery stores 2 times a year an average of 1.5 hours to prepare and submit a label for prior approval for a total of 1,575 responses and 2,362.5 hours.

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**SUBMITTING LABEL APPROVAL--GROUND/CHOPPED PRODUCT**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
Ests.	213	5	1,065	1.5	1,597.5
Grocery stores	255	2	510	1.5	765
Total	468		1,575	1.5	2,362.5

Grocer stores and warehouse clubs would not be required to submit labels to FSIS for review. All ground or chopped product will be subject to FSIS compliance review; therefore, producers of ground or chopped product, including retail facilities, will be required to maintain records to support the validity of nutrient declarations contained on product labels. FSIS estimates the average time for recordkeeping would be 30 minutes annually for 468 firms for a total of 1,575 responses and 787.5 hours.

### **GROUND/CHOPPED PRODUCT RECORDKEEPING**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Establishment	213	5	1,065	30	532.5
Grocery stores	255	2	510	30	255
Total	468		1,575	30	787.5

There are 27,998.5 burden hours related to labeling.

#### *Registration & Notification*

The Agency estimates that 1,494 producers (farms), loaders/haulers, wholesalers, brokers, importers and exporters would respond once taking 15 minutes to supply the information needed for a total of 374 hours.

#### **REGISTRATION OF CATFISH HANDLERS (FSIS Form 5020-2)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Firms	1,494	1	1,494	15	374

FSIS estimates that eight firms a year would notify (one time) the applicable FSIS District Office that they refused shipment of catfish product because it was potentially adulterated or misbranded for a total of 8 responses and 2 hours.

**NOTIFICATION OF ADULTERATED OR MISBRANDED PRODUCT**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Firms	8	1	8	15	2

There are 376 burden hours related to registration and notification.

The cost to the respondents is estimated at \$7,657,499.65 million annually. The Agency estimates that it will cost respondents \$37 an hour in fulfilling these paperwork requirements. Respondents will spend an annual total 206,959.45 hours and \$7,657,499.65 million.

### **13. Capital and Start-up Cost and Subsequent Maintenance**

FSIS estimates that there will be a total of \$2,130,000 in start-up costs for the 213 catfish plants who will have to implement HACCP. The Agency estimates that it will cost about \$10,000 an establishment mostly related to training.

### **14. Annual Cost To Federal Government:**

The cost to the Federal Government for implementing this program is estimated at \$740,000 annually. The cost estimate includes records review time of FSIS inspection personnel (GS 7/9/11) and staff officers (GS 11/12). The Agency estimates a cost of \$37 per hour for inspector time.

### **15. Reasons For Changes In Burden:**

This is a new information collection.

### **16. Tabulation, Analyses And Publication Plans:**

There are no plans to publish the data for statistical use.

### **17. OMB Approval Number Display:**

The OMB approval number will appear on the required FSIS forms. FSIS requests that it not be required to put the expiration date of the information collection of the forms. Being required to put the expiration date on the form would place a burden on the Agency because 1) it would require FSIS to print new forms with the expiration date on them and would render the forms unusable in three years; 2) at the end of the approval period FSIS could not print up new forms until OMB gave a new expiration date

causing unnecessary delay; and, 3) there is often a time lapse of several months between the date when the expiration expires and the time when OMB will finally give (usually) a three year approval to the extension or revision causing an almost impossible situation for the Agency of attempting to have forms with the correct expiration date on them.

**18. Exceptions to the Certification:**

There are no exceptions to the certification. This information collection accords with the certification in item 19 of the OMB 83-I.