

**SUPPORTING STATEMENT JUSTIFICATION FOR
VOLUNTARY RECALLS OF MEAT AND POULTRY PRODUCTS**

1. Circumstances Making Collection Of Information Necessary:

This information collection requests a revision of a currently approved information collection of burden hours for the voluntary recalls of meat and poultry products.

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.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.). These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged.

A firm that has produced or imported meat or poultry that is adulterated or misbranded and is being distributed in commerce, may voluntarily recall the product in question. Under the FMIA, firms are required to keep such records that fully and correctly disclose all transactions in their business (21 U.S.C. 642). Under the PPIA, firms are required to keep such records as are properly necessary for the effective enforcement of the PPIA (21 U.S.C. 460(b)).

When a firm voluntarily recalls product, FSIS conducts a recall effectiveness check.

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

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

Voluntary Recalls

When meat or poultry in commerce is adulterated or misbranded, FSIS requests that the

establishment that produced the product voluntarily recall the product in question. In conducting a recall, the Agency asks the establishment to provide it with some basic information, including the identity of the recalled product, the reason for the recall, and information about the distributors and customers of the product.

FSIS uses this information to notify the public concerning product subject to a recall and to check on the effectiveness of the recall.

Recall Effectiveness

FSIS checks on the effectiveness of the recall to ensure that all product subject to recall is accounted for. FSIS field personnel use FSIS Form 8400-4 A to determine (1) if the retail consignee received notification of the recall and (2) the amount of recalled product received. FSIS field personnel use FSIS Form 8400-4 B to verify that product held by the retail consignee was properly disposed.

There are a total of 8,600 burden hours for the information collection requests relating to voluntary recalls of meat and poultry products from commerce.

3. Use Of Improved Information Technology:

FSIS makes available an electronic version (PDF fillable) of the FSIS Form 8400-4 A and B to its personnel. The form can be filled out on the computer and then either emailed or printed off and submitted to the appropriate office.

4. Efforts To Identify Duplication:

FSIS has determined that these information collections will not duplicate any other information collections. The required records and reports are not available from other sources, either within government or from non-government sources. There is no similar 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. Approximately 1000 respondents are small businesses.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently would reduce the effectiveness of the meat and poultry inspection program that ensures that meat and poultry products are properly marked, labeled and packaged.

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.**

There are no special circumstances that require the collection of information to be inconsistent with 5 CFR 1320.6.

8. Consultation With Persons Outside The Agency:

In accordance with the Paperwork Reduction Act, FSIS published a 60 day notice of this information collection request in the Federal Register 76 FR 80327) on December 23, 2011, requesting comments on this information collection request. The Agency received one comment that stated that all meat and egg recalls should be mandatory and inspectors should inspect farms.

FSIS contacted two industry trade association (Ken Mastracchio, National Meat Association, 510-763-1533, and Lloyd Hontz, Grocery Manufacturers Association, 202-639-5924) that, in turn, contacted a few of its members. The members estimated the burden of recalls to be between 20 hours to over 200 hours depending on the scope of the recall. Based on these comments, the Agency has increased its estimate of the average burden hours to inform the Agency of a recall of a product from 20 hours to 40 hours.

9. Payment Or Gifts To Respondents:

Respondents do not receive 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:

The total estimated burden for this information collection is 8,600 burden hours. The burden estimates are broken down into two categories described in the pages that follow.

Recall of product	3,600
Recall Effectiveness Check	5,000
Total	8,600 hours

Voluntary Recall of Meat and Poultry Products

FSIS estimates that 90 establishments would once a year take an average of 40 hours to collect and inform the Agency about their recall of product for a total of 90 responses and 3,600 hours.

VOLUNTARY RECALL OF MEAT & POULTRY PRODUCTS

Type of Establish- Ment	No. of Respon- dents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat/ poultry ests.	90	1	90	2,400	3,600

Recall Effectiveness Check

FSIS estimates that 6,000 retail consignees would submit to an interview once a year for an average of 50 minutes for a total of 6,000 responses and 5,000 hours.

**RECALL EFFECTIVENESS CHECK
(FSIS Form 8400-4 A & B)**

Type of Establish-Ment	No. of Respon-dents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Retail Consignees	6,000	1	6,000	50	5,000

The cost to the respondents is estimated at \$318,200 annually. The Agency estimates that it will cost respondents \$37 an hour in fulfilling these paperwork and recordkeeping requirements. Respondents will spend an annual total of 8,600 hours and \$318,200.

13. Capital, Start-up Cost, And Subsequent Maintenance

There are no capital or start-up costs related to this information collection activity.

14. Annual Cost To The Federal Government:

The cost to the Federal Government for this information collection is \$ 634,285 annually. The cost estimate includes 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 the time of its personnel.

15. Reasons For Changes In Burden:

This is a revised information collection based on the most recent recall data, which support a total of 4,900 more burden hours. There are more burden hours because the number of recalls is trending higher and the number of respondents is increasing. The total number of respondents increased from 3,060 to 6,090. There are also more burden hours because, based on industry comments, the Agency increased its estimate of the average burden hours for informing the Agency of a recall of a product. The time for responses in minutes for voluntary recalls increased from 1,200 minutes to 2,400 minutes per response.

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 required FSIS forms. FSIS requests that it not be required to put the expiration date of the information collection on the forms. First, these forms are only used by FSIS personnel in gathering information from retail consignees and they are not seen by the public. Further, 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 current 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 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.

