

SUPPORTING STATEMENT JUSTIFICATION FOR VOLUNTARY RECALLS OF MEAT AND POULTRY PRODUCTS

1. Circumstances Making Collection Of Information Necessary:

This is a request to extend the approved information collection regarding 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 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.

Industry representatives use the FSIS Form 5020-3 *FSIS Preliminary Inquiry Worksheet* to provide firm contact information and specific details regarding adulterated or misbranded product in commerce, including product identifiers, product amounts and supplemental information. Recalling firms and distributors then use the FSIS Form 5020-4 *FSIS Recall Distribution Information Template* to provide the location and contact information of consignees who received recalled product. The FSIS Forms 5020-3 and 5020-4 were developed to assist the respondents in collecting some of the basic information they have always been required to provide FSIS. The burden estimate for providing the required information has not changed.

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 to determine (1) if the retail consignee received notification of the recall and (2) the amount of recalled product received.

There are a total of 6,600 burden hours for the information collection request relating to voluntary recalls of meat and poultry products from commerce.

3. Use Of Improved Information Technology:

FSIS makes available electronic versions (PDF fillable) of FSIS Forms 8400-4, 5020-3 and 5020-4.

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 in the *Federal Register* (89 FR 23537) on April 4, 2024, requesting comments on this information collection request. The Agency did not receive any public comments about the information collection. FSIS also contacted five individuals: Director of Regulatory Compliance Poultry Division, Tyson Foods, Inc., (479) 290-2716; Quality Assurance Manager, Prestage Foods of SC, LLC., (839) 432-4910; FSQA Regional Director, West, Sysco Corporation, (214) 485-5097; Food Safety Manager, BrucePac, (503) 874-3000 Ext. 2233; QA Manager-and Retail, Butterball, (919) 921-9017 to request input on the Agency's burden estimate. Based on their input, the Agency is making no change to the estimated burden estimate.

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 6,600 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	3,000	
Total	6,600	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 information 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
(can include new FSIS Forms 5020-3 and 5020-4)**

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
M/P ests.	90	1	90	2,400	3,600

Recall Effectiveness Check

FSIS estimates that 6,000 retail or wholesale consignees would submit to an interview once a year for an average of 30 minutes for a total of 6,000 responses and 3,000 hours¹.

**RECALL EFFECTIVENESS CHECK
(FSIS Form 8400-4)**

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/ Wholesale Consignees	6,000	1	6,000	30	3,000

The cost to the respondents is estimated at \$371,976 annually. The Agency estimates that it will cost respondents \$56.36 an hour, including fringe benefits, in fulfilling these information collection requirements. Respondents will spend an annual total of 6,600 hours and \$371,976. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2023.

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 these information collection requirements is \$887,828

¹ The estimate of 30 minutes in the table for the Recall Effectiveness Check and form 8400-4 includes time for the interview and discussion.

annually. The cost estimate includes reviews by staff officers at the GS 11/12 level. The Agency estimates a cost of \$51.79 per hour, including fringe benefits, for its personnel time.

15. Reasons For Changes In Burden:

There is no change in the estimated burden for this request for renewal. There are 6,090 respondents, 6,090 responses, and 6,600 total estimated burden hours.

16. Tabulation, Analyses And Publication Plans:

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

17. OMB Approval Number Display:

FSIS will display the OMB approval number and expiration date on any publication or document relating to activities under this information collection.

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.