

SUPPORTING STATEMENT JUSTIFICATION FOR REQUIREMENTS TO NOTIFY FSIS OF ADULTERATED OR MISBRANDED PRODUCT, PREPARE AND MAINTAIN WRITTEN RECALL PROCEDURES, AND REASSESSMENTS

1. Circumstances Making Collection Of Information Necessary:

This is a request for a new information collection, which addresses the regulatory requirements governing the requirements associated with notification, documentation, and recordkeeping for official meat and poultry establishments.

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 verifying that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged.

Section 11017 of the Food, Conservation, and Energy Act of 2008 (Pub. L. No. 110-246, 112 Stat 1651, 448-49), amended the FMIA and the PPIA by adding new sections 12 and 13 to the FMIA and by amending section 10 of the PPIA (21 U.S.C. 459). These new sections require official establishments that believe that product they have shipped or received that may be misbranded or adulterated and has entered into commerce are required to notify the Secretary of Agriculture. In addition, establishments are to prepare and maintain current recall procedures, document each reassessment of its HACCP plan, and make the recall procedures and written records of the establishment's HACCP plan reassessments available for official review and copying.

FSIS is codifying these statutory amendments in its regulations.

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

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

HACCP Plan Reassessment

Official establishments are to document each time they reassess their HACCP plans and make the reassessments available to FSIS officials for review and copying (9 CFR 417.4(a)). This information will

permit FSIS officials to monitor more closely establishments' HACCP plan reassessments.

Recall Notification and Procedures

Official establishments are to notify the FSIS District Office that they have received or have shipped into commerce misbranded or adulterated product (9 CFR 418.2). Moreover, establishments are to develop and maintain written recall procedures (9 CFR 418.3) and make the recall procedures available to FSIS for review and copying.

This information will facilitate recalls of adulterated or misbranded product.

3. Use Of Improved Information Technology:

Under the Government Paperwork Elimination Act, FSIS permits electronic recordkeeping.

4. Efforts To Identify Duplication:

No FSIS office, USDA agency, or any other Government agency requires information relating to meat and poultry recalls or HACCP plan reassessment for meat and poultry establishments. There is no available information that can be used or modified.

5. Methods To Minimize Burden On Small Business Entities:

Data required of small businesses are the same as for large ones. The information collection must apply to all meat and poultry establishments.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently will reduce the effectiveness of the meat and poultry products 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.

All information collection and recordkeeping activities in this submission are consistent with the guidelines above.

8. Consultation With Persons Outside The Agency:

In accordance with the Paperwork Reduction Act, FSIS embedded in its proposed rule (75 FR 14361; March 25, 2010) a 60-day notice requesting comments regarding this information collection request. FSIS received five comments on the information collection in the proposed rule, which are addressed in the final rule. The comments are also discussed below.

The National Turkey Federation commented that documentation of HACCP plan reassessment is a reasonable request of the agency given that annual reassessments are required. It would be helpful to provide guidance to the industry on the specific requirements of the documentation and make it clear what information is mandatory and what information is optional to include on forms.

The Agency responded to this comment on pg. 26932 of Final Rule. At this time, FSIS does not plan to publish any additional guidance documents for industry.

Agency Response : The Agency agrees with comments that the documenting of HACCP reassessments is beneficial. The Agency believes that documenting HACCP reassessments will facilitate verification that establishments have appropriately reassessed their HACCP plans. It will also help FSIS personnel to identify whether there are emerging hazards that the establishment has decided not to address.

The Association of Meat Processors commented that it should be clearly understood by all stakeholders what the Agency can and cannot do with the information provided. Is this information subject to Freedom Of Information Act (FOIA) requests? Would the Agency utilize the information to conduct further investigations such as the traceback to supplying establishments of contaminated raw materials?

The Agency responded to this comment on pg. 26931 of the Final Rule.

Agency's Response: FSIS understands the nature of these comments and that many meat and poultry establishments view the data in recall procedures as confidential commercial information. Pursuant to USDA's Freedom of Information Act (FOIA) regulations (7 CFR 1.1 et seq.), FSIS is responsible for making the determination with regard to the disclosure or nondisclosure of information in records obtained from businesses. When, in the course of responding to an FOIA request, FSIS cannot readily determine whether the information obtained from a person is confidential business information, the Agency seeks to obtain and carefully consider the views of the business and provide the business an opportunity to object to any decision to disclose the information.

Under this final rule, establishments are not required to submit their recall procedures to FSIS. They must, however, make the written recall procedures available for copying. FSIS will verify that all establishments maintain the required written recall procedures. FSIS will also protect establishments' confidential business information from public disclosure to the extent authorized under FOIA and in conformity with USDA's FOIA regulations.

The Rastelli Foods Group commented that establishments would need to disclose the entire recall plan and procedures. These plans can and do contain private and critical information. The establishments should be able to provide a Recall Policy without divulging actual specifics, except in the case of an actual recall.

The Agency responded to this comment on pg. 26931 of the Final Rule.

Agency's Response: FSIS understands the nature of these comments and that many meat and poultry establishments view the data in recall procedures as confidential commercial information. Pursuant to USDA's Freedom of Information Act (FOIA) regulations (7 CFR 1.1 et seq.), FSIS is responsible for making the determination with regard to the disclosure or nondisclosure of information in records obtained from businesses. When, in the course of responding to an FOIA request, FSIS cannot readily determine whether the information obtained from a person is confidential business information, the Agency seeks to obtain and carefully consider the views of the business and provide the business an opportunity to object to any decision to disclose the information.

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The American Meat Institute commented that to avoid confusion, the Agency must clarify that establishments are required to report information concerning only their direct consignees.

The Agency responded to this comment on pg. 26929 of the Final Rule.

Agency's Response: Under this rule, establishments must provide all available information about the "destination" of adulterated or misbranded product. This rule does not create a duty to seek out new information; however, if establishments have information about the destination of adulterated or misbranded product beyond their direct consignees, they must provide it to the Agency.

Food and Water Watch commented that FSIS should initiate immediate investigations to maximize the public health benefit from the information obtained by this rule, by maximizing the amount of contaminated product recalled.

The Agency responded to this comment on pg. 26929 of the Final Rule.

Agency's Response: FSIS agreed with commenters that 48 hours may be too long. The Agency has concluded that because notification can be made with a phone call, 24 hours is an appropriate time in which to expect official establishments that have shipped or received, or have reason to believe that they have shipped or received, adulterated or misbranded product, to notify the appropriate District Office of that situation. Therefore, the final rule requires official establishments to notify the appropriate District Office within 24 hours of learning or determining that an adulterated or misbranded product received by or originating from the establishment has entered commerce, if the establishment believes or has reason to believe that this has happened.

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

The total burden estimate for the reporting and recordkeeping requirements associated with this information collection is 47,475 hours.

The Agency estimates that 60 establishments will respond one time annually taking each establishment 15 minutes to notify the District Office that it has either received or shipped into commerce adulterated or misbranded product for an annual total of 60 responses and 15 burden hours.

**NOTIFICATION OF ADULTERATED OR MISBRANDED PRODUCT
(9 CFR 418.2)**

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
Ests.	60	1	60	15	15

FSIS estimates that 6,300 establishments will take 10 minutes, 5 times a year, to record the reassessment of their HACCP plans for a total of 31,500 responses and 5,250 hours.

**WRITTEN HACCP REASSESSMENT RECORDKEEPING
(9 CFR 417.4 (a))**

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
Ests.	6,300	5	31,500	10	5,250

FSIS estimates that 6,300 establishments will take 20 hours to develop written recall procedures for a total of 6,300 responses and 126,000 hours. Because this is a one time event and not an annual one, the Agency has spread the total annual burden hours over a three-year period to more accurately reflect the total annual burden hours—2,100 respondents and 42,000 hours annually.

DEVELOP RECALL PROCEDURES

(9 CFR 418.3)

Type of Establish-Ment	No. of Respon-dents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
Ests.	2,100	1	2,100	20	42,000

FSIS estimates that 6,300 establishments will file their written procedures one time annually for an annual total of 6,300 responses and 210 hours.

**RECALL PROCEDURES RECORDKEEPING
(9 CFR 9 CFR 418.3)**

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
Ests.	6,300	1	6,300	2	210

The cost to the respondents is estimated at \$1,661,625 annually. The Agency estimates that it will cost respondents \$35 an hour in fulfilling these paperwork and recordkeeping requirements. Respondents will spend an annual total of 47,475 hours and \$1,661,625.

13. Capital and Start-up Cost and Subsequent Maintenance

There are no capital and start-up costs and subsequent maintenance burdens.

14. Annual Cost To Federal Government And Respondents:

The cost to the Federal Government for these information collection requirements is \$35,000 annually. The Agency estimates a cost of \$35 per hour.

15. Reasons For Changes In Burden:

This is a new information collection resulting in a program change of 47,475 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 on any instructions it publishes relating to recordkeeping activities.

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.