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

1. Circumstances Making Collection Of Information Necessary:

This is a request for an extension of an approved information collection which addresses the regulatory 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 sections 12 and 13 to the FMIA and by amending section 10 of the PPIA (21 U.S.C. 459). These sections require official establishments that believe they have shipped into commerce or received adulterated or misbranded product 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.

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

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

Recall Notification and Procedures

FSIS requires that official establishments notify the appropriate District Office 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 CFR 418.2). Industry representatives of official establishments may now use **FSIS Form 5720–16**, *Industry Report of Adulteration*, to notify FSIS that an adulterated or misbranded meat, meat food, poultry, or poultry product

was received from or shipped to commerce by the official establishment. The form is available as a paper form and digitally in the FSIS Public Health Information System (PHIS) through the Adulterated Product Monitoring (APM) module.

FSIS also requires that establishments prepare and maintain written procedures for the recall of meat and poultry products produced and shipped by the establishment for use should it become necessary for the establishment to remove product from commerce. (9 CFR 418.3). These written recall procedures have to specify how the establishment will decide whether to conduct a product recall, and how the establishment will effect the recall should it decide that one is necessary.

HACCP Plan Reassessment

FSIS requires that establishments document each reassessment of the establishment's HACCP plans (9 CFR 417.4(a)). FSIS requires establishments to reassess their HACCP plans annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. For annual reassessments, if the establishment determines that no changes are necessary, documentation of this determination is not necessary.

3. Use Of Improved Information Technology:

Under the Government Paperwork Elimination Act, FSIS permits electronic recordkeeping. The APM module in PHIS is the electronic system establishments can use to complete the Industry Report of Adulteration.

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. Approximately, 2900 small businesses are affected by this

information collection.

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 published a 60-day notice of this information

collection request in the ***Federal Register*** (86 FR 19214) on April 13, 2021. FSIS received no relevant comments on the information collection. FSIS also contacted Kristine Johnson 618-550-0083; David Robinson 978-203-0370; Aaron Beaudoin 256-366-8006; Martin Victor 951-694-2079; and Dionne Meehan 952-258-4052 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 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. A SORN for the Public Health Information System (PHIS) collection published on March 15, 2018 (83 FR 11489).

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 9,960 hours.

The Agency estimates that 5,000 establishments will respond one time annually taking each establishment 30 minutes to notify the District Office (either verbally or electronically through the Public Health Information System) that it has either received or shipped into commerce adulterated or misbranded product for an annual total of 5,000 responses and 2,500 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.	5,000	1	5,000	30	2,500

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 100 establishments will take 20 hours to develop written recall procedures for a total of 100 responses and 2,000 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.	100	1	100	20	2,000

FSIS estimates that 6,300 establishments will take 2 minutes to 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 $554,075 annually. The Agency estimates that it will cost respondents $55.63 an hour, including fringe benefits, in fulfilling these information collection requirements. Respondents will spend an annual total of 9,960 hours and $554,074. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2020.

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 $50,120 annually. The Agency estimates a cost of $50.12 per hour, including fringe benefits, for its personnel time.

15. Reasons For Changes In Burden:

There is a decrease in the overall burden hours from 47,474 hours to 9,960 hours due to a decrease in the estimated number of respondents that develop recall procedures. There is also an increase in the number of responses from 39,960 to 42,900 due to the increased number of notifications of adulterated or misbranded product that occur with better of information technology data collection tools.

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.