

SUPPORTING STATEMENT JUSTIFICATION FOR APPLICATION FOR INSPECTION, ACCREDITED LABORATORIES, EXEMPTIONS

1. Circumstances Making Collection Of Information Necessary:

This information collection requests a revision of the burden hours approved under control number 0583-0082, which addresses some of the regulatory requirements in the application for inspection, accreditation of laboratories, and exemptions related to meat, poultry, and egg products inspection.

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.), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et. seq.) and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, et seq.). These statutes mandate that FSIS protect the public by ensuring that meat, poultry, and egg products are not adulterated, wholesome, and properly labeled and packaged.

FSIS requires meat, poultry, and import establishments to apply for a grant of inspection before they can receive Federal inspection. FSIS also requires establishments that wish to receive voluntary inspection to apply for inspection. Establishments that wish to export or import product most also submit certain documentation to the Agency.

The Federal Meat Inspection Act (21 U.S.C. 642) and the Poultry Products Inspection Act (21 U.S.C. 460 (b)) require certain parties to keep records that fully and correctly disclose all transactions involved in their businesses related to relevant animal carcasses and parts.

FSIS requires FSIS accredited non-Federal analytical laboratories to maintain certain paperwork and records. The Agency uses this collected information to ensure that all meat and poultry establishments produce safe, wholesome, and unadulterated product, and that non-federal laboratories accord with FSIS regulations.

In addition, FSIS also collects information to ensure that meat and poultry establishments exempted from Agency inspection do not commingle inspected and non-inspected meat and poultry products, and to ensure that retail firms qualifying for a retail store exemption and who have violated the provision of that exemption are no longer in violation.

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

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

Application for Inspection

All establishments that are required to slaughter or process meat and poultry products under Federal inspection must complete and submit an application, FSIS Form 5200-2, Application for Meat, Poultry, or Import Inspection, to receive a grant of inspection (9 CFR 304.1 and 381.17). Establishments that want voluntary inspection must complete and submit an application, FSIS Form 5200-6 (§§350.5, 351.4, 352.3, and 362.3).

Each establishment is required to furnish FSIS with its schedule of operations to permit assignment of inspectors. Each establishment must notify the inspectors about scheduling changes about once a year (9 CFR 307.4 and 381.37).

Establishments and other businesses are required to keep records of their transactions for meat, poultry, or egg products (9 CFR 320.1(b), 381.175(b), and 590.200). FSIS requires this information in case of need to track product.

Brokers that import egg products must complete and submit FSIS Form 5200-8, Import Request for Egg Products (9 CFR 590.920). This form accompanies each shipment of imported eggs. FSIS and U.S. Customs use the form to control the movement and disposition of imported eggs.

Establishments that export meat and poultry must complete FSIS Form 9080-3, Establishment Application for Export for every country they wish to export product (9 CFR 322.2 & 381.105). FSIS uses this information to track the export of product.

Accreditation of Laboratories

According to the type of accreditation sought, check samples of meat and poultry products with either known quantities of fat, water, salt, or protein (food chemistry samples) or known quantities of drug or other residues (residue samples) are sent by FSIS to the labs. The labs report the results on FSIS Form 11,120-1, Check Sample Results. FSIS uses this information once to determine whether the labs report the correct results and, therefore, should be accredited.

To maintain accreditation, labs are required to analyze check samples several times a year. Labs testing for residues complete FSIS Form 10,600-1 and labs testing for food chemistry complete FSIS Form 6200-18, Food Chemistry Interlaboratory Check Sample Results. FSIS uses this information to determine whether the labs are continuing to meet the accreditation requirements.

Pasteurized Egg Products Recognized Laboratories complete FSIS Form 10,000-8 to provide information necessary to ensure that labs are in compliance with program requirements (9 CFR 590.580). FSIS, state, PEPR Lab program, and TALP program labs are required to complete FSIS Form 10,000-7 to assist FSIS audits of the laboratories (9 CFR 319.10 & 590.580).

Recordkeeping for Certain Exemptions

Establishments engaging in custom exempt slaughter must keep records showing numbers and kinds of livestock slaughtered on a custom basis, the quantities and types of products prepared on a custom basis, and the names and addresses of the owners of the livestock and products (9 CFR 303.1(b)(3) and 381.10(a)(1)). FSIS reviews this information about once a year to ensure that custom operations are in compliance with the regulations.

If the Agency has reason to believe that a retail firm is in violation of retail store provisions, that

operator must keep records during a probation period that reflect the monthly sales of product (§§303.1(d)(3) and 381.10(d)(3)). FSIS will use this information to determine when establishments can be taken off probation.

There are a total of 114,300 burden hours for the information collection requests relating to application for inspection, accreditation of laboratories, and recordkeeping for exemptions.

3. Use Of Improved Information Technology:

Under the Government Paperwork Elimination Act, FSIS is offering electronic versions of FSIS Forms: 10,000-7, 10,000-8, 9080-3, 5200-8, 5200-6, and 5200-2. Records may be maintained electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data. The Agency estimates that 50% of the paperwork and recordkeeping will be done electronically.

4. Efforts To Identify Duplication:

No USDA agency, or any other Government agency, requires information regarding application for inspections, registration, exemptions, or accreditation of laboratories relating to meat, poultry, and egg 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.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently will reduce the effectiveness of the meat and poultry 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 maintain food safety, certain forms and recordkeeping requirements in this information collection will be done more than quarterly. All information collection and recordkeeping activities in this submission are consistent with the guidelines in 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 (72 FR 53752) on September 20, 2007, requesting comments regarding this information collection request. FSIS did not receive any comments. The Agency also contacted a trade association (Lloyd Hontz; 202/639-5924) to solicit comments from a few of its members. However, none of its members had comments.

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 114,300 hours. The burden estimates are broken down into three categories described in the pages that follow.

Application for Inspection	1,474.5
Transactions Recordkeeping	111,467
Accreditation for Laboratories	76.5
Exemptions	1,282
Total	114,300 hours

Application for Inspection

The Agency estimates that 400 establishments will complete the Application for Inspection once a year for an annual total of 400 responses. It will take 30 minutes to complete each form for an annual total of 200 burden hours.

APPLICATION FOR INSPECTION
(9 CFR 304.1 & 381.16/FSIS Form 5200-2)

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat	150	1	150	30	75
Poultry	30	1	30	30	15
Meat & Poultry	220	1	220	30	110
All Estabs.	400	1	400	30	200

FSIS estimates that 122 establishments will complete one FSIS Form 5200-6, Application/Approval for Voluntary Reimbursable Inspection Service, per year. It will take establishments an average of 15 minutes to complete the form for a total of 30.5 hours annually.

APPLICATION /APPROVAL FOR VOLUNTARY INSPECTION
(9 CFR 350.5/FSIS Form 5200-6)

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat	50	1	50	15	12.5
Poultry	12	1	12	15	3
Meat & Poultry	60	1	60	15	15
All Estabs.	122	1	122	15	30.5

FSIS estimates that 6,070 establishments will submit their Schedule of Operations once a year for a total of 6,070 responses. And the average response time will be 5 minutes for a total of 506 hours per year.

SCHEDULE OF OPERATIONS
(9 CFR 307.4(d)(1)/381.37(c))

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat	2,180	1	2,180	5	182
Poultry	490	1	490	5	41
Meat & Poultry	3,400	1	3,400	5	283
All Estabs.	6,070	1	6,070	5	506

FSIS estimates that 19 customs brokers will complete FSIS Form 5200-8 25 times a year taking 30 minutes each time for a total of 475 responses and 238 hours.

IMPORT REQUEST FOR EGG PRODUCTS
(9 CFR 590.920/5200-8)

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Brokers	19	25	475	30	238

FSIS estimates that 1,000 establishments will respond twice a year completing and submitting FSIS Form 9080-3, Establishment Application for Export, for an annual total of 2,000 responses. It will take an average of 15 minutes per response for an annual total of 500 hours.

ESTABLISHMENT APPLICATION FOR EXPORT OF MEAT/POULTRY/OTHER
(9 CFR /FSIS Form 9080-3)

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.	1,000	2	2,000	15	500

Transactions Recordkeeping

FSIS estimates that 16,720 establishments and brokers will make an average of 200 responses for an annual total of 3,344,000 responses. The response time will average 2 minutes for an annual total of 111,467 hours.

**TRANSACTIONS RECORDKEEPING
(9 CFR 350.5, 351.4, & 590.200)**

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	16,720	200	3,344,000	2	111,467

Accreditation of Labs

FSIS estimates that 108 laboratories will complete FSIS Form 5200-6, Food Chemistry Interlaboratory Check Sample Results, six times a year for an annual total of 648 responses. It will take the laboratories an average of 3 minutes per response for an annual total of 32 hours.

**FOOD CHEMISTRY INTERLABORATORY CHECK SAMPLE RESULTS
(9 CFR 318.21 7 & 381.153/FSIS Form 6200-18)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Accr. Labs	91	6	546	3	27.3
State Labs	17	6	102	3	5.1
All Labs	108	6	648	3	32

The Agency estimates that 19 laboratories will complete FSIS Form 10,120-1, Residue Check Sample Results, six a year for an annual total of 114 responses. It will take an average of 15 minutes per response for an annual total of 28.5 hours.

RESIDUE CHECK SAMPLE RESULTS

(9 CFR 318.21 & 381.153 /FSIS Form 10,120-1)

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Labs.	19	6	114	15	28.5

FSIS estimates that 35 accredited laboratories will complete and submit once a year FSIS Form 10,600-1, Domestic Chemical Report for an annual total of 35 responses and 2 hours.

**DOMESTIC CHEMICAL LABORATORY REPORT
(9 CFR 350.5/FSIS Form 10,600-1)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Labs	35	1	35	3	2

The Agency estimates that 30 labs will take 10 minutes to complete FSIS Form 10,000-8 for an annual total of 30 responses and 5 hours.

**PASTEURIZED EGG PRODUCTS RECOGNIZED LABORATORY PROGRAM
 INFORMATION UPDATE REQUEST FORM
 (9 CFR 590.580/FSIS Form 10,000-8)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Labs	30	1	30	10	5

FSIS estimates that 25 labs will 20 minutes to complete FSIS Form 10,000-7 once a year for a total of 25 responses and 9 hours.

**LABORATORY QUALITY DIVISION AUDIT EVALUATION FORM
(9 CFR 319.10 & 590.580/FSIS Form 10,000-7)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Labs	25	1	25	20	9

Exemptions

FSIS estimates that 3,130 establishments will respond twelve times a year in filing their custom exempt records for an annual total of 37,560 responses. Establishments will average two minutes in filing their forms for a total of 1,252 annual hours.

CUSTOM EXEMPT RECORDKEEPING

(9 CFR 303.1(b)(3) & 381.10(a)(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 Ests.	3,130	12	37,560	2	1,252

FSIS estimates that 74 firms required to keep certain records because of previous retail exempt violations will take two minutes to file the records once a year for an annual total of 888 responses and 30 hours.

ORDERED RETAIL STORE RECORDKEEPING
(9 CFR 303.1(d)(3) & 381.10(d)(3))

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.	74	12	888	2	30

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 \$700,000 annually. The costs arise primarily from the inspection review duties necessary to verify that establishments comply with the information collection responsibilities. 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 \$35 per hour for inspector time.

The cost to the respondents is estimated at \$4,000,500 million 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 114,300 hours and \$4,000,500 million.

15. Reasons For Changes In Burden:

The program adjustment is 114,300 due to this information collection being revised. There is a program decrease of 283 hours from the previously approved burden of 114,583 is due to the deletion of FSIS Form 10,110-6 (Official Sample Analytical Results) from the burden.

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.