

SUPPORTING STATEMENT JUSTIFICATION FOR ACCREDITED LABORATORIES, TRANSACTIONS, AND 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 wholesome, not adulterated, and properly labeled and packaged.

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.

Schedule of Operations

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).

Transactions Recordkeeping

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.

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 10,120-1, 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 439.20 & 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 113,483.9 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, and, 5200-8. 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 (76 FR 24850) on May 3, 2011, requesting comments regarding this information collection request. FSIS received one comment that the application for inspection should include all amenable species and ratites and squabs should be added to the form. Ratites and squabs are considered poultry under the Agency's regulations. Therefore, the Agency will not be adding a separate section on the form for ratites and squabs because there is already a section for poultry. 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 113,872.6 hours. The burden estimates are broken down into four categories described in the pages that follow.

Schedule of Operations	507.9
Transactions Recordkeeping	111,633.3
Accreditation for Laboratories	60.7
Exemptions	1,282
Total	113,483.9 hours

Schedule of Operations

FSIS estimates that 6,095 establishments will submit their Schedule of Operations once a year for a total of 6,095 responses. And the average response time will be 5 minutes for a total of 507.9 hours per year.

SCHEDULE OF OPERATIONS (9 CFR 307.4(d)(1)/381.37(d)(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
Meat	2,189	1	2,189	5	182.4
Poultry	507	1	507	5	42.25
Meat & Poultry	3,399	1	3,399	5	283.25
All Estabs.	6,095	1	6,095	5	507.9

Transactions Recordkeeping

FSIS estimates that 16,745 establishments and brokers will make an average of 200 responses for an annual total of 3,349,000 responses. The response time will average 2 minutes for an annual total of 111,633.3 hours.

**TRANSACTIONS RECORDKEEPING
(9 CFR 320.1(b), 381.175(b), & 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	16,745	200	3,349,000	2	111,633.3

Accreditation of Labs

FSIS estimates that 69 laboratories will complete FSIS Form 5200-6, Food Chemistry Interlaboratory

Check Sample Results, six times a year for an annual total of 414 responses. It will take the laboratories an average of 3 minutes per response for an annual total of 20.7 hours.

**FOOD CHEMISTRY INTERLABORATORY CHECK SAMPLE RESULTS
(9 CFR 439.20/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	55	6	330	3	16.5
State Labs	14	6	84	3	4.2
All Labs	69	6	414	3	20.7

The Agency estimates that 15 laboratories will complete FSIS Form 10,120-1, Residue Check Sample Results, six a year for an annual total of 90 responses. It will take an average of 15 minutes per response for an annual total of 22.5 hours.

RESIDUE CHECK SAMPLE RESULTS
(9 CFR 439.20/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.	15	6	90	15	22.5

FSIS estimates that 10 accredited laboratories will complete and submit once a year FSIS Form 10,600-1, Domestic Chemical Report for an annual total of 10 responses and 0.5 hours.

**DOMESTIC CHEMICAL LABORATORY REPORT
(9 CFR 439.20/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	10	1	10	3	0.5

The Agency estimates that 48 labs will take 10 minutes to complete FSIS Form 10,000-8 for an annual total of 48 responses and 8 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	48	1	48	10	8

FSIS estimates that 25 labs will take 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 439.20 & 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

The cost to the respondents is estimated at \$4,198,904.3 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 113,483.9 hours and \$4,198,904.3.

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 \$740,000 annually. The costs arise primarily from the inspection review duties necessary to verify that establishments comply with the information collection responsibilities. The Agency estimates a cost of \$37 per hour for inspector time.

15. Reasons For Changes In Burden:

Information Collection	2008 Total Annual Time in Hours	2011 Change in Information Collection	2011 Total Annual Time in Hours
Application for Inspection	200	Moved to PHIS information collection	N/A
Application/ Approval for Voluntary Inspection	30.5	Moved to PHIS information collection	N/A
Schedule of Operations	506	Increase in number of establishments by 25, so increase in number of	507.9

Information Collection	2008 Total Annual Time in Hours	2011 Change in Information Collection	2011 Total Annual Time in Hours
		responses by 25	
Import Request for Egg Products	238	Eliminated. Burden transferred to PHIS	N/A
Establishment Application for Export	500	Moved to PHIS information collection	N/A
Transactions Recordkeeping	111,467	Increase in the number of respondents by 25, so increase in number of responses by 5000	111,633.3

Information Collection	2008 Total Annual Time in Hours	2011 Change in Information Collection	2011 Total Annual Time in Hours
Food Chemistry Interlaboratory Check Sample Results	32	Decrease in the number of labs by 39, so decrease in number of responses by 234	20.7
Residue Check Sample Results	28	Decrease in the number of labs by 4, so decrease in the number of responses by 24	22.5
Domestic Chemical Laboratory Report	2	Decrease in number of labs by 15, so decrease in number of responses by 15	.5
Pasteurized Egg Products Recognized	5	Increase in the number of labs by 18, so	8

Information Collection	2008 Total Annual Time in Hours	2011 Change in Information Collection	2011 Total Annual Time in Hours
Laboratory Program Information Update Request Form		increase in the number of responses by 18	
Laboratory Quality Division Audit Evaluation Form	9	No change	9
Custom Exempt Recordkeeping	1,252	No change	1,252

Information Collection	2008 Total Annual Time in Hours	2011 Change in Information Collection	2011 Total Annual Time in Hours
Ordered Retail Store Recordkeeping	30	No change	30

This is a revised information collection based on the most recent data, which support a total of approximately 816 fewer burden hours. There are 816 fewer burden hours because there was a decrease in the number of labs and brokers that have to submit certain lab forms, and because four forms were removed and their burden shifted to the PHIS information collection. Despite this decrease in burden, the number of establishments has increased, and as a result the total number of responses has increased by 45,538.

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. Being required to put the expiration

date on the forms 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 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.