**SUPPORTING STATEMENT JUSTIFICATION** **FOR**

 **ACCREDITATION OF LABORATORIES, TRANSACTIONS, AND EXEMPTIONS**

**1. Circumstances Making Collection Of Information Necessary**:

This is a request to revise the information collection related to the accreditation of laboratories, transactions, and exemptions for 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 witheither 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 113,471 burden hours for the information collection requests relating the accreditation of laboratories, transactions, and exemptions for meat, poultry, and egg products inspection.

**3.** **Use Of Improved Information Technology:**

Under the Government Paperwork Elimination Act, FSIS is offering electronic versions of FSIS Forms: 6200-18, 10,600-1, 10,000-7, and 10,000-8. 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. There are 17,000 small businesses.

**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** (85 FR 39519) on July 1, 2020, requesting comments regarding this information collection request. FSIS received no comments. The Agency also contacted several outside individuals, Umed Singh (209-394-6914 ext 4137); Wade Whittington (479-290-4489); and Janet Smith (706-778-5100 ext 1329), to request input on the FSIS burden estimates for the FSIS forms. The outside individuals agreed that the FSIS burden estimate was accurate, so the Agency is making no changes to the estimated burden.

**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 113,471 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 47.8

Exemptions 1,282

Total 113,471 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 ofEstablishment | No. ofRespondents | No. of Re-ponses per Respondent | TotalAnnual 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 ofEstablishment | No. ofRespondents | No. of Re-ponses per Respondent | TotalAnnual 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 36 laboratories will complete FSIS Form 5200-6, Food Chemistry Interlaboratory Check Sample Results, six times each year for an annual total of 216 responses. It will take the laboratories an average of 3 minutes per response for an annual total of 10.8 hours.

**FOOD CHEMISTRY INTERLABORATORY CHECK SAMPLE RESULTS**

**(9 CFR 439.20/FSIS Form 6200-18)**

| Type ofEstablishment | No. ofRespondents | No. of Re-ponses per Respondent | TotalAnnual Responses | Time for Response in Mins. | Total Annual Time in Hours |
| --- | --- | --- | --- | --- | --- |
| Accr. Labs |  27 |  6  |  162 |  3 |  8.1 |
| State Labs |  9  |  6  |  54  |  3 |  2.7 |
| All Labs | 36 |  6  |  216  |  3 |  10.8 |

The Agency estimates that 13 laboratories will complete FSIS Form 10,120-1, Residue Check Sample Results, six a year for an annual total of 78 responses. It will take an average of 15 minutes per response for an annual total of 19.5 hours.

**RESIDUE CHECK SAMPLE RESULTS**

**(9 CFR 439.20/FSIS Form 10,120-1)**

| Type ofEstablishment | No. ofRespondents | No. of Re-ponses per Respondent | TotalAnnual Responses | Time for Response in Mins. | Total Annual Time in Hours |
| --- | --- | --- | --- | --- | --- |
| Labs. |  13 |  6  |  78 |  15 |  19.5 |

 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 318.21 (a)and (b)/FSIS Form 10,600-1)**

| Type ofEstablishment | No. ofRespondents | No. of Re-ponses per Respondent | TotalAnnual 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 ofEstablishment | No. ofRespondents | No. of Re-ponses per Respondent | TotalAnnual 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 ofEstablishment | No. ofRespondents | No. of Re-ponses per Respondent | TotalAnnual 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 ofEstablishment | No. ofRespondents | No. of Re-ponses per Respondent | TotalAnnual 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 ofEstablishment | No. ofRespondents | No. of Re-ponses per Respondent | TotalAnnual 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 $5,145,910 annually. The Agency estimates that it will cost respondents $45.35 an hour, including fringe benefits, in fulfilling these information collection requirements. Respondents will spend an annual total of 113,471 hours and $5,145,910. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2019.

**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 $907,000 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 $45.35 per hour, including fringe benefits for inspector time.

**15.** **Reasons For Changes In Burden:**

FSIS has reduced the burden estimate by 13 hours due to fewer respondents completing FSIS forms 6200-18 and 10,120-1. There are 26,176 respondents, 3,393,920 responses, and 113, 471 estimated 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.