SUPPORTING STATEMENT JUSTIFICATION FOR LABORATORY ASSESSMENT REQUESTS

1. Circumstances Making Collection Of Information Necessary:

This request is for a new information collection regarding laboratories that test food samples during illness outbreak investigations.

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.

As a public health regulatory agency, FSIS investigates reports of foodborne illness, contamination, and adulteration potentially associated with FSIS-regulated products. During these investigations, non-FSIS laboratories may test FSIS regulated product and share the results with FSIS. FSIS OPHS Science Staff (SciS) will review the results and associated documentation shared by the non-FSIS laboratory to determine whether FSIS will accept the results. Currently, there are 36 non-FSIS accredited and State laboratories certified to test food samples. If the SciS lead investigator determines the non-FSIS laboratory result is acceptable, FSIS may use the result to inform regulatory action (e.g. request a recall or detain product).

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

As part of the process to determine if the non-FSIS laboratory result is acceptable, the SciS lead investigator collects information from the non-FSIS laboratory and verifies that the non-FSIS laboratory can provide the appropriate certifications and documentation of accreditation, such as ISO17025, or another third-party accreditation entity covering the methods performed. The SciS lead investigator also verifies that the laboratory has submitted all the necessary information, including evidence of chain of custody,

the appropriate laboratory reports with sample identification, final results, and authorization by the responsible official for affirming results. The laboratory may use FSIS Form 8000-17, *Evidence Receipt and Chain of Custody*, to submit information to FSIS. Finally, the SciS investigator collects and verifies laboratory methods and quality assurance records documentation from the accredited, non-FSIS laboratory.

3. Use Of Improved Information Technology:

Under the Government Paperwork Elimination Act, FSIS is offering electronic versions of FSIS Forms. Records may be maintained electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data. The Agency estimates that 80% of the information will be collected electronically.

4. Efforts To Identify Duplication:

No USDA agency, or any other Government agency, requires information laboratory assessment requests 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:

There are no small businesses.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently will reduce the effectiveness of the meat, poultry, and egg 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 requirements in this information collection could be submitted more than quarterly. All information collection 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 17529) on March 30, 2020, requesting comments regarding this information collection request. FSIS received four comments. None of the four comments received were relevant to the information collection. FSIS also contacted several outside individuals, Debbie Gibson (406-444-5970); Nicole Smalls (919-857-4190); Matthew Forstner (651-201-6568); and Xiaorong Qian (615-262-6371), to request input on the FSIS burden estimates. The outside individuals generally agreed that the FSIS burden estimate was accurate. Based on input from the commenters, 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 information collection requirements associated with this information collection is 22.5 hours. The burden estimates are broken down into four categories described in the pages that follow.

Certification	3
Evidence Receipt & Chain of Custody	3
Laboratory Methods	12
Quality Assurance Records	4.5
Total	22.5 hours

Based on the agency's experience to date, FSIS estimates that 3 non-FSIS labs would take an average of 1 hour to provide certification information for a total of 3 responses and 3 hours annually.

PROVIDE CERTIFICATION INFORMATION

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
Non-FSIS Labs	3	1	3	1	3

Based on the agency’s experience to date, FSIS estimates that 3 non-FSIS labs would take an average of 1 hour to provide evidence and COC information for a total of 3 responses and 3 hours annually.

8,000-17 EVIDENCE RECEIPT & CHAIN OF CUSTODY

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
Non-FSIS Labs	3	1	3	1	3

Based on the agency’s experience to date, FSIS estimates that 3 non-FSIS labs would take an average of 4 hours to provide laboratory method records for a total of 3 responses and 12 hours annually.

LABORATORY METHODS

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
Non-FSIS Labs	3	1	3	4	12

Based on the agency’s experience to date, FSIS estimates that 3 non-FSIS labs would take an average of 1.5 hours to collect quality assurance information for a total of 3 responses and 4.5 hours annually.

QUALITY ASSURANCE RECORDS

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
Non-FSIS Labs	3	1	3	1.5	4.5

The cost to the respondents is estimated at $1,108 annually. The Agency estimates that it will cost respondents $49.24 an hour, including fringe benefits, in fulfilling these information collection requirements. Respondents will spend an annual total of 22.5 hours and $1,108. 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 $1,417 annually. The costs arise primarily from the review of results and associated documentation shared by the non-FSIS laboratories. The Agency estimates a cost of $63 per hour, including fringe benefits, for Agency personnel time.

15. Reasons For Changes In Burden:

FSIS was collecting non-FSIS laboratory assessment information without approval and is claiming this as a violation. This information collection has 3 respondents, 12 responses, and 22.5 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 information collection 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.