SUPPORTING STATEMENT JUSTIFICATION FOR
IMPORTED UNDENATURED INEDIBLE PRODUCT AND SAMPLES FOR
LABORATORY EXAMINATION, RESEARCH, EVALUATIVE TESTING,
OR TRADE SHOW EXHIBITION INFORMATION COLLECTION

1. Circumstances Making Collection of Information Necessary:

This information collection requests a revision of the information collection related to the importation of undenatured inedible product. FSIS has revised this collection to include Samples for Laboratory Examination, Research, Evaluative Testing, or Trade Show Exhibition and, thus changed the title of the collection to "Imported Undenatured Inedible Product and Samples for Laboratory Examination, Research, Evaluative Testing, or Trade Show Exhibition."

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 Egg Products Inspection Act (EPIA) (21 U.S.C. et seq.). These statutes mandate that FSIS protect the public by ensuring that meat and egg products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS uses the forms under this collection to identify and keep track of product not subject to FSIS import reinspection requirements.

2. How, By Whom and Purpose For Which Information is to be Used:

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

FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, et seq.) and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, et seq.). FSIS protects the public by verifying that meat and egg products are safe, wholesome, not adulterated, and correctly labeled.

Foreign governments are to petition FSIS for approval to import undenatured inedible egg products into the United States (9 CFR 590.45 (d)). Undenatured inedible meat and egg products may be imported into the United States if they meet the requirements of the regulations (9 CFR 325.11 (e) and 590.45 (d)).

Inedible poultry must be denatured, regardless of the intended use (9 CFR Part 381.193); thus, undenatured inedible poultry product may not be imported into the United States.

Firms complete FSIS Form 9540-4, “Permit Holder – Importation of Undenatured Inedible Product” for the undenatured inedible product that they are importing into the United States. FSIS uses the information on the form to keep track of the movement of imported undenatured inedible meat and egg products.

Additionally, meat, poultry, and egg product samples destined for laboratory examination, research, evaluative testing, or trade show exhibition are not subject to FSIS import reinspection requirements. Firms will be required to complete FSIS Form 9540-5, “Notification of Intent to Import Meat, Poultry, Or Egg Products ‘Samples for Laboratory Examination, Research, Evaluative Testing, or Trade Show Exhibition’” to ensure that samples imported into the United States are not mixed with product that will be sold or distributed in commerce. (9 CFR 327.19, and 381.207, and 590.960).

3. Use of Improved Information Technology:

Under the E-Gov Act, firms may submit notification and protocols electronically. Records may be maintained electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data.

4. Efforts to Identify Duplication:

No other Government agency requires information regarding undenatured inedible meat or egg products or samples for laboratory examination, research, evaluative testing, or trade show exhibition. 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. FSIS estimates that there are 10 small firms that are subject to 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;**

(Importers are required to collect and report information more than quarterly. Undenatured product must be reported every time it comes in, which happens frequently and not on an interval basis. Similarly, samples for laboratory examination, research, evaluative testing, or trade show exhibition must be reported as they are needed which is more frequently 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.**

There are no other circumstances that would cause the guidelines above not to be met by this information collection.

8. Consultation with Persons Outside the Agency:

In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice in the *Federal Register* on February 25, 2022, requesting comments on this information collection request (87 FR 10764).

FSIS received one comment that was not relevant to the collection. FSIS also contacted three persons to request input on the Agency's burden estimate for the FSIS Form 9540-4: Joyce Newell (928-778-5255); Jessica Chacon (504-368-3335); and Sue Dearlove (519-323-7962). Based on input from the three individuals, the Agency kept 15 minutes as the estimated response time for the 9540-4 form. FSIS also contacted three persons to request input on the Agency's burden estimate for the FSIS Form 9540-5: Gabriel Travaioli +55(19)99987-5192; Mary Jane O'Reilly (519-453-4996 ext 314); and Vanessa Valdivieso (877-232-7772). Based on input from the three individuals, the Agency reduced the previous estimate of 20 minutes to 15 minutes to complete the 9540-5 form.

9. Payment or Gifts to Respondents:

Respondents will not receive any gifts or payments.

10. Confidentiality Provided to Respondents:

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

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 requirements associated with this information collection is 9,489 hours.

The Agency estimates that 14 importers will 360 times a year spend 15 minutes each time filling out and submitting the 9540-4. There will be a grand total of 5,040 responses and 1,260 burden hours.

IMPORT OF UNDENATUREDINEDIBLE PRODUCT
(FSIS Form 9540-4)

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
Importers	14	360	5,040	15	1,260

The Agency estimates that 211 importers will 156 times a year spend 15 minutes each time filling out and submitting the 9540-5. There will be a grand total of 32,916 responses and 8,229 burden hours.

NOTIFICATION OF INTENT TO IMPORT MEAT, POULTRY, OR EGG PRODUCTS SAMPLES FOR LABORATORY EXAMINATION, RESEARCH, EVALUATIVE TESTING OR TRADE SHOW EXHIBITION

(FSIS Form 9540-5)

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
Importers	211	156	32,916	15	8,229

The cost to the respondents is estimated at $439,910 annually. The Agency estimates that it will cost respondents $46.36 an hour, including fringe benefits, in fulfilling these paperwork requirements. Respondents will spend an annual total of 9,489 hours and $439,910. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2021.

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 $22,570 annually. The costs arise primarily from the time spent by FSIS staff reviewing protocols and data. The Agency estimates a cost of $45.14, including fringe benefits, per hour.

15. Reasons for Changes in Burden:

The Agency has decreased the total burden by 14,441, from 23,930 to 9,489 hours, because the number of applications for importing meat, poultry or egg product samples destined for laboratory examination, research, evaluative testing or trade show exhibition has decreased. The number of responses has decreased from 73,320 to 37,956. Also, based on comments received, FSIS reduced the time on FSIS Form 9540-5 from 20 minutes to 15 minutes.

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 number on any instructions it publishes relating to these reporting 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.