

## **SUPPORTING STATEMENT JUSTIFICATION FOR IMPORTED UNDENATURED INEDIBLE PRODUCT INFORMATION COLLECTION**

### **1. Circumstances Making Collection of Information Necessary:**

This information collection requests a new information collection related to the collection of information related to the importation of undenatured inedible product.

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 will use a form to be able to track the importation of undenatured inedible meat and egg products into the United States.

### **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 will 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 will use the information on the forms to keep track of the movement of imported undenatured inedible meat and

egg products.

### **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. 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 will be required to collect and report information more 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 requesting comments on this information collection request (January 31, 2013; 78 FR 6803). The Agency received one comment in response to the Federal Register notice. The comment stated that 1) the information collected is important, 2) standard instructions and requirements are needed to help industry comply, and 3) the Agency must use all electronic means available as it relates to cost analysis. In addition, the commenter asked if the form is changed would the Agency request comments on it.

The Agency agrees that the information is important. FSIS provides instruction to trade on the web site [http://www.fsis.usda.gov/Regulations & Policies/undenatured inedible meat products/index.asp](http://www.fsis.usda.gov/Regulations%20&%20Policies/undenatured_inedible_meat_products/index.asp) Additionally, FSIS is working on an industry guidance document that will include more detailed instructions on many import processes including this one. Under the PRA, FSIS would seek public comment on any substantial revision to the form.

FSIS also directly contacted three firms to request comment on the Agency's estimates. One person commented that it took 7 minutes to complete the form approximately 40 times a year (Lloyd Woodward, 308/532-1250). Another commenter said that it took 4 to 5 minutes to complete the form about 350 to 400 times a year (Melissa McDowell, 64-3-688-3881). A third person said it takes 4-5 minutes to complete the form, and the company completes it 950 to 1,050 times a year (Bernadette Krassol, 64-6-974-5734).

In response to these comments, FSIS changed its estimate of the average number of times an importer will complete the form from 100 times a year to 200 times a year for a total of 4,000 responses and 667 burden hours.

**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 and recordkeeping requirements associated with this information collection is 667 hours.

The Agency estimates that 20 importers will 200 times a year spend 10 minutes each time filling out and submitting 9540-1. They will have a grand total of 4,000 responses and 667 burden hours.

**IMPORT OF UNDENATURED INEDIBLE 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	20	200	4,000	10	667

The cost to the respondents is estimated at \$24,679 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 667 hours and \$24,679.

**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 \$18,500 annually. The costs arise primarily from the time spent by FSIS staff reviewing protocols and data. The Agency estimates a cost of \$37 per hour.

**15. Reasons for Changes in Burden:**

This is a new information collection.

**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. 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 of the form. Being required to put the expiration date on the form would place a burden of 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 having 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.