

## **SUPPORTING STATEMENT JUSTIFICATION FOR PUBLIC HEALTH INSPECTION SYSTEM**

**TERMS OF CLEARANCE: FSIS has updated this Supporting Statement and the relevant ROCIS system data with the system of records entitled: USDA/FSIS-0004, Public Health Information System (PHIS) that published on March 15, 2018 (83 FR 11489).**

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

This request is for a revision of the information collection related to the FSIS Public Health Information System (PHIS).

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.), 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 safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS developed a Web-based system that improves FSIS inspection operations and facilitates industry members' applications for inspection, export, and import of meat, poultry, and egg products. Industry members use FSIS forms in PHIS. Industry is able to submit some of these forms through a series of screens in PHIS; other forms are available in PHIS only as electronic forms.

However, paper forms are also available to firms that do not wish to use PHIS. To submit information through PHIS, firms' employees need to register for a USDA eAuthentication account with Level 2 access. An eAuthentication account enables individuals within and outside of USDA to obtain user-identification accounts to access a wide range of USDA applications through the Internet. The Level 2 access provides users the ability to conduct official electronic business transactions. To register for a Level 2 eAuthentication account, users need to

go to a USDA site and show proof of their identity; they have to have access to the Internet and a valid email address.

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

The following is a discussion of the required information collection activities relating to PHIS.

Firms may complete screen sets in PHIS when exporting meat, poultry, and egg products (9 CFR 322.2, 381.107, & 590.200). A Transfer Certificate is submitted by exporters to FSIS when product is transferred from one establishment or plant to another facility before export. A "Split/Consolidations" Certificate is submitted by exporters to indicate that an export shipment approved by FSIS for export is being split and sent to two separate destinations or that two or more FSIS approved export shipments to the same country are being combined.

FSIS Form 9080-3, Establishment Application for Export, is currently completed by exporters to specify countries where they wish to export product (9 CFR 322.2 & 381.105). FSIS uses this information to track the export of product.

The Application for Export Certificate, FSIS Form 9060-6, is currently approved for the export of meat and poultry products. This form provides FSIS with important data necessary to facilitate the export of product (9 CFR 322.2 & 381.105).

The Meat and Poultry Export Certificate of Wholesomeness, FSIS Form 9060-5, is the FSIS standard export certification for all exports of meat (excluding Siluriformes) and poultry exports. (9 CFR 322.2 & 381.106).

The Fish and Fish Products Export Certificate, FSIS Form 9060-5S, is the FSIS standard export certificate for all exports of fish of the order Siluriformes.(9 CFR 322.2).

The Meat, Poultry, and Egg Products Certificate of Wholesomeness (Continuation Sheet), FSIS Form 9060-5A,

is the FSIS standard product continuation page used to capture additional products that will not fit in the product grid of the 9060-5 or 9060-5S. (9 CFR 322.2 & 381.106).

The Meat, Poultry, and Egg Products Certificate of Wholesomeness (Continuation Sheet), FSIS Form 9060-5B, is the FSIS standard remarks continuation page used to capture additional statements or information that will not fit in the remarks section of the 9060-5 or 9060-5S. (9 CFR 322.2 & 381.106).

The exporter of returned product is to complete FSIS Form 9010-1, Application for the Return of Exported Products to the United States, to arrange for the product's entry and to notify FSIS (9 CFR 327.17, 381.209, and 590.965).

The following three forms are available in PHIS but not as a series of screens. FSIS is requesting continued use of these forms. FSIS Form 5200-2, Application for Federal Inspection, is submitted by all official establishments in order to receive a grant of inspection (9 CFR 304.1 and 381.17).

FSIS Form 5200-6, Application for Approval of Voluntary Inspection, is submitted by all establishments that want voluntary inspection (9 CFR 350.5, 351.4, 352.3, and 362.3).

FSIS Form 5200-15, Hours of Operation, is submitted when an establishment wants to notify the Agency of a change in its hours of operation. (9 CFR 307.4, 381.37, 590.124, & 592.96).

There are a total of 115,117 burden hours for the information collection requests relating to PHIS.

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

Under the EGov Act, FSIS implemented PHIS—a web-based information system for industry's use. Establishments, plants, exporters, and importers will be able to access these forms/screen sets in PHIS.

### **4. Efforts To Identify Duplication:**

No other Government agency requires information regarding the application for inspection, and the exportation and importation of 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. Many small firms may elect not to use PHIS. This information collection will affect approximately 519 small entities.

#### **6. Consequences If Information Were Collected Less Frequently:**

To conduct the information collections less frequently would inhibit ability of FSIS to ensure that meat, poultry, and egg products are wholesome, unadulterated, and properly labeled and packaged.

#### **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 ensure that meat, poultry, and egg products are safe and wholesome, some information must be collected from firms more than quarterly. However, there are no other circumstances that will cause FSIS to not meet the guidelines listed above.

#### **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 March 21, 2018, (83 FR 12333). The Agency received no comments. FSIS contacted an industry association representative (Lloyd Hontz 202/639-5924) and requested that he ask a few of its members to comment on this package. Its members had no comments. Additionally, FSIS contacted Paul Clayton, USMEF, 303-226-7331, Lisa Picard, NTF, 202-989-0100, and Shelly McKee, US-APEEC, 770-413-0006, to request input on the FSIS burden estimates for the export certificate forms. The three individuals did not have comments on the burden estimates.

#### **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. A SORN for this collection published on March 15, 2018 (83 FR 11489).

**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 115,117 hours.

Total            115,117 hours

FSIS estimates that 50 exporters will spend 10 minutes to complete the certificate 500 times a year for a total of 25,000 responses and 4,166.6 hours.

**TRANSFER CERTIFICATE  
(9 CFR 322.2, 381.105, & 590.200)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Respon- dent	Total Annual Responses	Time for Respon- se in Mins.	Total Annual Time in Hours
Exporters	50	500	25,000	10	4,166.6

FSIS estimates that 50 exporters will spend 10 minutes to submit this certificate 1,200 times a year for a total

of 60,000 responses and 10,000 hours.

**SPLIT/CONSOLIDATION CERTIFICATE  
(9 CFR 322.2, 381.105, & 590.200)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Respon- den t	Total Annual Responses	Time for Respon- se in Mins.	Total Annual Time in Hours
Exporters	50	1,200	60,000	10	10,000

FSIS estimates that it takes exporters an average of 5 minutes to complete FSIS Form 9080-3, Application for Export. Approximately, 1,200 exporters will annually respond 2 times for a total of 2,400 responses and 199.9 hours.

**ESTABLISHMENT APPLICATION FOR EXPORT  
(9 CFR 590.200; FSIS Form 9080-3)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Respon- den t	Total Annual Responses	Time for Respon- se in Mins.	Total Annual Time in Hours

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden-t	Total Annual Responses	Time for Respon-se in Mins.	Total Annual Time in Hours
Exporters	1,200	2	2,400	5	199.9

FSIS estimates that 5,200 exporters will take 10 minutes to submit the certificate 100 times a year for a total of 520,000 responses and 86,666.6 hours.

**APPLICATION FOR EXPORT CERTIFICATE  
(9 CFR 590.200; FSIS Form 9060-6)**

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden-t	Total Annual Responses	Time for Respon-se in Mins.	Total Annual Time in Hours
Exporters	5,200	100	520,000	10	86,666.6

FSIS estimates that 500 firms will respond 10 times annually taking 30 minutes to complete an Application for Return of Exported Product form for a total of 5,000 responses and 2,500 hours.

**APPLICATION FOR RETURN OF EXPORTED PRODUCT**

**(FSIS Form 9010-1)**

Type of Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Firms	500	10	5,000	30	2,500

FSIS estimates that 406 establishments and plants will take 10 minutes to apply for federal inspection per year for a total of 406 responses and 67.6 hours.

**APPLICATION FOR FEDERAL INSPECTION  
(9 CFR 590.140 & 590.146; FSIS Form 5200-2)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Ests./ Plants	406	1	406	10	67.6

FSIS estimates that 132 establishments and plants will take 15 minutes to apply for voluntary inspection per

year for a total of 132 responses and 33 hours.

**APPLICATION/APPROVAL FOR VOLUNTARY INSPECTION  
(9 CFR 592.130 & 592.140; FSIS Form 5200-6)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Responden t	Total Annual Responses	Time for Respon se in Mins.	Total Annual Time in Hours
Establish ments/ Plants	132	1	132	15	33

FSIS estimates that 542 establishments and plants will spend 20 minutes and respond once a year for a total of 542 responses and 180.6 hours.

**HOURS OF OPERATION REQUEST/APPROVAL  
(9 CFR 307.4, 381.37, & 590.124, & 592.96; FSIS Form 5200-15)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Responden t	Total Annual Responses	Time for Respon se in Mins.	Total Annual Time in Hours
Establish ments/ Plants	542	1	542	20	180.6

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Responden t	Total Annual Responses	Time for Respon se in Mins.	Total Annual Time in Hours
plants					

FSIS estimates that 260 exporters will spend 25 minutes and respond 100 times a year for a total of 26,000 responses and 10,833 hours.

**MEAT & POULTRY EXPORT CERTIFICATE OF WHOLESOMENESS  
(9 CFR 322.2 & 381.106; FSIS Form 9060-5)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Responden t	Total Annual Responses	Time for Respon se in Mins.	Total Annual Time in Hours
Exporters	260	100	26,000	25	10,833

FSIS estimates that 2 exporters will spend 25 minutes and respond 14 times a year for a total of 28 responses and 12 hours.

**FISH AND FISH PRODUCTS EXPORT CERTIFICATE OF WHOLESOMENESS**

**(9 CFR 322.2; FSIS Form 9060-5S)**

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respon-den-t	Total Annual Responses	Time for Respon-se in Mins.	Total Annual Time in Hours
Exporters	2	14	28	25	12

FSIS estimates that 100 exporters will spend 10 minutes and respond 20 times a year for a total of 2,000 responses and 333 hours.

**MEAT, POULTRY & EGG PRODUCT EXPORT CERTIFICATE OF WHOLESOMENESS  
(CONTINUATION SHEET)**

**(9 CFR 322.2 & 381.106; FSIS Form 9060-5A)**

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respon-den-t	Total Annual Responses	Time for Respon-se in Mins.	Total Annual Time in Hours
Exporters	100	20	2,000	10	333

FSIS estimates that 100 exporters will spend 5 minutes and respond 15 times a year for a total of 1,500

responses and 125 hours.

**MEAT, POULTRY & EGG PRODUCT EXPORT CERTIFICATE OF WHOLESOMENESS  
(CONTINUATION SHEET)  
(9 CFR 322.2 & 381.106; FSIS Form 9060-5B)**

Type of Establish- Ment	No. of Respon- dents	No. of Res- ponses per Responden t	Total Annual Responses	Time for Respon se in Mins.	Total Annual Time in Hours
Exporters	100	15	1,500	5	125

The cost to the respondents for PHIS information collection activities is estimated at \$4,489,563 annually. The Agency estimates that it will cost respondents \$39 an hour in fulfilling these paperwork requirements. Respondents will spend an annual total of 115,117 hours and \$4,489,563. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2016.

**13. Capital and Start-up Cost and Subsequent Maintenance**

There are no related capital and start-up costs associated with these information collection activities.

**14. Annual Cost To Federal Government:**

The cost to the Federal Government for these information collection requirements is \$585,000 annually. FSIS estimates that it will cost the Federal Government \$39 an hour for Agency personnel time.

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

There is an increase of 11,303 burden hours and 29,528 responses due to the addition of FSIS export forms 9060-5, 9060-5S, 9060-5A, and 9060-5B. FSIS previously thought that FSIS employees were completing the 9060-5 forms, however, FSIS recently discovered that in most cases, the employees were passing the 9060-5 forms to the firms to complete. FSIS discovered the 9060-5 forms were in use without OMB approval. The 9060-5 forms were not approved under another OMB number. Additionally, the forms are now being added to PHIS with the new export module. Exporters are beginning to have the capability to complete them electronically.

## **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 the required FSIS forms. FSIS requests that it not be required to put the expiration date of the information collection of the forms. 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 for the Agency 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.