

SUPPORTING STATEMENT JUSTIFICATION FOR PUBLIC HEALTH INSPECTION SYSTEM

1. Circumstances Making Collection Of Information Necessary:

This information collection requests a new information collection regarding data collection associated with FSIS' new 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 is developing a new Web-based system that will improve FSIS inspection operations and facilitate industry members' applications for inspection, export, and import of meat, poultry, and egg products. When the Agency implements PHIS, industry members will use current and new FSIS forms in PHIS. Industry will be able to submit some of these forms through a series of screens in PHIS; other forms will be available in PHIS only as electronic forms.

However, paper forms will also be available to firms that do not wish to use PHIS, except for two forms, the Transfer Certificate and the Split/Consolidate Certificate. FSIS believes that these forms will only be used by large exporters who definitely will take advantage of PHIS.

To submit information through PHIS, firms' employees will 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 will provide users the ability to conduct official electronic business transactions. To register for a Level 2 eAuthentication account, users will need to go to a USDA site and show proof of their identity; they will 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.

With the implementation of PHIS, firms may complete up to three new forms (screen sets) in PHIS when exporting meat, poultry, and egg products (9 CFR 322.2, 381.107, & 590.200). FSIS Form 9080-4, Product List, will be used to provide details about products each FSIS—regulated firm exports, thus enabling FSIS to verify whether that product is eligible for export to the specified country. A Transfer Certificate will be submitted by exporters to FSIS for only a few countries when product is transferred from one establishment/plant to another facility before export. A Split/Consolidated Certificate will be 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. This form is currently approved for meat and poultry products (OMB Control number 0583-0082). FSIS is requesting its additional use for egg products (9 CFR 590.200) and to convert it to a set of screens for PHIS.

The Application for Export Certificate, FSIS Form 9060-6, is currently approved for the export of meat and poultry products (OMB Control number 0583-0094). This form provides FSIS with important data necessary to facilitate the export of product (9 CFR 322.2 & 381.105). FSIS is requesting the additional use of the form for egg products and its conversion to a set of screens for use in PHIS (9 CFR 590.200).

The exporter of product that is exported and then returned to this country 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). This form is currently approved under OMB Control number 0583-0138. FSIS is now requesting its conversion to a series of screens for inclusion in PHIS.

Importers of meat and poultry products into the United States currently complete FSIS Form 9540-1 for re-inspection of the product by FSIS (9 CFR 327.5 & 381.198(a)). This form is currently approved for the import of meat and poultry products (OMB Control number 0583-0094). The Agency has added several questions to it. FSIS is requesting its use also for egg products (9 CFR 590.900), a change from 5 minutes to 8 minutes to complete the form and to 3 minutes for its completion in PHIS--ACE. Because PHIS interacts with the U.S. Custom and Border Protection's ACE system, many of the 9540-1's fields will

be populated by data submitted by the importer to ACE. However, importers located in Puerto Rico, American Samoa, Guam, and Saipan will not have access to ACE. In addition, FSIS is requesting the form's conversion to a series of screens for inclusion into PHIS.

The following three forms will be available in PHIS but not as a series of screens. All official establishments currently complete and submit an application, FSIS Form 5200-2, Application for Federal Inspection, to receive a grant of inspection (9 CFR 304.1 and 381.17)(OMB Control number 0583-0082). FSIS is requesting that the form be changed to include egg products (590.140 & 590.146).

Establishments that want voluntary inspection currently complete and submit an application, FSIS Form 5200-6, Application for Approval of Voluntary Inspection (9 CFR 350.5, 351.4, 352.3, and 362.3) (OMB Control number 0583-0082). FSIS is now requesting that the form be changed to include egg products (592.130 & 592.140).

FSIS is requesting the use of new FSIS Form 5200-15, Hours of Operation Request/Approval, for an establishment or plant to use 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 148,015 burden hours for the information collection requests relating to PHIS.

3. Use Of Improved Information Technology:

Under the EGov Act, FSIS is implementing 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 2,750 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 December 8, 2010 (75 FR 763930). The Agency received one public comment form the U.S.

Meat Export Federation. The Agency response to the comment was uploaded into ROCIS.

In addition, FSIS contacted an industry association (Lloyd Hontz 202/639-5924) and requested that it ask a few of its members to comment on this package. Its members had no comments.

FSIS has determined that no SORN was needed for PHIS.

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 148,015 hours.

Total	148,015 hours
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FSIS estimates that 500 exporters will spend 10 minutes to complete this form 500 times a year for a total of 250,000 responses and 41,666.6 hours.

**MEAT, POULTRY, AND EGG PRODUCTS LIST
(9 CFR 322.2, 381.105, & 590.200; FSIS Form 9080-4)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Exporters	500	500	250,000	10	41,666.6

FSIS anticipates 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 Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Exporters	50	500	25,000	10	4,166.6

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 Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Exporters	50	1,200	60,000	10	10,000

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 Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours

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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 Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Exporters	5,200	100	520,000	10	86,666.6

The Agency 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 193 importers (other than those located on the islands) will take 3 minutes to submit this application through PHIS (with certain fields populated by ACE) 317 times a year for a total of 44,480 responses and 2,224 hours. Importers located on the three Pacific islands will take 8 minutes to submit an application 14 times a year for a total of 280 responses and 37.3 hours. Importers located on Puerto Rico will take 8 minutes to submit an application 62 times a year for a total of 2,046 responses and 272.8 hours. There is a grand total of 46,806 responses and 2,534.1 hours.

**IMPORT RE-INSPECTION APPLICATION
(9 CFR 327.4, 381.198, 590.900; FSIS 9540-1)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Importers	140	317	44,480	3	2,224
Importers (Pacific islands)	20	14	280	8	37.3
Importers (Puerto Rico)	33	62	2,046	8	272.8
All Importers	193		46,806		2,534.1

The Agency estimates that 406 establishments and egg products plants will take 10 minutes to submit this application once a 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

132 establishments and plants will take 15 minutes too 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 Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Establishments/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 Responde - nt	Total Annual Responses	Time for Respos e in Mins.	Total Annual Time in Hours
Establish ments/ plants	542	1	542	20	180.6

The cost to the respondents for PHIS information collection activities is estimated at \$5,476,555 annually. The Agency estimates that it will cost respondents \$37 an hour in fulfilling these paperwork requirements. Respondents will spend an annual total of 148,015 hours and \$5,476,555.

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 \$555,000 annually. FSIS estimates that it will cost the Federal Government \$37 an hour for Agency personnel time.

15. Reasons For Changes In Burden:

This is a new information collection of 148,015 burden hours that is captured in the following burdens:

Collection	Forms	Burden Hours
New forms	FSIS 9080-4, Product List; Transfer Certificate; Split Consolidated Certificate; FSIS 5200-15 Hours of Operation	56,013.8
Adding egg products burden to existing approved forms	5200-2, Application for Federal Inspection; 5200-6 Application for Approval of Voluntary Inspection; 9080-3, Establishment Application for Export; 9060-6, Application for Export Certificate	86,967.1
Adding egg products burden and additional questions to existing approved form	9540-1, Import Reinspection Application	2,534.1
Requesting approval for screen shots of an existing approved form.	9010-1, Application for Return of Exported Product	2,500
Total		148,015

The PHIS total hour burden includes some burden that is already part of currently approved information collections—0583-0082, 0583-0138, and 0583-0094. FSIS will file with OMB to reduce the burdens of these collections to reflect the transfer of burden hours to this new collection.

Hours Being Transferred from Other Approved Information Collections to PHIS

Approved Collection	Burden Hours Being Transferred to PHIS Information Collection
0583-0082	388.7
0583-0138	2,500
0583-0094	89,200.7
Total	92,089.4

The Agency believes that the implementation of PHIS will realize increased efficiencies for industry for export and import of product.

PHIS will streamline FSIS' import and export programs by automating the Agency's paper-based processes, including applications for import reinspection, establishment applications for approval for export, applications for export certificates, and the issuance of export certificates. The export certification process will provide FSIS and exporters improved efficiency, controls, and communication associated with the certification and exportation of meat, poultry, and processed egg products.

With PHIS, the industry will update the database once for a product they produce. The system will pull all the product attributes for that product for all exports to every country. Currently the exporter has to provide the information every time.

PHIS is designed to interface with U.S. Customs and Border Protection (CBP) Automated Commercial Environment system. It can now interface with FSIS' application for import reinspection in PHIS. Eventually, it will interface with the export forms in PHIS. Until such time that this interface can be achieved, industry will have direct access to the PHIS and will be able to enter the data, rather than completing the paper application.

By using the electronic application, the burden on industry completing the import application (FSIS Form 9540-1) is reduced because the PHIS is designed to: 1) allow the applicant to select from drop-down menus, reducing the amount of actual typing of data, and 2) auto filling of several fields based on the individual user.

In addition, the system is designed to receive foreign governments' inspection certificate data electronically. When PHIS is implemented, Australia and New Zealand will transmit certificates electronically, which will pre-populate approximately 66% of the fields for the on-screen application, thus further reducing the burden to industry. Shipments from Australia and New Zealand account for approximately 35 - 40% of all arriving shipments.

This automation will also help minimize human error and prevent fraud, waste, and abuse.

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.

