

SUPPORTING STATEMENT JUSTIFICATION FOR INFORMATION COLLECTION REQUIREMENTS RELATED TO MARKING, LABELING, AND PACKAGING OF MEAT, POULTRY, AND EGG PRODUCTS

1. Circumstances Making Collection of Information Necessary:

This information collection requests a revision of the burden hours approved under control number 0583-0092, which addresses the regulatory requirements for marking, labeling, and packaging; and for establishments that produce mechanically separated poultry.

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.

To control the manufacture of marking devices bearing official marks, FSIS requires official meat and poultry establishments and the manufacturers of such marking devices to submit an Authorization Certificate form to the Agency. To ensure that meat, poultry, and egg products are accurately labeled, FSIS approves meat, poultry, and egg products labeling. To ensure that packaging materials do not adulterate meat or poultry products, FSIS requires a written guaranty that the packaging materials conform to Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301, et seq.) regulations for food contact materials. FSIS also requires establishments that use advanced poultry/bone separation machinery and recovery systems to have controls in place, including recordkeeping, to ensure that products do not exceed the calcium level standard.

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

There are a total of 128,267 burden hours for the information collection requests relating to the marking, labeling, and packaging of meat, poultry, and egg products; and to the production of mechanically separated poultry. The following is a discussion of the required information collection and recordkeeping activities.

Marking

To control the manufacture of marking devices bearing official marks, FSIS requires official meat and poultry establishments and the manufacturers of such marking devices to submit an Authorization Certificate form (FSIS 5200-7) to the Agency (9 CFR 312.1, 317.3, 381.96, & 381.131). The establishment completes the first part of the Authorization Certificate requesting that certain brands or other devices be manufactured. The manufacturer of the brands then completes the second part of the Authorization Certificate, providing its business name and address, and serial numbers of brands and devices. Such certification is necessary to help prevent the manufacture and use of counterfeit marks of inspection.

Labeling

FSIS is implementing a web-based Label Submission Approval System, which will allow establishments to electronically submit label applications for approval. Therefore, FSIS is requesting permission to use a series of screens for FSIS Forms 7234-1 and 8822-4.

Meat, poultry, and egg products establishments must develop product labels (9 CFR 317.4, 381.115, & 590.410) in accordance with FSIS regulations. To receive approval for such labels, establishments must complete FSIS Form 7234-1. In addition to the form, respondents also submit duplicate copies of the labels. The establishment must maintain a copy of all the labeling used, along with product formulation and processing procedures. Respondents will use a new FSIS Form 8822-4 to request reconsideration of a label application that the Agency has modified or rejected.

Previously approved labeling that contains changes such as holiday season designs, addition or deletion of coupons, UPC production codes, or recipe suggestions; newly assigned or revised establishment numbers; changes in the arrangement or language of directions for opening containers or serving the product; or the substitution of abbreviations for words or vice versa, do not need additional FSIS approval (9 CFR 317.5). Establishments must keep a copy of the labeling used, along with the product formulation and processing procedures on file.

Packaging

FSIS requires establishments to keep a written guaranty on file to demonstrate that the packaging material they use to package product is safe and will not adulterate product (9 CFR 317.24 and 381.144).

Mechanically Separated (Kind of Poultry)

Poultry establishments producing product using advanced poultry/bone separation machinery and recovery systems must have adequate controls in place, including recordkeeping (9 CFR §381.173).

3. Use of Improved Information Technology:

Under the Government Paperwork Elimination Act, the Agency is providing electronic versions of FSIS Form 5200-7, FSIS Form 7234-1, and FSIS Form 8822-4. Records may be maintained electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data. The Agency estimates that 70% of the paperwork and recordkeeping is done electronically.

4. Efforts to Identify Duplication:

No USDA agency, or any other Government agency, requires information regarding the marking, labeling, or packaging of meat, poultry, or egg products; or the production of mechanically separated poultry. 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. The information collections must apply to all businesses producing inspected meat, poultry, and egg products. However, small businesses usually have fewer and less complex labels than do larger establishments and companies. Approximately, 5,500 small businesses will be affected by this information collection.

6. Consequences if Information Were Collected Less Frequently:

To conduct the information collections less frequently would reduce the effectiveness of the meat, poultry, and egg 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;
- 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.

Many establishments will develop, submit, and file more than one label per quarter. None of the other circumstances described above apply to 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 (76 FR 31930), on June 2, 2011, requesting comments regarding this information collection request. FSIS received two comments, one comment addressed an instruction in Form 8822-4, and one comment that was not directly related to the information collection. Regarding the first comment, the Agency took the comment on the wording of the section reading, "This sheet is being used for additional information required in Block(s)." FSIS corrected the wording to clearly indicate "This sheet is being used for additional information pertaining to Company's Reason(s) for Requesting Label Reconsideration."

The Agency also contacted a trade association to solicit responses from a few of its members (Lynn Morrissette; 703/850-5441). One member thought that the time estimates were low, but the other members did not comment. FSIS did not change its estimates based on this one comment.

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 128,267 hours. The burden estimates are broken down into four categories described in the pages that follow.

Marking	765
Labeling	124,011
Packaging	382
Mechanically Separated Poultry	3,109
Total	128,267 hours

Marking

It takes establishments and manufacturers an average of 4 minutes to complete the Authorization Certificate. FSIS estimates that 5,735 plants will complete the form once to use a marking device. The manufacturer must complete a form for each device it makes (5,735). FSIS estimates a total of 11,470 responses and 765 hours.

**AUTHORIZATION CERTIFICATE
(9 CFR 312.1, 317.3, 381.96 & 381.131/FSIS Form 5200-7)**

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
M/P Est.	5,735	1	5,735	4	382
Manufactur er	1	5,735	5,735	4	382
Total	5,736		11,470	4	765

Labeling

The Agency estimates that, on average, it takes 75 minutes to develop, submit, and maintain recordkeeping of a label, including 15 minutes to complete FSIS Form 7234-1. FSIS estimates that each year, approximately 20 times per year, 3,000 meat and poultry establishments, 84 egg product plants, and 598 foreign establishments will spend 75 minutes to develop, submit to FSIS, and maintain recordkeeping of labels, for a total of 73,640 responses and 92,050 hours.

**LABELING DEVELOPMENT, APPLICATION, & RECORDKEEPING
(9 CFR 317.4, 381.115, & 590.410/FSIS Form 7234-1)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat/Poultry	3,000	20	60,000	75	75,000
Egg Prod.	84	20	1,680	75	2,100
Foreign	598	20	11,960	75	14,950
All Ests.	3,682		73,640	75	92,050

FSIS estimates that, on average, it takes approximately 120 minutes to develop and submit a request for reconsideration of a label, including 15 minutes to complete FSIS Form 8822-4. The Agency estimates that each year, approximately twice per year, 60 meat and poultry establishments, 2 egg products plants, and 12 foreign establishments will complete FSIS Form 8822-4 for a total of 148 responses and 296 hours.

**REQUEST FOR LABEL RECONSIDERATION
(9 CFR 317.4, 381.115, & 590.410/FSIS Form 8822-4)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat/Poultry	60	2	120	120	240
Egg Prod.	2	2	4	120	8
Foreign	12	2	24	120	48
All Ests.	74		148	120	296

FSIS estimates that it takes approximately 15 minutes to make changes to and comply with recordkeeping requirements associated with generically approved labeling. The Agency estimates that 6,333 domestic and foreign establishments will annually make 20 generically approved labeling changes for a total of 126,660 responses and 31,665 hours.

**GENERIC LABEL PREPARATION AND RECORDKEEPING
(9 CFR 317.5)**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat/Poultry	5,735	20	114,700	15	28,675
Foreign	598	20	11,960	15	2,990
All Ests.	6,333		126,660	15	31,665

Packaging Materials Recordkeeping

Establishments will take 2 minutes to maintain the recordkeeping of the written packaging guarantee. The Agency estimates that 5,735 establishments will respond twice annually for a total of 11,470 responses and 382 hours.

**PACKAGING MATERIALS RECORDKEEPING
(9 CFR 312.1 & 381.96)**

Responders	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Meat/ Poultry Ests.	5,735	2	11,470	2	382

Mechanically Separated (Kind of Poultry)

FSIS estimates that 82 establishments that produce mechanically separated poultry will take 5 minutes per test 455 times annually to test for poultry bone solid size and particle content for an annual total of 37,310 responses and 3109 burden hours.

**TESTING FOR POULTRY BONE SOLID SIZE & PARTICLE CONTENT
(9 CFR 381.173)**

Responders	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Poultry	82	455	37,310	5	3,109

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

Total Cost to Respondents

The cost to the respondents is estimated at \$4,745,879 million 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 128,267 hours and \$4,745,879.

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:

The cost to the Federal Government for these information collection requirements is \$1,850,000 annually. The costs arise primarily from the inspection review duties necessary to verify that establishments comply with the information collection responsibilities. The Agency estimates a cost of \$37 per hour for its personnel time.

15. Reasons for Changes in Burden:

FSIS has decreased its estimate of total annual burden hours from 155,288 to 128,267. This decrease is the result of a change in the number of respondents FSIS estimates will be affected by this information collection. The number of estimated respondents has changed as a result of a reduction in the total number of official establishments between 2007 and today, even though FSIS has added a new form, FSIS Form 8822-4, Request for Label Reconsideration.

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.