

SUPPORTING STATEMENT JUSTIFICATION FOR OF MARKING, LABELING, AND PACKAGING OF MEAT AND POULTRY 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.

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 manufactures of such marking devices to submit a 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 does 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 advance meat 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 Information Is To Be Used:

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 manufactures of such marking devices to submit an Authorization Certificate form (FSIS 5200-7) to the Agency. 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 provides 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

Meat, poultry, and egg products establishments must develop product labels (9 CFR 317.4) in accordance with FSIS regulations. To receive approval for such labels, establishments must complete FSIS Form 7234-1. Respondents also submit in addition to the form, duplicate sketch copies of the labels. The establishment must maintain a copy of all the labeling used, along with product formulation and processing procedures.

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 312.1 and 381.96).

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).

There are a total of 155,288 burden hours for the information collection requests relating to the marking, labeling, and packaging of meat, poultry, and egg products.

3. Use Of Improved Information Technology:

Under the Government Paperwork Elimination Act, the Agency is providing an electronic version of FSIS Form 7234-1. Records may be maintained electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data. The Agency estimates that 50% 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. 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.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently will reduce the effectiveness of the meat and poultry 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. Hence, information collection and recordkeeping activities in this submission are consistent with the guidelines in 5 CFR 1320.6.

8. Consultation With Persons Outside The Agency:

In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice in the Federal Register (72 FR 51582), on September 10, 2007, requesting comments regarding this information collection request. FSIS received no comments. The Agency also contacted a trade association to solicit responses from a few of its members (Lloyd Hontz; 202/639-5924). Several members asserted that they submitted more labels than the Agency had estimated per plant and thought that the total number of label responses (including generic labels) seemed low. In response, FSIS revised its estimate of the number of labeling responses from 15 to 20 per establishment, which increased the total number of burden hours. One member thought that the time estimate for submitting labels was low, but another member believed that estimate was correct. FSIS did not change its estimate of how long it takes to develop and submit a label.

On December 20, 2007, on page 7342, a 30 day notice was published in the Federal Register but the burden hours shown were incorrect. Because of comments received from industry the burden hours increased from 85,508 to 155,288. Therefore, on December 28, 2007, on page 73757, a correction notice was published in the Federal Register.

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 155,288 hours. The burden estimates are broken down into four categories described in the pages that follow.

Marking	808
Labeling	143,980
Packaging	405
MS(S)	4,095
Total	155,288 hours

Marking

It takes establishments and manufacturers an average of 4 minutes to complete the Authorization Certificate. FSIS estimates that establishments/manufacturer will annually respond once for a total of 12,140 responses and 808 hours.

**AUTHORIZATION CERTIFICATE
(9 CFR 317.3 & 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.	6,070	1	6,070	4	404
Manufactur er	1	6,070	6,070	4	404
Total	6,071	1	12,140	4	808

Labeling

The Agency estimates that it takes on the average 75 minutes to develop, submit, and maintain recordkeeping of a label, including 15 minutes to complete FSIS Form 7234-1. Approximately 3,000 establishments, 190 egg product plants, and 1,275 foreign establishments a year will spend 75 minutes to develop, submit, and maintain recordkeeping of labels, with FSIS Form 7234-1, to FSIS for approval 15 times a year for a total of 89,300 responses and 111,625 hours.

**LABELING DEVELOPMENT, APPLICATION, & RECORDKEEPING
(9 CFR 317.4/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.	190	20	3,800	75	4,750
Foreign	1,275	20	25,500	75	31,875
All Ests.	3,820	20	89,300	75	111,625

It takes approximately 15 minutes to change and file the changes to a label associated with generic recordkeeping. The Agency estimates that 6,471 domestic and foreign establishments will annually make 20 generic labeling changes for a total of 129,420 responses and 32,355 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	6,070	20	121,400	15	30,350
Foreign	401	20	8,020	15	2,005
All Ests.	6,471	20	129,420	15	32,355

Packaging Materials Recordkeeping

Establishments will take 2 minutes to maintain the recordkeeping of the written packaging guarantee. The Agency estimates that 6,070 establishments will respond twice annually for a total of 12,140 responses and 405 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.	6,070	2	12,140	2	405

Mechanically Separated (Kind of Poultry)

FSIS estimates that 108 establishments that produce mechanically separated poultry will have an annual total of 49,140 responses and 4,095 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 Ests.	108	455	49,140	5	4,095

There is a total of 7, 695 recordkeeping burden hours for this information collection. There are 2,976 hours for label recordkeeping, 4,314 hours for generic label recordkeeping, and 405 hours for packaging materials recordkeeping.

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 \$1,750,000 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 \$35 per hour for its personnel time.

The cost to the respondents is estimated at \$5,435,080 million annually. The Agency estimates that it will cost respondents \$35 an hour in fulfilling these paperwork and recordkeeping requirements. Respondents will spend an annual total of 155,288 hours and \$5,435,050.

15. Reasons For Changes In Burden:

The adjustment from the previously approved burden of 82,348 hours to 155,288 hours is due to this information collection being revised. There is a increase of 72,940 due to the increased estimate of the number of responses (for submitting and preparing labels). The reason for the increase is because of continuing changes in the industry (the industry is producing more kinds of products and therefore more labels). Hence, the number of responses per establishment has increased since the last time this information collection was approved by OMB.

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.

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.