

## **TERMS OF CLEARANCE**

**When FSIS submitted its information collection request for Nutrition Labeling supplemental proposed rule, OMB filed a comment with a note: “Prior to the publication of the final rule, the agency should provide OMB with a summary of any comments made on the information collection and any changes made to the regulation.” A summary of the comments and the Agency’s response is included in the final rule. There were no changes made to the regulation from the supplemental proposed rule.**

### **SUPPORTING STATEMENT JUSTIFICATION FOR NUTRITION LABELING OF MAJOR CUTS AND GROUND/CHOPPED PRODUCTS**

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

This information collection requests a new information collection of burden hours for the regulatory requirements of nutrition labeling of major cuts of single ingredient raw meat and poultry products and ground or chopped meat and poultry products.

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 Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, et seq.). These statutes mandate that FSIS protect the public by ensuring that meat and poultry products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS is amending the Federal meat and poultry products inspection regulations to require nutrition labeling of the major cuts of single-ingredient, raw meat and poultry products, unless an exemption applies. When this proposed rule becomes effective, the guidelines for voluntary nutrition labeling will become mandatory for the major cuts of single-ingredient, raw products. Thus, the Agency is requiring that nutrition information be provided for these products either on their label or at their point-of-purchase. Without nutrition information for the major cuts of single-ingredient, raw products, the Agency

has concluded that these products would be misbranded under the FMIA and PPIA.

FSIS is also amending its regulations to require nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. Without nutrition information for single-ingredient, raw ground or chopped products, these products would be misbranded under the FMIA and PPIA.

The Agency has also determined that single-ingredient, raw ground or chopped meat and poultry products are different from other single-ingredient, raw meat and poultry products in several important respects and that these products are similar to products in the mandatory program that are required to bear nutrition labels. Thus, under this rule, the nutrition labeling requirements for all ground or chopped meat and poultry products will be consistent with the nutrition labeling requirements for multi-ingredient and heat processed products.

Finally, FSIS is amending the nutrition labeling regulations to provide that, when a ground or chopped product does not meet the regulatory criteria to be labeled “low fat,” a lean percentage claim may be included on the label or in labeling as long as a statement of the fat percentage also is displayed on the label or in labeling.

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

The following is a discussion of the required information collection and recordkeeping activities.

### *Major Cuts of Single Ingredient Product*

FSIS is requiring nutrition labeling on the major cuts of single-ingredient, raw meat and poultry products, either on their label or at their point-of-purchase, unless an exemption applies. If the manufacturer provides nutrition information on the label of individual packages of the major cuts of single-ingredient, raw meat or poultry products, the retailer is not required to provide the information at the point-of-purchase. However, if the manufacturer does not provide the nutrition information on the label of these products, the retailer is required to provide the information at their point-of-purchase (9 CFR 317.300(a) & 381.400(a)).

FSIS is estimating that all retailers would display point-of-purchase information for the major cuts of single-ingredient, raw meat and poultry products, because this is an inexpensive means of providing nutrition information for multiple products and because this rule will not require that manufacturers include nutrition labels on the major cuts of single-ingredient, raw meat and poultry products. There are a total of 37,455 burden hours that will occur in years 1 and 3 of the analysis.

Consumers will use this information to make better informed nutrition choices when purchasing these meat and poultry products. FSIS also intends to issue guidance associated with this rulemaking.

### Ground/Chopped Products

FSIS is requiring nutrition labels on all ground or chopped meat and poultry products, with or without added seasonings, unless an exemption applies. As part of routine duties, inspection program personnel will review these labels or labeling materials (9 CFR 317.301(a) & 381.401(a)).

Consumers will use this information to make better informed nutrition choices when purchasing these meat and poultry products.

There are a total of 28,606 first year burden hours for the development, approval, and recordkeeping relating to the nutrition labeling of ground or chopped meat and poultry products.

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

The type of information to be collected and the manner in which the information is to be presented are not currently amenable to the use of improved electronic information technology. FSIS intends to make available over the Internet nutrition labeling materials that can be used at the point-of-purchase of the major cuts.

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

FSIS has determined that these information collections will not duplicate any other information collections. The required records and reports are not available from other sources, either within government or from non-government sources. There is no similar 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. However, small businesses that produce 100,000 pounds or less annually of ground or chopped products are exempt from the nutrition labeling requirements for these products. FSIS estimates that there will be 50,000 small businesses affected by this rule.

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

To conduct the information collections less frequently would reduce the effectiveness of the meat and poultry inspection program that ensures that meat and poultry products are properly marked, 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.**

Some establishments may submit nutrition labeling more than once a quarter. There are no other special circumstances that require the collection of information to be inconsistent with 5 CFR 1320.6.

#### **8. Consultation With Persons Outside The Agency:**

In accordance with the Paperwork Reduction Act, notice of this paperwork collection was published in the proposed rule (66 FR 4969) in the Federal Register on January 18, 2001. FSIS received no comments on this paperwork collection. The Agency did not at that time submit an information collection request to OMB. In addition, FSIS published a supplemental proposed rule (74 FR 67736; December 18, 2009) that included a 60 day notice of an information collection. There were no comments on the information collection of the supplemental proposed rule.

FSIS consulted with three members of industry (Jessie Waller 800/843-6603 X1903, Sara Slater 970/506-7766, and Mike Frolkey 620/669-2883). One of the respondents believed the Agency's current estimate of time for developing, submitting, and filing labels was too little. One of the respondents thought that the time was overestimated. One respondent agreed with all of the Agency's estimates. FSIS did not change its estimates after consulting with industry.

#### **9. Payment Or Gifts To Respondents:**

Respondents do not receive 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 first year estimated burden for this information collection is 66,062 burden hours. The burden estimates are broken down into two categories described in the pages that follow.

Major Cuts of Single Ingredient Product	37,455
Ground/Chopped Products	28,607
Total	66,062 hours

Of the burden for ground/chopped products, the annual burden for recordkeeping is estimated at 1,788 hours. The recurring burden for obtaining and replacing point of purchase information for major cuts of single ingredient product in years 1 and 3 is 37,455 hours.

N.B. The number of respondents below represents the number of parent companies affected by the regulations rather than the number of individual establishments or retail stores because nutrition labels are designed for company wide use.

The Agency estimates that it will cost respondents \$34.75 an hour in fulfilling labeling development, approval, and recordkeeping requirements. The hourly wage rate for obtaining and replacing point of purchase information at retail establishments is \$21.11. Based on these wage rates and the hourly requirements identified above, the cost to the respondents is estimated at \$1,784,734 ( $34.75 \times 28,606 + 21.11 \times 37,455$ ).

### Major Cuts of Single Ingredient Product

FSIS estimates that obtaining point-of-purchase materials and making them available for consumers will take an average of 30 minutes for 74,910 retail establishments for a total of 74,910 responses and 37,455 hours.

**OBTAINING/DISPLAYING POINT OF PURCHASE MATERIALS  
(9 CFR 317.300(a) & 381.400(a))**

Type of Establish- Ment	No. of Respon- dents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Recurring Time Requiremen t in Hours
Retail ests.	74,910	1	74,910	30	37,455

Ground/Chopped Products

Costs for label development, legal and regulatory approval, and recordkeeping requirements are included in those costs identified as administrative costs in Table 12 of the final regulatory impact analysis. This analysis assumes that of an average \$319 per label administrative costs, an average of \$278 per label are entirely attributable to paperwork burden. The Agency estimates that the total amount of time required to perform these functions is 8 hours per label.

FSIS estimates that one-time, first year development cost of nutrition labels for ground or chopped products will take an average of 6 hours. Labels developed at official establishments will be submitted to FSIS. FSIS estimates that 363 official establishments producing ground or chopped product will develop an average 6.6 labels to FSIS for approval; 255 grocery stores will develop 4.57 labels; and 11 warehouses will develop 1.33 labels. This will result in a one-time, first year total of 3,576 responses and 21,455 hours.

**DEVELOPMENT OF NUTRITION LABELS FOR GROUND/CHOPPED PRODUCTS  
(9 CFR 317.301(a) & 381.401(a))**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
Establishment	363	6.6	2,396	6	14,375
Grocery stores	255	4.57	1,165	6	6,992
Warehouse clubs	11	1.33	15	6	88
Total	629	5.68	3,576	6	21,455

FSIS estimates that it will take the same establishments identified above an average of 1.5 hours to prepare and submit the label for prior approval. This is a one-time, first year requirement resulting in a paperwork burden of 5,364 hours.

**SUBMITTING LABEL APPROVAL--GROUND/CHOPPED PRODUCT  
(9 CFR 317.301(a) & 381.401(a))**



Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
Establishment	363	6.6	2,396	1.5	3,594
Grocery stores	255	4.57	1,165	1.5	1,748
Warehouse clubs	11	1.33	15	1.5	22
Total	629	5.68	3,576	1.5	5,364

Grocer stores and warehouse clubs are not required to submit labels to FSIS for review. All ground or chopped product will be subject to FSIS compliance review; therefore, producers of ground or chopped product, including retail facilities, will be required to maintain records to support the validity of nutrient declarations contained on product labels. FSIS estimates the average time for recordkeeping will 629 firms be 30 minutes annually for a total of 3,576 responses and 1,788 hours.

**GROUND/CHOPPED PRODUCT RECORDKEEPING  
(9 CFR 317.301(a) & 381.401(a))**

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Establishment	363	6.6	2,396	30	1,198
Grocery stores	255	4.57	1,165	30	583
Warehouse clubs	11	1.33	15	30	7
Total	629	5.68	3,576	30	1,788

### 13. Capital, Start-up Cost, And Subsequent Maintenance

There are capital and start-up costs related to this information collection activity. Retail stores to use nutritional labels to ground and chopped product will have to either (Option 1) upgrade store scale-printers, redesign store labels, and conduct nutritional analysis of each product, or (Option 2) design new labels, conduct nutritional analysis, and purchase new pre-printed labels. FSIS believes that most retail stores will use Option 1. It will cost an average of \$1,600 per scale, an average of 1.5 scales per store for 23,479 retail stores for a total of \$56.35 million. Label redesign will cost \$1,557 per label and nutritional analysis will cost \$690 for each product; there are approximately 1,180 unique ground/chopped products for a total cost of \$2.65 million.

Processing establishments will have costs associated with label redesign, prepress, plate engraving, and conducting nutritional analysis for each product. Average costs are label redesign is \$1,597, \$401 for prepress preparation, \$323 for engraving, and \$690 for nutritional analysis. Total cost is estimated to be \$5.8 million.

Retail stores will have capital costs associated with point of purchase materials of \$28 for placards

and \$37.17 for metal frames for a total of \$5.67 million. Total cost will be \$70.47 million.

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

The annual cost to the Federal Government for these information collection requirements is \$370,000 annually. The cost estimate includes records review time of FSIS inspection personnel (GS 7/9/11) and staff officers (GS 11/12). The Agency estimates a cost of \$37 per hour for inspector time.

**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:**

The OMB approval number will appear on required FSIS forms.

**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.