

SUPPORTING STATEMENT JUSTIFICATION FOR MECHANICALLY TENDERIZED BEEF PRODUCTS INFORMATION COLLECTION

1. Circumstances Making Collection of Information Necessary:

This request is for a renewal of the information collection related to mechanically tenderized beef 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.). This statute mandates that FSIS protect the public by ensuring that meat products are safe, wholesome, unadulterated, and properly labeled and packaged.

FSIS requires the use of the descriptive designation “mechanically tenderized” on the labels of raw or partially cooked needle or blade tenderized beef products, including beef products injected with marinade or solution, unless such products are destined to be fully cooked at an official establishment. Beef products that have been needle or blade tenderized are referred to as “mechanically tenderized” products. FSIS requires that the product name for such beef products include the descriptive designation “mechanically tenderized” and an accurate description of the beef component. FSIS also requires that the print for all words in the descriptive designation as the product name appear in the same style, color, and size and on a single-color contrasting background. In addition, FSIS requires that labels of raw and partially cooked needle or blade tenderized beef products destined for household consumers, hotels, restaurants, or similar institutions include validated cooking instructions that inform consumers that these products need to be cooked to a specified minimum internal temperature, and whether they need to be held at that minimum temperature for a specified time before consumption, i.e., dwell time or rest time, to ensure that they are thoroughly cooked.

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

Establishments must add the designated description “Mechanically Tenderized” and validated cooking instructions to the labels of mechanically tenderized beef products. These labels are eligible to

receive generic label approval.

Consumers use the information added to the labels of raw or partially cooked mechanically tenderized beef products to ensure that they thoroughly cook these products.

3. Use of Improved Information Technology:

Under the Government Paperwork Elimination Act, FSIS permits the use of electronic recordkeeping. The Agency estimates that 80% of the paperwork and recordkeeping will be done electronically.

4. Efforts to Identify Duplication:

No USDA agency, or any other Government agency, requires information regarding the labeling of mechanically tenderized beef 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 and poultry products. However, small businesses usually have fewer and less complex labels than do larger establishments and companies. Approximately, 542 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;**
(Many establishments will develop, submit, and file more than one label per quarter)
- **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.

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*, on February 2, 2018, (83 FR 4894). The Agency received one comment that was not relevant to the information collection. FSIS contacted an industry association representative (Lloyd Hontz 202/639-5924) and requested that he ask a few of its members to comment on the burden estimates in the collection. Its members had no 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 additional assurance of confidentiality is provided with this information collection. Any and all

information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a.

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 19,719 hours.

FSIS estimates that it takes approximately 13 minutes to make changes to prepare generically approved labeling. The Agency estimates that 555 official establishments will make a total of 8,451 responses for 1,831.05 burden hours.

**GENERIC LABEL PREPARATION FOR MECHANICALLY TENDERIZED BEEF PRODUCTS
(9 CFR 317.2(e)(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
Ests.	555	15.227	8,451	13	1,831.05

FSIS estimates that it will take 555 establishments 2 minutes to comply with recordkeeping requirements associated with mechanically tenderized beef products for a total of 8,451 responses and 281.7 burden hours.

**RECORDKEEPING FOR MECHANICALLY TENDERIZED BEEF PRODUCTS
(9 CFR 317.2(e)(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
Ests.	555	15.227	8,451	2	281.7

FSIS estimates that it will take 2 hours each for 555 official establishments to develop valid cooking instructions for a total of 8,451 responses and 16,902 hours.

**DEVELOP VALID COOKING INSTRUCTIONS FOR MECHANICALLY TENDERIZED BEEF PRODUCTS
(9 CFR 317.2(e)(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
Total	555	15.227	8,451	120	16,902

FSIS estimates that it will take 5 minutes for 555 official establishments to maintain records of valid cooking instructions for a total of 8,451 responses and 704.25 hours.

RECORDKEEPING VALID COOKING INSTRUCTIONS FOR MECHANICALLY TENDERIZED BEEF PRODUCTS

(9 CFR 317.2(e)(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
Total	555	15.227	8,451	5	704.25

Total Cost to Respondents

The cost to the respondents is estimated at \$769,041 annually. The Agency estimates that it will cost respondents \$39 an hour in fulfilling these paperwork and recordkeeping requirements. Respondents will spend an annual total of 19,719 hours and \$769,041. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2017.

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 \$39,000 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 \$39 per hour for its personnel time.

15. Reasons for Changes in Burden:

There is no change in burden for this information collection.

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.