

SUPPORTING STATEMENT JUSTIFICATION FOR PROHIBITION OF SPECIFIED RISK MATERIALS

1. Circumstances Making Collection Of Information Necessary:

This information collection requests a revision of a currently approved information collection of burden hours which addresses the regulatory requirements in prohibiting specified risk materials (SRMs) associated with the slaughter of cattle and the processing of cattle and parts of cattle. FSIS is incorporating another currently approved information collection for the transport of specified risk materials into this information collection.

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 statute mandates that FSIS protect the public by ensuring that meat products are safe, wholesome, not adulterated, and properly labeled and packaged.

FSIS requires official establishments that slaughter cattle and/or process carcasses or parts of cattle develop written procedures for the removal, segregation, and disposition of SRMs. The Agency requires that these establishments maintain daily records sufficient to document the implementation and monitoring of their procedures for the removal, segregation, and disposition of SRMs, and any corrective actions taken to ensure that such procedures are effective (9 CFR 310.22).

FSIS also requires official slaughter establishments that transport carcasses or parts of cattle that contain vertebral columns from cattle 30 months of age and older to another federally inspected establishment for further processing to maintain records that verify that the official establishment that received the carcasses or parts, removed and properly disposed of the portions of the vertebral column designated as SRMs (9 CFR 310.22(g)).

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

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

This monitoring and recordkeeping is necessary for establishments to further ensure—and for FSIS to verify—that meat and meat products distributed in commerce for use as human food do not contain SRMs.

There are a total of 123,916 burden hours for the information collection request relating to paperwork and recordkeeping associated with SRMs and the slaughter of cattle and the processing of carcasses and cattle parts.

3. Use Of Improved Information Technology:

Under the Government Paperwork Elimination Act, records may be maintained electronically provided that appropriate controls are implemented to ensure the integrity of the electronic data.

4. Efforts To Identify Duplication:

No USDA agency, or any other Government agency, requires information regarding exportation, transportation and importation of meat and poultry 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. For reasons of public health, the information collection must apply to all establishments slaughtering cattle. FSIS estimates that 1,000 small establishments come under this regulation.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently will reduce the effectiveness of the meat 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.

To ensure that beef is free of BSE records of daily procedures and corrective actions concerning SRMs associated with slaughtered and processed cattle carcasses must be kept. Consequently, the 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 (75 FR 43137; July 23, 2010). There were no comments on the information collection. The Agency also contacted a trade association (Lloyd Hontz,) that solicited comments from a few of its members on this information collection. None had any comments to make.

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 123,916 hours. The burden estimates are described in the pages that follow.

Total	123,916 hours
-------	---------------

FSIS estimates that 37 establishments will once a year take 480 minutes (8 hours) to develop written procedures for a total of 37 responses and 296 hours.

**DEVELOP WRITTEN PROCEDURES FOR SRMs
(9 CFR 310.22)**

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
Ests.	37	1	37	480	296

It will take about 7 minutes a day to record and file SRMs monitoring procedures records. FSIS estimates that 3,512 establishments will respond 300 times annually for a total of 1,053,600 responses and 122,920 hours.

**SRMs MONITORING & RECORDKEEPING
(9 CFR 310.22)**

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
Ests.	3,512	300	1,053,600	7	122,920

FSIS estimates that 35 establishments will respond 150 times that receive carcasses or parts that contain vertebral column from cattle 30 months or older will take 2 minutes to submit the

proper documentation for an annual total of 5,250 responses and 350 hours.

**OBTAIN COPY OF SRM HANDLING RECORDS
(9 CFR 310.22(g))**

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
Ests.	35	150	5,250	2	350

It will take about 2 minutes for transporting establishments to file these records. FSIS estimates that 35 establishments will respond 150 times for an annual total of 5,250 responses and 350 hours.

**RECORDKEEPING
(9 CFR 310.22(g))**

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
Ests.	35	150	5,250	2	350

The cost to the respondents is estimated at \$4,584,892 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 123,916 hours and \$4,584,892.

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 \$2,200,000 annually. The costs arise primarily from the inspection review duties necessary to verify that

establishments comply with the information collection responsibilities. 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:

There is an adjustment increase of 700 hours because FSIS is incorporating the SRM Transport information collection (0583-0140) into 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.