

SUPPORTING STATEMENT JUSTIFICATION FOR ADVANCED MEAT RECOVERY SYSTEMS

1. Circumstances Making Collection Of Information Necessary:

This information collection requests an extension of the information collection of burden hours which addresses the regulatory requirements in production of meat from Advanced Meat Recovery systems.

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 that official establishments that produce meat from AMR systems ensure that bones used for AMR systems do not contain brain, trigeminal ganglia, or spinal cord, to test for calcium (at a different level than previously required), iron, spinal cord, and dorsal root ganglia (DRG), to document their testing protocols, to assess the age of cattle product used in the AMR system, and to document their procedures for handling product in a manner that does not cause product to be misbranded or adulterated, and to maintain records of their documentation and test results (9 CFR 318.24).

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

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

Official establishments that produce meat from AMR systems must ensure that bones used for AMR systems do not contain brain, trigeminal ganglia, or spinal cord; test for calcium (at a different level than previously required), iron, spinal cord, and dorsal root ganglia (DRG); document their testing protocols, to assess the age of cattle product used in the AMR system; and document their procedures for handling product in a manner that does not cause product to be misbranded or adulterated, and to maintain records of their documentation and test results. This testing and recordkeeping is necessary for establishments to ensure (and for FSIS to verify) that the meat product produced by the use of AMR systems is free from Bovine Spongiform Encephalopathy (BSE).

There are a total of 25,209 burden hours for the information collection requests relating to AMR systems for meat products.

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. The information collections must apply to all establishments producing meat product using AMR systems.

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.

To ensure that meat produced under AMR systems is free of BSE, testing must be conducted at least daily. 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 (72 FR 33193; June 15, 2007); the Agency received no comments. In addition, FSIS contacted a trade association that requested comments from its members but received no comments (Lloyd Hontz; 202/639-5924).

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 25,209 hours. The burden estimates are described in the pages that follow.

Total	25,209 hours
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It will take establishments an average of 180 minutes to develop written procedures, including testing protocols. FSIS estimates that 3 new establishments will respond one time for a total of 3 times and 9 hours.

**DEVELOP WRITTEN PROCEDURES
(9 CFR 318.24)**

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
AMR Ests.	3	1	3	180	9

The Agency estimates that it takes 30 minutes to test for calcium and iron. Approximately 56 establishments a year will respond 300 times for a total of 16,800 responses and 8,400 hours.

**TEST FOR CALCIUM & IRON
(9 CFR 318.24)**

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
AMR Ests.	56	300	16,800	30	8,400

The Agency estimates that it takes 30 minutes to test for spinal cord and dorsal root ganglia (DRG). Approximately 56 establishments a year will respond 300 times for a total of 16,800 responses and 8,400 hours.

**TEST FOR SPINAL CORD & DRG
(9 CFR 318.24)**

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
AMR Ests.	56	300	16,800	30	8,400

FSIS estimates that 56 establishments will respond 300 times a year in recording procedures in handling AMR livestock for a total of 16,800 responses. It will 30 minutes per response for a total of 8,400 hours.

**PROCEDURES RECORDKEEPING
(9 CFR 318.24)**

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
AMR Ests.	56	300	16,800	30	8,400

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 \$105,000 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 \$35 per hour for inspector time.

The cost to the respondents is estimated at \$756,270 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 25,209 hours and \$756,270.

15. Reasons For Changes In Burden:

The burden of 25,209 is due to a program adjustment of a previously approved information collection. A decrease of 47 burden hours from the previous total of 25,256 is due to fewer establishments.

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.