

SUPPORTING STATEMENT JUSTIFICATION FOR ADVANCED MEAT RECOVERY SYSTEMS

1. Circumstances Making Collection Of Information Necessary:

This is a request for renewal of the information collection that addresses the regulatory requirements in the production of meat from Advanced Meat Recovery (AMR) 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 21,259 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. FSIS estimates that there are 47 small establishments affected by this information collection.

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. No other circumstances exist that would cause the Agency to conduct this information collection in a manner differently than described above.

8. Consultation With Persons Outside The Agency:

In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice in the **Federal Register** (85 FR 7713; February 11, 2020). FSIS received one public comment but it was not relevant to the information collection. The Agency also consulted with three outside persons regarding the information collection: Nancy Lopez (806-206-3956); Emma Williams (479-750-5309); and Landon Detweiler (717-355-5425), to request input on the FSIS burden estimates. The three individuals agreed that the FSIS burden estimate for the information collection requirements related to advanced meat recovery systems remains accurate.

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 21,159 hours. The burden estimates are described in the pages that follow.

Total 21,159 hours

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 annually 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 47 establishments a year will respond 300 times for a total of 14,100 responses and 7,050 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.	47	300	14,100	30	7,050

The Agency estimates that it takes 30 minutes to test for spinal cord and dorsal root ganglia (DRG). Approximately 47 establishments a year will respond 300 times for a total of 14,100 responses and 7,050 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.	47	300	14,100	30	7,050

FSIS estimates that 47 establishments will respond 300 times a year in recording procedures in handling AMR livestock for a total of 14,100 responses. It will take 30 minutes per response for a total of 7,050 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.	47	300	14,100	30	7,050

The cost to the respondents is estimated at \$959,561 annually. The Agency estimates that it will cost respondents \$45.35 an hour, including fringe benefits, in fulfilling these information collection requirements. Respondents will spend an annual total of 21,159 hours and \$959,561. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2018.

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 \$136,050 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 \$45.35 per hour, including fringe benefits, for Agency personnel time.

15. Reasons For Changes In Burden:

There is no change in burden requested for this information collection renewal. Annually, there are 21,159 hours, 47 respondents, and 42,303 responses.

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.