SUPPORTING STATEMENT JUSTIFICATION FOR
PROCEDURES FOR THE NOTIFICATION OF NEW TECHNOLOGY AND REQUESTS FOR WAIVERS

1. Circumstances Making Collection of Information Necessary:

This information collection requests a revision of previously approved burden hours, which addresses the regulatory requirements for meat, poultry, and egg products establishments and plants in implementing new technologies.

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 Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 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 established flexible procedures to actively encourage the development and use of new technologies in meat and poultry establishments and egg products plants (68 FR 6873). These procedures facilitate notification to the Agency of any new technology that is intended for use in meat and poultry establishments and egg products plants so that the Agency can decide whether the new technology requires a pre-use review.

If a new technology could affect product safety, FSIS regulations, inspection procedures, or the safety of Federal inspection program personnel, or requires a waiver of a regulation, FSIS will advise the firm that a pre-use review is necessary. A pre-use review often includes an in-plant trial. If an in-plant trial is necessary, FSIS will request that the firm submit a protocol that is designed to collect relevant data to support the use of the new technology.

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

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

Notification

Before introducing new technology into an official establishment or plant, firms should submit notification and documentation of the new technology to FSIS describing the operation and purpose of the new technology (68 FR 6873). The document should explain why the new technology will not:

- adversely affect the safety of the product,
- jeopardize the safety of Federal inspection program personnel,
- interfere with inspection procedures.

FSIS will make every effort to review the documentation and notify the firm within 60 days whether it has no objection to the use of the new technology or if it needs a pre-use review.

Development of Protocols

If FSIS determines that the proposed use of the new technology could adversely affect product safety, interfere with FSIS inspection procedures, jeopardize the safety of inspection program personnel, or require a waiver of a regulation, then a pre-use review is needed. Title 9 CFR 303.1(h), 381.3(b), and 590.10 authorize the Administrator to waive for limited periods any provision of the regulations to permit experimentation so that new procedures, equipment, and processing techniques may be tested to facilitate definite improvements. Typically, when a pre-use review is needed, the firm will develop a protocol for an in-plant trial of the new technology. The firm then must submit a protocol that is designed to collect relevant data to support the use of the new technology.

In-plant Trials Data Collection and Recordkeeping

Firms that conduct in-plant trials must collect and record the data on a regular, on-going basis.

In-plant Monthly Data Collection and Recordkeeping

Firms that operate under a waiver must collect and record data on a regular, on-going basis.

There are a total of 12,800 burden hours for the information collection requests relating to the notification of new technology procedures.

3. Use of Improved Information Technology:

Under the E-Gov Act, firms may submit notification and protocols electronically. 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 FSIS office, USDA agency, or any other Government agency requires information regarding the use of new technology in meat, poultry, and egg products establishments and plants. 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 meat, poultry, and egg products establishments and plants under FSIS inspection implementing new technology. There are no small businesses.

6. Consequences If Information Were Collected Less Frequently:

To conduct the information collections less frequently will 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;**
- **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.**

During the protocol establishments and plants may be required to report data gained from their study of the new technology more frequently that quarterly. All 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 on December 27, 2016 (81 FR 95099) requesting comments regarding this information collection request. The Agency received no comments in response to the Federal Register notice. FSIS also directly contacted three industry members who had no comment in response to the Agency's burden hour estimate: David McNeal, (770) 967-0532); LuAnn Maloney (215) 299-6000; and Mike Harvey (209) 581-9576.

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 12,800 hours. The burden estimates are broken down into three categories described in the pages that follow.

Notification	600
Development of Protocol	4,000
In-plant Trials	4,000
In-plant Monthly Data	4,200
Total	12,800 hours

Notification

FSIS estimates that it will take 8 hours for firms to complete a notification of intent to use new technology. 75 firms will annually respond once for a total of 600 hours.

NOTIFICATION OF NEW TECHNOLOGY
(68 FR 6873)

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
Firms	**75**	**1**	**75**	**480**	**600**

Development of Protocols

The Agency estimates that it will take 80 hours to develop a protocol. Approximately, 50 firms once a year will develop a protocol for submission.

DEVELOPMENT OF PROTOCOLS
(68 FR 6873)

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
Firms	**50**	**1**	**50**	**4,800**	**4,000**

In-plant Trial Data Collection and Recordkeeping

The Agency estimates that 50 firms will spend 80 hours collecting data and recordkeeping during the duration of the in-plant trial.

In-Plant Trials
(68 FR 6873)

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
Firms	**50**	**1**	**50**	**4, 800**	**4,000**

In-plant Monthly Data Collection and Recordkeeping

The Agency estimates that 35 firms will spend 120 hours collecting data and recordkeeping annually for the duration of the waiver.

In-Plant Monthly Data
(68 FR 6873)

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
Firms	**35**	**1**	**35**	**7,200**	**4,200**

The cost to the respondents is estimated at $560,264 annually. The Agency estimates that it will cost respondents $61 an hour in fulfilling these paperwork and recordkeeping requirements. Respondents will spend an annual total of 12,800 hours and $560,224. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2016.

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 $301,784 annually. The costs arise primarily from the time spent by FSIS staff reviewing notifications, protocol submissions, and in-plant data. The Agency estimates a cost of $39 per hour.

15. Reasons for Changes in Burden:

FSIS has increased its estimate of total annual burden hours from 3,616 to 12,800. The increase of 9,184 hours accounts for in-plant trials, and the monthly data collection and recordkeeping requirements for establishments operating under a waiver.

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.