SUPPORTING STATEMENT JUSTIFICATION FOR
NOTIFICATION OF NEW TECHNOLOGY PROCEDURES

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 will 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.

There are a total of 8,600 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.

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 August 13, 2010 (72 FR 24266) requesting comments regarding this information collection request. The Agency received one comment in response to the Federal Register notice. The commenter felt that the Agency underestimated the time required to respond to each of the three categories of information described by this information collection request (time required to prepare a notice of intent to use new technology; time required to develop a protocol for an in-plant trial; and time required to collect and record data during an in-plant trial). The commenter did not provide alternative estimates. FSIS also directly contacted three industry members to request comment on the Agency's burden hour estimate (Mike Harvey, Enviro Tech Chemical Services, (209) 581-9576; LuAnn Maloney, FMC Corporation, (215) 299-6000; and David McNeal, Meyn America, (770) 967-0532). They had no comment in response to the Agency's burden hour estimate.

FSIS did not change its burden hour estimate in response to the comment received. First, FSIS recognizes that some establishments will spend less time responding to this information collection than the Agency estimated, and others will spend more time. On average, FSIS believes that its burden hour estimate is accurate. Second, with respect to the third category of information (time required to collect and record data during an in-plant trial), the commenter based its argument on the total length of time it takes to conduct an in-plant trial, which can sometimes be months. But this overstates the time associated with information collection. FSIS's information collection burden hour estimate is correctly

based on the time spent collecting and recording data during the course of an in-plant trial, which is significantly less than the total number of hours spent conducting the in-plant trial.

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 8,600 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 Data	4,000
Total	8,600 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 2,000 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

The cost to the respondents is estimated at $541,800 million annually. The Agency estimates that it will cost respondents $63 an hour in fulfilling these paperwork and recordkeeping requirements. Respondents will spend an annual total of 8,600 hours and $541,800.

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 $192,400 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 $37 per hour.

15. Reasons for Changes in Burden:

FSIS has increased its estimate of total annual burden hours from 8,400 to 8,600. This increase is the result of a change in the number of respondents FSIS estimates will be affected by this information collection. FSIS is: (1) decreasing its estimate of the number of respondents who will provide notification

of a new technology from 250 to 75; (2) increasing its estimate of the number of respondents who will develop new technology protocols from 40 to 50; and (3), increasing its estimate of the number of respondents who will conduct in-plant trials from 40 to 50. These changes are based on FSIS's experience since this information collection was last approved. FSIS has not changed its estimate of the response time required under each category. The result is an increase in the total estimated burden hours from 8,400 to 8,600.

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.