**SUPPORTING STATEMENT JUSTIFICATION FOR**
***SALMONELLA* INITITATIVE PROGRAM**

## 1. Circumstances Making Collection of Information Necessary:

This information collection requests a new information collection related to the Salmonella Initiative Program (SIP) for meat and poultry products establishments.

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.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 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.

SIP offers incentives to meat and poultry slaughter establishments to control Salmonella in their operations. SIP does this by granting waivers of regulatory requirements with the condition that establishments test for Salmonella, Campylobacter (if applicable), and generic E. coli or other indicator organisms and share all sample results with FSIS. The Federal Register notice of July 13, 2011 opened SIP to all meat and poultry slaughter establishments, and all establishments receiving a waiver must participate in SIP. SIP benefits public health because it encourages establishments to test for microbial pathogens, which is a key feature of effective process control.

## 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.

Under SIP, establishments will share their data with FSIS this will help the Agency in formulatiing its policy. Furthermore, if the establishment's results show it is not meeting the Agency's current performance standards for turkeys or young chickens, it is to increase testing, determine whether its waiver is affecting its public health protection performance, and take steps to regain process control in order to minimize the presence of pathogens of public health concern.

SIP establishments are not routinely required to provide FSIS with isolates, but, if requested,

establishments must work with FSIS on a mutually agreeable means for doing so. A SIP establishment will not be suspended or lose its waiver solely because of its Salmonella testing results. The Agency intends to conduct its own unannounced, small-set sampling to verify the consistent performance of all establishments, including those participating in SIP.

Establishments that want to enter SIP must send a protocol to FSIS informing the Agency about their plans for implementing SIP in their establishment, including data collection, objectives and methods of evaluating the new technology for which they are receiving the regulatory waiver.

Establishments in SIP must collect and record data on a regular, on-going basis. They must retain their records for one year.

**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 other Government agency requires information regarding Salmonella in official establishments. 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 official meat and poultry establishments that volunteer to join SIP. FSIS estimates that 50 small establishments will choose to participate in SIP.

**6. Consequences If Information Were Collected Less Frequently:**

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

Establishments will be required to collect and record data more frequently that quarterly. There are no other circumstances that would cause the guidelines above not to be met by this information collection.

## 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 July 13, 2011 (72 FR 24266) requesting comments regarding this information collection request. The Agency received no comments in response to the Federal Register notice.

FSIS also directly contacted three establishments to request comment on the Agency’s estimates

(Ken Suber, 706/621-2069; Kevin Ingram, 912/318-3306; Jonathan McKoy, 256/840-2958). They all agreed with the Agency's estimates.

**9. Payment or Gifts to Respondents:**

Respondents will not receive any gifts or payments.

**10. Confidentiality Provided to Respondents:**

No additional assurance of confidentiality is provided with this information collection. Any and all information obtained in this collection shall not be disclosed except in accordance with 5 U.S.C.552a."

**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 206,000 hours. The burden estimates are broken down into three categories described in the pages that follow.

| | |
|---|---|
| Development of Protocols | 24,000 |
| Data Collection | 156,000 |
| Recordkeeping | 26,000 |
| Total | 206,000 hours |

*Development of Protocols*

The Agency estimates that it will take 80 hours to develop a protocol for SIP. Approximately, 300 establishments will develop a protocol for submission. (Based on Agency experience with its New Technology program, FSIS estimated that on the average it would take 80 hours for an establishment to develop a protocol to successfully implement the pathogen testing and data collection associated with SIP).

**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 Hours | Total Annual Time in Hours |
|---|---|---|---|---|---|
| Ests. | 300 | 1 | 300 | 80 | 24,000 |

*Data Collection*

The Agency estimates that 300 establishments will 20 times a week spend 30 minutes each time collecting data for SIP. They will have a grand total of 312,000 responses and spend 156,000 hours annually collecting data.

**SIP DATA COLLECTION**
**(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 |
|---|---|---|---|---|---|
| Ests. | 300 | 1,040 | 312,000 | 30 | 156,000 |

*Recordkeeping*

FSIS estimates that 300 establishments will have 1,040 responses at 5 minutes a response for a grand total of 312,000 responses and 26,000 hours annually.

**SIP RECORDKEEPING**
(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 |
|---|---|---|---|---|---|
| Ests. | 300 | 1,040 | 312,000 | 5 | 26,000 |

The cost to the respondents is estimated at $7,622,000 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 206,000 hours and $7,622,000.

**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 $185,000 annually. The costs arise primarily from the time spent by FSIS staff reviewing protocols and data. The Agency estimates a cost of $37 per hour.

**15. Reasons for Changes in Burden:**

This is a new 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.