

SUPPORTING STATEMENT JUSTIFICATION FOR SALMONELLA INITIATIVE PROGRAM

1. Circumstances Making Collection of Information Necessary:

This is a request for a revision to the approved information collection related to the *Salmonella* Initiative Program (SIP) for meat and poultry products establishments. This renewal contains an increase of 9,363 burden hours.

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. 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 share their data with FSIS. This helps the Agency in formulating its policy. Furthermore, if an 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 conducts 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 15 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 than 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 28, 2020 (85 FR 45370) requesting comments regarding this information collection request. The Agency received no comments in response to the **Federal Register** notice. FSIS also contacted four establishments to request comment on the Agency's estimates (Yolanda Quinteros, 330-804-1770; Danah Vetter, 479-466-4969; Pamela Abney, 302-604-1519, and Juan DeVillena, 678-294-0558). 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 17,628 hours. The burden estimates are broken down into three categories described in the pages that follow.

Development of Protocols	2,650
Data Collection	12,838
Recordkeeping	2,140
Total	17,628 hours

Development of Protocols

The Agency estimates that it will take 25 hours to develop a protocol for SIP. Approximately, 106 establishments will develop a protocol for submission. They will have a grand total of 106 responses and spend 2,650 hours annually collecting data.

**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.	106	1	106	25	2,650

The Agency estimates that 79 establishments will respond 325 times and spend 30 minutes each time collecting data for SIP. They will have a grand total of 25,675 responses and spend 12,838 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.	79	325	25,675	30	12,838

FSIS estimates that 79 establishments will have 325 responses at 5 minutes a response for a grand total of 25,675 responses and 2,140 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.	79	325	25,675	5	2,140

The cost to the respondents is estimated at \$799,430 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 17,628 hours and \$799,430. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2019.

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 \$59,193 annually. The costs arise primarily from the time spent by FSIS staff reviewing protocols and data. The Agency estimates a cost of \$45.35 per hour. The hourly rate for the respondents was attained from the Department of Labor Bureau of Labor and Statistics wage data, May, 2019.

15. Reasons for Changes in Burden:

The previous OMB approval for this collection was for 8,265 burden hours; however, the Agency has experienced an increase in SIP participation. Therefore, FSIS is asking OMB to approve a renewal of this collection with an increase in burden hours from 8,265 to 17,628, an increase in responses from 12,025 to 25,675, and an increase in respondents from 50 to 79.

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.