

SUPPORTING STATEMENT JUSTIFICATION FOR SANITATION SOPS AND PATHOGEN REDUCTION/HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

1. Circumstances Making Collection Of Information Necessary:

This is a request for an extension of the previously approved information collection under control number 0583-0103 which addresses the regulatory requirements in the Sanitation SOPs and Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) 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.) and the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 et seq.). These statutes mandate that FSIS protect the public by verifying that meat and poultry products are safe, wholesome, not adulterated, and properly labeled and packaged.

FSIS has established requirements applicable to meat and poultry establishments designed to reduce the occurrence and numbers of pathogenic microorganisms on meat and poultry products, reduce the incidence of foodborne illness associated with the consumption of those products, and provide a new framework for modernization of the current system of meat and poultry inspection. The regulations (1) require that each establishment develop and implement written sanitation standard operating procedures (Sanitation SOPs); (2) require regular microbial testing by slaughter establishments to verify the adequacy of the establishments' process controls for the prevention and removal of fecal contamination and associated bacteria; (3) establish pathogen reduction performance standards for Salmonella that slaughter establishments must meet; and (4) require that all meat and poultry establishments develop and implement a system of preventive controls designed to improve the safety of their products, known as HACCP.

2. How, By Whom and Purpose Information Is To Be Used:

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

Standard Operating Procedures (SOP) for Sanitation

Official establishments must develop and maintain a SOP for sanitation that is used by inspection personnel in performing monitoring verification tasks. The SOP's require no new requirements in the Federal meat and poultry products inspection regulations. However, 9 CFR 416.11 does require establishments to develop, implement, and maintain, in a written plan, the establishment's Sanitation Standard Operating Procedures to meet the requirements of Part 416. The SOP's specify the cleaning and sanitizing procedures for all equipment and facilities involved in the production of every product. Section 416.12 requires that Sanitation SOPs describe all procedures that an establishment will conduct daily to prevent direct contamination or adulteration of product. According to §416.14, SOPs must be revised, as needed, to keep them effective and current. When establishments take corrective actions, §416.15(b) requires that establishments modify their SOPs, if necessary. Section 416.16 details the recordkeeping requirements associated with Sanitation SOPs. Establishments must maintain daily records sufficient to document the implementation and monitoring of SOPs, including corrective actions taken. Records must be maintained for at least six months and made available to FSIS. FSIS does not review or approve the plans. In most cases, inspectors review the records once a day.

Microbiological Testing

Each slaughter establishment must develop written procedures outlining specimen collection and handling for E. coli process control verification testing. The slaughter establishments are responsible for entering the results into a statistical process control chart. The data and chart will be available for review by the Inspector-in-Charge, upon request. Generally, FSIS reviews this data only as part of investigating regulatory non-compliance. For example, if an establishment has recurring non-compliances, such as the presence of fecal material on carcass, FSIS may review the E. coli testing data in making enforcement action determinations.

Sections 310.25(a) and 381.94(a) of Title 9 detail the requirements for the sampling and testing of carcasses for generic E. coli. Section 310.25(a) specifies that establishments that slaughter livestock must test for E. coli. Section 310.25(a)(iii) requires establishments to maintain records of the analytic results of the sampling tests. According to §310.25(a)(2)(i), establishments must prepare written specimen collection procedures. These written procedures must be made available to FSIS upon request. The frequency of sampling/testing varies according to the amount of volume of product slaughtered by the establishment. Section 310.25(a)(4) requires that establishments maintain accurate records of all test results, which are to be made available to FSIS upon request.

FSIS is responsible for performing the sampling and testing of product for Salmonella.

HACCP

Part 417 in Title 9 sets forth the HACCP requirements for establishments. Section 417.2(b) requires establishments to develop and implement a written HACCP plan and §417.2(c) specifies the contents of the HACCP plan. Section 417.4 (a)(3) requires a reassessment of the HACCP plan annually or as needed (any modifications would have to be added to the existing HACCP plan). Section 417.5 details the HACCP records that establishments must maintain. And §417.7 requires that only individuals trained in the seven HACCP principles may develop or modify and reassess an establishment's HACCP plan.

Establishments develop written HACCP plans that include: identification of the processing steps which present hazards; identification and description of the critical control point (CCP) for each identified hazard; specification of the critical limit which may not be exceeded at the CCP, and if appropriate, a target limit; description of the monitoring procedure or device to be used; description of the corrective action to be taken if the limit is exceeded; description of the records which will be generated and maintained regarding this CCP; and description of the establishment verification activities and the frequency at which they are to be conducted. Critical limits which are currently a part of FSIS regulations or other requirements must be included.

FSIS does not review or approve the plans. However, plans should be on file and available to FSIS

program employees upon request.

Establishments will keep records for measurements during slaughter and processing, corrective actions, verification check results, and related activities that contain the identity of the product, the product code or slaughter production lot, and the date the record was made. The information will be recorded at the time that it is observed, and the record will be signed by the operator or observer.

The HACCP records will be reviewed by an establishment employee other than the one who produced the record, before the product is distributed in commerce. If a HACCP-trained individual is on-site, that person should be this second reviewer. The reviewer will sign the records.

HACCP records generated by the processor will be retained on site for at least 1 year for slaughter and refrigerated product and two years for shelf-stable products. Off-site storage of records is permitted after 6 months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request. Records should be available to FSIS program employees upon request for verification of the HACCP system.

Lastly, establishments may have prerequisite programs that are designed to provide the basic environmental and operating conditions necessary for the production of safe, wholesome food. Because of its prerequisite programs an establishment may decide that a food safety hazard is not reasonably likely to occur in its operations. The establishment would need to document this determination in its Hazard Analysis and include the procedures it employs to ensure that the program is working and that the hazard is not likely to occur (9 CFR 417.5 (a)(1)). The prerequisite program and the laboratory results generated in auditing the program are to be available to FSIS upon request.

Supplier Information

In addition, FSIS requires Federal grinding establishments maintain and are able to supply upon request the following information concerning the suppliers of source materials: the name, point of contact, and phone number for the establishments supplying the source materials for the lot of ground beef sampled; and the supplier lot numbers, production dates, and other information that would be useful to

know about suppliers.

Under §320.1(b)(1), establishments and retail facilities are required to keep records of each transaction involving their purchasing or receiving any meat or meat food product. These records must show the name or description of the articles they purchase or receive (320.1(b)(1)(i)) and the name and address of the seller of the articles they purchase (320.1(b)(1)(iv)). Establishments and retail facilities must provide FSIS access to these records (320.4, 21 U.S.C. 642).

3. Use Of Improved Information Technology:

Under the Government Paperwork Elimination Act, the records may be maintained electronically on computers provided that appropriate controls are implemented to ensure the integrity of the electronic data. FSIS estimates that 60% of the recordkeeping will be done electronically.

In addition, establishments may use video equipment to record and keep records. The Agency estimates that .1% of official establishments will use video records.

4. Efforts To Identify Duplication:

No FSIS office, USDA agency or any other Government agency requires information regarding pathogen reduction and HACCP systems for 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 businesses slaughtering and processing meat and poultry products to ensure wholesome and unadulterated products. However, small businesses under FSIS inspection almost always are small or very small establishments. Therefore, because these small and very small establishments are low volume establishments the amount of microbiological testing is less than for higher volume establishments. Moreover, small and very small operations are usually less complex than larger operations and require less sophisticated HACCP plans to be developed and maintained. FSIS estimates that there are 4,500 small

businesses under HACCP.

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 and poultry establishments are producing wholesome and unadulterated product, FSIS requires the use of the internationally recognized food safety system—HACCP. In order to effectively monitor and verify official establishment's use of HACCP, the Agency must require daily

information collection and recordkeeping by the industry. Therefore, this information collection request is consistent with 5 CFR 1320.5. 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 10402; February 24, 2020). FSIS received two public comments that were 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 Sanitation SOPs and Pathogen Reduction/HACCP 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

A. The total burden estimate for the reporting and recordkeeping requirements associated with this information collection is 7,045,283. The burden estimates are broken down into four categories

described in the pages that follow.

Standard Operation Plans for Sanitation	2,142,788
Microbiological Testing	113,202
HACCP	4,786,793
Supplier Information	2,500
Total	7,045,283

Standard Operation Procedures (SOP) for Sanitation

Development

FSIS has updated its estimates of the labor hours required to develop SOPs for sanitation at federally inspected establishments. Experts estimate that, on average, low and medium volume establishments require 500 hours to develop an SOP and high volume establishments require 1,000 hours to do so^{1,2}. The Agency estimates that there will be 20 new establishments a year coming under inspection that will consequently have to develop and write their SOP. There will be approximately 11 new low volume establishments that will spend an annual total of 5,500 hours developing their SOP; they will annually have a total of 11 responses with 500 hours for each response. There will be approximately 7 new medium volume establishments that will spend an annual total 3,500 hours developing their SOP; they will annually have a total of 7 responses with 500 hours for each response. And there will be approximately 2 high volume establishments that will spend an annual total of 2,000 hours developing their SOP; they will annually have a total of 2 responses with 1,000 hours for each response.

1FSIS contracted RTI International (Contract No. AG-3A94-B-13-0003) to collect data on the costs of food safety interventions. The full report is available at: <http://www.fsis.usda.gov/wps/wcm/connect/0cdc568e-f6b1-45dc-88f1-45f343ed0bcd/Food-Safety-Costs.pdf?MOD=AJPERES> Viator. C. Et. Al. 2015. Costs of Food Safety Investments. Table 4-2 Costs of SSOP Plan Development, Validation and Reassessment.

2 FSIS assumed that low and medium volume establishments are equivalent to HACCP size *small* in the “Cost of Food Safety Interventions” report. In addition, FSIS assumed that high volume establishments are equivalent to large HACCP size establishments in the report. This assumption holds for all the following estimates.

**Sanitation Standard Operating Procedures (SOPs)-Plan
Development
(9 CFR 416.12)**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	11	1	11	30,000	5,500
Medium	7	1	7	30,000	3,500
High	2	1	2	60,000	2,000
All Establishments	20		20		11,000

Evaluation and Revision

Low volume establishments may have to evaluate and revise their SOPs 3 times a year; medium volume establishments will evaluate and revise their establishments 2 times a year; high volume establishments will evaluate and revise their SOPs 7 times a year. Evaluation and revision of SOPs includes both analysis and the time it takes to actually modify the SOPs. Experts estimated that it will take 1,800 minutes for low and medium volume establishments, and 3,600 minutes high volume establishments to

reassess and modify a SOP³. FSIS estimates that 3,459 low volume establishments will annually have a total of 10,377 responses and 311,310 hours. The 2,239 medium volume establishments will annually have a total of 4,478 responses and 134,340 hours. The 389 high volume establishments will annually have a total of 2,723 responses and 163,380 hours. And all 6,087 establishments will annually have a grand total of 17,578 responses and 609,030 hours.

Sanitation Standard Operating Procedures (SOPs)- Plan Evaluation and Revision (9 CFR 416.14)

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	3,459	3	10,377	1,800	311,310
Medium	2,239	2	4,478	1,800	134,340
High	389	7	2,723	3,600	163,380
All Establishments	6,087		17,578		609,030

Recordkeeping

³ Viator. C. Et. Al. 2015. Costs of Food Safety Investments. Table 4-2 Costs of SSOP Plan Development, Validation and Reassessment. <http://www.fsis.usda.gov/wps/wcm/connect/0cdc568e-f6b1-45dc-88f1-45f343ed0bcd/Food-Safety-Costs.pdf?MOD=AJPERES>

The burden of documenting the adherence to a SOP is based on three components; recording, reviewing, and storage. Recording encompasses conducting and inscribing the finding from an observation and filing of the document produced (cf. §416.16). This action is assumed to take 30, 60, and 120 minutes per day in a low, medium, and high volume establishment, respectively. FSIS estimates that annually each of the 3,459 low volume establishments will perform recordkeeping duties 260 times with a total for all low volume establishments of 899,340 responses and 449,670 hours. Each of the 2,239 medium volume establishments will annually perform recordkeeping duties 260 times with a total for all medium volume establishments of 582,140 responses and 582,140 hours. Each of the 389 high volume establishments will annually perform recordkeeping duties 260 times with a total for all high volume establishments of 101,140 responses and 202,280 hours. And each of the 6,087 establishments will annually perform recordkeeping duties an average of 260 times for a grand total for all establishments of 1,582,620 responses and 1,234,090 hours.

**Sanitation Standard Operating Procedures (SOPs)-Recording and filing
(9 CFR 416.16)**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	3,459	260	899,340	30	449,670
Medium	2,239	260	582,140	60	582,140
High	389	260	101,140	120	202,280
All Establishments	6,087		1,582,620		1,234,090

Record Review

Review of the records generated is assumed to take 5,10, and 20 minutes per day for a low, medium, and high volume establishment, respectively (cf. §§416.14 and 416.15). The Agency estimates that each of the 3,459 low volume establishments will annually review its SOP records 260 times for a total for all low volume establishments of 899,340 responses and 74,945 hours. Each of the 2,239 medium volume establishments will annually review its SOP records 260 times for a total for all medium volume establishments of 582,140 responses and 97,023 hours. And each of the 389 high volume establishments will annually review its SOP records 900 times for a total for all high volume establishments of 350,100 responses and 116,700 hours. And 6,087 establishments will annually review their SOP records a grand total for all establishments of 1,582,620 responses and 288,668 hours.

**Sanitation Standard Operating Procedures (SOPs)- Record Review
(9 CFR 416.14 and 416.15)**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	3,459	260	899,340	5	74,945
Medium	2,239	260	582,140	10	97,023
High	389	900	350,100	20	116,700
All Establishments	6,087		1,582,620		288,668

Burden

The burden estimate is 2,142,788 hours for Sanitation SOP information collection activities.

Microbiological Testing

Development

Agency subject matter experts estimate the time to develop a microbial sampling and analysis plan is 25 hours. Sample collection times were estimated to range from 15 to 20 minutes, with an average of 17.5 minutes (cf. §§310.25(a)). To enter data into the chart, review, and file the information will take 5 minutes per sample (cf. §§310.25(a)). The Agency estimates that new establishments will each spend an 1,500 minutes to develop a microbial sampling and analysis program, including 4 livestock establishments for 100 annual hours and 4 State programs for 100 annual hours for a grand total of 8 establishments and 200 hours a year⁴.

**Microbial Testing-Plan Development
(9 CFR 310.25(a))**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Livestock	4	1	4	1,500	100
State	4	1	4	1,500	100
All	8				

⁴ Under the Modernization of Poultry Slaughter Inspection rule, FSIS replaced 9 CFR 381.94(a) with 381.65(g) which requires establishments to incorporate microbiological sampling plans in their HACCP plans <http://www.fsis.usda.gov/wps/wcm/connect/00ffa106-f373-437a-9cf3-6417f289bfc2/2011-0012.pdf?MOD=AJPERES>

Establishments	8	3,000	200
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Revision

FSIS estimates that establishments will have to revise their microbial sampling and analysis program 3 times a year. Reassessment of microbial sampling and analysis programs includes both analysis and the time it takes to actually modify their microbial sampling and analysis program. It will take each establishment 2 hours to reassess their microbial sampling and analysis program. The 789 livestock establishments will have an annual total of 2,367 responses and 4,734 hours. The 1,415 State establishments will have an annual total of 4,245 responses and 8,490 hours. And all 2,204 establishments will have an annual grand total of 6,612 responses and 13,224 hours.

**Microbial Testing- Plan Reassessment
(9 CFR 310.25(a))**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Livestock	789	3	2,367	120	4,734
State	1,415	3	4,245	120	8,490
All Establishments	2,204		6,612		13,224

Sample Collection

FSIS estimates that each of the 561 low volume establishments will have to annually collect samples 26 times for a total for all low volume establishments of 14,586 responses and 7,293 hours. Each of the 169 medium volume establishments will have to annually collect samples 86 times for a total for all low volume establishments of 14,534 responses and 7,267 hours annually. Each of the 59 high volume establishments will have to annually collect samples 1,758 times for a total for all high volume establishments of 103,722 annual responses and 51,861 hours. Each of the 1,415 State establishments will have to annually collect samples 27 times for a total for all state establishments of 38,205 responses and 19,103 hours. And each of the 2,204 total number of establishments will have to annually collect a total of 171,047 annual responses and 85,524 hours.

**Microbial Testing- Sample Collection
(9 CFR 310.25(a))**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	561	26	14,586	30	7,293
Medium	169	86	14,534	30	7,267
High	59	1,758	103,722	30	51,861
State	1,415				

All Establishments	27	38,205	30	19,103
	2,204	171,047		85,524

Recording

FSIS estimates that each of the 561 low volume establishments will have to annually record microbial testing results 26 times for a total for all low volume establishments of 14,586 responses and 1,216 hours. Each of the 169 medium volume establishments will have to annually record microbial testing results 86 times for a total for all medium volume establishments of 14,534 responses and 1,211 hours. Each of the 59 high volume establishments will have to annually record microbial testing results 1,758 times for a total for all high volume establishments of 103,722 responses and 8,644 hours. Each of the 1,415 State establishments will have to annually record microbial testing results 27 times for a total for all state establishments of 38,205 responses and 3,184 hours. And each of the 2,204 establishments will have to record microbial testing results 171,047 annual responses and 14,254 hours.

**Microbial Testing- Recording
(9 CFR 310.25(a))**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	561	26	14,586	5	1,216
Medium	169	86	14,534	5	1,211
High					

	59	1,758	103,722	5	8,644
State	1,415	27	38,205	5	3,184
All Establishments	2,204		171,047		14,254

Burden

The burden estimate is 113,435 hours for microbiological testing information collection activities.

Establishments do not incur information collection burden during the development of the baseline studies from which the E. coli regulatory evaluation criteria are derived. FSIS inspectors collect samples from carcasses and Agency experts, microbiologists and statisticians, analyze the test results and develop the criteria.

FSIS conducts the sampling associated with the Salmonella performance standard criteria. Establishments do not have any associated information collection burden related to such sampling. Also, establishments do not incur information collection burden during the development of the baseline studies from which the Salmonella performance standards are derived. FSIS inspectors collect samples from carcasses, and Agency experts, microbiologists and statisticians analyze the test results and develop the criteria.

HACCP

FSIS defined 9 HACCP processes that encompass all meat and poultry products produced. FSIS used information available through the LIS database and the PBIS inspection system to categorized inspected establishments under the processes. Establishments categorized as low, medium, and high

volume had on average 2.3, 2.8, and 3.6 HACCP processes, respectively. State establishments could not be categorized by average number of HACCP processes due to a lack of production information. However, based on discussions with program officials, it was assumed that each State establishment had 2.1 HACCP processes.

Although the amount of time to develop a plan for each process varies based on the processes difficulty, it was estimated that low, medium, high volume and state establishments will need an average of 136, 126, 113, and 78 hours to develop each plan (cf. §§417.2 and 417.3). The Agency took into account that higher volume establishments usually have more resources at their disposal to develop their HACCP plans than lower volume establishments. It was determined that there are 7.4 CCPs for each processing plan in Federal establishments, 5 CCPs for each slaughter plan in Federal establishments, and 5 CCPs for both types of plans in State slaughter establishments. It was estimated that recording and filing will take 5 minutes per CCP and review will take 2 minutes per CCP (cf. §417.5).

Plan Development⁵

The Agency estimates that 6 new low volume establishments will each spend 30,000 minutes for an annual total of 3,000 hours developing their HACCP plans. The 5 new medium volume establishments will each spend 30,000 minutes for an annual total of 2,500 hours developing their HACCP plans. The 5 new high volume establishments will each spend 60,000 minutes for an annual total of 5,000 hours. The 4 new State establishments will each spend 30,000 minutes and an annual total of 2,000 hours developing their HACCP plans. And all 20 new establishments will spend a grand total of 971,250 hours developing their HACCP plans.

⁵ Time estimates for developing a HACCP plan were obtained from the "Cost of Food Safety Interventions" report. Low and medium volume establishments are assumed to be equivalent to small establishments in the report and to spend 500 hours, on average, developing a HACCP plan. High volume establishments are assumed to be equivalent to large establishments in the report and to spend 1,000 hours developing a HACCP plan. Only 1 of the 1,415 State establishments is large, thus the agency assumed that State establishments would take the same amount of time as small establishments to develop a HACCP plan (500 hours). Viator. C. Et. Al. 2015. Costs of Food Safety Investments. Table 4-1 Costs of HACCP Plan Development, Validation and Reassessment.

**Hazard Analysis and Critical Control Point System-Plan
Development
(9 CFR 417.2)**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	6	1	6	30,000	3,000
Medium	5	1	5	30,000	2,500
High	5	1	5	60,000	5,000
State All Establishments	4	1	4	30,000	2,000
	20		20		12,500

Reassessment

FSIS estimates that every establishment will have to reassess its HACCP plan and CCPs 5 times a year. Establishments will spend an average of 2,700 minutes per reassessment. Reassessment of HACCP plans includes both analysis and the time it takes to actually modify their HACCP plan. The 2,656 low volume establishments will have annual total of 13,280 responses and 398,400 hours. The 1,628 medium volume establishments will have an annual total of 8,140 responses and 244,200 hours. The 388 high volume establishments will have an annual total of 1,940 responses and 116,400 hours. The 1,415 State establishments will have an annual total of 7,075 responses and 212,250 hours. And all 6,087 establishments will have a grand total of 30,435 responses and 971,250 hours.

**Hazard Analysis and Critical Control Point System-Plan Reassessment
(9 CFR 417.4)**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	2,656	5	13,280	1,800	398,400
Medium	1,628	5	8,140	1,800	244,200
High	388	5	1,940	3,600	116,400
State All Establishments	1,415	5	7,075	1,800	212,250
	6,087		30,435		971,250

Recordkeeping

The Agency estimates that each of the 2,656 low volume establishments will have to annually perform recordkeeping activities 2,387 times for a total for all low volume establishments of 6,339,872 responses and 528,323 hours. Each of the 1,628 medium volume establishments will have to annually perform recordkeeping activities 3,918 times for a total for all medium volume establishments of 6,378,504 responses and 531,542 hours. Each of the 388 high volume establishments will have to annually perform recordkeeping activities 10,251 times for a total for all high volume establishments of 3,977,388

responses and 331,449 hours. Each of the 1,415 State establishments will have to annually perform recordkeeping activities 2,017 times for a total for all State establishments of 2,854,055 responses and 237,838 hours. And each of the total 6,087 establishments will have to annually perform recordkeeping activities for a grand total of 19,549,819 responses and 1,629,152 hours.

**Hazard Analysis and Critical Control Point System-Recordkeeping
(9 CFR 417.5)**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	2,656	2,387	6,339,872	5	528,323
Medium	1,628	3,918	6,378,504	5	531,542
High	388	10,251	3,977,388	5	331,449
State	1,415	2,017	2,854,055	5	237,838
All Establishment s	6,087		19,549,819		1,629,152

Record review

FSIS estimates that each of the 2,656 low volume establishments will have to annually review its HACCP records 2,387 times for a total of 6,339,872 responses and 211,329 hours. Each of the 1,628 medium volume establishments will have to annually review its HACCP records 3,918 times for a total of 6,378,504 responses and 212,617 hours. Each of the 388 high volume establishments will have to annually review its HACCP records 10,251 times for a total of 3,977,388 responses and 132,580 hours. Each of the

1,415 State establishments will have to annually review its HACCP records 2,017 times for a total of 2,854,055 responses and 95,135 hours. And all of the 6,087 establishments will each have to annually review its HACCP a grand total of 19,549,819 responses and 651,661 hours.

**Hazard Analysis and Critical Control Point System-Record Review
(9 CFR 417.5)**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in mins	Total Annual time in hours
Low	2,656	2,387	6,339,872	2	211,329
Medium	1,628	3,918	6,378,504	2	212,617
High	388	10,251	3,977,388	2	132,580
State All Establishments	1,415	2,017	2,854,055	2	95,135
	6,087		19,549,819		651,661

Prerequisites

The Agency estimates that 20 establishments will spend 24 hours developing new prerequisite programs for a total of 20 annual responses and 480 hours. And 6,087 establishments will annually each spend 1 hour in recordkeeping and make 250 responses for an annual total of 1,521,750 responses and

1,521,770 hours.

**Prerequisite Programs
(9 CFR 417.5)**

Type of establishment	Type of collection	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in hours	Total Annual time in hours
All	Prerequisite Program Development	20	1	20	24	480
All	Prerequisite Program Recordkeeping	6,087	250	1,521,750	1	1,521,750
All	Total			1,521,770		1,522,230

The burden estimate is 4,786,793 hours for HACCP information collection activities.

Supplier Information

The Agency estimates that 2,500 grinding establishments will once a year spend an hour on gathering supplier information regarding suppliers of source materials for ground beef.

**Supplier Information
(9 CFR 320.1(b)(1))**

Type of establishment	No. of respondents	Number of responses per respondent	Total Annual Responses	Time for response in hours	Total Annual time in hours
All	2,500	1	2,500	1	2,500

The burden estimate for supplier information is 2,500 hours.

The cost to the respondents is estimated at \$687,619,621 annually. The Agency estimates that it will cost respondents \$97.60 an hour in fulfilling these information collection requirements. Respondents will spend a grand total annually of 7,045,283 hours and \$687,619,621. 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 will approximately a total of \$600,000 capital and start-up costs for the 20 new plants that come under inspection every year.

14. Annual Cost To Federal Government:

The cost to the Federal Government for implementing this program is estimated at \$40,030,899 annually. The Agency estimates a cost of \$45.35 per hour, including fringe benefits, for inspector time. Inspection personnel will review Sanitation SOP records on the average of 15 minutes once a day in each establishment. The Agency estimates a total of 555,439 hours for inspection personnel. Inspection personnel will spend an average of 20 minutes per week per establishment in 2,204 establishments reviewing the microbial program analyses. There will be a total of 38,202 hours. Inspection personnel will review HACCP records an average of 15 minutes a week for an annual total of 100,000 hours. Inspection personnel will review prerequisite program records an average of 15 minutes a week resulting in an annual total of 28,652 hours. And approximately 8,000 inspection personnel will spend 20 hours a year in HACCP training, correlation meetings, and reviewing relevant issuances for an annual total of 160,000 hours. FSIS estimates that inspection personnel will examine the supplier information in 2,500 establishments one time for 10 minutes for an annual total of 417 hours. The Federal Government will expend a total of 882,710 hours.

15. Reasons For Changes In Burden:

There is no change in burden requested for this information collection renewal. Annually, there are 7,045,283 hours, 6,087 respondents, and 44,185,915 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.