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

1. Circumstances Making Collection Of Information Necessary:

This information collection requests an extension and revision of the burden hours approved under control number 0583-0103 which addresses the regulatory requirements in the 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 ensuring that meat and poultry products are safe, wholesome, unadulterated, 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 the establishment 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 noncompliances, 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.

Section 381.94(a) specifies that establishments that slaughter poultry must test for E. coli. Section 381.94 (a) requires establishments to maintain records of analytic results of the sampling tests. According to §381.94 (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 381.94(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 provided that appropriate controls are implemented to ensure the integrity of the electronic data. FSIS estimates that 40% of the recordkeeping will be done electronically.

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.

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 necessarily require daily information collection and recordkeeping by the industry. Therefore, this information collection request is consistent with 5 CFR 1320.5.

8. Consultation With Persons Outside The Agency:

In accordance with the Paperwork Reduction Act, FSIS published a 60-day notice in the Federal Register (72 FR 2852) on January 23, 2007, requesting comments regarding this information collection request. The Agency received no comments. In addition, FSIS contacted an industry association (Lloyd Hontz, (202/639-5924) that

solicited comments from a few of its members. However, the members had no concerns to raise about the information collection *per se*.

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 6,505,024. The burden estimates are broken down into four categories described in the pages that follow.

Standard Operation Plans for Sanitation	1,788,403
Microbiological Testing	280,451
HACCP	4,418,959

Supplier Information	2,500
Total	6,492,313

Standard Operation Procedures (SOP) for Sanitation

Development

Agency subject matter experts and private consultants estimated that it takes an average of 5, 10, and 25 hours to write a sanitation program for low, medium, and high volume establishments, respectively. 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 55 hours developing their SOP; 7 medium volume establishments that will spend an annual total 70 hours developing their SOP; and 2 high volume establishments that will spend an annual total of 50 hours developing their SOP.

SANITATION STANDARD OPERATING PROCEDURES (SOPs) – Plan Development (9 CFR 416.12)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Low	11	1	11	300	55
Medium	7	1	7	600	70
High	2	1	2	1,500	50
All Estabs.	20	1	20	525	175

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. It will take 60, 180, and 360 minutes for low, medium, and high volume establishments to reassess and modify a SOP. FSIS estimates that 5,188 low volume establishments will annually have a total of 15,564 responses and 15,564 hours. The 2,167 medium volume establishments will annually have a total of 4,334 responses and 13,002 hours. The 366 high volume establishments will annually have a total of 2,526 responses and 15,156 hours. And all 7,721 establishments will annually have a grand total of 22,460 responses and 43,722 hours.

SANITATION STANDARD OPERATING PROCEDURES (SOPs) -- Plan Evaluation and Revision (9 CFR 416.14)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Low	5,188	3	15,564	60	15,564
Medium	2,167	2	4,334	180	13,002
High	366	7	2,526	360	15,156
All Estabs.	7,721	2	22,460	180	43,722

Recordkeeping

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 5,188 low volume establishments will perform recordkeeping duties 260 times with a total for all low volume establishments of 1,348,880 responses and 674,440 hours. Each of the 2,167 medium volume establishments will annually perform recordkeeping duties 260 times with a total for all medium volume establishments of 563,420 responses and 563,420 hours. Each of the 366 high volume establishments will annually perform recordkeeping duties 260 times with a total for all high volume establishments of 95,160 responses and 190,320 hours. And each of the 7,721 establishments will annually perform recordkeeping duties an average of 260 times for a grand total for all establishments of 2,007,460 responses and 1,428,180 hours.

SANITATION STANDARD OPERATING PROCEDURES (SOPs) -- Recording and filing (9 CFR 416.16)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Low	5,188	260	1,348,880	30	674,440
Medium	2,167	260	563,420	60	563,420

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
High	366	260	95,160	120	190,320
All Estabs.	7,721	260	2,007,460	60	1,428,180

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 5,198 low volume establishments will annually review its SOP records 260 times for a total for all low volume establishments of 1,351,480 responses and 112,623 hours. Each of the 2,167 medium volume establishments will annually review its SOP records 260 times for a total for all medium volume establishments of 563,420 responses and 93,903 hours. And each of the 366 high volume establishments will annually review its SOP records 900 times for a total for all high volume establishments of 329,400 responses and 109,800 hours. And 7,721 establishments will annually review their SOP records a grand total for all establishments of 2,244,300 responses and 316,326 hours.

SANITATION STANDARD OPERATING PROCEDURES (SOPs) -- Record Review
(9 CFR 416.14 and 416.15)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden t	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Low	5,198	260	1,351,480	5	112,623
Medium	2,167	260	563,420	10	93,903
High	366	900	329,400	20	109,800
All Estabs.	7,721	260	2,244,300	8	316,326

Burden

The burden estimate is 1,789,403 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) and 381.94(a)). To enter data into the chart, review, and file the information will take 5 minutes per sample (cf. §§310.25(a) and 381.94(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, 2 poultry establishments for 50 annual hours, and 4 State programs for 100 annual hours for a grand total of 10 establishments and 250 hours a year.

MICROBIAL TESTING -- Plan Development
(9 CFR 310.25(a) & 381.94(a))

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden t	Total Annual Responses	Time for Respons e in Mins.	Total Annual Time in Hours
Livestock	4	1	4	1,500	100
Poultry	2	1	2	1,500	50
State	4	1	4	1,500	100
Total	10	1	10	1,500	250

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 1,031 livestock establishments will have an annual total of 3,093 responses and 6,186 hours. The 416 poultry establishments will have an annual total of 1,248 responses and 2,496 hours. The 1,463 State establishments will have an annual total of 4,389 responses and 8,778 hours. And all 2,910 establishments will have an annual grand total of 8,730 responses and 17,460 hours.

MICROBIAL TESTING -- Plan Reassessment
(9 CFR 310.25(a) & 381.949a))

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Livestock	1,031	3	3,093	120	6,186
Poultry	416	3	1,248	120	2,496
State	1,463	3	4,389	120	8,778
Total	2,910	3	8,730	120	17,460

Sample Collection

FSIS estimates that each of the 800 low volume establishments will have to annually collect samples 26 times for a total for all low volume establishments of 20,800 responses and 10,400 hours. Each of the 447 medium

volume establishments will have to annually collect samples 86 times for a total for all low volume establishments of 38,442 responses and 19,221 hours annually. Each of the 200 high volume establishments will have to annually collect samples 1,758 times for a total for all high volume establishments of 351,600 annual responses and 175,800 hours. Each of the 1, 463 State establishments will have to annually collect samples 27 times for a total for all state establishments of 39,501 responses and 19,751hours. And each of the 2,910 total number of establishments will have to annually collect on the average 251 samples for a grand total for all establishments of 450,343 annual responses and 223,172 hours.

MICROBIAL TESTING -- Sample Collection
(9 CFR 310.25(a) & 381.94(a))

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Low	800	26	20,800	30	10,400
Medium	447	86	38,442	30	19,221
High	200	1,758	351,600	30	175,800
State	1,463	27	39,501	30	19,751
Total	2,910	251	450,343	30	223,172

Recording

FSIS estimates that each of the 800 low volume establishments will have to annually record microbial testing results 26 times for a total for all low volume establishments of 20,800 responses and 1,733 hours. Each of the 447 medium volume establishments will have to annually record microbial testing results 86 times for a total for all medium volume establishments of 38,442 responses and 3,204 hours. Each of the 200 high volume establishments will have to annually record microbial testing results 1,758 times for a total for all high volume establishments of 351,600 responses and 29,300 hours. Each of the 1,463 State establishments will have to annually record microbial testing results 27 times for a total for all state establishments of 39,501 responses and 3,292 hours. And each of the 2,910 establishments will have to annually record microbial testing results an average of 251 times for a grand total for all establishments of 450,000 responses and 37,569 hours.

MICROBIAL TESTING -- Recording
(9 CFR 310.25(a) & 381.94(a))

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Low	800	26	20,800	5	1,733
Medium	447	86	38,442	5	3,204
High	200	1,758	351,600	5	29,300
State	1,463	27	39,501	5	3,292
Total	2,910	251	450,343	5	37,569

Burden

The burden estimate is 280,451 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 Development

The Agency estimates that 6 new low volume establishments will each spend 8,160 minutes for an annual total of 816 hours developing their HACCP plans. The 5 new medium volume establishments will each spend 7,560 minutes for an annual total of 630 hours developing their HACCP plans. The 5 new high volume establishments will each spend 6,780 minutes for an annual total of 118 hours. The 4 new State establishments will each spend 4,680 minutes and an annual total of 312 hours developing their HACCP plans. And all 20 new establishments will each average 1,359 minutes and spend a grand total of 1,876 hours developing their HACCP plans.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM -- Plan Development
(Part 417.2)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Low	6	1	6	8,160	816
Medium	5	1	5	7,560	630
High	5	1	5	6,780	118
State	4	1	4	4,680	312
All Estabs.	20	1	20	1,359	1,876

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 1,500 minutes per reassessment. Reassessment of HACCP plans includes both analysis and the time it takes to actually modify their HACCP plan. The 2,694 low volume establishments will have annual total of 13,470 responses and 336,750 hours. The 2,118 medium volume establishments will have an annual total of 10,590 responses and 264,750 hours. The 366 high volume establishments will have an annual total of 1,830 responses and 45,750 hours. The 2,543 State plants will have an annual total of 12,715 responses and 317,875 hours. And all 7,721 establishments will have a grand total of 38,605 responses and 965,125 hours.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM -- Plan Reassessment (Part 417.4)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Low	2,694	5	13,470	1,500	336,750
Medium	2,118	5	10,590	1,500	264,750
High	366	5	1,830	1,500	45,750
State	2,543	5	12,715	1,500	317,875
All Estabs.	7,721	5	38,605	1,500	965,125

Recordkeeping

The Agency estimates that each of the 2,694 low volume establishments will have to annually perform recordkeeping activities 2,387 times for a total for all low volume establishments of 6,430,578 responses and 535,882 hours. Each of the 2,118 medium volume establishments will have to annually perform recordkeeping activities 3,918 times for a total for all medium volume establishments of 8,298,324 responses and 691,527 hours. Each of the 366 high volume establishments will have to annually perform recordkeeping activities 10,251 times for a total for all high volume establishments of 3,751,866 responses and 312,655 hours. Each of the 2,543 State establishments will have to annually perform recordkeeping activities 2,017 times for a total for all State establishments of 5,129,231 responses and 427,436 hours. And each of the total 7,721 establishments will have to annually perform recordkeeping activities an average of 3,528 times for a grand total of 23,609,999 responses and 1,967,500 hours.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM -- Recordkeeping (Part 417.5)

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
Low	2,694	2,387	6,430,578	5	535,882
Medium	2,118	3,918	8,298,324	5	691,527
High	366	10,251	3,751,866	5	312,655
State	2,543	2,017	5,129,231	5	427,436
All Estabs.	7,721	3,528	23,609,999	5	1,967,500

Record review

FSIS estimates that each of the 2,694 low volume establishments will have to annually review its HACCP records 2,387 times for a total of 6,430,578 responses and 214,353 hours. Each of the 2,118 medium volume establishments will have to annually review its HACCP records 3,918 times for a total of 8,298,324 responses and 276,611 hours. Each of the 366 high volume establishments will have to annually review its HACCP records 18,200 times for a total of 6,661,200 responses and 222,040 hours. Each of the 2,543 State establishments will have to annually review its HACCP records 2,017 times for a total of 5,129,231 responses and 170,974 hours. And all of the 7,721 establishments will each have to annually review its HACCP records an average of 3,528 times for a grand total of 26,519,333 responses and 883,978 hours.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM -- Record Review (Part 417.5))

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Responden t	Total Annual Responses	Time for Respons e in Mins.	Total Annual Time in Hours
Low	2,694	2,387	6,430,578	2	214,353
Medium	2,118	3,918	8,298,324	2	276,611
High	366	18,200	6,661,200	2	222,040

Type of Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
State	2,543	2,017	5,129,231	2	170,974
All Estabs.	7,721	3,528	26,519,333	2	883,978

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 2,400 establishments will annually each spend 1 hour in recordkeeping and make 250 responses for an annual total of 600,000 responses and 600,000 hours.

HAZARD ANALYSIS AND CRITICAL CONTROL POINT SYSTEM – Prerequisite Programs

(Part 417.5)

Type of Establishment	Type of Collection	No. of Respondents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
All	Prerequisite Program	20	1	20	24	480

Type of Establishment	Type of Collection	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Hours	Total Annual Time in Hours
	Development					
All	Prerequisite Program Recordkeeping	2,400	250	600,000	1	600,000
All	Total	2,400	250	600,020	1	600,480

The burden estimate is 4,418,959 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 Establish-Ment	No. of Respon-dents	No. of Res-ponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
All Estabs.	2,500	1	2,500	60	2,500

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

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 implementing this program is estimated at $27,645,150 million annually. The cost estimate includes records review time of FSIS inspection personnel (GS 7/9/11) and staff officers (GS 11/12). The Agency estimates a cost of $30 per hour 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 579,075 hours for inspection personnel in all 7,721 establishments for a total of $17,372,250. Inspection personnel will spend an average of 20 minutes per week per establishment in 2,910 establishments reviewing the microbial program analyses. There will be a total of 50,440 hours for a total of $1,513,200. Inspection personnel will review HAACP records an average of 15 minutes a week for all 7,721 establishments for an annual total of 100,373 hours and $3,011,190. Inspection personnel will review prerequisite program records an average of 15 minutes a week for 2,400 establishments resulting in an annual total of 31,200 hours and $936,000. 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 and $4,800,000. 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 and $12,510.

The cost to the respondents is estimated at $389,416,440 million annually. The Agency estimates that it will cost respondents $60 an hour in fulfilling these paperwork requirements. Respondents will spend an annual total 1,788,403 hours and $107,304,180 on Sanitation SOPs. Respondents will spend an annual total of 280,451 hours and $16,827,060 on responding to microbial sampling program requirements. Respondents will spend 4,418,959 hours and $265,137,540 responding to HACCP requirements. Respondents will spend 2,500 hours and $150,000 annually on maintaining supplier information. Respondents will spend a grand total annually of 6,492,313 hours and $389,538,780 million.

15. Reasons For Changes In Burden:

The number of burden hours decreased from 7,469,639 to 6,492,313 because more recent and better data showed that the number of plants (and the number of high volume plants) has decreased. In addition, the $243,000 in costs due to annualized capital/start up costs has been removed because HACCP is fully implemented in the industry.

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.