Under the previous terms of clearance for the approval of the current information collection for Listeria Controls of Ready-to-Eat product the Agency had to address several questions raised by OMB before this information collection could receive approval.

...the agency should determine whether annual updates of production at the level of detail currently required are necessary. As establishments adapt to the new regulatory approach, the agency should determine whether the detailed information on approaches for Listeria reduction could be collected on a less frequent basis, e.g., establishments with no change in approach to Listeria reduction, could report Production volume and verify/certify that distribution of production and approach remains unchanged.

In the final rule that FSIS is pursuing for Listeria controls in RTE establishments, the Agency will permit RTE establishments after their initial submission of their annual production volume and related information to not have to report the information again until changes occur in their estimated annual production volume or their Listeria controls.

In addition, the agency should provide to OMB a full explanation/demonstration of how the information is used to conduct risk based inspections.

Each page in FSIS Form 10,240-1 collects specific establishment information for production volume of specific ready-to-eat (RTE) products regulated by 9 CFR 430.1 (Requirements for Specific Classes of Products) and information concerning establishment control measures for Listeria monocytogenes regulated by 9 CFR 430.4 (Control of *Listeria monocytogenes* in Post-Lethality Exposed Ready-to-Eat Products). The pages are arranged such that page 1 collects information only from establishments claiming to follow Alternative 1 control measures (establishments using both a post-lethality treatment (such as steam or hot water pasteurization or high pressure process) and an antimicrobial agent (such as sodium diacetate, potassium lactate, or inhibitor packaging) or process (such as freezing or drying) in post-lethality exposed RTE products). Page 2 collects information from establishments claiming to follow Alternative 2 control measures (only a post-lethality treatment or an antimicrobial agent or process is used in combination with a sanitation program and testing). Page 3 collects information from establishments claiming to follow Alternative 3 (only a sanitation program with testing is used). Page 4 provides instructions and definitions not provided on pages 1 through 3. This format allows establishments to report production of RTE products under more than one sanitation control alternative. Repetition of establishment profile information on the first three pages permits segregation of pages as complete blocks of establishment information by alternative.

Below is a detailed discussion of the information collected by the form and how the Agency uses the data.

Page 1. Alternative 1 (establishments using both a post-lethality treatment (such as steam or hot water pasteurization or high pressure process) and an antimicrobial agent (such as sodium diacetate, potassium lactate, or inhibitor packaging) or process (such as freezing or drying) in post-lethality exposed RTE products)
Elements 1a. through f. 1a. Establishment Name, 1b. Establishment Number, 1c. Street Address, 1d. City, 1e. State, and 1f. Zip Codes are used to identify and update the establishment information and verify that we have the current establishment information in our database.

Page 1. Element 2. requires the listing of pounds of RTE products produced under the definition of post-lethality exposed products in 9 CFR 430.1 in the categories of deli meat sliced (within the establishment) and unsliced (to be sliced later outside the establishment), hot dog products (as defined by 9 CFR 319.180 and 9 CFR 319.181 (9 CFR 430.1)), fully cooked products, fermented products (with or without cooking), dried products, salt-cured products, frozen products, and paté. Each of these RTE product categories is used as a weighted risk factor in the establishment Listeria monocytogenes risk ranking algorithm on a monthly basis to identify plants with the greatest risk to be selected for sampling verification. A negative sample verifies that the zero tolerance policy for Listeria monocytogenes in product is met. A positive sample indicates the need for corrective action and further testing and possible regulatory action. The risk ranking algorithm has been peer reviewed and is posted on the FSIS website in the FSIS Risk Assessment for Risk-Based Verification Sampling of *Listeria monocytogenes*. This information is used to populate the establishment risk ranking algorithm with the most current RTE product volume risk factor data which constitute important risk factors and determine establishment risk and therefore ranks the establishment for prioritization in sampling verification testing on a monthly basis. Even though establishment risk factors taken from FSIS Form 10,240.1 may only change infrequently, it is necessary to update the establishment database used in generating monthly establishment risk rankings whenever a new form is submitted. The monthly risk ranking variability is dependent on positive and negative Listeria monocytogenes culture results from RTE products, food contact surfaces used in producing these products, and the processing environmental areas in which these products are produced. Positive cultures increase establishment risk ranking and negative cultures reduce establishment risk ranking across the risk alternatives.

Page 1. Element 3. requires checking the appropriate boxes on the form identified for deli meat unsliced, deli meat sliced, hot dogs, fully cooked products, fermented products, dried products, salt-cured products, frozen product, and paté that may be produced annually and fulfill the requirements for validation categories A and B and food contact surface testing category C.

Category A requires a statement of validated Listeria monocytogenes log reduction by the applied post-lethality treatment as either more than 2 logs, 2 logs, 1 log, or less than 1 log. These are all in logarithm base 10 units for the number of

bacteria per gram of product or similar unit. These data are used to confirm that the establishment conforms to 9 CFR 430.4 that requires a validated Listeria monocytogenes log reduction for the post-lethality treatment used. This is also documentation for confirming and updating the validation for the log reduction achieved by the post-lethality process used according to 9 CFR 417.4 for verifying this requirement in the establishment HACCP plan. The purpose of collecting this information is for verification that a validated post-lethality process is being used so that the data can be used for risk factors in the establishment risk ranking algorithm. Specific data on individual establishments are needed to assess individual plant risk and rank the establishment according to the reported product volume and risk alternative claimed since the risk ranking of each establishment's claimed risk alternative is calculated monthly and the alternative with the greatest risk is used to constitute the monthly sampling verification frame.

Category B requires a statement of validated log increase in Listeria monocytogenes allowed by the antimicrobial agent or process used for each of the RTE product categories produced. There are check boxes for less than 1 log, 1 log, 2 logs, and more than 2 logs for each of the seven RTE product categories. These are all in logarithm base 10 units for the number of bacteria per gram of product or similar unit. These data are used to confirm that the establishment conforms to 9 CFR 430.4 that requires a validated Listeria monocytogenes permitted log increase for the antimicrobial agent or process used. This is also documentation for updating the validation of the permitted log increase of the antimicrobial agent or process used. The purpose of collecting this information is for verification that a validated permitted log increase from antimicrobial agent of process is being used in the establishment HACCP plan accordance with 9 CFR 417.4. This verification is the basis for including the establishment data in the risk ranking algorithm so that the establishment risk can be calculated on a monthly basis.

Category C requires a statement for the frequency of testing food contact surfaces per line per year for Listeria monocytogenes verification testing for each of the RTE product categories produced. There are four check boxes with one for greater than four times, one for three to four times, one for two times, and one for less than two times. These data are used to update the 2003 dynamic in-plant model for *Listeria monocytogenes* Deli Meat Risk Model taken from the FDA/FSIS Quantitative Assessment of Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods (Sept 2003). Frequency of testing is one of the risk factor distributions that must reflect the current establishment activity distribution to be accurate. Current accuracy of the risk assessment model is needed because it provides the basis for the establishment risk ranking algorithm used to rank plants on a monthly basis. This information is needed to update the establishment risk ranking algorithm used on a monthly basis. This information confirms that the establishment is eligible for alternative 1 risk, which usually means the establishment will be sampled at the lowest verification frequency compared to another establishment producing the same volumes of RTE products but in a higher risk alternative. This is an important incentive for establishments to adopt the lowest risk alternative economically possible. Establishments operating under the lowest risk alternatives have been shown to have

the smallest public health risk.

Page 1. Elements 4, 5, and 6. These are for printed name/title of authorized establishment official, the corresponding signature, and the data. These elements are necessary to validate the documentation provided such that a legal document is produced.

Page 2. Alternative 2 (establishments using only a post-lethality treatment (such as steam or hot water pasteurization or high pressure process) or an antimicrobial agent (such as sodium diacetate, potassium lactate, or inhibitor packaging) or process (such as freezing or drying) in post-lethality exposed RTE products)
Elements 1a. through f. 1a. Establishment Name, 1b. Establishment Number, 1c. Street Address, 1d. City, 1e. State, and 1f. Zip Codes are used to identify the establishment and verify that we have the current establishment information in our database.

Page 2. Element 2. requires the listing of pounds of RTE products produced under the definition of post-lethality exposed products in 9 CFR 430.1 in the categories of deli meat sliced (within the establishment) and unsliced (to be sliced later outside the establishment), hot dog products (as defined by 9 CFR 319.180 and 9 CFR 319.181 (9 CFR 430.1)), fully cooked products, fermented products (with or without cooking), dried products, salt-cured products, frozen products, and paté. Each of these seven elements is used as a weighted risk factor in the establishment Listeria monocytogenes risk ranking algorithm on a monthly basis to identify plants with the greatest risk to be selected for sampling verification. A negative sample verifies that the zero tolerance policy for Listeria monocytogenes in product is met. A positive sample indicates the need for corrective action and further testing and possible regulatory action. The risk ranking algorithm has been peer reviewed and is published on the FSIS website. This information is used to populate the establishment risk ranking algorithm with the most current RTE product volume risk factor data and alternative assignment which constitute important risk factors and determine establishment risk and therefore ranks the establishment for prioritization in sampling verification testing on a monthly basis.

Page 2. Element 3. requires checking the appropriate boxes on the form identified for deli meat unsliced, deli meat sliced, hot dogs, fully cooked products, fermented products, dried products, salt-cured products, frozen product, and paté that may be produced annually.

There are four question categories labeled A through D for element 3. The questions are to be answered as A and B (for establishments using antimicrobial agents only) or C and D (for establishments using a post-lethality treatment only). Establishments answering A and B must fulfill the requirements for validation category A used for validation of permitted log increase in Listeria monocytogenes when using an antimicrobial agent or process and category B for recording the

frequency of testing of food contact surfaces per line each year if using an antimicrobial agent. Category A has four levels for maximum allowable growth: less than 1 log; 1 log; 2 logs; more than 2 logs. Category B has four levels of testing frequency per line annually: more than 8 times; 5 to 7 times; 4 times; and less than 4 times.

Establishments answering C and D must fulfill the requirements for validation category C for maximum allowable log increase using the post-lethality treatment and category D for recording the frequency of food contact surface testing per line annually when using the post-lethality treatment only. Category C has four levels of answers for the validated log reduction of Listeria monocytogenes in product when using a post-lethality treatment only: more than 2 logs; 2 logs; 1 log; less than 1 log. Category D has four levels of answers for frequency of testing food contact surfaces per line annually when using a post-lethality treatment only: more than 8 times; 5 to 8 times; 4 times; less than 4 times.

This information is required for verification that the establishment is eligible for alternative 2a (answers only to question categories A and B) or alternative 2b (answers only to question categories C and D) so that the element 2 information may be used to update the establishment database used for Listeria monocytogenes risk-based sampling verification. The classification of an establishment to alternative 2a or 2b in the risk ranking algorithm is an important incentive due to a lower frequency of sampling verification testing by FSIS that is directly related to a lower public health risk relative to higher risk alternatives. Alternative 2a has a diminished public health risk relative to alternative 2b and alternative 2 has a relatively lower frequency of sampling verification than alternative 3. The documentation of the answers to questions A through D are required from 9 CFR 430.1, 9 CFR 430.4, and 9 CFR 417.4 to verify the establishment is operating under alternative 2a or alternative 2b. This information is required for use of the product volume data in the establishment risk ranking algorithm and the proper establishment assignment to risk alternative since alternative is also a risk factor in the risk ranking algorithm.

Page 2. Elements 4, 5, and 6. These are for printed name/title of authorized establishment official, the corresponding signature, and the data. These elements are necessary to validate the documentation provided such that a legal document is produced.

Page 3. Alternative 3 (establishments using only a sanitation program with testing).
Elements 1a. through g. 1a. Establishment Name, 1b. Establishment Number, 1c. Street Address, 1d. City, 1e. State, 1f. Zip Code, and 1g. Plant Size Category are used to identify the establishment and verify that we have the current establishment information in our database. Plant size is used as the proxy risk factor for total production volume in the original in-plant dynamic model for deli meat (2003). Plant size is used to subcategorize three levels of risk within the alternative risks. In total, there are twelve subcategories used as risk factors in the establishment risk ranking algorithm.

Page 3. Element 2. requires the listing of pounds of RTE products produced under the definition of post-lethality exposed products in 9 CFR 430.1 in the categories of deli meat sliced (within the establishment) and unsliced (to be sliced later outside the establishment), hot dog products (as defined by 9 CFR 319.180 and 9 CFR 319.181 (9 CFR 430.1)), fully cooked products, fermented products (with or without cooking), dried products, salt-cured products, frozen product, and paté. Each of these seven elements is used as a weighted risk factor in the establishment Listeria monocytogenes risk ranking algorithm on a monthly basis to identify plants with the greatest risk to be selected for sampling verification.

Page 3. Element 3. has question categories A, B, and C. Question A asks for the testing frequency of food contact surfaces per line per month in six levels for each of the RTE product categories (sliced deli meat, unsliced deli meat, hot dogs, fully cooked product, fermented product, dried product, salt-cured product, frozen product, and paté) . The frequency levels are: more than 4 times; 4 times; 3 times; 2 times; 1 time; less than 1 time. The frequency of testing distribution of establishments is required for updating the in-plant dynamic model for determining establishment risk at the risk alternative level and individual establishment risk using the risk ranking algorithm, which is derived from the in-plant dynamic model. Performance measures for the risk-based sampling verification testing program are derived from the 2001 FDA/FSIS risk assessment model based on the 2003 in-plant dynamic model estimates of Listeria monocytogenes product contamination at retail that is converted to expected foodborne cases of human listeriosis due to consumption of FSIS regulated products. Current performance measures rely on calibrating the expected number of listeriosis cases from alternative 3 with the accumulated laboratory confirmed cases of listeriosis due to public health surveillance of sporadic and outbreak cases.

The agency should also ensure that this collection is fully compliant with E-Gov initiatives (GPEA).

Establishments may submit FSIS Form 10,240-1 electronically.

SUPPORTING STATEMENT JUSTIFICATION FOR
LISTERIA CONTROL FOR READY-TO-EAT PRODUCTS

1. Circumstances Making Collection Of Information Necessary:

This information collection requests a revision to an approved information collection for regulatory reporting requirements associated with the control of Listeria monocytogenes in Ready-to-Eat products (RTE).

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, unadulterated, and properly labeled and packaged.

FSIS is requiring official establishments that produce certain ready-to-eat (RTE) meat and poultry products to take measures to prevent product adulteration by the pathogenic environmental contaminant Listeria monocytogenes. The regulations (9 CFR 430.4) particularly affect establishments that produce RTE meat and poultry products that are exposed to the environment after lethality treatments and that support the growth of L. monocytogenes. Establishments must employ one of four distinct methods found in the regulations. These establishments must share with FSIS data and information relevant to their controls for L. monocytogenes (§430.4(f)).

Listeria monocytogenes control alternatives for establishments that produce ready-to-eat (RTE) meat and poultry products:

Alternative 1. Control of L. monocytogenes in a post-lethality exposed RTE product through a post-lethality treatment and an antimicrobial agent or process that suppresses or limits the growth of L. monocytogenes.

Alternative 2. Control of L. monocytogenes in such a product is accomplished through either a post-lethality treatment or an antimicrobial agent or process that suppresses or limits the growth of L.

monocytogenes, But not both.

Alternative 3. (i) Control of L. monocytogenes in such a product that is not a deli product is accomplished by sanitation procedures only.

(ii) Control of L. monocytogenes in such a post-lethality exposed deli product is accomplished by sanitation procedures only. After two consecutive positive tests for Listeria spp. or Listeria-like organisms on a food contact surface in the post-lethality exposure area, the establishment must hold subsequent lots of product until corrective actions have been completed in area of the food contact surfaces and until the held product has been sampled and tested using sampling plans whose level of confidence is sufficient to enable the establishment to determine that the product is not adulterated with L. monocytogenes. Alternatively, the held lots may be reprocessed or destroyed for human food purposes.

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

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

RTE Production Volume Estimate

Official establishments that produce RTE meat and poultry products must annually furnish FSIS with information on the production volume of RTE products affected by the regulations and the control measures used by the establishments (§430.4). The establishments must provide an estimate of production volume by product type and regulatory control method used for the upcoming year.

FSIS will use the information collected from the Production Information on Post-Lethality Exposed RTE Products form to help target resources and direct verification activities. The Agency plans to schedule verification tests more frequently for processing operations that incorporate Listeria controls with less risk reduction potential than other controls. The information obtained through the use of the form will enable the Agency to identify and distinguish among establishments and RTE product processing operations and enable the Agency to determine relative volumes of product produced under various Listeria control approaches. The data will be used to modify the current FSIS risk assessment of Listeria monocytogenes in deli meats, which in turn will be used to evaluate the Agency's risk-based verification sampling protocols for deli meats.

The relative product volume information is also necessary to establish a sounder scientific basis for the Agency's automated programs for random sampling of RTE products and for trend analysis. The Agency needs to know, for example, the changes of prevalence of Listeria in RTE products as

establishments change Listeria control methods or adopt new processes that eliminate product exposure to the post-lethality processing environment. The information from the form and the results of verification activities associated with the Listeria control regulation will help the Agency to decide how much verification testing for Listeria to do in a given year, what products processed under what conditions to test, and how many laboratory and other resources to allocate to Listeria control rather than to other important public health activities.

The "sub-questions" for each Alternative on the form provide important information to the Agency allowing it to characterize the relative risks associated with the product and the Listeria control chosen by the establishment. Establishments that achieve greater log reductions or stricter growth limitations would be presumed to have more effective controls. The characterization of relative risks will provide the Agency with the basis for a risk-based sampling plan of RTE establishments and/or products. The Agency also will take the relative risks into account when deploying inspection resources.

Recognizing the dynamic nature of the processed RTE foods industry, and that changes in equipment and processes are relatively frequent, FSIS is asking that establishments provide the information the information requested on the form at least annually. The Agency will then have reasonably accurate information on the Listeria control methods that establishments are using and the amount and types of products affected by the controls.

If an establishment produced several kinds of deli product, it would only have to provide aggregate estimates of its deli products on the form.

Develop Microbiological Sampling Plan

RTE establishments must develop a microbiological sampling and testing plan to support the efficacy of sanitation controls, including test and hold procedures for product to test for L. monocytogenes or other indicator organisms (§430.4). RTE establishments need to develop microbiological sampling plans to ensure that their sanitation procedures are adequate.

Food-Contact Surface Sampling

RTE establishments must sample food-contact surfaces (§430.4). RTE establishments are required to sample and test food contact surfaces to verify that their Listeria Controls are working. Controls that provide less risk reduction call more for testing.

Hold and Test Sampling

Some RTE establishments will have to hold and test product for L. monocytogenes and other indicator organisms (§430.4). RTE establishments that use Listeria controls that have less risk-reduction potential and produce products that pose greater risks must have procedures for holding and testing product when necessary to verify that their post-lethality exposed products are not adulterated.

There are a total of 30,055 burden hours for the information collection requests related to the control of L. monocytogenes.

3. Use Of Improved Information Technology:

Under the Government Paperwork Elimination Act, FSIS is offering an electronic fillable PDF version of the form that may be submitted electronically. Establishments may also use electronic recordkeeping.

4. Efforts To Identify Duplication:

No FSIS office, USDA agency or any other Government agency requires information regarding Listeria control by production type and volume for RTE product. There are no other requirements for RTE establishments to sample product for Listeria or test food-contact surfaces. 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 producing RTE meat and poultry products to ensure wholesome and unadulterated products.

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 satisfy food safety concerns it is necessary to collect some information more frequently than quarterly; 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, on March 7, 2007, FSIS published in the Federal Register a 60-day notice (72 FR 10135) requesting comments regarding this information collection request. The Agency received no comments on the paperwork burden. FSIS also contacted an industry trade association (Lloyd Hontz; 202/639-5924) which in turn contacted a few of its members. Only one member had comments. Because of the member's comments, FSIS doubled its estimate on the amount of time it takes large RTE establishments to estimate their ready-to-eat production volume.

9. Payment or Gifts to Respondents:

Respondents will not receive any gifts or payments.

10. Confidentiality Provided To Respondents:

No assurances other than routine protection provided under the Freedom of Information Act have been provided to respondents.

11. Questions Of A Sensitive Nature:

The applicants are not asked to furnish any information of a sensitive nature.

12. Estimate of Burden

The total burden estimate for the reporting and recordkeeping requirements associated with this information collection is 30,055 hours. The burden estimates are broken down into four categories described in the pages that follow.

RTE Production Volume Estimate	4,160
Development of Microbiological Sampling Plan	285
Reassess and Revise Sampling Plan	8,320
Sampling Food-Contact Surfaces	17,170
Test and Hold Product Sampling	120
Total	30,055

RTE Production Volume Estimate

FSIS estimates that there are 3,590 RTE establishments and that they will average one response per year for a total of 3,590 responses. The Agency estimates that 190 large RTE establishments will take 240 minutes, 1,400 small RTE establishments will take 60 minutes, and 2,000 very small RTE establishments will also take 60 minutes to develop their RTE Production Volume Estimate for a total of 4,160 hours.

RTE PRODUCTION VOLUME ESTIMATE
(9 CFR 430.4--FSIS Form 10,240-1)

Type of Establish-ment	No. of Respondents	No. of Re-sponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
RTE Large	190	1	190	240	760
RTE Small	1,400	1	1,400	60	1,400
RTE Very Small	2,000	1	2,000	60	2,000
Total	3,590	1	3,590	60	4,160

Develop Microbiological Sampling Plans

RTE establishments must plan, conduct, and report sampling of food-contact surfaces. FSIS estimates that it will take 1 large RTE establishments 3,600 minutes, 4 small RTE establishments and 5 very small RTE establishments 1,500 minutes to develop a microbiological sampling and testing plan to support the efficacy of the sanitation controls, including the development of test and hold procedures. And 10 RTE establishments will each develop one plan for a total of 10 responses and 285 hours.

DEVELOP RTE MICRO SAMPLING PLAN
(9 CFR 430.4)

Type of Establish-ment	No. of Respondents	No. of Re-sponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
RTE Large	1	1	1	3,600	60
RTE Small	4	1	4	1,500	100
RTE Very Small	5	1	5	1,500	125
Total	10	1	10	1,500	285

Reassess and Revise Microbiological Sampling Plan

The Agency estimates that small and very small RTE establishments may have to reassess their sampling plans as frequently as twice a year and large RTE establishments four times a year for a total of for an annual total of 7,560 responses. It will take large RTE establishments 120 minutes and small and very small RTE establishments 60 minutes to reassess and revise their sampling plans for an annual total of 8,320 hours.

REASSESS AND REVISE RTE SAMPLING PLANS
(9 CFR 430.4)

Type of Establish-ment	No. of Respondents	No. of Re-sponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
RTE Large	190	4	760	120	1,520
RTE Small	1,400	2	2,800	60	2,800
RTE Very Small	2,000	2	4,000	60	4,000
Total	3,590	2	7,560	60	8,320

Food-Contact Surface Sampling

The Agency estimates that it will take an average of 60 minutes for large RTE establishments and 30 minutes for small and very small RTE establishments to conduct a food contact surface sampling.

RTE establishments under Alternative I—30 large establishments, 100 small establishments, and 20 very small establishments--will sample once a year; RTE establishments under Alternative II—120 large establishments, 800 small establishments, and 480 very small establishments--will sample once a quarter. RTE establishments under Alternative III i—30 large establishments, 300 small establishments, and 1,000 very small establishments—will test once a month. And for those under Alternative III ii—10 large establishments will sample 4 times a month, 200 small establishments will sample 2 times a month, and 500 very small establishments will sample once a month. Therefore, there is a grand annual total of 4,975 respondents who will have 33,990 responses and 17,170 hours.

SAMPLING FOOD CONTACT SURFACES – ALTERNATIVE I
(9 CFR 430.4)

Type of Establish-ment	No. of Respondents	No. of Re-sponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
RTE Large	30	1	30	60	30
RTE Small	100	1	100	30	50
RTE Very Small	20	1	20	30	10
Total	150	1	150	30	90

SAMPLING FOOD CONTACT SURFACES – ALTERNATIVE II

(9 CFR 430.4)

Type of Establishment	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
RTE Large	120	4	480	60	480
RTE Small	800	4	3,200	30	1,600
RTE Very Small	480	4	1,920	30	960
Total	1,400	4	6,600	30	3,040

SAMPLING FOOD CONTACT SURFACES – ALTERNATIVE III i
(9 CFR 430.4)

Type of Establish-ment	No. of Respondents	No. of Re-sponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
RTE Large	30	12	360	60	360
RTE Small	300	12	3,600	30	1,800
RTE Very Small	1,000	12	12,000	30	6,000
Total	1,330	12	15,960	30	8,160

SAMPLING FOOD CONTACT SURFACES – ALTERNATIVE III ii
(9 CFR 430.4)

Type of Establish-ment	No. of Respondents	No. of Re-sponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
RTE Large	10	48	480	60	480
RTE Small	200	24	4,800	30	2,400
RTE Very Small	500	12	6,000	30	3,000
Total	710	15	11,280	30	5,880

Hold and Test Product Sampling

And some RTE establishments may have to hold and test product for Listeria monocytogenes and other indicator organisms. Large establishments will take 60 minutes to hold and test and small and very small RTE establishments will take 30 minutes to hold and test product. The Agency estimates that one large establishment, 36 small establishments, and 82 very small establishments will have to hold and test twice a year for a total of 238 annual responses and 120 hours.

HOLD AND TEST PROCEDURES SAMPLING FOR RTE PRODUCT
(9 CFR 430.4)

Type of Establish-ment	No. of Respondents	No. of Re-sponses per Respondent	Total Annual Responses	Time for Response in Mins.	Total Annual Time in Hours
RTE Large	1	2	2	60	2
RTE Small	36	2	72	30	36
RTE Very Small	82	2	164	30	82
Total	119	2	238	30	120

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 collecting this information is estimated at $300,000 annually. The cost estimate includes a cost of $30 an hour for inspection program personnel time.

The cost to respondents is estimated at $901,650 annually. The Agency estimates it will cost respondents $30 an hour in fulfilling these paperwork requirements. Respondents will spend an annual total of 30,055 hours and $901,650 on this requirement.

15. Reasons For Changes In Burden:

This is an adjustment of -139,267 hours due to fewer larger plants based on the most recent plant data.

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 the form the Agency uses to collect the data.

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.