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 (L. 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 L. 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)).

L. monocytogenes control alternatives for establishments that produce 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 the 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 (FSIS Form 10,240-1) to help target resources and direct verification activities. The Agency plans to schedule verification tests more frequently for processing operations that incorporate L. monocytogenes 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 L. monocytogenes control approaches. The data will be used to modify the current FSIS risk assessment of L. 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 L. monocytogenes in RTE products as establishments change L. monocytogenes 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 L. monocytogenes control regulation will help the Agency to decide how much verification testing for L. monocytogenes to do in a given year, what products processed under what conditions to test, and how many laboratory and other resources to allocate to L. monocytogenes 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 L. monocytogenes 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 requested on the form at least annually. The Agency will then have reasonably accurate information on the L. monocytogenes 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 L. monocytogenes 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 L. monocytogenes 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 26,317 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 L. monocytogenes control by production type and volume for RTE product. There are no other requirements for RTE establishments to sample product for L. monocytogenes 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 August 6, 2010, FSIS published in the Federal Register a 60-day notice (75 FR 47524) requesting comments regarding this information collection request. The Agency received no comments on the paperwork burden. FSIS also contacted an industry trade association (Jay Wenther; 717/367-1168) which in turn contacted a few of its members. Four members had comments. Most of the comments regarding RTE Production Volume Estimate, Development of Microbiological Sampling Plan, and Sampling Food-Contact Surfaces stated burden estimates that were close to FSIS' burden estimates. Therefore, FSIS continues to believe its burden estimates for these categories are accurate. Because of the members' comments on Reassess and Revise Sampling Plan and Test and Hold Product Sampling, FSIS doubled its estimate on Hold and Test Product Sampling and increased the estimate for the number of times per year entities hold product. FSIS also increased its estimate of the time it takes to reassess and revise a sampling plan by 30 minutes.

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 26,317 hours. The burden estimates are broken down into four categories described in the pages that follow.

RTE Production Volume Estimate	2,426
Development of Microbiological Sampling Plan	285
Reassess and Revise Sampling Plan	7,080
Sampling Food-Contact Surfaces	16,050
Test and Hold Product Sampling	476
Total	26,317

RTE Production Volume Estimate

FSIS estimates that there are 2,129 RTE establishments and that they will average one response per year for a total of 2,129 responses. The Agency estimates that 99 large RTE establishments will take 240 minutes, 961 small RTE establishments will take 60 minutes, and 1,069 very small RTE establishments will also take 60 minutes to develop their RTE Production Volume Estimate for a total of 2,426 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	99	1	99	240	396
RTE Small	961	1	961	60	961
RTE Very Small	1,069	1	1,069	60	1,069
Total	2,129		2,129		2,426

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		10		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 an annual total of 4,456

responses. It will take 99 large RTE establishments 150 minutes and 961 small and 1,069 very small RTE establishments 90 minutes to reassess and revise their sampling plans for an annual total of 2,129 respondents 4,456 responses and 7,080 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	99	4	396	150	990
RTE Small	961	2	1,922	90	2,883
RTE Very Small	1,069	2	2,138	90	3,207
Total	2,129		4,456		7,080

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—17 large establishments, 59 small establishments, and 35 very small establishments--will sample once a year; RTE establishments under Alternative II—89 large establishments, 397 small establishments, and 227 very small establishments--will sample once a quarter. RTE establishments under Alternative III i—30 large establishments, 573 small establishments, and 784 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 2,901 respondents who will have 30,887 responses and 16,050 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	17	1	17	60	17
RTE Small	59	1	59	30	29.5
RTE Very Small	35	1	35	30	17.5
Total	111		111		64

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	89	4	356	60	356
RTE Small	397	4	1,588	30	794
RTE Very Small	227	4	908	30	454
Total	713		2,852		1,604

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	573	12	6,876	30	3,438
RTE Very Small	784	12	9,408	30	4,704
Total	1,367		16,644		8,502

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	500	12	6,000	30	3,000

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
Small					
Total	710		11,280		5,880

Hold and Test Product Sampling

And some RTE establishments may have to hold and test product for L. monocytogenes and other indicator organisms. Large establishments will take 60 minutes to hold and test and small and very small RTE establishments will take 60 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 four times a year for a total of 476 annual responses and 476 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	4	4	60	4
RTE Small	36	4	144	60	144
RTE Very Small	82	4	328	60	328
Total	119		476		476

The cost to respondents is estimated at $973,729 annually. The Agency estimates it will cost respondents $37 an hour in fulfilling these paperwork requirements. Respondents will spend an annual total of 26,317 hours and $973,729 on this requirement.

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 $370,000 annually. The cost estimate includes a cost of $37 an hour for inspection program personnel time.

15. Reasons For Changes In Burden:

This is a revised information collection based on the most recent plant data, which support a total of 3,738 fewer burden hours than the previous information collection. Even though we have increased some of our estimates for the time of responses in a few of the categories due to comments from members of the industry, there has been an overall decrease of 3,738 burden hours because there are 1,461 fewer establishments producing post-lethality-exposed RTE products due to decline or consolidation 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:

The OMB approval number will appear on required FSIS forms. FSIS requests that it not be required to put the expiration date of the information collection on the form. Being required to put the expiration date on the form would place a burden on the Agency because 1) it would require FSIS to print new forms with the expiration date on them and would render the forms unusable in three years; 2) at the end of the approval period FSIS could not print up new forms until OMB gave a new expiration date causing unnecessary delay; and, 3) there is often a time lapse of several months between the date when the expiration expires and the time when OMB will finally give (usually) a three year approval to the extension or revision causing an almost impossible situation of attempting to have forms with the correct expiration date on them.

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.