Appendix A

Final Regulatory Impact Analysis

FSIS is amending its regulations to require that official establishments that produce certain ready-to-eat (RTE) meat and poultry products (MPPs) take measures to prevent product adulteration by L. monocytogenes (Lm). These amended regulations primarily affect establishments that produce RTE MPPs that are exposed to the environment following lethality treatment and that support the growth of Lm.

The final rule takes into account the differences in the risk of Lm contamination by type of RTE MPP product and by the manner in which the pathogen is controlled in the production process. It takes into account these differences by identifying four alternative Lm control approaches applying to RTE MPPs that are exposed to the plant environment after undergoing a process that is lethal to the pathogen. Each alternative involves a different level of pathogen control and to each there corresponds a preferred level of monitoring and verification, based on science and the nature of the product.

Need for the Rule

This action is compelled by recent outbreaks of food borne illness related to the consumption of adulterated RTE

meat and poultry products, coupled with information on the pathogenicity of the organism and the findings of the risk assessment and risk ranking conducted by FDA and FSIS. Lm contamination is often a result of post processing contamination or growth of the organism after it leaves the Federal establishment. FSIS concluded before beginning this rulemaking that many establishments were not effectively implementing HACCP plans and Sanitation SOPs to prevent L. monocytogenes from contaminating the RTE product in the post-lethality processing environment.

Given the pathogenicity of L. monocytogenes, the opportunity for it to contaminate RTE product in the post-lethality environment, and the significant consequences that this contamination can have, FSIS is amending its regulations. The Agency is adding provisions that require establishments that produce post-lethality exposed RTE product to include in their HACCP plans or in their Sanitation SOPs or other prerequisite programs measures that prevent product adulteration by L. monocytogenes.

Market Failure. This final rule addresses a market failure. Market failures occur when resources are misallocated or allocated inefficiently. Markets fail, in the current case, because processors may not always be provided with sufficient incentives to allocate the

additional resources and efforts needed to provide effective prevention methods for pathogen contamination in their products. These incentives are lacking because consumers cannot identify (and reward) those firms that produce RTE MPPs and are implementing the desired food safety safeguards. Therefore, consumers are unable to distinguish these products from those produced by lower cost firms that are applying less effective pathogen prevention methods. The lack of information on the safety of the products produced by the establishments in this latter group is a major concern of this rule. The recent FSIS risk assessment clearly indicates that products from establishments that are not taking these precautions can lead to illness or death.

The provisions of this final rule are designed to provide establishments a choice of selected, proven technologies to minimize the presence of Listeria in their processing environment. The use of these technologies and documentation of records on the environment of these establishments, brought about by this final rule, will provide the kind of information, and needed food safety assurance, that is lacking for consumers.

Rationale for the Approach Taken

The economic rationale for the requirements of the final rule is that it recognizes that a combination of interventions have been shown to be more effective that a single intervention and builds this into the framework of regulation. Second, the requirements recognize that the level of risk varies by product and how it is produced. Third, the requirements provide incentives for the establishment to adopt sanitation and testing practices that are most suitable for its products and processes. And lastly, these incentives for establishments have been shown to be preferable over mandatory requirements.

The FDA/FSIS risk ranking[1] found that RTE MPPs posed a moderate to high human health risk, particularly among vulnerable populations. These products include deli meats, hotdogs, meat spreads, pâté, and deli salads that include RTE meat or poultry products as components. The risk ranking indicates that among the RTE MPPs, deli meats pose an especially high risk.

[1] FDA, FSIS, CDC. "Draft Assessment of the Relative Risk to public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods". The document is available at www.foodsafety.gov.

The FSIS Risk Assessment for L. monocytogenes in Ready-to-Eat Deli Meats[2] (FSIS Lm risk assessment) estimated the reduction in fatalities among vulnerable populations from consuming contaminated deli meats that might be achieved through in-plant sanitation with verification testing regimes of increasing intensity. These results were compared with estimates for similar fatality reductions that might be achieved by applying post-lethality treatments or growth inhibiting additives or processes. Based on the finding of the FSIS Lm risk assessment, the Agency concluded that a combination of interventions, including sanitation coupled with verification testing, and the use of growth inhibitors, appears to be more effective in controlling Lm than a single intervention in these operations.

FSIS considered the findings of the FDA/FSIS risk ranking and the Agency's Lm risk assessment and the public comments that had been submitted on the Agency's proposed rule regarding control of Lm in RTE products. Many of the comments expressed opposition to proposed mandatory testing frequencies -- either the frequencies themselves or the fact that they would be mandated. Instead of mandatory

[2] USDA, FSIS. "Draft Risk Assessment for Listeria Monocytogenes in Ready-to-eat Deli Meat Products". FSIS. March 2003. The risk assessment is available at www.fsis.usda.gov.

testing requirements, the Agency is requiring that establishments incorporate appropriate verification methods into their HACCP plan, Sanitation SOP, or prerequisite program. This approach provides establishments with incentives to test for Lm and the flexibility to implement control measures that are appropriate for the types of products produced and processing methods at the establishment.

The final rule sets out four alternative Lm control approaches. For the purposes of this analysis, FSIS has grouped the affected establishments according to their use of these Lm control approaches.

Changes between the Proposed and the Final Rule

FSIS considered four regulatory options for this final rule that had been generated from comments on the proposed rule. The options were: (1) no action; (2) a sanitation performance standard for reduction of Lm in RTE MPPs; (3) mandatory testing frequencies for Listeria species on food contact surfaces different from the frequencies proposed; and (4) a warning label to inform consumers in vulnerable groups of the potential for Lm contamination.

FSIS determined that: (1) comments supported a final rule; (2) scientific support for a sanitation performance

standard was lacking; (3) mandatory testing frequencies were objectionable for reasons given in the comments; (4) a warning label would be inappropriate because, under the law, all RTE meat and poultry products must be not adulterated and thus safe for all consumers.

FSIS adopted a modification of the third option. It will require establishments to describe their testing programs in their HACCP plans or in their Sanitation SOPs or other prerequisite programs, as appropriate for products and processing technologies. It will also require establishments to set the frequency of their verification tests for Lm on food contact surfaces, but will not mandate a specific frequency. The Lm control alternative influences the frequency of verification testing at an establishment. Verification testing is expected to be most frequent for establishments that produce post-lethality exposed deli meats and hotdogs and rely exclusively on sanitation and verification testing to control Lm.

The final rule identifies four Lm control alternatives that are typical of industry practices. The purpose of these control alternatives is to link the usage of HACCP or sanitation procedures with the risk of Lm contamination based on the FDA/FSIS risk ranking and the FSIS Lm risk assessment. The control approaches are: (1) A HACCP-based

post-lethality treatment plus Lm growth limiting measures; (2) A HACCP-based post-lethality treatment or Lm growth limiting measures; (3) Solely sanitation and verification control measures in its post-lethality treatment and no Lm growth inhibiting measures – and producing a class of post-lethality exposed product that is not a deli product or a hotdog product; and (4) Solely sanitation and verification control measures in its post-lethality treatment and no Lm growth inhibiting measures – and producing a class of post-lethality exposed product that is a deli product or a hotdog product. For the purposes of this analysis, FSIS has grouped all establishments producing RTE MPPs that are exposed post-lethality according to their current and expected use of these Lm control approaches and this analysis will refer to these establishment groups as establishment group (EG) 1 through 4.

The proposed rule would have required RTE MPP establishments to control Lm either in their HACCP plans or their Sanitation SOPs. The final rule requires establishments to include post-lethality treatments in their HACCP plans and allows them to have other types of Lm contamination controls in their HACCP plans or in their Sanitation SOPs or other prerequisite programs. This modification of the proposal is based on the finding that

the establishment's use of a post-lethality treatment represents a determination by the establishment that Lm is a hazard reasonably likely to occur.

The prerequisite program provisions in the final rule respond to comments that the Agency should provide establishments with greater flexibility in implementing Lm contamination controls. In particular, RTE MPP establishments usually do not control post-processing contamination through HACCP alone, but through a variety of prerequisite programs.

In response to public comments, the final rule also does not mandate food contact surface (FCS) testing frequencies. Instead, the final rule sets out specific requirements, for Alternatives 2 and 3 for sanitation procedures that are included in HACCP plans, or in Sanitation SOPs or other prerequisite programs. Establishments are allowed to choose their own testing methods and frequencies for verifying the effectiveness of their procedures.

The sanitation procedure requirements for Alternative 3 establishments that that process hotdog and deli meat products and control for Lm using sanitation procedures only, include hold-and-test provisions. These procedures are invoked when follow-up testing to verify corrective

actions in response to Listeria-positive FCS test results. A second positive FCS test for L. monocytogenes or an indicator organism entails withholding from commerce product that was in contact with the contaminated surface. Shipments can resume when subsequent tests in the same area of the plant are negative. The product can be tested under a sampling plan that provides sufficient confidence to enable the product to be released into commerce. The requirements for Alternative 3 establishments that process deli meats and hotdogs represent a modification of the hold-and-test procedures that the proposal would have required (proposed §430.4(b)) but imposes this requirement only on establishments producing hotdog and deli-meat type products. This particular change from the proposal is responsive to comments opposing mandatory testing frequencies and the proposed hold-and-test requirements, which would have applied to all RTE MPPs. The requirements for Alternative 3 establishments that process deli meats and hotdogs are also responsive to the FDA/FSIS risk ranking which identified hot dog and deli-meat products as posing a moderate to high risk for listeriosis on a per annum basis (as opposed to a per serving basis), and the FSIS Lm risk assessment which evaluated the risk-reduction effectiveness of various combinations of in-plant

interventions, including FCS testing, with and without test and hold actions.

The final rule also differs from the proposal by requiring RTE MPP establishments to furnish FSIS with at-least-annual estimates of production volume by type of RTE MPP and by alternative Lm control program used. This change responds to comments on the proposed rule indicating opposition to the use of establishment size criteria in determining verification testing intensity and to information provided in the public comments indicating that there may not be a connection between establishment size and volume of production. These comments noted that production volume is dependent on factors other than establishment size, such as technology.

Finally, the rule allows labels on RTE MPPs to show that the products were processed in a manner to eliminate, reduce, or limit the growth of Lm, provided that the claim is validated. This provision is not a regulatory requirement in that it does not mandate such labeling, but is intended to encourage the industry to implement effective Lm controls and to provide useful information to consumers, especially vulnerable subpopulations.

Coverage

FSIS found that that the final rule will affect 2,930 federally inspected RTE MPP establishments and about 2,046 State-inspected establishments. About 144 of these establishments are considered large, 1276 small and 3,556 very small, using the size criteria adopted by FSIS in implementing the HACCP regulations. FSIS was able to determine that the baseline numbers of federally and State-inspected establishments in the respective Lm control groups 1 through 4 are, respectively: 49; 2,297; 1,864; and 766. These numbers are expected to change as a result of this rule.

FSIS was further able to determine that, because of the intensity of verification testing that sanitation-and-testing establishments would have to implement to ensure that product contaminated with Lm is not shipped, a certain percentage of establishments in this group are likely to decide to put their Lm controls in their HACCP plans or to adopt Lm growth suppressing or limiting methods. They would decide, therefore, to "move or migrate" into the grouping of establishments that take either the first or the second Lm control approach. The number of establishments in establishment groups 1 through 4 is expected to be 95, 2,363, 1,864, and 654, respectively, after the final rule goes into effect. The expected

movement among establishment groups is discussed in detail in a later section.

The numbers of establishments in each of these Lm control groupings will determine the allocation of FSIS inspection resources for Lm control verification. FSIS will verify that establishments that produce RTE products are carrying out Lm control procedures in their post-lethality processing areas as described in their HACCP plans or their Sanitation SOPs or other prerequisite programs, and that they are complying with the requirements of this final rule. In addition to verifying establishment Lm controls, the Agency will verify that any label claims regarding Lm control have been validated. The frequency of FSIS verification testing of establishment Lm controls is expected to be higher for each successive Lm control alternative. In other words, the frequency will be lowest for establishments that use control Alternative 1 and highest for establishments that use control alternative 3 and that produce deli meats and hotdogs.

Establishment Groups

Grouping by Control Method. For the purposes of this analysis, four establishment groups can be identified in the final rule. The four groups are composed respectively of the establishments choosing L. monocytogenes control

Alternatives 1 through 3, and the deli meat- and hotdog-producing establishments choosing Alternative 3 (9 CFR 430.4(b)(1), (b)(2), (b)(3)(i) and (b)(3)(ii)):

Establishment Group One (9 CFR 430.4(b)(1)):

Establishments apply a post-lethality (PL) treatment to their products or process **AND** use a Lm growth inhibiting agent or process. Products produced by establishments in EG 1 are expected to present the least risk of possible Lm contamination of products because they use a combination of intervention measures. EG 1's HACCP, Sanitation SOP or other prerequisite program controls and FSIS's "normal" verification procedures are expected to provide information that is adequate to assure the establishment and FSIS inspection personnel that an adulterated product is not being produced.

Establishment Group Two (9 CFR 430.4(b)(2)):

Establishments apply **EITHER** a post-lethality treatment to their products **OR** use a Lm growth inhibiting agent or process. Because establishments in EG 2 apply a PL treatment to their products or use a growth inhibiting agent or process, but not both, this group's products present a somewhat higher level of risk. They still would be considered "safe" with a high degree of certainty, but this final rule will provide additional assurance that the

products are not adulterated by requiring EG 2 establishments to test food contact surfaces (FCSs) and make the test results available to FSIS.

Establishment Group Three (9 CFR 430.4(b)(3)(i)):

Establishments use **NEITHER** a PL treatment **NOR** a growth inhibiting agent or process, but has Sanitation standard operating procedures (Sanitation SOP) or other prerequisite programs **AND** produce a class of post-lethality exposed product that is not a deli product or a hotdog product.

Establishment Group Four (9 CFR 430.4(b)(3)(ii)):

Establishments use **NEITHER** PL treatments **NOR** Lm growth inhibiting agents or processes in their RTE MPP production, **BUT** have Sanitation SOP or other prerequisite programs **AND** produce a class of post-lethality exposed product that is a deli product or a hotdog product. Establishments in EG 4 produce RTE MPPs that have been identified in recent risk assessments as posing significant risk of Lm contamination in their post-processing environment and significantly contribute to illnesses and deaths. The Lm control measures for establishments in EG 4 are similar to those of EG 3, but FSIS feels that specific holding action requirements are justified to ensure that no adulterated product enters commerce when a second consecutive positive FCS test in the post-lethality processing environment of a

EG 4 is found. A guide to the final rule requirements by establishment group is given in Table 1.

Table 1. Summary of final rule requirements by establishment group.

Item	Establishment Group			
	1	2	3	4
(1) Inclusion of a PL treatment to their product or process as a CCP in the establishment's HACCP plan.	R	R	NR	NR
(2) Validation of (1) as being effective in eliminating L. monocytogenes.	R	R	NR	NR
(3) Verification of (1) to be effective in accordance with 417.4 on a continuous basis and provision of them to FSIS.	R	R OR	NR	NR
(4) Apply a bacteriostatic agent or process that eliminates L. monocytogenes growth in the product.	R	R	NR	NR
(5) Validation of (4) as being effective in eliminating L. monocytogenes.	R	R	NR	NR
(6) Verification of (4) to be effective in accordance with 417.4 on a continuous basis and provision of them to FSIS.	R	R	NR	NR
(7) FCS testing with a frequency determined by the establishment to be effective.	NR	R	R	R
(8) Provision of FCS testing results to FSIS.	NR	R	R	R
(9) Establishment's sanitation plan explains how FCS is kept sanitary and free of L. monocytogenes.	NR	R	R	R
(10) Specific requirements on holding of each lot of product associated with two consecutive FCS positives, until two consecutive FCS negatives.	NR	NR	NR	R
NR = Not required; R = Required.				

Analysis of Costs

Number of Establishments. The preliminary regulatory impact analysis relied on the 1997 Census of Manufacturers for an initial count of RTE MPP establishment numbers. 1,630 establishments were identified as producing a RTE MPP. The estimated number of establishments affected by the proposed rule was expected to be fewer than the actual number total for many reasons, but chiefly because the Census classifies businesses according to their principal activity. In some cases, the production of RTE MPP might be a secondary activity. This undercounting was a major deficiency in the preliminary regulatory impact analysis (PRIA). FSIS has corrected this problem and is estimating the impacts of the final rule considering both federally and State-inspected establishments producing RTE MPPs.

Basing the analysis on a more realistic estimate of the number and types of establishments affected by the rule provides a better estimate of industry impacts. However, using this approach, the product-specific information, such as the value of production, that was available through Census data, can not be used. Also, certain assumptions must be made in manipulating the data for both federally and State-inspected establishments to avoid double counting

and to estimate HACCP process categories for RTE MPPs at State-inspected establishments.

FSIS used the 2001 Performance-Based Inspection System (PBIS) databases to identify Federal-inspected establishments that have at least one HACCP process category code (actually, the pertinent procedure code from FSIS's inspection system procedure guide) associated with a RTE MPP. The 2001 PBIS database showed that there were 2,930 federally inspected establishments with 3,556 HACCP process category codes associated with RTE MPPs. Establishments were grouped into HACCP establishment size categories by cross tabulating this data with the 2001 Enhanced Facilities Database (EFD). (HACCP establishment size categories have been defined since the publication of the PR/HACCP rule (61 FR 38806; July 25, 1996) as large: more than 500 employees; small: between 499 and 10 employees; and very small: fewer than 10 employees or less than $2.5 million in annual sales.) To obtain the number of unique establishments in each HACCP process category code, the number of HACCP plans for each HACCP process code was divided by the average number of HACCP plans per establishment in each size category (bottom of Table 2).

The EFD identified 2,046 State-inspected RTE MPP establishments comprised of 1,992 very small establishments

and 54 small establishments. To obtain an estimate of the product types produced at State-inspected plants, the total number of State-inspected establishments was distributed across the four HACCP process category codes in the same proportion that was found in federally inspected establishments (Table 3).

Table 2. Federally inspected RTE MPP establishments by HACCP process category code, 2002.

Item	HACCP Establishment Size Category			Total
	L	S	VS	
O3E- Not heat-treated, shelf-stable	5	68	88	161
O3F- Heat-treated, self-stable	41	238	405	684
O3G-Fully cooked, not shelf-stable	122	1,079	1,319	2,520
O3I-Product w/ secondary inhibitors	9	68	72	149
Total HACCP plans	177	1,453	1,884	3,514
Total Unique Federally inspected Establishments	144	1,222	1,564	2,930
HACCP plans/establishment	1.23	1.19	1.20	1.20
"Adjusted" number of federally-inspected establishments by HACCP Process Category Code (Number of HACCP Process Category Codes by Size Category divided by HACCP plans/establishment)				
Item	L	S	VS	Total
O3E- Not heat-treated, shelf-stable	4	57	73	134
O3F- Heat-treated, self-stable	33	200	336	570
O3G-Fully cooked, not shelf-stable	99	907	1,095	2,101
O3I-Product w/ secondary inhibitors	7	57	60	124
Total Federal-inspected RTE MPP establishments	144	1,222	1,564	2,930

Table 3. State-inspected RTE MPP establishments by HACCP process category code, 2002.

Item	Distribution of federally-inspected establishments			
HACCP Process Category Code	HACCP Establishment Size Category			Total
	L	S	VS	
	Percent			
O3E- Not heat-treated, shelf-stable	2.8	4.7	4.7	4.6
O3F- Heat-treated, self-stable	23.2	16.4	21.5	19.5
O3G-Fully cooked, not shelf-stable	68.9	74.3	70.0	71.7
O3I-Product w/ secondary inhibitors	5.1	4.7	3.8	4.2
Total Federal-inspected RTE MPP establishments	100	100	100	100
Item	"Adjusted" number of State-inspected establishments			
O3E- Not heat-treated, shelf-stable	0	3	93	96
O3F- Heat-treated, self-stable	0	9	428	437
O3G-Fully cooked, not shelf-stable	0	40	1,395	1,435
O3I-Product w/ secondary inhibitors	0	3	76	79
Total State-inspected RTE MMP establishments	0	54	1,992	2,046

Table 4. Total number of RTE MPP Federally and State-inspected establishments by HACCP process category code, 2002.

Item	HACCP Establishment Size Category			Total
HACCP Process Category Codes	L	S	VS	
O3E- Not heat-treated, shelf-stable	4	60	166	230
O3F- Heat-treated, self-stable	33	209	764	1,007
O3G-Fully cooked, not shelf-stable	99	948	2,490	3,536
O3I-Product w/ secondary inhibitors	7	60	136	203
Total RTE MPP establishments	144	1,276	3,556	4,976

The total number of establishments producing RTE MPP products is estimated to be 4,976: 59 percent federally

inspected and 41 percent State-inspected. Of the total, 4.6 percent are associated with the O3E HACCP code; 20.2 percent with the O3F code; 71.1 percent with the O3G code; and, 4.1 percent with the O3I code (Table 4). Further analysis of HACCP size categories shows that 71.5 percent of all RTE MPP establishments are very small; 25.6 percent are small; and, 2.9 percent are large.

Product groups. The PRIA classified RTE MPP establishments by the expected range of potential cost impact on those establishments: those likely to incur the greatest costs, moderate costs, minor costs, and no likely costs (Table 3 in Federal Register, Vol. 66, No. 39). This grouping was based on the likely impact from both the proposed testing programs as well as the proposed changes in lethality and stabilization performance standards. The final rule concerns only that section of the proposed rule dealing strictly with FSIS's desire to increase safeguards with respect to possible Lm contamination. Because of this and also because products and production processes vary across the same product classification, it is not feasible to disaggregate in the fashion of the PRIA. However, it appears that the largest impact will be on establishments producing cooked RTE MPP products – those products associated with HACCP process code O3G. There is little

likelihood that there will be any cost impact on RTE MPP establishments producing products in the O3E, O3F and O3I HACCP process codes, except for costs attributable to a possible increase in FCS testing mandated by the rule. These costs are expected to be minor because many of the establishments in the HACCP process category codes already apply an agent or process that inhibits Lm growth so many of these establishments "qualify" to be classified in EG 2.

Establishments associated with the O3G HACCP process category code produce cooked RTE MPPs which may or may not be able to apply post-lethality treatment to products, apply antimicrobial agents, or include procedures in either Sanitation SOPs or prerequisite programs. In some cases, FCS testing and disclosure of those results to FSIS may result in minor cost increases similar to those for 03E, 03F, and 03I HACCP process category codes. For other products in the 03G HACCP process code, they could be produced under any of the four alternative post-lethality Lm control regimes identified in this final rule. In those cases, the costs could be significantly higher. Accordingly, the cost impact discussion is presented by each establishment group, type of products produced, and their associated establishment numbers and size distribution.

Impacts according to establishment group. The Agency anticipates that the measures taken by establishments will differ by establishment group. The following describes the major types of responses expected to be taken in response to the final rule for those establishments switching establishment groups and/or validating current Lm controls.

EG 1 EG 2 Impacts.

(1) *Incorporation of post-lethality treatments and/or their validation for FSIS*: Many establishments are currently using post-lethality measures to address possible Lm contamination. These actions may have been taken in response to client requirements, the recent FSIS Lm intensified verification program, or in anticipation of further FSIS action. The costs of these actions taken by establishments are not attributed to the final rule. However, measures taken to satisfy this requirement or to validate these measures to FSIS are attributed to the final rule. These measures include: post-lethality heating (may not be feasible for many products, especially those with a high fat content); high-pressure systems, which may be limited to a few specialty items and usually have a low throughput; and irradiation, which is not permitted to be applied to RTE MPPs at present. FSIS expects establishments using post-lethality treatments to verify

that their treatments are effective and also to monitor FCSs to assure that the treatment is effective. This level of verification FCS testing for establishments in EG 1 is expected to be about twice yearly.

(2) *Use of agent in product formulation or change in processes to inhibit Lm growth in product*: FSIS has recently permitted the use of certain food additives that inhibit Lm growth (65 FR 17128, March 31, 2000). These additives include lactate and diacetates that have been applied increasingly to cooked and cured RTE MPPs such as hotdogs. The cost to establishments of taking measures involving the use of these additives is not attributable to the final rule. The Agency estimates that up to 70 percent of all hotdog manufacturers have recently changed their product formulations to incorporate one of the recently permitted food additives. Changes in a process that would help inhibit the Lm growth in the product include: lowering the pH or water activity levels and refrigerating or freezing the product following processing. Growth inhibiting processes uses antimicrobial agents to control growth in post-lethality exposed products such as many hotdogs and certain other kinds of sausages. Verification FCS testing for establishments in EG 2 would be expected at least once per quarter. This level of

testing would be expected whether the establishment administered a PL treatment or applied a Lm growth inhibiting agent or included a process in either a Sanitation SOP or prerequisite program.

EG 3 and EG 4 Impacts.

(1) *FCS testing frequencies*: For the purpose of this analysis, the minimum level of FCS testing expected for establishments in EG 3 is at least once per month: once a month for high, once a month for small, and once a month for very small establishments. Also, the minimal level of FCS testing for EG 4 is: at least weekly for high-volume establishments, semi-monthly for small volume establishments, and monthly for very small (or low volume) establishments (4-2-1). These testing frequencies are illustrative in that the actual testing frequencies incorporated into final compliance guidelines may differ.

A potential unintended impact of the rule for establishments in EG 4 might be the incentive to reduce their current level of FCS testing if results are to be shared with FSIS. An establishment in this group may conduct fewer tests if results could lead to costly hold-and-test actions. This potential unintended impact was not be quantified in this analysis.

EG 4 Impacts.

(1) *Hold and Test*: EG 4 establishments may be unable to (1) apply a post-lethality treatment or (2) apply an agent or include a process in either the Sanitation SOP or prerequisite program for a variety of reasons. Product from these establishments can be held on the basis of FCS testing results shared with the Agency. Multiple episodes of holding product may be incurred in the case of two consecutive positive FCS test results.

Baseline

Establishment Types. The compliance cost impacts of the rule differ significantly among establishment groups and by HACCP size category. The current distribution of establishments by group and size serves as the baseline for determining the distribution of compliance cost and also the starting point for the expected establishment shifts among establishment groups discussed below.

Table 4 indicates that 1,440 establishments produced RTE MPPs in the O3E, O3F, and O3I HACCP process category codes. For purposes of this analysis, these establishments are distributed 90 percent in EG 2 and 10 percent in EG 3. The high proportion in EG 2 is a result of the use of growth inhibitors in most of these products which include cured and salted products. These products have not been associated with listeriosis outbreaks.

The remaining 3,536 establishments in O3G produce cooked RTE MPPs that may be produced by any of the four Lm control methods. These establishments were partitioned into the four establishment groups as follows:

(1) From a December 2002 FSIS hotdog and deli meat survey, we know that there are 1,712 operations producing hotdogs and/or deli meats. Given that 38 percent of these operations produce both hotdogs and deli meats, the actual number of unique establishments involved is 1,061 ((1-.38) x 1,712).

(2) The number of establishments producing cooked products other than hotdogs and/or deli meats was estimated by subtracting the number of single establishments producing hotdogs and/or deli meats from the total number of establishments producing cooked products (3,536 – 1,061 = 2,475).

(3) FSIS inspection program personnel were contacted to estimate the proportion of establishments producing hotdog/deli meat and other cooked products in each of the establishment groups. These estimates, provided in Tables 5 and 6, were used to partition the establishments producing hotdog and deli meats and the other cooked RTE MPPs by establishment group (Table 7).

Table 5. Percentage of hotdog and deli meat establishments by establishment group, 2002			
Item	HACCP Establishment Size Category		
Establishment group	L	S	VS
1	0.15	0.05	0.03
2	0.65	0.30	0.12
3	0.00	0.00	0.00
4	0.20	0.65	0.85
Source: FSIS Hotdog and deli meat industry survey, December 2002.			

Table 6. Percentage of remaining establishments in O3G Code by establishment group, 2002			
Item	HACCP Establishment Size Category		
Establishment group	L	S	VS
1	0.00	0.00	0.00
2	0.75	0.50	0.25
3	0.25	0.50	0.75
4	0.00	0.00	0.00
Source: FSIS inspection program personnel, January 2003.			

Table 7. Total number of RTE MPP Federally and State-inspected establishments by establishment group, 2002.				
Item	HACCP Establishment Size Category			
Establishment Group	L	S	VS	Total
1	9	24	16	49
2	108	675	1514	2297
3	13	269	1581	1864
4	13	308	445	766
Total RTE MPP establishments	143	1276	3556	4976

Health Consequences. The baseline for comparing human health benefits associated with the rule is established by the "Draft FSIS Risk Assessment for Listeria Monocytogenes

in Ready-to-eat Deli Meat Products"[3] (Lm Risk Assessment). The Lm Risk Assessment concludes that 320 deaths are attributable to RTE deli meats. It is not possible at this time to identify the number or deaths attributable to RTE MPPs, which in addition to deli meats includes hotdogs, fermented sausages, and related products.

The FDA/FSIS risk ranking model[4] estimates that there are about 340 billion servings of all RTE products consumed per year. RTE MPPs are contained within the following classes: reheated franks, non-reheated franks, deli meats, fermented sausages, pâté, and deli-salads. These classes comprise about 43 billions servings. The deli meat class is responsible for 49 percent of the 43 billion servings of RTE MPP. The two hotdog classes are together responsible for 15 percent of the servings of RTE MPP. Based on these estimates, there could be as many 375 annual fatalities associated with RTE MPPs.

The Lm Risk Assessment, because of its focus on deli meats, is only able to estimate the human health benefits associated with the rule as it affects this category of

[3] USDA, FSIS. "Draft Risk Assessment for Listeria Monocytogenes in Ready-to-eat Deli Meat Products". FSIS. March 2003. The risk assessment is available at www.fsis.usda.gov.

[4] FDA, FSIS, CDC. "Draft Assessment of the Relative Risk to public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods". The document is available at www.foodsafety.gov.

products. For purposes of establishing a baseline for potential human health benefits, deli meats are divided into two categories: products sliced and packaged at the establishment; and retail sliced product. Pre-packed products are post-lethality exposed and the focus of the regulation. Retail-sliced products are not post-lethality exposed until prepared for use or sale at a retail location. The human health exposure to each type of product is a function of its share of total RTE deli meats consumed and the level of contamination in each type of product. Actions by FSIS can reduce the exposure to some, but not all RTE deli meat.

The Economic Research Service estimates that pre-packaged product accounts for 46 percent ($11.6 billion) of total sales of RTE deli meats ($25.2 billion) and retail sliced product the remaining 54 percent ($13.6 billion).[5] Volume of product in the categories would provide a more suitable basis for establishing a baseline level.

There is considerable uncertainty about the level of contamination in each type of product when purchased. A

[5] The estimate is based on information from the A.C. Nielson Co. 2001 Consumer Expenditure Study as reported in Progressive Grocer, September, 2002. The data sources are: supermarket checkout scanner data from a representative sample of 10,000 U.S. supermarkets, a representative consumer panel consisting of 55,000 households, and Progressive Grocer estimates.

recent study by Gombas, Chen, Clavero, and Scott[6] finds that there is a 0.4 percent prevalence rate for Lm in pre-packaged product and a 2.7 percent prevalence rate for Lm in retail sliced product at the retail level. If 0.4 percent of pre-packaged product was found to be contaminated at the processing plant, it follows that 0.4 percent of the 2.7 percent prevalence rate at retail might be due to contamination at the processing site. That means that the prevalence of product solely contaminated during retail slicing is 2.3 percent (the observed 2.7 percent minus the 0.4 percent that was contaminated at the processor site). Using this information and the relative market share weights for pre-packaged and retail sliced deli meats from ERS provides a weighted average exposure rate for deli meats:

.004(0.46) + 0.004(0.54) + .027 (.54) = .0164 or,

.004 + .01242 = .01642

The pre-packaged product share of the weighted average exposure rate is 24.4 percent (.004/.01642 = 0.2436) and the retail sliced product share is the remaining 75.6 percent. Therefore, the human health baseline risk which

[6] "Survey of Listeria monocytogenes in Ready-to-Eat Foods", Journal of Food Protection 66(H):559-569.

the FSIS can affect at federally inspected establishments is a potential maximum 78 deaths (24.4 x 320).

The Agency has several concerns about this approach to establish a baseline level of human health risk. The prevalence levels estimated by Gombas, et al. and based on National Food Processing Association (NFPA) Survey data, taken at retail establishments, are significantly lower than those found by FSIS and reported in the Lm Risk Assessment Model. Levine, et al.[7] reported 1999 prevalence levels of Lm at 2.71 percent for cooked, roast, and corned beef and 4.58 percent in sliced ham and other pork luncheon meats. All samples were collected at production facilities, not at retail. The prevalence levels from the NFPA and FSIS studies are not entirely comparable, but they do seem to be inconsistent, even after taking into account basic limitations in the data used in both studies. The NFPA survey data describe the difference in prevalence between product contaminated at processing and product contaminated at retail. It is important to recognize that some of the product found contaminated at retail was contaminated at the processor but was only detected at retail. It is difficult to reconcile FSIS product sampling

[7] Levine P, Rose B, Green S, Ransom G, and Hill W (2001). Pathogen testing of ready-to-eat meat and poultry products collected at

which finds 2.7-4.6 percent of RTE meats positive for Lm, with the finding based on the NFPA survey data that only 0.4 percent of packaged RTE meats are positive at retail outlets. Some net growth, not dying off, of Lm within contaminated packages between processor and retail is expected. The Agency concludes that there is much uncertainty about the true proportion of products contaminated at the processor and at the retail facility and among products affected by the rule and not affected by the rule.

All things considered, the Agency concludes that it is appropriate to make at least a 50-percent reduction in the potential deaths and illnesses averted due to Lm control measures taken by RTE MPP establishments as a result of this rule (versus the 24.4 percent based on the estimate presented). This percentage takes into account the study by Gombas, et al., and discussions with FSIS industry experts, risk assessors, and microbiologists. Consequently, the maximum potential reduction in fatalities achieved through Agency measures for RTE deli meat products is 180 (320 x .5). This level would be somewhat higher if

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federally-inspected establishments in the United States, 1990 to 1999. Journal of Food Protection 64(8):188-1193.

hotdogs, fermented sausage, and related products were included in the Lm Risk Assessment.

Expected Movement Among Establishment Groups

There are six major industry cost impacts that are expected with the final rule. Most of these impacts arise because some establishments are expected to shift into establishment groups that entail different technologies than they currently employ. These shifts are attributed to compliance with requirements of the rule. Costs are estimated on the basis of such shifts among the establishment groups. The movements among establishment groups are based on the experience and judgment of FSIS personnel which were pooled together to produce certain guidelines to estimate the expected movement of establishments across establishment groups, depending on their establishment size. For large establishments, it is expected that, based on this collective judgment, 20 percent of the establishments in EG 2 (that were already applying a PL treatment and referred to as EG 2A) would move into EG 1 (Table 8). These seven establishments already had the necessary equipment for these treatments, but simply had not validated their use. Therefore, only very little additional cost was involved for these establishments to move into EG 1 (along with the adoption

of applying a Lm inhibiting agent or process). A 10-percent shift in establishments in EG 2B and EG 4 is expected because these establishments have not incurred the high initial costs of the post lethality equipment, resulting in a shift of seven establishments from EG 2B and two from EG 4. No establishment shifts in EG 3 are anticipated. In total, the application of these guidelines produced an increase of 16 establishments in EG 1 (Table 9).

Table 8.Rules employed in estimating large establishment shifts across establishment groups.

	Went to:				Came from:		
Estab. Group	1	2A	2B	4	2A	2B	4
1	NA	--------	----------	--------	20% of 34	10% of 74	10% of 13
2A /1	2A-1 above.	NA	----------	--------	----------	----------	----------
2B /1	2B-1 above.	--------	NA	--------	----------	----------	25% of 13
3	----------	--------	----------	--------	----------	----------	----------
4	4-1 above.	--------	4-2B above.	NA	----------	----------	----------

/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.

Table 9. Absolute levels and changes in large establishments across establishment groups.

Item	Start and End Levels			Went to:					Came from:			
Estab. Group	Old	New	Change	1	2A	2B	4	Total	2A	2B	4	Total
1	9	25	16	0	0	0	0	0	7	7	2	16
2A /1	34	27	-7	-7	0	0	0	-7	0	0	0	0
2B /1	74	70	-4	-7	0	0	0	-7	0	0	3	3
3	14	14	0	0	0	0	0	0	0	0	0	0
4	13	8	-5	-2	0	-3	0	-5	0	0	0	0
All Estab.	144	144	0	-16	0	-3	0	-19	7	7	5	19

/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.

For small establishments, the combination of the high cost of technologies involved in EG 1 and/ or EG 2 plus their limited volume of production is expected to lower their propensity for establishments to shift to another establishment group. Also, characteristics of their products and their production are expected to limit establishment shifts. Because of these constraints, it is expected that only 31 establishments (or 10 percent of the small establishments in EG 4) are likely to migrate to EG 1 as a result of the final rule (Table 10). Recall that all such movement involves the purchase and use of new technology. For most of these establishments, the option of adding a Lm inhibiting agent or process is probably a more attractive, least-cost option. As a result, 25 percent of the existing number of small establishments in EG 4 (or 77 establishments) is expected to shift into EG 2. No small establishments in EG 3 are expected to shift establishment groups. In total, 108 small establishments are expected to shift from EG 4 into either EG 1 or EG 2 (Table 11).

Table 10. Rules employed in estimating small establishment shifts across establishment groups.

	Went to:				Came from:		
Estab. Group	1	2A	2B	4	2A	2B	4
1	NA	--------	----------	--------	----------	----------	10% of 308
2A /1	----------	NA	----------	--------	----------	----------	----------

2B /1	----------	--------	NA	--------	----------	----------	25% of 308
3	----------	--------	----------	--------	----------	----------	----------
4	4-1 above.	--------	4-2B above.	NA	----------	----------	----------
/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.							

Table 11. Absolute levels and changes in small establishments across establishment groups.

Item	Start and End Levels			Went to:					Came from:			
Estab. Group	Old	New	Change	1	2A	2B	4	Total	2A	2B	4	Total
1	24	55	31	0	0	0	0	0	0	0	31	31
2A /1	114	114	0	0	0	0	0	0	0	0	0	0
2B /1	561	638	77	0	0	0	0	0	0	0	77	77
3	269	269	0	0	0	0	0	0	0	0	0	0
4	308	200	-108	-31	0	-77	0	-108	0	0	0	0
All Estab.	1276	1276	0	-31	0	-77	0	-108	7	7	108	108
/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.												

For very small establishments, the combination of high costs associated with technologies necessary to "qualify" for EG 1 or EG 3 and the nature of their product or production is expected to make it highly unlikely that any establishment will move into a different establishment group as a result of this final rule. The total expected establishment movements expected as a result of this final rule are given in the table below (Table 12).

Table 12. Changes in all establishments across establishment groups.

Item	Establishment Size			
Establishment Group	Large	Small	Very Small	Total
1	16	31	0	+47
2A /1	-7	0	0	-7
2B /1	-4	77	0	+73
3	0	0	0	0
4	-5	-108	0	-113
All Establishments	0	0	0	0

/1 2A refers to those establishments applying only a PL treatment; 2B refers to those establishments applying only a Lm inhibiting agent or process to their product or process.

Cost to validate a post-lethality treatment for establishments in EG 1 and EG 2. It is expected that 43 HACCP plans of 35 establishments (of the original 49 establishments in EG 1) will need to be validated (Table 13). This represents only about 15 percent of all the HACCP plan validations that will occur as a result of the final rule. This number of HACCP plan validations is based on a 50-percent validation rate currently being attained by large establishments, 30-percent rate by small, and a 10-percent rate by very small establishments. These rates are based on information that FSIS obtained from industry sources and in its public meetings related to the proposed rule and Lm risk assessment. Given the high relative numbers of small and very small establishments whose HACCP plans require validation, the total number of establishments affected is 35.

The major impact of the need for HACCP plan validation occurs in establishments already in EG 2 that have an unvalidated PL treatment (60 percent of all expected validation expenses incurred by establishments that already apply a PL treatment). To calculate this impact, establishments in EG 2 are grouped by the same validation

rate used for EG 1 establishments above. To the extent that PL treatments are validated by the manufacturer, validation costs would be lower.

Some validation costs are incurred by establishments in EG 2 that are expected to move into EG 1 (20 percent of the large establishments that currently have a PL treatment and 10 percent of those that do not have a PL treatment in EG 2) and some establishments in EG 4 that are expected to move into EG 1 (10 percent of the large and small establishments currently in EG 4).

Table 13. Costs for validation of PL treatments as CCPs in HACCP plans

Item	HACCP Establishment Size Category			
	L	S	VS	Total
	$thousand			
Cost per Plan	20	10	5	
Existing EG 1 HACCP plans				
Number of plans	6	20	17	43
Number of establishments	5	17	14	35
	$thousand			
Cost	$116.6	197.4	85.2	399.2
Establishments in EG 2 moving to EG 1 incurred by establishments that already apply a PL treatment				
Number of plans	13	0	0	13
Number of establishments	10	0	0	10
	$thousand			
Cost	266.5	0	0	266.5
Establishments in EG 4 moving to EG 1				
Number of plans	2	37	0	39
Number of establishments	1	31	0	32
	$thousand			

Cost	31.1	366.6	0	397.7
Cost for existing EG 2 HACCP plans				
Number of plans	17	95	60	171
Number of establishments	14	80	50	143
	$thousand			
Cost	334.9	946.2	300.5	1,581.5
Total Number of HACCP Plan Validations and Cost				
Number of plans	37	151	77	266
Number of establishments	30	127	64	222
	$thousand			
Total Cost, EG 1 and EG 2	749.1	1,510.1	385.7	2,644.8

Cost to install a post-lethality (PL) treatment.

Establishments in EG 1 and about half in EG 2 already have a PL treatment by virtue of being classified in that establishment group. Establishments in EG 4 and those in EG 2 that use an agent or have a process to control Lm do not necessarily have a PL treatment. Seven large establishments are expected to move from EG 2 to EG 1 and 1 large establishment moving from EG 4 will need to install PL treatments. 31 small establishments are expected to move from EG 4 to EG 1 and will make similar adjustments.

The Agency received comments to the proposed rule indicated that such investments, like high pressure processing units, cost up to $1.0 million to $1.5 million per unit. FSIS is using $1.5 million and $1.25 million as the expected capital costs of such equipment for large and small establishments, respectively. FSIS received comments

regarding per-pound operating expenses for various post-pasteurization processes, but was unable to use this information because of the lack of data on average production per establishment. FSIS assumes annual operating expenses are 10 percent of the initial capital cost.

The changes in the industry (movement among establishment groups) reflected by the installation of post-lethality treatments are given in Table 14.

Table 14. Costs for post-lethality treatments, equipment and annual operating.

Item	HACCP Establishment Size Category			
	L	S	VS	Total
	$thousand			
PL Equipment Cost per Establishment	1,500.0	1,250.0	NA	NA
Establishments moving from EG 2 to EG 1				
Number of establishments	7	0	0	7
	$thousand			
Equipment cost	11,149.4	0	0	11,149.4
Establishments moving from EG 4 to EG 1				
Number of establishments	1	31	0	32
	$thousand			
Equipment cost	1,897.2	38,536.9	0	40,434.1
Total establishment movements to EG 1				
Number of establishments	8	31	0	39
	$thousand			
Total equipment costs	13,046.6	38,536.9	0	51,583.5
Annual operating costs	1,304.7	3,853.7	0	5,158.4
Total first year	14,351.3	42,390.6	0	56,741.9

costs				

Cost to add agent or alter process to inhibit Listeria growth in the final product. One of the major impacts of the rule is that it encourages establishments in EG 4 to move into EG 2 by adding an agent or altering their production processes to inhibit Lm growth in the product. Adding such treatments would eliminate the need for more frequent verification testing. It is expected that 25 percent of the large and small establishments in EG 4 will move to EG 2 by doing so--3 large and 77 small establishments. The costs associated with this impact are subject to several factors. They include each establishment's unique situation with respect to product type, facility size, and equipment. Assuming that the cost to add agents or alter a process includes a one-time cost of installing equipment to add agents or alter production processes of $150,000 for a large, $125,000 for a small, and $100,000 for a very small establishment, the initial treatment cost totals $10.1 million. Using an operating cost of 10 percent of the initial cost produces a corresponding annual outlay of about $1 million (Table 15).

Table 15. Costs for Lm growth inhibiting treatments or processes, initial and annual operating.				
Item	HACCP Establishment Size Category			
	L	S	VS	Total
	$thousand			
Initial cost per establishment	150.0	125.0	100.0	
	Number of Establishments			
Establishments in EG 4 moving to EG 2	3	77	0	80
	$thousand			
Initial cost	474.3	9,634.2	0	10,108.5
Annual operating costs	47.4	963.4	0	1,010.9
Total costs	521.7	10,597.6	0	11,119.4

Cost of FCS testing for Listeria species. As with the third impact discussed above, the testing provisions of the rule encourage establishments to move from EG 4 into EG 1 and EG 2 (Table 16). These establishments are expected to be mostly small establishments attempting to avoid frequent FCS verification testing requirements for EG 4 establishments and the potential exposure to holding product upon two consecutive positive FCS verification test results. Almost half of the large establishments that were previously in EG 4 are expected to migrate either to EG 1 or to EG 2.

The costs of testing for the remaining 2,518 establishments in EG 3 and EG 4 are based on several assumptions. They include: the actual level of FCS

verification testing being conducted at the present time, the percentage of establishments conducting this level of verification testing, the number of production lines by establishment size, and the costs of testing. The assumptions used in this analysis are supported by observations by FSIS inspection personnel and by various recent surveys conducted by FSIS and the industry. For example, in the recent FSIS hotdog and deli-meat survey, about 20 percent of large, 26 percent of small, and about 5 percent of very small establishments stated that they conducted FCS verification testing for Listeria spp. The Lm growth inhibiting processes and ingredients used in producing these products probably lowers the level of verification testing being conducted by establishments producing other RTE MPPs. Therefore, FSIS believes that the actual proportion of establishments in EG 3 and EG 4 that conduct FCS tests is probably double the proportions reported in the recent hotdog and deli-meat survey for the small and very small establishments. That is, FSIS assumes that the current FCS verification testing levels for large, small, and very small RTE MPP producing establishments are 100 percent, 50 percent, and 10 percent, respectively (See middle rows in Table 17).

Table 16. Number of Federally and State-inspected RTE MPP establishments by establishment group resulting from FCS testing provisions. (Numbers in parenthesis are baseline numbers from Table 7).				
Item	HACCP Establishment Size Category			
Establish-ment Group	L	S	VS	Total
1	25 (9)	55 (24)	16 (16)	95 (49)
2	97 (108)	752 (675)	1514 (1514)	2363 (2297)
3	13 (13)	269 (269)	1581 (1581)	1864 (1864)
4	8 (13)	200 308)	445 (445)	654 (766)
Total establish-ments	143	1276	3556	4976

Table 17. Assumptions concerning FCS testing in EG3 and EG4				
Item	HACCP Establishment Size Category			
Assumption	L	S	VS	Total
Assumed lines/establishment	6	4	2	
Observed average testing frequencies for those that conduct FCS testing (number of times per month)				
EG 3	1	1	1	
EG 4	4	2	1	
Proportion of establishments conducting FCS testing at above frequencies				
EG 3	1.00	0.50	0.10	
EG 4	0.90	0.50	0.10	
Number of tests not conducted by establishments not testing at the above frequencies				
EG 3	0	539	2846	3385
EG 4	20	802	802	1623
Total	20	1341	3647	5007
Cost of testing shortfall by EG 3 and EG 4 at above frequencies,($35/test):	$thousand			
EG 3	0.0	18.9	99.6	118.5
EG 4	0.7	28.1	28.1	56.8
Total cost for increased FCS testing	0.7	47.0	127.7	175.3

Cost of Production Adjustments. As was discussed in the PRIA, it is expected that a series of Lm contamination events may occur in some establishments. The PRIA expected that most – about 85 percent – of the establishments that obtain one positive FCS test result could remedy the cause of the Lm contamination at no additional cost through more stringent sanitation and handling techniques. The remaining 15 percent of establishments are expected to encounter a greater degree of difficulty. Some of these establishments (as discussed in the PRIA) will probably encounter Lm contamination problems that could be remedied at a cost of $2,000 per line (these establishments consist of 7 percent of the establishments experiencing at least one positive FCS verification test result); another 7 percent are expected to encounter more serious contamination problems that would need to be remedied by actions costing up to about 1/10 of one percent of gross sales; and a final group made up of 1 percent of the establishments that discover that they have a chronic Lm contamination problem and have to cease their RTE MPP production altogether. No comments were received that would either support or refute this scenario or the set of assumptions needed in describing it. Some commented at the May 2001 public meeting that inclusion of these possible

eventualities would help complete the analysis. These results are expected to only apply to establishments in EG 4 who face the highest level of FCS verification testing. The underlying assumptions and resultant cost implications are given in Table 18.

Some explanation of the cost estimates of this impact is needed. First, the calculations for cost estimates for minor remedies are the same as in the PRIA. That is, the number of firms in each establishment group is faced with a $2000 per line cost times the number of lines in the establishment for production adjustments. Second, the cost estimates for major repairs are slightly different from those in the PRIA. In the PRIA, the value of shipments for the 1,479 establishments was available and estimated by Census at $25.2 billion for 1999. In the PRIA, this value of shipments was distributed across the 133 large establishments, 840 small ones and 506 very small ones using an average distribution for value of shipments by those size categories of 80-percent (for large), 15-percent (for small), and 5-percent for very small). This average distribution was derived from averages across broad categories of agricultural commodities. A much different distribution of value of production was found in the Fall 2002 FSIS survey of hotdog and deli meat establishments.

It found a value of production distribution of 48-percent (large), 48-percent (small), and 4-percent (very small). The final regulatory impact analysis uses a distribution of 65, 35, and 5 in conjunction with the original $25.2 billion for total value of shipments. This calculation produced average per establishment value of shipment estimates of $123 million for large establishments, $9 million for small establishments, and $2 million for very small establishments. This estimate is important because it serves as the basis for calculating the costs to remedy the major cases of Lm contamination. As in the PRIA it is expected that a small number of establishments whose contamination problems will be perceived to be prohibitively costly to "fix" and/or not feasible to undertake without complete modernization or renovation. Without making these needed capital improvements, their only option is to either partially or entirely cease RTE MPP production. FSIS expects that up to two small and four very small establishments may be in this situation.

Table 18. Assumptions about production adjustments to eliminate L. monocytogenes contamination and associated costs

Item	HACCP Establishment Size Category			
	L	S	VS	Total
Lines per establishment	6	4	2	NA

Proportion of establishments with no major L. monocytogenes contamination problems by establishment group:				
EG 3	0.95	0.95	0.9	NA
EG 4	0.85	0.85	0.85	NA
Number of establishments				
EG 3	1	13	158	172
EG 4	1	30	67	98
Total	2	44	225	270
Number of establishments incurring a $2,000 per line costs				
EG 3	0	0	158	158
EG 4	1	14	31	46
Total	1	14	189	204
Number of establishments incurring a major L. monocytogenes contamination problem				
EG 3	0	0	0	0
EG 4	1	14	31	46
Total	1	14	31	46
Number of establishments incurring a severe L. monocytogenes contamination problem				
EG 3	0	0	0	0
EG 4	0	2	4	6
Total	0	2	4	6
Production adjustment Costs	$thousand			
EG 3	0	0	632.4	632.4
EG 4	77.9	238.7	202.4	519.0
Costs of production adjustments	77.9	238.7	834.8	1,151.4

Costs related to possible hold-and-test actions.

Hold-and-test actions are expected to be taken by establishments in EG 4 and to a lesser extent in EG 3. For purposes of this analysis, 50 percent of the EG 3 and 95 percent of the EG 4 establishments that are expected to

have some problems with Lm contamination are also expected to be faced with one or more hold and test events annually. This calculation suggested that seven small and 79 very small establishments in EG 3 and one large establishment and 29 small and 63 very small establishments in EG 4 are expected to take one or more hold-and-test actions over a typical year. In addition to the number of establishments affected, there are five other factors that affect this cost impact. These are: (1) the amount of production likely affected (based on the number of lines times number of shifts and production per shift estimates); (2) the pounds per pallet that will need to be handled and placed into storage; (3) the average number of days that the product will be held in storage; (4) the number of times per year that a hold-and-test action occurs; and, (5) the cost per day per pallet in handling and storage. Also, the amount of existing available storage will influence any expected burden placed on establishments. The recent FSIS hotdog and deli-meat survey found that up to 40 percent of establishments have sufficient storage to hold product, but for only one to two days of production. Even though this finding only reflects the capacity of hotdog and deli-meat establishments, FSIS does not anticipate any serious problems with establishments finding available storage for

holding product under possible increased hold-and-test situations on their premises or at other locations. FSIS bases its estimate for expected industry-wide costs of hold-and test on parameters stated in Table 19. These costs are intended to include the transportation, handling and storage costs associated with product that has been tested and may or may not prove to be contaminated with Lm. For example, the $119,500 cost calculation for hold and test expected to be incurred by very small establishments was made by multiplying the expected number of affected establishments (79) times the number of expected hold and test occurrences per year (3) times the daily cost of holding (5 days times 5.6 pallets times $18 per pallet per day). Similar calculations were made for other affected establishments in the other HACCP establishment size categories and establishment groups. FSIS does not consider that the costs associated with the handling and eventual disposition of contaminated product, including its possible destruction, should be attributed to this final rule. It is believed that this product would have or should have been discovered and appropriately disposed of under current good manufacturing practices had they been followed by the establishment. Also to the extent that some of these products are normally refrigerated, these

holding cost estimates would over-estimate the impact on the industry.

Table 19. Cost of hold-and-test actions				
Item	HACCP Establishment Size Category			
Assumption	L	S	VS	Total
	Pounds			
Production affected	228,000	28,400	5,600	
	Number of:			
Pallets (1000 lbs. per pallet)	228	28	6	
Average days in storage	5	5	5	
Hold and test frequencies				
EG 3	3	3	3	
EG 4	6	6	6	
	Dollars			
Handling and storage cost per day ($/pallet)	18	18	18	
Handling and storage costs				
	$thousands			
EG 3	20.7	51.7	119.5	191.9
EG 4	144.2	437.9	191.9	774.1
Cost of hold and test	164.9	489.6	311.4	966.0

Analysis of Alternatives

For purposes of the analysis, the expected frequency of FCS verification testing for Listeria spp. for establishments in EG 2 is once per line per quarter; for EG 3, at least once per line per month; and for EG 4, once per line per month for very small establishments; semi-monthly for small producing establishments and weekly for high volume producing establishments (4-2-1). These testing frequencies are to be considered minimum expected levels

for the purposes of estimating costs and benefits. Conditions may warrant a higher frequency of FCS verification testing to assure FSIS that establishments' sanitation or prerequisite plans are adequately addressing the risk of possible contamination in its products. As an additional precaution, FSIS is requiring that after a second positive Listeria spp. FCS test result in an EG 4 establishment, hold and test actions are taken until such time that FSIS is assured that this action is no longer needed.

The FSIS Lm Risk Assessment found an increase in median lives saved as FCS verification testing frequencies increase relative to the baseline. The minimum FCS verification testing frequency for EG 4 (4-2-1) results in 25 deaths averted if there is 100 percent adoption of this testing frequency by all establishments producing deli meats.

An alternative FCS verification testing frequency could be 40-20-10 for EG 4. In this case, the reduction in human health risk increases to 89 deaths averted, given 100 percent adoption. At an extremely high level of testing, such as 60-60-60 (for either FCS verification testing for Listeria spp. or product testing for Lm), 153 deaths are averted given 100 percent adoption. Also, at these high

levels of FCS verification testing, hold and test protocols were shown to reduce the level of Lm contamination at retail.

Extremely high FCS verification testing levels may not be required to assure adequate sanitation. Nor are they necessarily effective from an economic perspective. Costly hold and test actions increase with FCS verification testing frequency. As such costs increase, establishments producing RTE MPPs, especially small and very small establishments, may eliminate product lines or cease production entirely. FSIS recognizes, however, that FCS verification testing frequencies higher than 4-2-1 may be appropriate for establishments with a history of poor sanitation controls or evidence of producing adulterated product.

Another concern about high FCS verification testing frequencies is the likelihood that many establishments that produce RTE MPPs using traditional methods will no longer produce such products. To the extent that this reduces the amount of adulterated product, this rule and its emphasis on FCS verification testing is appropriate. It may be inappropriate for any product that FCS testing for Listeria species is not a reliable indicator for Lm product contamination. FSIS believes that its establishment

categorization in this final rule will place only those products in EG 4 where intense sanitation and verification testing is most appropriate. However, extremely high verification testing frequencies in most cases may be unnecessary and burdensome.

The risk assessment clearly shows that a combination of post-lethality treatment or Lm growth inhibition along with sanitation and FCS verification testing and other measures is more effective than a "sanitation coupled with FCS verification testing only" strategy. This result also reinforces the observed industry practice of maintaining a series of adequate precautions throughout slaughter and processing, and of not exclusively relying on verification of sanitation through FCS testing alone to assure that products are not adulterated. FCS verification testing of sanitation procedures for Listeria species can compliment these other measures, e.g. post processing pasteurization, the addition of Lm growth inhibiting packaging. To the extent that establishments take a series of steps to address their possible Lm contamination, the need for higher FCS verification testing frequencies, and its impact of inspection personnel to review these data, is reduced.

Summary of Direct Industry Costs

The PRIA identified three major possible industry-wide impacts from mandatory FCS verification testing: HACCP plan modification costs ($1.28 million); direct testing costs ($1.75 million); and, production adjustments ($2.5 million). The total first-year cost of these impacts was $5.53 million--$3.8 million in one-time outlays and $1.75 million in recurring annual costs associated with testing).

The Final Regulatory Impact Analysis (FRIA) reflects many comments received in the public comment period. In addition to the impacts identified in the PRIA, the FRIA estimates (1) the cost of PL treatments (initial and annual operating); (2) the cost of using an agent or process to inhibit Lm growth (initial and annual operating); and, (3) the costs of holding product while awaiting confirmation of FCS verification testing.

The validation of PL treatments and related HACCP plan modifications results in a one-time cost of $2.6 million. The estimated cost in the FRIA is higher than that in the PRIA due to an increase in the number of establishments affected. The FRIA estimate may be conservative as it does not take into account the use of validation studies conducted by PL equipment manufacturers. Direct testing costs are substantially lower than estimated in the PRIA ($175,260 versus $1.75 million) because the expected

movement of establishments out of EG 4 and into the other establishment groups where higher FCS verification testing is not expected. Production adjustments are estimated at $1.15 million in one-time costs in the FRIA compared to $2.5 million in the PRIA. The difference is due mainly to fewer expected cases where establishments are not able to overcome their Lm contamination problem. More establishments adopt PL treatments and move into EG 1 or EG 2. The total of the two, one-time cost components (production adjustments and use of PL treatments) is the same as that estimated in the PRIA ($3.8 million as opposed to $3.75 million estimated in the PRIA). Verification testing costs, as noted above, are substantially lower than that estimated in the PRIA.

The additional costs associated with the installation of PL treatments and/or altering their production to incorporate an agent or process to inhibit Lm growth introduces potentially large cost outlays, especially for the initial, one-time investments in plant and equipment (Table 20). The initial industry-wide, one-time cost outlays for equipment associated with production adjustments and PL treatments are expected to be as high as $51.6 and $10.1 million, respectively. The annual operating (recurring) costs of $5.2 and $1 million,

respectively, make first-year costs for these two technologies, $56.7 and $11.1 million, respectively.

Table 20. Total Expected Industry-wide Costs				
Item	HACCP Establishment Size Category			Total
	L	S	VS	
	$thousand			
PL validation	749.1	1,510.1	385.7	2,644.8
PL Equipment & operations	14,351.3	42,390.6	0	56,741.
Growth inhibiting agent or process	521.7	10,597.6	0	11,119.4
FCS testing	.7	46.9	127.7	175.3
Production adjustments	77.9	238.7	834.8	1,151.4
Product handling and storage	165.0	489.6	311.4	966.0
Total Costs	15,865.7	55,273.5	1,659.5	72,798.7

Converting initial costs into an annual equivalent cost of capital recovery provides a more accurate measure of economic impacts[8]. Using a 7-percent discount rate over ten years results in annualized cost of $9.3 million for PL validation, installation, agent and/or process alteration cost, and production adjustments. The annual operating (recurring) costs are estimated at $7.3 million. Combining these two estimates produces a total annual cost of the final rule of $16.6 million (bottom of Table 21).

Table 21. Total Annualized Industry-wide Cost Impact, by establishment size.		
Item	HACCP Establishment Size Category	

[8] Lynn E. Bussey, The Economic Analysis of Industrial Projects, Engelwood Cliffs, New Jersey, 1978.

	L	S	VS	Total
	$thousand			
Initial	14,347.9	49,919.9	1,220.5	65,488.2
Recurring	1,517.8	5,353.5	439.1	7,310.4
Total	15,865.6	55,273.5	1,659.5	72,798.6
	22%	76%	2%	100%
Annualized Cost	10 year, 7-percent			
Initial	2,042.8	7,107.5	173.8	9,324.0
Recurring	1,517.8	5,353.6	439.1	7,310.4
Total	3,560.6	12,461.1	612.8	16,634.5
	21%	75%	4%	100%

Possible Indirect and Unintended Cost Impacts

The focus of the cost discussion thus far was mainly on industry-wide direct compliance costs: these costs, on an annual basis, were estimated at $16.6 million, roughly one-half of one percent of the total annual value of industry sales ($16.6 million divided by $25.2 billion). In addition, some discussion was made of the possible impacts that the final rule may have on lowering product quality, reducing current FCS testing frequencies in some establishments, and forcing some establishments to exit the industry. However, these impacts were not quantified. Two other possible indirect cost impacts are on consumers and other sectors of the economy.

No market product quantity and price data are available to calculate the possible consumer price implications brought about by the higher compliance costs identified in this analysis. This information, plus an

estimation of any reduction in market supplies, could be used to calculate the social costs of shifts in supply and demand in a consumer- and producer-surplus framework. Also, a complicating factor in estimating possible market supply reductions is to what extent imported product could be substituted for any US RTE MPP production cutback. Without such information, one can only say that higher industry compliance costs and lower market supplies would be expected to raise consumer prices to some extent. From the information provided in this analysis (the expected small cost impacts relative to total value of production and the likely small quantity cut-backs), it is expected that these impacts would be minimal.

A related issue is the possible impact on other sectors of the economy. Census data show that swine, beef, dairy, and poultry industries supply significant amounts of raw product to the RTE MPP industry. Because, however, the quantity effect is expected to be minimal, these upstream suppliers of raw material are not expected to be significantly affected by the final rule.

Analysis of Benefits

The analysis of benefits resulting from the final rule examines the reduction in human health risk (deaths and illnesses caused by listeriosis) from actions taken as a

result of this final rule by RTE MPP establishments in only one product group: deli meats (primarily sliced luncheon meats). This analysis of benefits thus differs from that in the PRIA which examined the reduction in human health risk from all RTE MPPs.

FSIS is focusing on deli products for several reasons. First, the FDA-FSIS risk assessment identified this product group as having the highest risk of all food classes and the cause of a large share of listeriosis deaths and illnesses. Second, the FSIS Lm Risk Assessment, when calibrated to a revised version of FDA-FSIS risk assessment, tied risk mitigation actions at deli-meat producing establishments to potentially lower rates of listeriosis death and illnesses. FSIS plans to modify the model to capture the dynamics of Lm contamination and containment in other RTE MPP products, such as hotdogs, along with the impact of production volume. Third, the FSIS Lm Risk Assessment, having been presented to the public for comment, has been revised to the extent possible at this time.

The analysis of benefits uses the FSIS Lm Risk Assessment to evaluate the human health risk reduction effects of sanitation coupled with FCS verification testing, the use of growth inhibiting packaging (GIP); and

the use of PL treatments. The likely reduction in listeriosis deaths from a 100-percent adoption of these practices and treatments by the industry is given in Table 22. FSIS is reporting three values for the possible benefits derived from this rule: the median, the 5th percentile, and the 95th percentile for each scenario (baseline, sanitation/FCS verification testing, Lm growth-inhibiting packaging (GIP) and post-lethality processing (PP) + GIP). This range of values represents the uncertainty in the true number of averted number of deaths per year. The reported results imply 90 percent certainty that the true value lies between the 5th and 95th percentiles. Each uncertainty distribution is the result of three hundred computer simulations, each simulation consisting of 100,000 iterations, of the FDA-FSIS risk ranking model. The risk characterization portion of that model comprises 4,000 combinations of the exposure distributions for the 23 different food groups in the FDA-FSIS risk ranking model. The median reports the mid-point value of deaths averted from these multiple computer simulations for each scenario. The median is reported because it is the preferred measure of central tendency in the FDA-FSIS risk ranking. Furthermore, the distribution of results suggests that the mean, as an alternative

measure of central tendency, is less informative about the shape of the distribution because of the influence of outliers in its calculation. Illnesses are estimated using the standard .20 case-fatality rate commonly reported in the literature.

Table 22. Incremental Reductions in Deaths Due to Various Interventions (assuming 100% industry-wide adoption)

	Averted Deaths			Averted Illnesses		
Scenario	Median	5%	95%	Median	5%	95%
FCS testing /1	25 (24)	8 (8)	25 (24)	125 (120)	42 (40)	125 (120)
GIP	141 (135)	48 (45)	165 (158)	707 (675)	240 (225)	823 (790)
PP & GIP	238 (227)	77 (72)	272 (261)	1188 (1135)	384 (360)	1360 (1305)
/1 FCS testing at a 4-2-1 rate.						
/2 Numbers in parentheses exclude reductions in neonate deaths.						

The greatest reduction in listeriosis deaths and illnesses would occur if all establishments used both PP and GIP. However, 100 percent adoption is not possible for a variety of reasons, including technical -- not all products are amenable to the use of PL or GIP -- and economic -- the costs are prohibitive in relation to the value of the product.

The analysis of costs described movements among establishment groups that are likely to occur as a result of the final rule. These movements are the basis for estimating the human health benefits of the final rule. Establishment group net movements are placed on a

percentage basis of establishments in each size class (Table 23). The absolute changes in establishment numbers are converted into percentage increases by dividing the number establishments estimated to adopt one or more measures by the total number of establishments in that size class. For example, 2 of the 42 large establishments producing deli meats (4.8 percent) are estimated to adopt PL and GIP measures. Next, the percentage change in establishments is weighted by the relative volume of deli meats produced by that size class. The two large establishments are estimated to account for 2.3 percent of deli-meat production (4.8 times 0.48). The summation of these weighted percentages produces the percentage increase in that technology which is adopted as a result of the final rule. Thus, deli-meat producing establishments adopting PL and GIP represent a 5.4-percent increase in the amount of deli-meat production that is produced using this technology. Likewise, the percent increase in the amount of production using GIP and FCS sanitation/verification testing is 8.9 and 13.3 percent, respectively.

Table 23. Number of establishments adopting various interventions

	HACCP Establishment Size Category			Average
Item	L	S	VS	
Product Volume Weights	0.48	0.48	0.04	

Deli-meat producing stab.	42	311	340	
Mitigation Measure	Number of Establishments			
Establishments adopting PL and GIP	2	20	0	
	Percent			
Establishments	4.8	6.4	0.0	
Product	2.3	3.1	0.0	5.4
Mitigation Measure	Number of Establishments			
Establishments adopting GIP	1	50	0	
	Percent			
Establishments	2.4	16.1	0.0	
Product	1.2	7.7	0.0	8.9
Mitigation Measure	Number of Establishments			
Establishments adopting FCS Testing at a 4-2-1 rate	0	66	260	
	Percent			
Establishments	0.0	21.2	76.5	
Product	0.0	10.2	3.1	13.3

The results in Tables 22 and 23 are used to estimate the possible reduction in listeriosis deaths that may be attributed to actions taken be deli-meat producing establishments as a result of the final rule (Table 24).

This analysis excludes neonate deaths estimated by the FSIS risk assessment because of concerns about using the standard values for a statistical life, which are derived from adult lives. Of course, it is obvious that averting such neonate losses is a potentially significant benefit. However, excluding these losses does not substantially affect the conclusions of this analysis.

Calculations combining information from Tables 22 and 23 are fairly straightforward: for example, the 13.3 percet

increase in adoption rates of sanitation coupled with FCS verification testing translates into 3.1 fewer listeriosis deaths at the median (0.133 from Table 23 times 24 from Table 22); 1.0 fewer at the 5th percentile (0.133 x 8.0); and, 3.1 fewer at the 95th percentile (0.133 x 24). Similar calculations for the other two mitigation measures result in a total reduction of 27.3 at the median; 8.9 at the 5th percentile; and, 31.2 at the 95th percentile. The corresponding reductions in illnesses are 136.7 at the median, 44.6 at the 5th percentile, and 156.0 at the 95th percentile, respectively.

Table 24. Reduction in listeriosis deaths due to various interventions

Interventions	Averted Deaths		
	Median	5th percentile	95th percentile
FCS Testing (4-2-1)	3.1	1.0	3.2
GIP	12.0	4.0	14.0
PL & GIP	12.2	3.9	14.0
Total Reduction	27.3	8.9	31.2

The Economic Research Service of USDA presented a method for estimating the human health benefits of reduced listeriosis at a public meeting on the proposed rule held in May 2001. To estimate the benefits, it was assumed that 5 percent of the cases were moderate, and that moderate cases resulted in hospital costs of $10,300 per case. The remaining 95 percent of the illness were severe, resulting

in hospital costs of $28,300 per case[9]. Using these assumptions and excluding the loss in productivity of those affected and any pain and suffering, the benefits of the reduction in illness-related losses due to the final rule are estimated to be $3.7 million at the median (0.05 x 136.7 x $10,300) + (0.95 x 136.7 x $28,300)) and $1.2 million at the 5th and $4.3 million at the 95th percentile.

ERS estimated the value of statistical life at $4.8 million[7] as a proxy for the cost of one fatality. Based on this estimate, the annual human health benefits from the implementation of the final rule are $134.9 million at the median (the $3.7 million above plus 27.3 x $4.8 million) and $44.0 million at the 5th percentile and $154.0 million at the 95th percentile.

Given the limitations in data and the output of the risk assessment dealing only with deli meats and as per the discussion found earlier concerning the estimates of health consequences, FSIS believes that this estimate may be overstated by as much as 50 percent. If so, the adjusted annual net benefits then become $50.8 million, $5.4 million

[9] Stephen Crutchfield, "The Benefits of Reducing Listeria in ready to Eat Products." 2001. Presented at public meeting, "Performance Standards for the Production of processed Meat and Poultry Products," May 9-10, 2001. FSIS-USDA Washington, D.C. Roberts, Tanya, and Robert Pinner. Economic Impact of Disease Caused by Listeria monocytogenes." In Miller, AJ, Smith JL, and Somkuti GA, (Eds.) Foodborne Listeriosis.

and $60.4 million at the median, 5th and 95th percentile levels, respectively (Table 25). It appears that a downward adjustment in total benefits of 85 percent would be necessary to lower net benefits to near zero.

Table 25. Summary of Annual Total and Net Benefits

Item	No adjustment	Benefits reduced 50 percent	Benefits at Breakeven (15%)
	$million		
Total Benefits			
Median	134.9	67.5	20.2
5th percentile	44.0	22.0	6.6
95th percentile	154.0	77.0	23.1
Net Benefits			
Median	118.3	50.8	3.6
5th percentile	27.4	5.4	-10.0
95th percentile	137.4	60.4	6.5
Net benefits hold industry-wide compliance cost of this regulation constant at $16.6 million.			

Compliance with Regulatory Flexibility Act of 1996

The Administrator has determined that for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-612), this rule will have a significant economic impact on a substantial number of small entities. As discussed above, FSIS estimates that the Lm sanitation coupled with FCS verification testing provisions of this final rule may result in annual costs to small and very small producers of post-lethality exposed RTE MPPs of $12.5 and $0.6 million, respectively. These establishments incur about 79 percent

Amsterdam, the Netherlands: Elsevier Science Publishing Co., 1990, pp. 137-144.

of the total industry-wide costs of compliance with the sanitation coupled with FCS verification testing provisions of this final rule.

The Small Business Regulatory Enforcement Fairness Act of 1996 (P. L. 104-121) requires, among other things, that for each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis under section 604 of title 5, United States Code, the agency must publish one or more guides to assist small entities in complying with the rule, and must designate such publications as "small entity compliance guides". The guides must explain the actions a small entity is required to take to comply with a rule or group of rules. FSIS is developing guidance to assist small and very small establishments in fulfilling their responsibilities under the final rule. The guides will include instructions on how establishments that produce post-lethality exposed RTE MPPs can conduct sanitation coupled with FCS and product verification testing. Establishments that wish to use the guides may incorporate their features into their HACCP plans, Sanitation SOPs or other prerequisite programs. Because FSIS is basing its guidance on existing research and industry practices that are known to be effective, the Agency also will consider the processing instructions to be

already validated. That is, an establishment may follow the guidance without contracting for or conducting additional validation of the content of the materials.

FSIS is examining other options to minimize the potential negative economic effects of these proposed regulations on small businesses, including encouraging research that would facilitate validation of pathogen lethality in many products, especially those produced by traditional methods by small and very small establishments.

Types of Entities and Production Affected by the Final Regulations. The preliminary RIA found that small and very small establishments made up about 91 percent of the number of establishments in the US RTE MPP industry and were expected to incur up to 69 percent of the cost of complying with the requirements of the proposed rule. The FRIA finds that small and very small establishments make up about 97 percent of the number of establishments in the industry and are expected to incur nearly 80 percent of total cost impact on the industry. As was also stated in the FRIA, the final rule only involves that part of the original proposal dealing with FCS verification testing for Lm or indicator organism and also uses a more accurate baseline for the number of establishments affected by the final rule.

An important note to consider throughout this analysis is that much of the projected impacts originate from expected movements of establishments from one establishment group to another. As was stated in the preliminary RIA, "mandatory Listeria testing is the most difficult provision in the proposed rule to analyze because of the uncertainty of current practices and how establishments will react to the proposed rule. Major uncertainties include: the degree to which firms will switch to a Listeria-related CCP in their HACCP plan, the degree to which firms will be able to resolve their Listeria-related problems if they present themselves, and the degree to which they must increase their testing." This problem is further compounded in this analysis because the final rule is not limited to whether establishments either elect to incorporate a Lm-related CCP in their HACCP plan or face mandatory testing. In this analysis, it is possible for establishments to address possible Lm contamination in their operations through a variety of methods.

A large share of the cost impact is on small establishments, which are expected to absorb nearly 75 percent of the total industry-wide cost impact (Table 26 and 27). These establishments have the same incentives to move to new post-pasteurization technologies as do very

small establishments, but their production volumes more easily justify the associated high capital and recurring expenditures. Very small establishments will likely have to increase sanitation coupled with FCS verification testing to comply with this final rule. Large establishments are likely to complete the process of adopting new technologies. The expected impacts on large, small, and very small establishments are discussed below.

Large establishments.

As discussed in the "Baseline" section of this analysis, most (131 out of 144 large establishments) already fall into either establishment group 1, 2 or 3. This number is expected to increase by 5 establishments as a result of the final rule, leaving only 8 establishments in the establishment group 4: those establishments required to conduct more intense sanitation coupled with FCS L. spp. verification testing than establishments producing product in the other establishment groups. Many of these firms already employ post-pasteurization technologies, but need them validated to comply with the final rule. In fact, six of the existing establishments in EG 1 and four of the establishments from EG 2 already employ the technology, but simply have not validated their processes. It is expected

that total validation costs will run about $749,000 in first-year costs for these establishments.

The remaining establishments are likely to have high enough product volume levels to justify the acquisition of new post-pasteurization technologies and/or to alter product formulations and packaging. The remaining eight establishments (seven of the ten establishments from EG 2 (or 10 percent of the establishments in EG 2 that do not apply a post-pasteurization step)); and one from EG 4 (or 10 percent of the establishments in EG 4) all are expected to need post-pasteurization equipment and have their processes validated. The resulting large initial cost outlays plus the estimated recurring annual operating costs are expected to total $14.3 million in first-year costs. This cost represents about 90 percent of all the costs that are expected to be incurred by large establishments as a result of this final rule. The remaining costs are incurred by those establishments electing to add an inhibiting agent or process in their production or to a lesser degree, as a result of sanitation coupled with FCS verification testing and possible subsequent actions related to hold and test and finding remedies to possible persistent Lm contamination problems.

Small Establishments.

It is estimated that there are 1,276 small establishments producing RTE MPPs. FSIS estimates that 108 small establishments will migrate to other establishment categories as a result of the final rule. This is a costly undertaking, especially for those establishments that elect to migrate into EG 1. Due to the high cost of both technologies (post-lethality processing and adding an agent or process to the product) and because their products must conform to both process adjustments, it is expected that only 31 establishments (or 10 percent of the small establishments that were formally in EG 4) migrate to EG 1 as a result of the final rule. All movement involves the purchase and use of new technology which is expected to cost these establishments over $42 million. About twice the number of establishments that is expected to migrate to EG 1 is expected to migrate to EG 2. This move is less costly and it is expected that more RTE MPPs lead themselves to the addition of an inhibiting agent or process. These 77 establishments are expected to incur $10.6 million in first-year, total direct and recurring costs. All of the 108 establishments are expected to migrate from EG 4.

Very small establishments.

It is estimated that there are 3,556 very small establishments producing RTE MPPs. The preliminary RIA had an estimate of only 524 establishments, acknowledging that that estimate severely underestimated the true number of very small establishments. Due to the combination of high costs and technical difficulties faced by very small establishments, FSIS projects that no very small establishments will shift into a different establishment group. Consequently, FSIS does not expect that very small establishments will incur any costs associated with the adoption of post lethality treatment methods or by incorporating an inhibiting agent or process in their production. Instead, most of the entire cost impact of this final rule on very small establishments is expected to originate from sanitation coupled with FCS verification testing and the possible production adjustments and additional handling and storage associated with increased testing and the higher likelihood of incurring Listeria species positive FCS test results. A small amount of costs are expected to be incurred by those very small establishments that currently employ un-validated post-lethality processing technologies.

Summary.

Small establishments make up 26 percent of the establishments, yet are expected to incur up to 75 percent of the aggregate cost burden. Much of these expected costs are in large capital expenditures in post lethality processing equipment and in changing their production process to incorporate Lm growth inhibiting agents or processes. This cost impact would be reduced to the extent that these cost estimates over-estimate the actual costs of acquiring these technologies or over-estimate the establishment movements. It is unlikely that actual cost impacts would exceed those estimated in this analysis. Very small establishments make up 71 percent of the number of establishments in the industry and yet are expected to incur only 4 percent of the total costs of this final rule. This estimate may under-estimate their exposure to cost increases related to FCS testing. Thus, it is unlikely that actual cost impacts would be lower than those estimated in this analysis. The estimates for large establishments are highly contingent on their movement into EG1 and EG2. To the degree that actual movements into these establishment groups occur, the estimates in this analysis should reflect these expected cost outlays.

Table 26. Potential First-Year Total Direct and Recurring Cost Impacts Across HACCP Establishment Size Categories.

Cost Component	HACCP Establishment Size Category			
	L	S	VS	Total 2/
	$thousand			
PL Validation	749.0	1,510.1	385.7	2,644.8
PL Installation	14,351.3	42,390.6	0	56,741.9
Growth Inhibitor	521.7	10,597.6	0	11,119.3
FCS testing	0	46.8	127.5	175.3
Production Adjustments	77.9	238.7	834.8	1,151.4
Handling & Storage	165.0	489.6	311.4	966.0
Total Costs Above	15,865.6	55,273.5	1,659.5	72,798.6
Total Costs broken into one-time, initial year costs and recurring costs.				
One-time, initial year	14,347.9	49,919.9	1,220.4	65,488.2
Recurring	1,517.8	5,353.6	439.0	7,310.4

Table 27. Estimated Total Cost Impact of Final Rule, Annualized.

Annualized Cost	10 year, 7-percent			
	HACCP Establishment Size Category			
	L	S	VS	Total
	$thousand			
One-time costs	2,042.8	7,107.5	173.8	9,324.0
Recurring	1,517.8	5,353.6	439.1	7,310.4
Total	3,560.6	12,461.1	612.8	16,634.5
	Percent			
Total Costs	21	75	4	100
	Percent			
Establishments	3	26	71	100