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Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products; Final Rule

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 430

[Docket No. 97–013F]

RIN 0583–AC46

Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Interim final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending its regulations to require that official establishments that produce certain ready-to-eat (RTE) meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes.* In particular, under these regulations, establishments that produce RTE meat and poultry products that are exposed to the environment after lethality treatments and that support the growth of *L. monocytogenes* will be required to have, in their hazard analysis and critical control point (HACCP) plans, or in their sanitation standard operating procedures or other prerequisite programs, controls that prevent product adulteration by *L. monocytogenes.* The establishments must share with FSIS data and information relevant to their controls for *L. monocytogenes.* The establishments also must furnish FSIS with information on the production volume of products affected by the regulations. The establishments may make claims on the labels of their RTE products regarding the processes they use to eliminate or reduce *L. monocytogenes* or suppress or limit its growth in the products.

DATES: This interim final rule is effective on October 6, 2003.

Comments on the information presented under ''Paperwork Reduction Act'' must be received by August 5, 2003.

Recognizing, however, that some approaches to *L. monocytogenes* control set out in this interim final rule are novel, FSIS will accept comments on the rule until December 8, 2004, for the purpose of reviewing and evaluating the effectiveness of these approaches.

ADDRESSES: One original and two copies of each comment should be sent to FSIS Docket #97–013F, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102 Cotton Annex, 300 12th Street, SW., Washington, DC 20250–3700. Comments will be available for public inspection in the Docket Clerk's Office between 8:30 and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Acting Assistant Deputy Administrator, Policy Analysis and Formulation, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 205–0495. Copies of references cited in this document are available in the FSIS Docket Clerk's Office, Room 102, Cotton Annex, 300 12th Street, SW., Washington DC 20250–3700. The Office is open 8:30 a.m. to 4:30 p.m., Monday through Friday.

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I. Background

The Food Safety and Inspection Service (FSIS) administers the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPIA; 21 U.S.C. 451 *et seq.*) to ensure that meat, poultry, and egg products prepared for distribution in commerce are wholesome, not adulterated, and properly marked, labeled, and packaged. The FMIA and PPIA prohibit anyone from selling, transporting, offering for sale or transportation, or receiving for transportation in commerce, any adulterated or misbranded meat or poultry product (21 U.S.C. 610, 458).

Under the Acts, a meat or poultry product is adulterated if, among other circumstances, it bears or contains any poisonous or deleterious substance that may render it injurious to health (21 U.S.C. 601(m)(1), 453(g)(1)); if it is for any reason unsound, unhealthful, unwholesome, or unfit for human food (21 U.S.C. 601(m)(3), 453(g)(3); or if it has been prepared, packed, or held under insanitary conditions whereby it may have been rendered injurious to health (21 U.S.C. 601(m)(4), 453(g)(4). Such a product is misbranded if, among other circumstances, it fails to bear directly or on its container the official inspection legend (*e.g.*, for meat products, ''U.S. Inspected and Passed'' plus the official establishment number) prescribed in the regulations (21 U.S.C. 601(n)(12), 453(h)(12)). The Acts require FSIS to carry out an inspection of meat, meat food products, and poultry products to ensure that the products are not adulterated (21 U.S.C. 606, 455), and if the products are found upon inspection to be not adulterated, they must bear directly or on their containers the official inspection legend (21 U.S.C. 606, 607, 457).

The Acts give FSIS broad authority to promulgate such rules and regulations as are necessary to carry out the Acts (21 U.S.C. 621, 463). The Acts require FSIS to prescribe rules and regulations governing the sanitary conditions under which the establishments that produce these products are to be operated (21 U.S.C. 608, 456).

On February 27, 2001, FSIS proposed (66 FR 12589) to establish several new requirements for the processing of ready-to-eat (RTE) and other meat and poultry products. The Agency proposed food safety performance standards for all RTE and all partially heat-treated meat and poultry products. The proposed performance standards set both levels of pathogen reduction and limits on pathogen growth that official meat and poultry establishments must achieve in order to produce products that are not adulterated. FSIS also proposed to allow the use of customized, plant-specific processing procedures and to eliminate its regulations that require that both RTE and not-ready-to eat pork and products containing pork be treated to destroy trichina (*Trichinella spiralis*).

Finally, FSIS proposed environmental testing requirements intended to verify measures to reduce the incidence of *L. monocytogenes* in RTE meat and poultry products. Specifically, FSIS proposed to

require establishments that produce RTE meat and poultry products to test food contact surfaces for *Listeria* species to verify that establishments were controlling the presence of *L. monocytogenes* within their processing environments. Under the proposal, establishments that developed and implemented HACCP controls for *L. monocytogenes* would be exempt from these testing requirements because the HACCP regulations require on-going monitoring and verification to demonstrate that the food safety system is working.

In this interim final rule, FSIS is amending its regulations only in regard to the control of *L. monocytogenes* in RTE products. FSIS plans to address the other proposed provisions in future **Federal Register** publications. In view of recent outbreaks of foodborne listeriosis, as well as recent recalls of meat and poultry products adulterated by *L. monocytogenes,* the Agency has decided to adopt these regulations before completing action on the other provisions of the proposal.

II. Listeria monocytogenes

L. monocytogenes is a pathogenic bacterium found in the environment (*e.g.*, in soil, water, and vegetation and on the surfaces of equipment, floors, and walls) and is often carried by healthy animals (including humans). *L. monocytogenes* is spread very easily by direct food contact with a contaminated surface, and it can survive and grow in a refrigerated, packaged RTE product.

L. monocytogenes grows under low-oxygen conditions and at low refrigeration temperatures and survives for long periods of time in the environment, on foods, in processing plants, and in household refrigerators. Although frequently present in raw foods of both plant and animal origin, it also can be present in cooked foods because of post-processing contamination. Consumption of food contaminated with *L. monocytogenes* can cause listeriosis. Listeriosis is a potentially fatal disease in newborns, the elderly, and persons with weakened immune systems, such as those with chronic disease or human immunodeficiency virus (HIV) infection or those taking chemotherapy for cancer. Listeriosis is also a major concern in pregnant women. Even though symptoms may be relatively mild in the mother, the illness can be transmitted to the fetus, causing illness or fetal death.

Each year, according to the Centers for Disease Control and Prevention (CDC), *L. monocytogenes* causes an estimated 2,493 cases of listeriosis. Of these, 2,298 persons are hospitalized, and 499 persons die. The case-fatality rate is high across the whole population—20 deaths per 100 cases of illness. Epidemiologic surveillance data show that the case-fatality rate varies by age, with a higher case-fatality rate among newborns and the elderly.[1]

L. monocytogenes is one of several foodborne pathogens that have been a special focus of public health strategies, such as Healthy People 2010. Organized by the Department of Health and Human Services (HHS), Healthy People 2010 is a comprehensive, nationwide health promotion and disease prevention agenda for increasing the quality and years of healthy life. The food safety objectives of Healthy People 2010 include infection reduction targets for pathogens of concern. The 2010 target for *L. monocytogenes* is to reduce by 50 percent the rate of illnesses below the 2001 level of 0.5 cases per 100,000 population.

A number of factors can cause or contribute to *L. monocytogenes* contamination of RTE meat and poultry products in a meat or poultry processing establishment. First, if the pathogen is already present in product ingredients, a processing error, such as incorrect formulation or inadequate processing time or temperature, can result in the production of products containing live organisms. Second, a product that has undergone a successful lethality treatment can be contaminated by biofilms on food-contact surfaces of equipment used for processing, handling, or packaging the product. The product can also be exposed to environmental contamination or cross-contamination in the post-lethality processing environment. One cause of cross-contamination can be plant construction in the post-lethality area of the establishment, unless precautions are taken to protect the products during the period of construction. Serious outbreaks of listeriosis have occurred because of the failure to take such precautions during facilities construction or remodeling.

Additional causes of contamination or cross contamination can be poor facilities design or plant equipment layout. Cross-contamination can occur if the flow paths of raw product and finished products cross or if vehicle or personnel traffic from outside the plant or from a raw-product area of the plant enters an area where exposed finished products are handled. Contamination or cross-contamination also can occur if processing equipment has not been designed for easy cleaning, or if equipment or facilities have hard-to-reach niches that can harbor *L. monocytogenes* or other pathogens.

III. Events Leading Up to the Proposed Rule

Outbreaks and Recalls

During the 1980's, *L. monocytogenes* began to emerge as a problem in processed meat and poultry products. FSIS and FDA worked with processing plants to improve their procedures and emphasized a ''zero tolerance''—no detectable levels of viable pathogens—for the organism in RTE products. Between 1989 and 1993, the rate of illness from *L. monocytogenes* declined 44 percent.

In the fall of 1998, State health departments and the CDC investigated an outbreak of foodborne illness in which hotdogs and, possibly deli (luncheon) meats, were implicated. CDC and FSIS investigators isolated the outbreak strain, a strain of *L. monocytogenes*, from an opened and previously unopened package of hotdogs manufactured by a single plant. CDC eventually reported 101 illnesses, 15 adult deaths, and 6 stillbirths or miscarriages associated with the outbreak.

Another outbreak of listeriosis occurred between May and December 2000 and was spread over 10 States. CDC linked a strain of *L. monocytogenes* to 29 illnesses—8 perinatal and 21 non-perinatal—resulting in 4 deaths and 3 in miscarriages or stillbirths. Subtyping by pulsed-field gel electrophoresis (PFGE) showed the *L. monocytogenes* strains to be indistinguishable from one another.

The outbreak was linked to eating turkey deli meat. Thirteen stores and delicatessens where patients reported purchasing turkey meat obtained their turkey meat from at least 27 federally inspected establishments. Two establishments were linked to 10 of 11 patients. FSIS traced the implicated turkey meat to a Texas poultry processor.

1999 Reassessment Notice

In 1999, with the emergence of an especially virulent strain of *L. monocytogenes*, the Agency concluded that many establishments should reassess their HACCP plans. FSIS published in the **Federal Register** a Notice (64 FR 28351; May 26, 1999) advising manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to ensure that the plans were, in fact, adequately

[1] Mead, P. S., L. Slutsker, V. Dietz, L. F. McCraig, S. Bresee, C. Shapiro, P. M. Griffin, and R. V. Tauxe. 1999. Food-related illness and death in the United States. *Emerging Infectious Diseases* 5:607–625.

addressing *L. monocytogenes*. If the reassessment revealed that *L. monocytogenes* was a hazard reasonably likely to occur in an establishment's production process, the establishment would have to address the hazard in its HACCP plan.

The same month, FDA and FSIS announced plans to conduct a quantitative microbial risk assessment to determine the extent of consumer exposure to foodborne *L. monocytogenes* in RTE foods (64 FR 24661; May 7, 1999).

FSIS Action Plan

A May 5, 2000, Presidential directive on *L. monocytogenes* in RTE foods revised the Healthy People 2010 target date for reducing illnesses caused by the pathogen up to 2005 and set other objectives. HHS and USDA responded to this directive with an eight-point action plan providing for consumer, health-care provider, and industry education; redirection of enforcement strategies, including increased microbial sampling; enhanced disease surveillance; coordinated research activities; and proposing new regulations. For its part, FSIS announced its intention to publish a proposed rule that would, among other things, require establishments to conduct environmental testing for *Listeria* species in order to verify the effectiveness of their sanitation standard operating procedures (Sanitation SOPs).

FDA/FSIS Draft Risk Ranking

FDA and FSIS made public a preliminary draft of a risk ranking in January 2001 (66 FR 5515; January 19, 2001). The risk ranking (*see http://www.foodsafety.gov/dms/lmrisk.html*) estimated the relative risks of serious illness and death from listeriosis that may be associated with consumption of different types of RTE foods. The risk ranking did not cover listerial gastroenteritis, a less serious infection with mild flu-like symptoms. The risk ranking (1) estimated the potential level of exposure of three age-based U.S. population groups to *L. monocytogenes* contaminated foods in 20 food categories and (2) related this exposure to public health consequences. The food categories studied included foods with a history of *L. monocytogenes* contamination. The models used in the risk ranking provided a means of predicting the likelihood that severe illness or death will result from consuming foods contaminated with this pathogen. Estimates were made of the relative risks posed by the food categories, but the risk ranking did not predict the precise public health consequences attributable to any particular contaminated food.

The foods considered in this risk ranking were RTE foods that are generally eaten without being cooked (*e.g.*, cheese) or are typically reheated (*e.g.*, frankfurters) before consumption. The main categories considered were seafood, produce, dairy, meat, and combination foods. The population groups evaluated were: (1) perinatal, including fetuses and neonates from 16 weeks after fertilization to 30 days postpartum. These are pregnancy-associated cases where exposure occurs most often *in utero* as a result of foodborne *L. monocytogenes* infections of the mothers during pregnancy and may result in spontaneous abortions, stillbirths, and neonatal infections; (2) elderly, that is, individuals who are 60 or more years of age; and (3) the intermediate-age group, including the remaining population, both healthy individuals (with very low risk of severe illness or death from *L. monocytogenes*) and certain susceptible population groups.

The population groups included individuals with increased susceptibility to listeriosis, such as acquired immune deficiency syndrome (AIDS) patients or individuals taking drugs that suppress the immune systems (*e.g.*, cancer or transplant drugs). Individuals within these susceptible population groups account for most of the cases of listeriosis within the intermediate-age group. The risk ranking focused on the overall burden of listeriosis on public health and includes the occurrence of both sporadic illnesses (*i.e.*, illnesses not associated with a documented outbreak) and outbreak illnesses.

The results of the risk ranking indicated that certain RTE meat and poultry products presented a relatively moderate to high risk for listeriosis. These included pâtés and meat spreads, deli meats, hotdogs, and deli salads containing meat or poultry products. Further, there was a significant opportunity for recontamination of RTE meat and poultry products in the processing establishment.

IV. Proposed Rule Provisions on *L. monocytogenes*

The Agency concluded 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. The Agency therefore resolved to proceed to rulemaking to correct the problem. In February 2001, FSIS issued a proposed rule that would require that establishments that produce post-lethality exposed RTE meat or poultry products conduct testing of food contact surfaces for *Listeria* species in areas of the establishments into which the products are routed after undergoing lethality treatment and before final product packaging. All establishments would be required to do this unless they had incorporated one or more controls validated to prevent, reduce to an acceptable level, or eliminate the *L. monocytogenes* from their products into their HACCP systems.

The proposed testing was intended to verify that the establishment's Sanitation SOP was preventing direct product contamination by *L. monocytogenes* after the products had undergone a lethality treatment. FSIS recognized that there is a significant risk for RTE meat and poultry products to become re-contaminated by *L. monocytogenes* if they came into contact with the pathogen, and that testing was necessary to verify that the procedures conducted under the Sanitation SOP had killed or eliminated the pathogen.

Under the proposal, if an establishment found that a food contact surface had tested positive for *Listeria* species, the establishment would have to take the corrective action necessary to properly clean the surfaces and to prevent product that may have become contaminated through contact with the surface from entering commerce.

Under the proposal, an establishment that had identified *L. monocytogenes* as a hazard reasonably likely to occur in its HACCP plan, and that had established CCPs for *L. monocytogenes*, was exempt from the proposed mandatory testing frequency requirement because HACCP regulations already require monitoring and verification, including testing frequency, as validated in the HACCP plan. An establishment that did not explicitly identify *L. monocytogenes* as a hazard reasonably likely to occur, but whose HACCP controls for biological hazards effectively prevented, eliminated, or reduced product contamination by the pathogen, would have had to make only minor amendments in its HACCP plan and supporting documentation to reflect that *L. monocytogenes* had been identified as a hazard addressed by the HACCP plan. In any case, if HACCP controls were implemented, the establishment would have to develop and validate the monitoring and verification procedures used to document the on-going effectiveness of the system. FSIS did not specify minimum monitoring and verification requirements for these processors.

The Agency has made it clear that, in its view, contamination with *L. monocytogenes* is a hazard reasonably likely to occur in all RTE meat and poultry products that are exposed to the processing environment post-lethality. Significant concerns about such contamination underlay the Agency's May 26, 1999, **Federal Register** Notice advising manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to determine whether the plans were appropriately addressing *L. monocytogenes*. In the proposal, however, the Agency acknowledged that, even though *L. monocytogenes* was a significant concern in RTE products, it may not be necessary to address this pathogen in the HACCP plan itself. FSIS acknowledged that this pathogen may be present but not necessarily likely to occur because the establishment had measures in place, such as Sanitation SOPs, that effectively prevented contamination by the pathogen in the food processing environment. An establishment might have incorporated the controls in its Sanitation SOP and thereby prevented the pathogen from posing a contamination hazard in the processing environment.

Consequently, to verify that such plants were effectively preventing environmental contamination, FSIS proposed to require that establishments without HACCP controls for *L. monocytogenes* test food contact surfaces for *Listeria* species at a frequency that was based on the relative size of the establishments. FSIS proposed that large establishments subject to the requirement conduct at least four such tests per line per month; small establishments at least two per line per month; and very small establishments at least once per line per month. A large establishment was one employing more than 500 employees; a small establishment from 10 to 499 employees; and a very small establishment one employing fewer than 10 employees and grossing less than $2.5 million in sales. These are the same size criteria the Agency had used in its 1996 final rule on HACCP systems (61 FR 38806).

The Agency solicited information on the proposed rule, including the efficacy of the testing frequencies, their potential cost to industry, the relationship between *Listeria* species on food contact surfaces and *L. monocytogenes* in product, and the various factors that might be important in devising effective testing protocols.

FSIS also proposed that establishments take certain actions after obtaining a positive food contact surface test result for *Listeria* species. An establishment with such a result would have to take the corrective action defined in its Sanitation SOP. The establishment would have to have in place procedures to determine which lots of product might be affected; to hold, sample, and test that product; and to dispose of affected product appropriately. FSIS acknowledged that some establishments would have to modify their Sanitation SOP corrective actions to include such elements.

FSIS requested comment on whether *Listeria*-positive test results on different food contact surfaces (such as surfaces that had been treated with a bactericide versus those that had not) should be treated differently; whether the Agency should establish more specific requirements on product sampling following a *Listeria*-positive test on a food contact surface; and whether an establishment should have to determine whether a *Listeria*-positive sample is *L. monocytogenes* before having to initiate product testing.

FSIS stated in the preamble of the proposal that if a sampled lot is found to be positive for *L. monocytogenes*, and the product from the lot is already in commerce, the Agency would request that the product be recalled. Further, the Agency stated, if product is found to be positive for *L. monocytogenes*, the establishment that produced it would likely have to establish controls for the pathogen within its HACCP plan.

FSIS noted that the two provisions addressing *Listeria* contamination contained in the proposed rule, HACCP and Sanitation SOPs, required specific daily action to ensure that product is not adulterated. FSIS stated that, as of the time of the proposal, it did not consider programs outside of Sanitation SOPs and HACCP to be sufficient to prevent the hazards associated with post-lethality contamination with *Listeria* in the manufacture of RTE products. For one thing, the Agency noted, documentation of corrective and preventive actions taken in such programs, known as GMPs (good manufacturing practices) or prerequisite programs, generally was not being provided to the Agency.

Compliance guidance: In the proposal, FSIS made a commitment to provide compliance guidance to establishments on testing frequencies and methodologies and appropriate corrective actions to take following positive tests on samples from food contact surfaces. FSIS also said it would publish guidance on available interventions (techniques for killing *L. monocytogenes*) establishments can implement as CCP's. FSIS made the draft compliance guidance available on its Web site after publication of the proposal.

Opportunity for Public Comment

FSIS provided a 90-day comment period. On April 13, 2001, FSIS published a **Federal Register** notice (66 FR 19102) extending the comment period an additional 30 days, through June 28, 2001, to provide opportunity for the public to comment on issues raised at a technical conference and public meetings that the Agency held May 8–10, 2001, on the proposed regulations. After the extended comment period expired, the Agency announced, in a July 3, 2001, **Federal Register** notice (66 FR 35112), that at the request of a consortium of trade associations, the Agency was reopening the comment period for an additional 30 days, until September 10, 2001. The consortium had said that it needed the additional time to review the large amount of scientific and economic data presented at the May 8–10 meetings, FSIS's draft compliance guidelines, and the draft FDA/FSIS risk ranking on the relationship between foodborne *L. monocytogenes* in RTE foods and human health.

Public Meetings on Listeria

During the development both of the proposal and this interim final rule, FSIS held a series of meetings with constituents and with technical and scientific experts on the problem of *L. monocytogenes* and how to control it. Some meetings were prompted by large-scale product recalls due to contamination with the pathogen or actual outbreaks of listeriosis.

In February 1999, following the late-1998 listeriosis outbreak and a recall of hotdogs and deli meats that had been contaminated with *L. monocytogenes*, FSIS held a public meeting on the food safety issues related to *L. monocytogenes* in meat and poultry products. At the meeting, industry and government procedures were discussed, including sampling programs for RTE products and the best ways to educate ''at risk'' populations about *Listeria*.

On May 15, 2000, FSIS held a public meeting to discuss current Agency initiatives to prevent human illness from *L. monocytogenes* in RTE meat and poultry products; the use of *Listeria* species as an indicator organism for *L. monocytogenes*; and the efficacy of environmental testing for *Listeria* species.

On May 8, 2001, FSIS held a public meeting to discuss scientific research and new technologies for detecting and controlling *L. monocytogenes* in RTE

meat and poultry products. At this meeting, FSIS requested data relevant to the proposed regulation regarding frequencies of testing for environmental *Listeria* species and the correlation of potential product contamination with production volume.

On November 18, 2002, FSIS held a public meeting to provide a forum for experts from government, academia, industry, and elsewhere to discuss current research and information related to improving the safety of RTE products. The topics discussed included the role of environmental and product testing, decontamination strategies, and consumer behaviors related to RTE foods. At the meeting, FSIS released a new draft directive (Directive 10,240.3, discussed below) on FSIS microbiological testing of RTE products for a number of organisms, including *L. monocytogenes*.

An additional public meeting was held February 26, 2003, to discuss an FSIS draft risk assessment which had been conducted to determine the likelihood that *L. monocytogenes* may contaminate RTE meat and poultry products during production and packaging processes. The Agency's draft risk assessment was released February 14, 2003, and was posted on the FSIS Web site (at *http://www.fsis.usda.gov/OPHS/lmrisk/DraftLm22603.pdf*). Copies also were made available in the FSIS Docket Room. Public and peer reviewer comments on the risk assessment and the Agency's response to the comments also can be viewed in the Docket Room and on the Web site.

V. FSIS Risk Assessment of *L. monocytogenes* in RTE Meat and Poultry Products

The FSIS risk assessment and the FDA/FSIS risk ranking on *L. monocytogenes* in RTE foods sold at retail provided a framework for evaluation of, and data on, risk mitigation strategies, including in-plant measures, to inform the Agency in this rulemaking as it considered the need to address potential contamination of RTE products by the pathogen.

FSIS initiated its *Listeria* risk assessment in February 2002 in response to public comments on the proposed rule that suggested the need for a stronger scientific basis for provisions requiring the testing of food contact surfaces for *Listeria* species. The risk assessment was developed: (1) To provide insight into the relationship between *Listeria* species on food contact surfaces and *L. monocytogenes* in RTE meat and poultry products exposed to the environment after the lethality treatment (post-lethality exposure); and (2) to evaluate the effectiveness of food contact surface testing and sanitation regimes, pre- and post-packaging interventions, growth inhibitors, and combinations of these interventions to mitigate contamination of RTE meat and poultry products that are post-lethality exposed, and to reduce the subsequent risk of illness or death from *L. monocytogenes*.

FSIS risk managers asked that the FSIS risk assessors evaluate the effect of various food contact surface testing and sanitation regimes in reducing *L. monocytogenes* contamination of products and the effect of other pre- or post-packaging antimicrobial interventions and of growth inhibitors in reducing such contamination. The risk managers also sought guidance from the risk assessors on testing and sanitation of food contact surfaces for *Listeria* species.

Given the available data and the fact that deli meats comprised about 80 percent of the listeriosis cases associated with ready-to-eat product, the FSIS risk assessment addressed only deli products. In order to evaluate the specific FSIS risk management questions, the risk assessment assumed that all *L. monocytogenes* on RTE product comes from the food contact surfaces and not from inadequate lethality treatment.

Using available data, the FSIS risk assessors developed a dynamic in-plant Monte Carlo simulation model (referred to as the in-plant model) quantitatively characterizing the relationship between *Listeria* species in the in-plant environment and *L. monocytogenes* in a production lot of RTE product at retail.

The outputs of the in-plant model (*e.g.*, concentration of *L. monocytogenes* on deli meats at retail) were used as inputs into the two major components of the FDA/FSIS risk ranking model discussed earlier: the exposure assessment and the associated dose-response relationship for deli meats.

In the FDA/FSIS risk ranking, the retail-to-table exposure assessment for deli meats and the associated dose-response relationship were developed to identify which RTE foods pose the greatest risk for causing listeriosis. Two components of the FDA/FSIS risk ranking model, the exposure assessment for deli meats and the dose-response relationship, were later updated with data and information provided during the public comment period on the draft FDA/FSIS risk ranking. The updated exposure assessment is used to track the level of *L. monocytogenes* in deli meat from retail to table and, using the updated dose-response relationship for *L. monocytogenes*, provides estimates of the subsequent risk of illness or death from consuming deli meats.

The outputs of the FSIS risk assessment model were calibrated to the *L. monocytogenes* concentration in deli meats at retail in the updated FDA/FSIS exposure assessment. That is, the FSIS output data were statistically compared with standard data on *L. monocytogenes* from a reputable third-party to determine whether the output data deviated from the standard data. Calibration of risk assessment models is intended to ensure the accuracy of risk estimates.

By modeling changes in in-plant practices, such as the frequency of testing and sanitation of food contact surfaces, the FSIS risk assessment model provides insight into the effects of these practices on the annual risk of illness or death from *L. monocytogenes* in RTE meat and poultry products. The risk assessment model was designed to provide numerous outputs that depended on the selection of in-plant practices, such as ''test and hold,'' responding after an initial positive food contact surface sample, or alternatively, after consecutive positive samples, and that were based on various plant characteristics (*e.g.*, plant size or production volume).

The most significant findings of the risk assessment model are: (1) The proposed minimal frequency of testing and sanitation of food contact surfaces (66 FR 12589, February 27, 2001) results in a small reduction in the levels of *L. monocytogenes* on deli meats at retail; and (2) combinations of interventions (*e.g.*, sanitation/testing of food contact surfaces, pre- and post-packaging lethality interventions, and growth inhibitors) appear to be much more effective than any single intervention in mitigating the potential contamination of finished RTE products with *L. monocytogenes* and reducing the subsequent risk of illness or death.

Specific model outputs relating to *L. monocytogenes* concentrations in deli products at retail and the resulting public health impacts of various interventions were developed and were presented at a public meeting on February 26, 2003. FSIS accepted comments on its draft risk assessment at the public meeting and afterward, until March 14, 2003 (68 FR 6109; February 6, 2003). The comments received have been included in the record of this rulemaking proceeding. An analysis of comments and responses is available in the FSIS Docket Clerk's Office and on the FSIS Web site at: *http://www.fsis.usda.gov*.

VI. Comments on the Proposal and FSIS Response

On the proposed requirements for controlling *Listeria* in RTE products in the February 27, 2001, **Federal Register** document, FSIS received 28 comments. Comment summaries, grouped by topic, and Agency responses follow.

Support for the Proposal

Comment: Three comments supported the proposed rule and favored even more stringent requirements. They said that manufacturers of RTE products should be required to implement programs for detecting and eliminating *L. monocytogenes* harborages and should perform tests for *L. monocytogenes* and *Listeria* species. All establishments that produce such products should have control programs that include environmental testing. The Agency should require establishments that have CCPs for *L. monocytogenes* to conduct testing. Also, the proposed required sampling frequencies should be increased and the intervals between tests specified. FSIS should mandate specific testing frequencies for product testing to be conducted following an environmental test that is positive for *Listeria.* Two of the commenters suggested that *Listeria* species is an appropriate indicator for *L. monocytogenes*.

The commenters said that FSIS should require even more intensive environmental and product testing than that proposed. Final product testing as well as environmental testing should be required; eventually, continuous product testing should be performed. One commenter opposed the notion of adopting food irradiation as a solution for potential contamination of RTE products.

One commenter said that the Agency should require establishments to test a statistically significant amount of RTE product for *L. monocytogenes*. The establishments also should conduct environmental testing for the organism. If the products are produced by an establishment that does not conduct RTE product testing as part of its HACCP plan, the products should carry warning labels.

Commenters said that FSIS should maintain its ''zero tolerance'' for *L. monocytogenes* in RTE products rather than setting a minimum colony-forming-unit (CFU) level for the organism in the products, as some have suggested.

A commenter said that official establishments should identify sources of *L. monocytogenes* in their Sanitation SOP.

Response: FSIS agrees with comments that supported establishment use of effective process controls combined with environmental testing to verify the effectiveness of sanitation programs. The Agency also agrees with the comment that establishments should address sources of *L. monocytogenes* either in their HACCP plans or in their Sanitation SOPs or other appropriate procedures. This interim final rule provides a framework within which establishments must meet this objective and provides flexibility for doing so.

FSIS does not agree that it is necessary to mandate *Listeria* testing for establishments that have a CCP for *L. monocytogenes*. Such establishments are already required to validate and verify the CCP's, and microbiological testing is an important means of validation and verification.

FSIS also believes that, if it mandated a high frequency of environmental or product testing, the Agency would be foreclosing unnecessarily the use of effective control programs or strategies adopted by establishments that might require testing at frequencies different from those mandated. In this interim final rule, FSIS is not adopting the proposed frequency requirements. Instead, the Agency is requiring establishments to adopt one of several alternatives that are appropriate for their products and process controls that are effective in addressing *L. monocytogenes*.

On the question of a ''zero tolerance'' for *L. monocytogenes* and particularly with respect to RTE products that support growth of the pathogen, FSIS currently regards any amount of the organism as a product adulterant. As stated above, because the product is RTE, it is likely to be consumed without any effort to kill the pathogen, and the presence of the pathogen may render the product injurious to health (21 U.S.C. 601(m)(1), 453(g)(1)) and would cause the product to be unhealthful.

General Comments on the Proposal and Its Scientific Basis

Comment: A number of commenters said that the proposed testing requirements are arbitrary, unsupported by the FDA/FSIS risk ranking, and generally unscientific (*i.e.*, they were not based on the relative risk posed by establishments, products, or processes).

Response: FSIS agrees, in principle, that mandating a testing frequency is not well founded. In this interim final rule, FSIS is not adopting the proposed provisions for testing food contact surfaces at specified frequencies. Under the interim final rule, establishments will have to implement effective controls for *L. monocytogenes*. The interim final rule is based on the Agency's conclusion that establishments that process post-lethality exposed RTE products must address *L. monocytogenes* in their food safety systems. Those establishments that rely only on sanitation procedures to control the pathogen should carry out more intensive verification procedures, such as food contact surface testing, to ensure that the procedures are effective, and that products are not contaminated, than establishments that controls the pathogen through their HACCP plans.

Severity of Effects

Comment: In framing the rule, FSIS should consider the relative risk of illness posed by RTE products and the severity of effects.

Response: FSIS has taken into account the relative risk of illness and death posed by the processes and products addressed by this interim final rule as reported in the FDA/FSIS risk ranking of RTE foods sold at retail and the FSIS risk assessment.

Success of Industry Efforts

Comment: The industry has been successful in lowering the incidence of foodborne listeriosis. The industry's efforts will help the country achieve the Department of Health and Human Service's ''Healthy People 2010'' goals for lowering the incidence of listeriosis in the population within the timeframe established in the May 5, 2000, Presidential directive. Thus, the Agency's proposal to require environmental testing is unjustified, especially in view of the fact that HACCP was intended to obviate the need for this type of prescriptive requirement.

Response: Although it is early to determine whether the ''Healthy People 2010'' goals for reducing listeriosis (to 0.25 cases per 100,000 population) will be achieved, recent data from CDC indicate that from 1996 to 2002 there was a 38-percent decline in the number of cases per 100,000 population (to .27 overall). Nonetheless, meat and poultry products have been implicated in a substantial proportion (nearly half) of listeriosis cases. FSIS believes that the meat and poultry industry, together with other segments of the food industry, is capable of contributing significantly to the achievement of the Nation's goals for *Listeria* control, particularly by focusing on higher-risk meat and poultry products and on mandatory control procedures—the approach taken in this interim final rule. This interim final rule does not, however, mandate specific testing frequencies.

Effectiveness of Industry Controls

Comment: Some commenters stated that the current HACCP and Sanitation SOP requirements are adequate for ensuring control of *Listeria*. Therefore, the need for regulatory change in this area is questionable.

Response: It is true that validated HACCP plans and effective Sanitation SOPs should be sufficient to address the *Listeria* hazard. The continuing occurrence of product contamination and of significant outbreaks of illness in which meat and poultry products are implicated, however, suggest that establishments have not appropriately addressed the hazard in their HACCP plans, and that the effectiveness of establishment Sanitation SOPs used to control *L. monocytogenes* contamination is not being ensured. The Agency has therefore concluded that it is necessary to require establishments to take specific steps to control the *Listeria* hazard.

Ubiquity of L. monocytogenes and Difficulty of Controlling It

Comment: Several commenters stated that it is important to recognize how ubiquitous *L. monocytogenes* is in the environment and that elimination of *L. monocytogenes* from all food is probably impossible. Thus, the commenters believe, it is not appropriate to require product testing on the basis of a single positive test for *Listeria* spp. on a food contact surface. Some commenters said that environmental testing results should not lead to enforcement actions.

Response: While FSIS does not think that the ubiquity of an organism in the environment argues against regulations requiring control of the organism, the Agency agrees that a more flexible approach to *L. monocytogenes* control than that taken in the proposal is warranted and desirable. FSIS is not adopting the proposed requirement to test product after the first positive test on a food contact surface. Although a positive test for *Listeria* species on a food contact surface does not necessarily mean that product is adulterated, or that enforcement action should be taken, such a finding does suggest the need for corrective action. FSIS inspection program personnel are instructed to verify that the establishment takes the corrective actions it has developed, whether as part of a HACCP plan or of a Sanitation SOP or other prerequisite program.

On the other hand, FSIS regards a positive test for *L. monocytogenes* on a food contact surface as evidencing an insanitary condition that may render product injurious to health. RTE product that comes into contact with the sampled surface at the time it was contaminated with the pathogen and is not subject to any further lethality treatment is adulterated, and FSIS inspection program personnel will take the appropriate action in response to such a finding as set out in Agency directives.

Incentives and Disincentives

Comment: The proposed testing requirements are a disincentive to control *L. monocytogenes* and may actually increase risk of foodborne listeriosis. Establishments might test for the organism at a lower rate than they currently do lest positive tests lead to unwarranted enforcement actions by FSIS. Many small and very small establishments have already implemented *L. monocytogenes* control measures (GMPs, Sanitation SOPs, and testing) in excess of the proposed requirements.

Response: FSIS agrees that mandating testing at a fixed frequency might discourage some establishments that are making strong efforts at *Listeria* control that include regular testing. This recognition factored into the Agency's decision not to adopt the proposed testing frequencies in this interim final rule.

Comment: FSIS should provide incentives for finding harborages, taking corrective actions, and preventing the recurrence of contamination.

Response: FSIS agrees with the comment. When the interim final rule becomes effective, FSIS verification testing will be more intensive in establishments where controls are less rigorous. (*See* discussion of new Directive 10,240.4 below.) Whether FSIS takes an enforcement action will depend on whether establishments are correcting insanitary conditions that may result in product adulteration.

FSIS believes that this interim final rule gives establishments the flexibility to adopt innovative and effective *Listeria* control methods. Moreover, the interim final rule includes a provision enabling establishments to declare on their product labels their use of *Listeria* control measures, provided that the establishments can validate the declarations.

HACCP, Sanitation SOPs, Prerequisite Programs, Directives or Performance Standards

Listeria Controls in HACCP Plans

Comment: Some commenters favored using equipment design, GMPs, and facilities management techniques to control *L. monocytogenes*. They stated that FSIS should recognize that enhanced and focused sanitation and employee behavior programs can be effective preventive and corrective actions. These commenters argued that contamination occurring in a post-lethality processing area is a sanitation, and not a HACCP, issue.

Others argued, to the contrary, that *L. monocytogenes* should be controlled by CCPs in an establishment's HACCP plan.

Response: FSIS is persuaded that *L. monocytogenes* contamination is being prevented in many establishments by Sanitation SOPs and other prerequisite programs. Where these programs are effective, an establishment may conclude in its hazard analysis that *L. monocytogenes* is not a hazard reasonably likely to occur. Of course, in the Agency's view, it is also appropriate to address this hazard in a HACCP plan. Thus, the Agency is allowing establishments the latitude to include *L. monocytogenes* control measures in HACCP plans or to address potential contamination by this pathogen in Sanitation SOPs or other prerequisite programs. It is important to note that if an establishment is applying a post-lethality treatment to an RTE product, the establishment must have concluded that *L. monocytogenes* is a hazard reasonably likely to occur in the product. For this reason, the establishment must include that treatment as a CCP in its HACCP plan.

Comment: Since no technology exists to completely eliminate *L. monocytogenes* from products, a CCP for controlling *L. monocytogenes* is infeasible. Establishments should focus their resources on sanitation and plant improvement projects rather than on HACCP CCPs. Allowing plants to develop CCPs instead of testing, they said, would result in decreased consumer protection.

Response: FSIS disagrees. A CCP in a HACCP plan is a point, step, or procedure in a food process where the occurrence of an identified hazard can be prevented, eliminated, or reduced to an acceptable level. Various methods are available to prevent, eliminate, or reduce *L. monocytogenes* in the RTE products that are subject to this interim final rule and their effectiveness can be validated. For example, a post-lethality heat treatment of a packaged product can eliminate the pathogen. Thus, establishments that use post-lethality treatments for this purpose should include the treatments in their HACCP plans. But establishments may use other methods, including the addition of antimicrobial agents, that have the effect of limiting or suppressing growth of *L.*

monocytogenes in the products. These methods need not be in the establishments' HACCP plans, so long as the plant is regularly ensuring that these methods are working effectively and is making its records that relate to these methods available to FSIS inspection personnel.

Use of Process Controls and Technologies to Control Listeria

Comment: FSIS should encourage establishments to adopt effective process controls, such as food irradiation and high-pressure processing, rather than imposing testing requirements. Relying solely on Sanitation SOPs or GMPs would fail to control *L. monocytogenes*. Further, products that are subject to an in-package lethality treatment before being shipped should be exempt from both environmental and product testing requirements.

Response: FSIS has designed the interim final rule to be sufficiently flexible that establishments will be able to implement a variety of technologies to address *L. monocytogenes*. Of course, before establishments can take advantage of food irradiation for the types of products covered by this interim final rule, FDA approval will be necessary.

FSIS agrees that effective process controls will yield more beneficial results than testing requirements of the kind proposed and that establishments may use various methods to prevent or control *L. monocytogenes* contamination. Therefore, FSIS is not adopting the proposed testing frequency requirements. The Agency is permitting establishments that produce RTE products to implement the type of HACCP or sanitation program that is most appropriate for their production situation and is not imposing uniform testing requirements of the kind proposed. FSIS recognizes that different validation or verification testing regimes are appropriate for different types of products or process control programs, and that a combination of interventions, including post-lethality treatments, sanitation and testing, processing, and the use of growth inhibitors, appears to be most effective in controlling *L. monocytogenes*.

Resource Allocation to Testing or Process Controls

Comment: FSIS has not shown how the proposed, prescriptive, environmental testing will reduce the incidence of *L. monocytogenes* in RTE products. If plants devote resources to environmental testing rather than to effective sanitation activities, consumer protection would decrease. Also, FSIS should let establishments use prerequisite programs instead of CCPs in the HACCP plan to control *L. monocytogenes*.

Response: FSIS acknowledges that testing by itself is insufficient to control *L. monocytogenes* but needs to be a part of a sanitation control program. FSIS regards testing as an essential means of verifying the effectiveness of sanitation procedures to control *L. monocytogenes*, whether the procedures are incorporated in a HACCP plan, a Sanitation SOP, or another prerequisite program. Devoting resources to a testing program developed for this purpose actually supports the control measures.

The proposed *Listeria* testing requirements, which would have mandated specific testing frequencies, were intended for Sanitation SOP verification. Although this interim final rule does not adopt the proposed testing frequency requirements, establishments that do not apply post-lethality treatments to their post-lethality exposed RTE products will have to include at least some food-contact surface testing in their sanitation programs. Such testing is intended to ensure that their measures for controlling, or preventing contamination by, *L. monocytogenes*, whether in HACCP plans or in Sanitation SOPs or other prerequisite programs, are effective.

Comment: FSIS should set a performance standard for *L. monocytogenes* as it has for other pathogens of concern. The Agency should also give establishments the flexibility to meet the standard. Thus, the Agency should consider the problem of pathogen growth after processing and give plants maximum flexibility in testing for *L. monocytogenes*.

Response: FSIS considered the option of adopting a process performance standard for controlling *L. monocytogenes* but determined that there was insufficient scientific information on which to base such a standard. Nonetheless, the Agency has given the establishments flexibility in deciding how to address this pathogen.

FSIS Directive on Microbial Sampling Procedures for RTE Products

Comment: Some commenters said that the Agency should continue to have its personnel use FSIS Directive 10,240.2, which sets out the procedures to be followed when Agency personnel conduct microbiological sampling in establishments that produce RTE products, rather than issuing new regulations. They said that FSIS could revise the Directive and conduct some food contact surface testing, either in all establishments that produce RTE products or just in establishments that do not conduct their own sampling.

Response: FSIS disagrees with the assertion that a regulation is not necessary to ensure effective control of *L. monocytogenes* in RTE products. As noted, with respect to the risk ranking, there is a significant opportunity for recontamination of RTE products in establishments. Many establishments are not implementing HACCP, Sanitation SOPs, or prerequisite programs in a manner that is effective in eliminating *L. monocytogenes* in RTE products. It should also be noted that FSIS replaced its Directive 10,240.2 in December 2002 with a new directive (10,240.3) with updated inspection verification activities. This new directive will be further revised to reflect the requirements of this interim final rule.

Inspection and Enforcement

Comments: FSIS inspectors should be trained to understand *Listeria* testing and the evaluation of the testing results because the considerations involved are complex. FSIS should make compliance guidance materials available for industry review before final regulations take effect.

Response: FSIS will be training its field inspection personnel to ensure that the interim final rule is properly implemented. FSIS's Food Safety Regulatory Essentials training, which addresses RTE products, is being given to all consumer safety inspectors. Regarding guidance materials, FSIS will provide comprehensive guidance to facilitate implementation of this interim final rule by all affected establishments. FSIS will make this guidance material available on its Web site well before this interim final rule takes effect.

Correlation Between Testing and Establishment Size and Production Volume

Comments: There is no evidence that the testing frequencies proposed, which are based on establishment size, will lead to reductions in the rate of listeriosis.

Also, requiring a large establishment to test more frequently than a small one because that establishment manufactured more product is not supportable. The Agency's preliminary economic impact analysis indicated that a small establishment could produce more product than a large establishment because factors other than employees were involved.

Response: FSIS agrees that there is no necessary correspondence between

establishment size and the rate of listeriosis or the degree of risk posed by the products the establishment manufactures. This is one reason why the Agency is not adopting the food contact-surface testing frequencies it proposed. Instead, the Agency is allowing establishments flexibility in designing measures to address *L. monocytogenes*, including appropriate testing and hold-and-test strategies for their products.

FSIS also understands that production volume does not necessarily correspond to establishment size. The Agency has concluded that having better and more comprehensive information about the production volume of RTE products will help it to more efficiently target its resources in verifying establishment *L. monocytogenes* controls.

Hold and Test

Comments: Some commenters stated that requirements for establishments to hold and test product after initial positive tests from environmental sampling would be complicated and likely to result in errors. Such regulation would therefore prove ineffective.

Other commenters insisted that, after an environmental positive, it would be appropriate for an establishment to follow hold-and-test procedures. They said that establishments should regard positive tests for *Listeria* from a non-food contact surface as indicating a sanitation or *Listeria* control problem and that if the positive test were from a food contact surface, all product from the shift represented by the sample should be held and tested before release.

Response: FSIS proposed requirements for food contact-surface testing rather than tests from the general plant environment. In this interim final rule, with the exception of one provision, FSIS is allowing the industry flexibility in designing procedures to be carried out following positive tests for an indicator organism, such as *Listeria* species. However, if a product has been in contact with a food contact surface that has tested positive for *L. monocytogenes*, it is considered adulterated and must be withheld from commerce. FSIS believes that this flexibility should result in the adoption of hold-and-test procedures that are not needlessly complicated and do not result in errors.

Costs and Benefits

Comments: Some commenters stated that the proposed regulations that require establishments to hold and test product after positive environmental test results would impose significant costs that would be especially burdensome to small businesses. Further, it was asserted that establishments unable to hold product because of customer demand or lack of storage facilities would run the risk of incurring the costs associated with increased product recalls.

Commenters argued that FSIS provided little justification for its *Listeria* testing policies in its proposal. They stated that it is difficult to estimate the number of listeriosis cases that might arise from contamination of meat and poultry products and discrepancies in the Agency's proposal illustrated this fact. For example, there is a significant data gap in the relationship between a product contact surface that tests positive for *Listeria*-like, *Listeria* species, and *L. monocytogenes* and whether the product will be positive and the risk to consumers. Commenters suggested that FSIS estimate the reductions in foodborne illness that would result from the regulation and provide further analysis or quantification of costs and benefits.

Response: FSIS agrees that the proposed testing frequency requirements would not be without cost and is interested in ensuring the accuracy of its estimates. To this end, the Agency has accepted data that were submitted by several commenters on this matter and has used the data in preparing the final regulatory impact analysis.

FSIS agrees that the costs associated with product recalls may far exceed those associated with hold-and-test procedures.

On the effect of *Listeria* control regulations on small businesses, FSIS agrees that a relatively large proportion of small establishments will be affected by this interim final rule. FSIS has prepared compliance guidance for such establishments, including guidance specifically intended to assist them in HACCP plan validation with respect to *L. monocytogenes* control, and is making this guidance available with this interim final rule in the FSIS Docket Room and on the Agency's Web site. Also, FSIS will mail the guidance material to all RTE operations before the effective date of this interim final rule.

FSIS agrees with the comments on the difficulties involved in determining the relationship between listeriosis cases and meat and poultry product contamination and with the suggestion that FSIS estimate the reductions in foodborne illness that could result from the regulation. FSIS initiated a risk assessment of in-plant processing of RTE products to determine the relationship between various food contact surface testing and sanitation regimes and other pre- and post-packaging interventions in mitigating contamination of RTE products with *L. monocytogenes* and in reducing the subsequent risk of illness or death and has further analyzed the costs and benefits. FSIS considered the results of the risk assessment in developing this interim final rule. In the final regulatory impact analysis, the Agency analyzes the effect of the interim final rule in terms of the reduction of illness and death from listeriosis.

Definition of RTE and Relative Risk of Different RTE Products

Comments: Commenters expressed concern about the terminology that the Agency used in its proposal. These concerns were related to the scope and effects of the regulation. The commenters said that FSIS should more clearly define RTE products. Some of them stated that frozen products ought not to be considered RTE for the purposes of the rule. To include such products in the RTE category, they argued, would be contrary to previous FSIS policy (Agency directives), the FDA's model food code, and the FDA/FSIS risk ranking model for *Listeria* in RTE foods. The commenters argued that another category of products, dried meat and fermented products, also should not be considered RTE for the purposes of the rule, for their water activity (a_w) puts them at low risk as a medium for growth of *L. monocytogenes*.

The commenters suggested that instead FSIS should define RTE products as ''refrigerated foods of extended shelf life (>10 days) that can support the growth of *L. monocytogenes* and that will be consumed without further listericidal treatment.'' The commenters added that FSIS should base *L. monocytogenes* control requirements on risks posed by specific types of products.

Response: The Agency has revised the definition of RTE to be consistent with the definition of RTE used in the 2001 Food Code. FSIS does not believe that frozen foods, as a broad category, can be excluded from the definition of RTE for this rule. Rather, the Agency will continue to follow its existing practice of determining whether foods should be considered RTE because of the manner of processing and the handling instructions provided to consumers. Some instructions direct that the product must receive further preparation for safety purposes.

Several labeling features or statements are used exclusively on RTE products or non-RTE products, but not on both. RTE products often include phrases indicating that they do not require

further preparation for safety, *i.e.*, ''fully cooked,'' ''Ready-to-eat,'' and ''Heat and Serve.'' Features that are used exclusively on non-RTE products to inform consumers that the products must be cooked to be safe for consumption include the Safe Handling Instructions, which indicate that the meat or poultry portion have not received an adequate lethality treatment and such phrases as, ''Raw,'' ''Uncooked,'' ''Not Ready-to-Eat,'' and ''Ready-to-Cook.''

Cooking instructions alone, however, are not a reliable labeling feature for consumers to determine whether a product requires cooking for safety. Phrases such as ''Cook and Serve,'' ''See cooking instructions,'' and ''Cook thoroughly'' have been used interchangeably on both RTE and NRTE meat and poultry products.

FSIS will continue to consider frozen foods that provide clear instructions to consumers about safe handling and cooking requirements as not-RTE and therefore not subject to this regulation. Frozen products that do not meet these requirements will be considered RTE.

The Agency does not agree that either frozen foods or dried meat and fermented products should be excluded from the definition just because they pose a low risk for *L. monocytogenes*. In both cases, the products are lower in risk because they have undergone a process that is either lethal to or suppresses or limits the growth of pathogens, including *L. monocytogenes*. For this reason, FSIS believes that establishments producing these products should also be required to incorporate in their operations measures addressing *L. monocytogenes* to ensure that the products can be consumed safely without further preparation.

Tolerance for L. monocytogenes and Food Safety Objectives (FSO's)

Comments: Some commenters recommended that FSIS establish a tolerance for *L. monocytogenes* in certain products that do not support growth of the organism. The commenters suggested that a FSO would be consistent with the concepts favored by the Codex Alimentarius Commission and the standards applied by some of this Nation's trading partners. A more rigorous standard could be applied to product that is intended for vulnerable populations.

Response: Establishing a tolerance for *L. monocytogenes* is outside the scope of this rulemaking. The Agency is not in a position to set a regulatory tolerance for *L. monocytogenes* in RTE products, for a number of reasons, including the fact that the Agency is unable routinely to identify the end users of the products.

Absent a conclusive demonstration to the contrary, the Agency must regard any amount of *L. monocytogenes* in a RTE product as an adulterant under the FMIA or PPIA (21 U.S.C. 601(m), 453(g)).

Labeling and Consumer Education

Comments: Some commenters said that development of meaningful ''use-by'' dating that reflects the safety of the product is a practical impossibility. They said that ''use-by'' dates would only be effective for products that are ''refrigerated foods of extended shelf life (>10 days) that can support the growth of *L. monocytogenes* and that will be consumed without further listericidal treatment.''

Other commenters maintained that FSIS should require RTE products to have a uniform expiration dating system to identify product that should be frozen or not consumed after a specified number of days. Some commenters said that RTE products should carry warning labels if they are produced by a plant that does not conduct product testing for *L. monocytogenes* as a feature of its HACCP system. Also, they said, because of the possibility that RTE products might be contaminated with *L. monocytogenes*, the products should carry safe-handling labels until testing is required.

Response: FSIS proposed some revisions to the special-handling label requirements that are not addressed in this interim final rule. The Agency did not propose use-by labeling but requested comment on the feasibility of requiring such labeling, including the most effective way to implement it, the assumptions retailers and consumers should be expected to make in using it, scientific and economic data on the shelf-life and safety of RTE meat and poultry products, the kinds of post-lethality interventions that should be expected for products bearing use-by labeling, and the content of the labeling (66 FR 12635). FSIS notes that the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) is currently addressing safety-based use-by dates. FSIS will consider the NACMCF findings and other information of the kind requested in the proposal before any further rulemaking on the issue.

VII. The Interim Final Rule: Control of *L. monocytogenes*

FSIS has considered the information presented in comments on the proposal, public meetings, the FDA/FSIS risk ranking, and the FSIS risk assessment. 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*.

FSIS is adding several definitions (9 CFR 430.1) to the regulations. FSIS is defining ''deli product'' and ''hotdog product,'' which are a particular focus of the regulations because of the risks they pose. The Agency is also adding several definitions relating to conditions affecting RTE products after the products have undergone a process that destroys *L. monocytogenes* (9 CFR 430.1).

The first definition in 9 CFR 430.1 is for ''antimicrobial agent,'' which FSIS is defining to mean a substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism or of suppressing or limiting its growth throughout the shelf life of the product. In the context of this regulation, an antimicrobial agent may be added to a post-lethality exposed product (also defined) after its initial lethality treatment. An antimicrobial agent, such as acid from fermentation, may also be an inherent component of the product or a result of its formulation. In any case, the effect of the use of the antimicrobial agent is to limit or suppress growth of *L. monocytogenes*.

''Antimicrobial process'' is defined to mean an operation, such as freezing, that is applied to an RTE product and that has the effect of suppressing or limiting the growth of a microorganism. In the context of this regulation, the process is typically applied to a post-lethality exposed product after its initial lethality treatment, and the effect of the process in limiting or suppressing growth of *L. monocytogenes* continues throughout the shelf life of the product. If a product were frozen, the effect of freezing the product could only continue throughout the shelf life of the product if the product were maintained continuously in a frozen state.

The Agency is defining ''post-lethality exposed product'' as RTE product that comes into direct contact with a food contact surface after undergoing a lethality treatment that is a usual and necessary step in the production of the product, *e.g.*, the cooking step for a hotdog or other cooked sausage. A

definition of ''lethality treatment'' is provided. The ''post-lethality processing environment'' is defined as the area of an establishment into which product is routed after undergoing a lethality treatment.

''Post-lethality treatment'' is defined as a lethality treatment applied to a product after post-lethality exposure. A post-lethality treatment might be an additional heat step or other pasteurization process, such as high-pressure processing. A ''post-lethality treatment'' to reduce or eliminate *L. monocytogenes* is to be distinguished from the use of an antimicrobial agent or process that suppresses or limits the growth of the pathogen. Antimicrobial agents include lactic acid in certain types of sausage products or ingredients of growth-limiting packaging (*e.g.*, cellulose containing an antimicrobial substance). An example of a growth suppressing or limiting process is freezing.

FSIS is defining ''prerequisite program'' as a procedure or set of procedures designed to provide the basic environmental or operating conditions necessary for the production of safe, wholesome food. The definition is adapted from ''Hazard Analysis and Critical Control Point Principles and Application Guidelines,'' which was adopted August 14, 1997, by the National Advisory Committee on Microbiological Criteria for Foods and has wide currency in the food industry. Prerequisite programs are a part of the decision-making documentation that is associated with the hazard identification and selection of CCPs in a HACCP plan. An establishment is required by 9 CFR 417.5 to maintain such documentation because the existence of an effective Sanitation SOP or other prerequisite program affects the outcome of an establishment's hazard analysis.

The definition of a ''prerequisite program'' is being provided, and the use of such a program in the new regulations is being permitted, in response to industry comments on the proposal emphasizing the importance of prerequisite programs in preventing *L. monocytogenes* contamination. One commenter stated that post-processing contamination by *L. monocytogenes* is best controlled through prerequisite programs.

Finally, FSIS is adopting the definition of a ''ready-to-eat'' product that, although similar to the one proposed, conforms with the 2001 Model Food Code. Thus, an RTE meat or poultry product is one that is ''in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.''

In a new section on control of *L. monocytogenes* in post-lethality exposed RTE products, 9 CFR 430.4, FSIS first states its basic finding that *L. monocytogenes* is a hazard in such products, and that establishments must control this hazard through their HACCP plans or prevent it in the processing environment through Sanitation SOPs or other prerequisite programs. FSIS is making this finding, as it states in 9 CFR 430.4(a), based on the fact that RTE products that have been subjected to a lethality treatment but then exposed to the environment may be recontaminated with *L. monocytogenes.*

An establishment may determine that recontamination is not reasonably likely to occur in its post-lethality exposed RTE products because it has an effective Sanitation SOP or some other prerequisite program that effectively prevents *L. monocytogenes* contamination. If an establishment makes this determination, under 9 CFR 417.5(a)(2), the regulation requiring establishments to keep documentation supporting the selection of CCPs or critical limits, the basis for this determination must be documented and made available to the Agency. FSIS is aware that, in their hazard analyses, establishments have been taking their Sanitation SOPs and other prerequisite programs into consideration. Thus, an establishment that produces RTE products may not identify *L. monocytogenes* as such a hazard to be addressed in its HACCP plan, it must nonetheless effectively address this pathogen in its food safety system.

The Agency is requiring, in 9 CFR 430.4(b), that an establishment that produces post-lethality exposed RTE product must meet the specific requirements of one of three alternative programs for addressing *L. monocytogenes*. In the view of FSIS, any situation involving establishment measures to address post-lethality contamination of RTE products by *L. monocytogenes* is covered by one of the alternatives. Under this interim final rule, the first alternative relies largely on control though HACCP and an antimicrobial agent or process that suppresses or limits the growth of the pathogen. Each successive alternative places a greater reliance on the rigor of sanitation procedures, including verification testing, than on post-lethality treatments, to control *L. monocytogenes*. Consequently, the frequency and intensity of FSIS verification is likely to be greater for Alternatives 2 and 3, as more reliance is placed on sanitation.

Alternative 1. In the first alternative, an establishment controls *L. monocytogenes* by using a post-lethality treatment of the product *and* an antimicrobial agent or process that suppresses or limits the growth of the pathogen. As mentioned previously, the use of the post-lethality treatment to reduce or eliminate *L. monocytogenes* reflects a determination that the pathogen may be present in the product—in other words, that it is a hazard reasonably likely to occur. Therefore, the establishment must include the post-lethality treatment in its HACCP plan. The point in the process at which the treatment is applied is, by definition, a ''critical control point'' under 9 CFR 417.1 in that it is a step in a process at which control is applied to prevent, eliminate, or reduce to acceptable levels a food safety hazard, *L. monocytogenes*. The post-lethality treatment incorporated in the HACCP plan must be validated in accordance with 9 CFR 417.4 as being effective in reducing or eliminating *L. monocytogenes*.

The use of an antimicrobial agent or growth suppressing or limiting process may not in practice have the *L. monocytogenes* reduction effect of a post-lethality treatment, but still be an effective measure because it inhibits growth of the pathogen, thus, limiting the possibility that any *L. monocytogenes* that survives the post-lethality treatment will grow out and presents a food safety hazard. In Alternative 1, FSIS is giving the establishment the choice of including the antimicrobial agent or process in its Sanitation SOP or other prerequisite program or as a CCP in its HACCP plan.

FSIS recognizes that an establishment electing to adopt Alternative 1 may employ an antimicrobial agent or process as part of its initial lethality treatment and that the agent or process may have a continuing bactericidal effect on *L. monocytogenes* that persists even through post-lethality exposure and distribution. In such a case, the antimicrobial agent or process could serve as both a post-lethality treatment and growth inhibitor. Thus, neither an additional post-lethality treatment nor an additional antimicrobial agent or process is necessary to qualify for Alternative 1. The establishment would need to have documentation on file to demonstrate that the conditions of Alternative 1 are being met through the application of the initial antimicrobial agent or process.

As with the post-lethality treatment, if the antimicrobial agent or process is

included as a CCP in the HACCP plan, it must be validated as effective in suppressing or limiting growth of the pathogen. The establishment must also verify the effectiveness of the control measures in accordance with 9 CFR 417.4. If the agent or process is included in the establishment's sanitation program, it must be in compliance with the general sanitation regulations and the Sanitation SOP requirements in 9 CFR part 416. The control measures, if included in the HACCP plan, must be validated as effective. The establishment's regular monitoring of its operation must be verified. Sanitation procedures must be in compliance with the general sanitation regulations and the Sanitation SOP requirements, as applicable.

In addition, the establishment is required to make the results of its verification measures, under whichever program—HACCP, Sanitation SOP, or other prerequisite program—available upon request to FSIS inspection personnel.

FSIS has concluded, and this conclusion is informed by the FSIS risk assessment, that Alternative 1, which involves a combination of interventions that includes a post-lethality treatment and the application of an antimicrobial agent or process, is likely to be among the most effective means of reducing the risk of *L. monocytogenes* contamination and hence of listeriosis mortality among vulnerable populations.

Alternative 2. An establishment may choose to address *L. monocytogenes* by using a post-lethality treatment *or* an antimicrobial agent or process that suppresses or limits the growth of the pathogen. As with Alternative 1, the post-lethality treatment, if used, must be included as a CCP in the establishment's HACCP plan. The application of the antimicrobial agent or the growth suppressing or limiting process must be included in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. Whichever program includes the application of the antimicrobial agent or the growth suppressing or limiting process, the establishment must have documentation to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting the growth of *L. monocytogenes*.

In addition, FSIS is providing that if the establishment chooses Alternative 2 and chooses to use only a post-lethality treatment of product, it would likely be subject to more frequent verification testing than if it chose Alternative 1. FSIS has concluded that multiple steps are more likely to reduce the risk of *L. monocytogenes* contamination of RTE products and subsequent adverse public health effects. Without an antimicrobial to suppress or limit the growth of *L. monocytogenes* that may survive the post-lethality treatment, it becomes more important to verify the effectiveness of that treatment.

The establishment may choose not to rely on a post-lethality treatment to reduce or eliminate *L. monocytogenes*, but to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. If so, it becomes extremely important to minimize any possibility of post-lethality contamination. The establishment's sanitation program must, therefore, provide for the testing of food contact surfaces in the post-lethality processing environment to ensure that the establishment's sanitation program is effective in keeping those surfaces sanitary and free of *L. monocytogenes* or of indicator organisms that would reflect the presence of *L. monocytogenes*. The program must delineate the frequency with which testing will be done, state the size and location of the sample sites (so that the area represented by a sample can be known), and provide an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or the indicator organism is being maintained. The program also must identify the conditions under which the establishment will implement hold-and-test procedures after a positive test for *L. monocytogenes* or indicator organisms.

As under the Alternative 1, the establishment must make the verification results of the effectiveness of its controls from its HACCP, Sanitation SOP, or other prerequisite program available upon request to FSIS inspection personnel.

For Alternative 2, if the measures for addressing *L. monocytogenes* are in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment's documentation of its program and of its results and its implementation of the program must be sufficient to support a finding, during validation or reassessment, under 9 CFR 417.4, that the HACCP plan is adequate and that the HACCP plan in operation is not inadequate within the meaning of 9 CFR 417.

Alternative 3. An establishment that processes RTE products may control *L. monocytogenes* in the post-lethality processing environment through sanitation procedures only. If incorporated in the HACCP plan, the sanitation procedures followed in this alternative must be validated and verified in accordance with 9 CFR 417.4. Also, sanitation in the post-lethality processing area must be maintained in accordance with 9 CFR 416.

As in Alternative 2, FSIS is requiring that the sanitation procedures in the post-lethality processing environment include testing of food contact surfaces to ensure that the surfaces are sanitary and free of *L. monocytogenes* or an indicator organism. The procedures must delineate the frequency of testing; state the size and location of sample sites; and provide an explanation of why the testing is sufficient to ensure that the establishment's sanitation procedures are effectively keeping *L. monocytogenes* or indicator organisms from contaminating product. The establishment must identify in its procedures the conditions under which it will implement hold-and-test procedures to ensure that *L. monocytogenes* or indicator organisms are not contaminating product.

Establishments that adopt Alternative 3 will need to address in their decisionmaking documents why the sanitation procedures they employ, the frequency of testing they carry out, and the circumstances in which they test the product and hold it pending receipt of test results are appropriate and adequate to prevent the contamination of their product by *L. monocytogenes* and to ensure that contamination is discovered if it has occurred.

Because establishments using Alternative 3 are relying only on sanitation procedures and because verification activities are so important to ensuring the on-going effectiveness of such measures, FSIS has concluded that establishments electing to adopt Alternative 3 are likely to be subject to a higher frequency of testing by FSIS than establishments using Alternative 1 or 2. As is the case with establishments adopting the other alternatives, an establishment that has adopted Alternative 3 must make the verification results obtained from its own food contact surface testing available on request to FSIS inspection personnel.

Under Alternative 3, more stringent requirements apply to an establishment that processes deli meats or hotdogs. These products were shown in the FDA/FSIS risk ranking to pose a relatively high risk of listeriosis, in terms of cases per annum. Thus, in order to provide the assurance that comes from increased verification, FSIS expects the frequency of its own testing, as well as the establishment's testing, to be higher

than that for other products produced under the Alternative 3 approach.

Under Alternative 3, for establishments producing deli meats and hotdogs, FSIS is requiring specific procedures for holding and testing product to minimize the risk of contaminated product entering commerce. These procedures are to be followed if an establishment has had a positive test for an indicator organism, such as *Listeria* species, on a food contact surface in the post-lethality processing environment.

After the establishment takes corrective action to clean the food contact surface, the establishment must verify that the corrective action has been effective through follow-up testing in the post-lethality processing area. This testing is to include targeting the specific site on the food contact surface area that was the most likely source of contamination by the organism and must include such additional tests of the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective action. (If the initial positive test was for *L. monocytogenes*, the product is considered adulterated and must be withheld from commerce even before the results of further testing are available.)

If, during this follow-up testing, the establishment obtains a second positive test result for the indicator organism on a sample from the previously tested area, the establishment must hold lots of product produced between the second positive test result and completion of the corrective action until samples from the food contact surfaces in the same area test negative for *L. monocytogenes* or the indicator organism. The establishment may sample and test the held product, using a sampling method that will provide a level of statistical confidence that is sufficient to establish that the product is not adulterated with *L. monocytogenes*, and it can release the product into commerce if the results are negative.

For Alternative 3, if the measures for addressing *L. monocytogenes* are in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment's documentation of its program and of its results and its implementation of the program must be sufficient to support a finding, during validation or reassessment, under 9 CFR 417.4, that the HACCP plan is adequate and that the HACCP plan in operation is not inadequate within the meaning of 9 CFR 417 part 1.

Estimates of annual production volume. As previously stated in this document, some commenters observed that a large establishment may not necessarily produce more RTE product than a small establishment. FSIS agrees and regards production volume as a more important risk factor than establishment size. FSIS intends to target its inspection resources on the higher volume operations. To do this effectively, FSIS will need data on the annual production volume of post-lethality exposed RTE products produced, by product, and by *L. monocytogenes* control alternative (1, 2, or 3), and other related information (such as the establishment's own testing procedures). The affected establishments will have to provide FSIS with this information at least annually. The Agency expects to have an electronic form available for this purpose (9 CFR 430.4(f)).

Labeling Incentive

Finally, FSIS is allowing establishments that use post-lethality treatments or antimicrobial agents or processes that are effective in destroying *L. monocytogenes* or in limiting its growth to declare this fact on the labels of their products. The purpose of the labeling is to inform consumers about measures that have been taken to ensure the safety of the products and thus to enable the consumers to select such products in preference to others. This provision is entirely voluntary, but FSIS believes that labeling claims about treatments that eliminate, suppress, or limit the growth of *L. monocytogenes* can be of value to consumers, especially those in groups most vulnerable to foodborne infection.

For example, products with antimicrobial agents can be viewed as containing substances that reduce the presence of pathogens or the likelihood of foodborne illness, provided that the products are appropriately handled throughout the distribution chain and prepared safely by the consumer. Thus, a label statement should identify the presence of ingredients and their purpose of use but not claim that the product is somehow ''safer than'' other untreated products.

Examples of statements that can be made are: ''Sprayed with a solution of sodium lactate to prevent the growth of *L. monocytogenes*'' or ''Contains sodium diacetate and sodium lactate to prevent the growth of *Listeria monocytogenes*.''

New and Existing Regulatory Requirements

The regulations promulgated in this interim final rule include new requirements and reiterate for clarity certain existing regulations. The definitions in § 430.1 are new, as are the provisions in § 430.4 specifying the three permissible alternatives for addressing *L. monocytogenes*. Similarly, the provisions in this interim final rule requiring that measures included in the establishment's Sanitation SOP or other prerequisite program are new. The provision requiring that RTE establishments report at least annually the volume of production by type of RTE product and by alternative for controlling or addressing *L. monocytogenes* is new. Also new are the sanitation procedure requirements that include hold-and-test provisions.

Although the use by industry and the Agency's acceptance of prerequisite programs is not new, the provisions on prerequisite programs in this interim final rule constitute explicit recognition, for the first time in the codified regulations, of such programs. The requirement that documentation of prerequisite programs and the results of such programs be available to the Agency also makes explicit an implied requirement in the HACCP regulations.

Also, the requirement that a post-lethality treatment be included in an establishment's HACCP plan is made explicit for the first time in this interim final rule. The requirement to maintain documentation on Sanitation SOPs or other prerequisite programs that are used to support a decision not to identify *L. monocytogenes* as a hazard reasonably likely to occur that must be controlled makes explicit a requirement in the HACCP regulations (9 CFR 417.5). The provision for validation of controls included in a HACCP plan just reiterates existing requirements of 9 CFR 417.4. Similarly, the requirement that Sanitation SOPs be evaluated routinely to ensure their effectiveness reiterates the requirements in 9 CFR 416.14.

The requirement to verify, that is, to evaluate routinely and maintain, the effectiveness of the Sanitation SOP, is already a regulation (at 9 CFR 416.14). Also, the requirement to follow existing sanitation requirements in the post-lethality processing environment simply reiterates the general sanitation regulations (9 CFR 416) that are applicable everywhere in an official establishment.

Finally, the provision for RTE product labeling that declares the fact of an *L. monocytogenes* control treatment or ingredient is new, but permissive. RTE product labeling may, under current regulations, bear such statements if the statements are valid.

VIII. Implementation

Implementation Strategy

FSIS has designed this interim final rule to recognize that there are alternative, effective ways to ensure that post-lethality exposed RTE products do not become contaminated with *L. monocytogenes*. While each approach can be effective in preventing such contamination, Alternatives 1 and 2 present a greater opportunity for mitigating the risk of RTE product contamination than does Alternative 3 because under Alternatives 1 and 2, products are formulated or processed in a manner either to eliminate *L. monocytogenes* or to limit its growth, should it be present.

Hence, in implementing this interim final rule, FSIS plans to conduct verification activities, including testing, that focus most intensively on Alternative 3 establishments and, within that group, on establishments that produce deli meats and hotdogs to verify that the total food safety system under which these products are produced is working properly.

FSIS is aware that the regulated industry is using antimicrobial agents at levels that provide some limitation of growth, that some establishments use these agents at levels that allow no more than 2-$\log_{10}$ growth throughout the shelf-life of the product, and that other establishments are using the agents at levels that more severely limit growth. FSIS believes that the majority of products formulated with the higher levels of antimicrobial agents are cured products because they better tolerate the agents, and the products do not have unacceptable organoleptic qualities. For this reason, the FSIS verification testing program for Alternative 2 will cover establishments that produce products formulated with antimicrobial agents but will focus on establishments using lower levels of antimicrobial agents because there is some potential for pathogen growth in the products. However, FSIS does not intend to conduct its verification testing at such establishments at a rate that is any higher than that for establishments in Alternative 3 and certainly not at a rate as high as that for establishments using Alternative 3 and producing deli meats or hotdogs.

FSIS intends to collect information about the RTE products produced by establishments using Alternatives 1 through 3. The information will include estimates of production volume for post-lethality exposed products, so that the Agency can develop annual sampling frequencies for the establishments and the products. FSIS will make the sampling frequency information available to the establishments so that they will have some indication of how the risk of *L. monocytogenes* contamination is tied to FSIS verification testing.

FSIS is continuing to model scenarios in its risk assessment model and will use this information in determining where to direct its verification testing resources to ensure that such products are not adulterated. In the meantime, FSIS will continue to use currently available production volume figures in directing these resources.

The Agency expects to weight its sample scheduling process so that a large-volume establishment will be targeted more frequently than an establishment with a lower volume of production. Because, under this interim final rule, all establishments must have written programs that address *Listeria* and share their testing results with FSIS, FSIS believes that there will be no need to phase in the implementation of the interim final rule for establishments of different sizes or of different production volume capacity. The effective date will be October 6, 2003, for all establishments. During the 120 days before the interim final rule becomes effective, FSIS will issue a new directive (Directive 10,240.4, discussed below). The Agency is now making available new compliance guidelines that will contain information about the effects of sanitation and testing, as well as the effectiveness of various levels of antimicrobials.

New Directive for FSIS Inspection Program Employees

Through a new directive replacing FSIS Directive 10,240.3 that issued in December 2002, FSIS will conduct a risk-based verification testing program to assess the effectiveness of RTE operations in controlling *L. monocytogenes.* FSIS will identify the general features of the design of its verification testing program. Each fiscal year, FSIS identifies the general number of samples that it expects to collect throughout the year associated with RTE products. In order to implement this interim final rule, FSIS expects to apportion the types of products sampled with an emphasis on deli meats and hotdogs produced under Alternative 3. All RTE products are subject to being tested.

Until FSIS has actual production volume and associated data obtained through the reports required by 9 CFR 430.4(f), FSIS likely will continue sampling in the same manner currently employed by the Agency. FSIS intends to build in the production volume feature, as soon as possible, in order to ensure that larger volume production is verified more frequently than smaller volume production. In addition, FSIS will continue to assess information about sanitation non-compliances and other plant performance indicators when determining which operations should be tested, but with an emphasis on products that allow for growth of *L. monocytogenes.*

As FSIS obtains information on the effectiveness of establishment process controls for *L. monocytogenes*, the Agency should be able to reduce the intensiveness of verification testing at establishments with more effective controls.

Generally, FSIS expects to collect for *L. monocytogenes* testing just one sample unit of RTE product from a production lot at an establishment selected for sampling. FSIS is considering taking more than one product sample from an establishment that produces product without post-lethality treatments or growth inhibitors, particularly deli meat and hotdog operations. Finally, FSIS expects to collect food contact surface samples and environmental samples mainly from operations that have a history of problems associated with the proper control for *L. monocytogenes*, or that produce RTE products, particularly deli meats and hotdogs, that allow for the growth of *L. monocytogenes.*

IX. Consumer Outreach Effort

Food safety education is one risk management strategy FSIS uses to reduce the incidence of illness associated with *L. monocytogenes* in RTE meat and poultry products. Safe handling, storage and preparation of RTE meat and poultry products can help reduce the risk of illness, particularly for those populations most at risk of contracting listeriosis: pregnant women, newborns, older adults, people with weakened immune systems caused by cancer treatment, AIDS, diabetes, kidney disease, and organ transplants. FSIS reaches these audiences through printed materials, the FSIS Web site, electronic communication, the media, and other information multipliers, in collaboration with other Federal agencies, educators, and healthcare professionals, and through the USDA Meat and Poultry Hotline.

For example, FSIS has worked with the Association of Women's Health, Obstetric and Neonatal Nurses, the International Food Information Council Foundation, FDA, and CDC to produce a patient education sheet, ''Listeriosis and Pregnancy: What is Your Risk?'' targeted to both pregnant women and

their healthcare providers. The Spanish version will be printed in spring 2003. In addition, FSIS is completing a low literacy flyer aimed at pregnant women entitled, ''Protect Your Baby and Yourself from Listeriosis'' with input from WIC nutritionists, public health nurses, and extension food safety specialists. To reach other vulnerable groups, discussions are underway with transplant organizations, community health clinics, geriatric organizations, dialysis centers, and AIDS/HIV care organizations to determine how best to reach these individuals. Through the newly launched Food Safety Education Mobile, informational materials will be distributed as the vehicle travels throughout the country.

In addition to providing education on safe food handling, FSIS will provide information to consumers regarding new labels that processors may voluntarily use under this regulation to inform consumers of interventions used to reduce contamination.

X. Executive Order 12866 and Effect on Small Entities

This interim final rule has been reviewed by the Office of Management and Budget under E.O. 12866 and has been determined to be economically significant. FSIS is amending the Federal meat and poultry inspection regulations by adding requirements for establishments that produce certain RTE meat and poultry products to take measures to prevent product adulteration by the pathogen *L. monocytogenes.* Establishments that produce RTE meat and poultry products that are exposed to the environment after lethality treatments must include in their HACCP plans or their Sanitation SOPs or other prerequisite programs measures designed to prevent product adulteration by *L. monocytogenes.* The establishments also must share with FSIS all data relevant to the validation, operation, and verification of their controls for *L. monocytogenes.*

This action is compelled by outbreaks of foodborne illness in which RTE meat and poultry products contaminated with *L. monocytogenes* were implicated, coupled with information on the pathogenicity of the organism and the findings of the risk assessment and risk ranking conducted by FDA and FSIS. Although FSIS now routinely conducts food contact surface and environmental sampling in select establishments that produce such products, and performs product testing in nearly all RTE establishments for the presence of this pathogen before the products are distributed, until now there have been no specific regulatory requirements for controlling the pathogen. Appendix A, published at the end of this interim final rule in this issue of the **Federal Register**, contains the final regulatory analysis required by E.O. 12866 and the Regulatory Flexibility Act (at 5 U.S.C. 604), including a discussion of the need for the regulations, regulatory alternatives considered by FSIS, and a cost-benefit analysis. This interim final rule provides affected small and very small establishments with the flexibility to minimize the costs associated with this rule by implementing Sanitation SOPs or other prerequisite programs. FSIS is providing compliance guidance for these establishments in accordance with the Small Business Regulatory Enforcement Fairness Act. In addition, in verifying compliance with this interim final rule, the Agency plans to conduct testing at modulated frequencies, taking into account all relevant factors, including the alternative employed to address *L. monocytogenes*, production volume by type of RTE product produced, and the establishment's compliance history.

Summary of Final Regulatory Impact Analysis (FRIA)

Benefits

FSIS has estimated the benefits of this interim final rule in terms of averted deaths and illnesses resulting from actions taken by establishments that produce RTE meat and poultry products so far with respect to only one product group: Deli meats. FSIS has concentrated on this product group for several reasons: The FDA/FSIS risk ranking identified deli meats as posing the most overall risk to public health. The FSIS in-plant risk assessment tied risk mitigation actions to possible reductions in deaths and illnesses from listeriosis when the FSIS risk assessment model was calibrated with the FDA/FSIS risk ranking model, and when containment strategies for *Listeria* contamination of RTE meat and poultry products were simulated. The FSIS risk assessment model has been presented to the public, along with estimates of reduced listeriosis mortality resulting from actions taken by establishments that prepare or process the products.

The FRIA relies on results from the FSIS in-plant risk assessment model and considers the adoption by large, small, and very small deli-meat producing establishments of stratagems of varying rigor for controlling *L. monocytogenes.* The analysis shows that adoption of *L. monocytogenes* mitigation measures induced by this interim final rule results in a total median reduction of deaths from listeriosis of 27.3; with 8.9 deaths averted at the 5th percentile and 31.2 at the 95th percentile. These gains are attributable to an expected shift—discussed in detail in Appendix A—of establishments from sanitation-only to ''Alternative 1'' and ''Alternative 2'' methods of addressing *L. monocytogenes.* The corresponding reductions in illnesses are 136.7 at the median, with 44.6 at the 5th percentile, and 156.0 at the 95th percentile.

Using a method used by USDA's Economic Research Service (ERS) for estimating the human health benefits of reduced listeriosis, the benefits of the reduction in illness-related losses due to the interim final rule are estimated to be $3.7 million at the median ((.05 x 136.7 x $10,300) + (.95 x 136.7 x $28,300)) and $1.3 million at the 5th and $4.4 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 implementation of the interim final rule are $134.9 million at the median (the $3.7 million above plus 27.3 × $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 fact that the risk assessment addresses only deli meats, FSIS believes that this estimate may be overstated by at least 50 percent. If so, the adjusted annual net benefits then become $50.8 million at the median, $5.4 million at the 5th percentile, and $60.4 million at the 95th percentile. FSIS performed a sensitivity analysis on the benefits estimates. Given the cost estimates, the total benefits of this rule would have to be 85 percent lower than estimated for the net benefits to lower to zero.

Cost Impacts

FSIS estimated the cost impacts of this interim final rule on all affected establishments. The FRIA adds several cost impacts in addition to those considered in the preliminary regulatory impact analysis (PRIA). The PRIA identified major cost impacts from mandatory food contact surface testing, HACCP plan modification, and production adjustments. In addition to these and in response to comments, the FRIA considers the costs, both fixed and recurring, associated with the installation by establishments of post-lethality treatments; the costs, both fixed and recurring, associated with product formulation or process changes to include antimicrobial agents or processes that limit the growth of *L. monocytogenes*; and the costs to establishments required to hold and test products pending confirmation of

positive food contact-surface tests for *Listeria* species.

FSIS estimates that the interim final rule will have combined one-time and recurring costs to large establishments totaling about $15.9 million, to small establishments about $55.3 million, and to very small establishments about $1.7 million. FSIS assumes a 10-year useful life for the changes (*e.g.*, post-lethality treatment validation, installation, antimicrobial agent or process alteration, and production adjustments) for which establishments incur one-time costs and, using a 7-percent discount rate, the Agency annualizes these one-time costs over the useful life of the changes. Adding these to the annual recurring costs, FSIS obtains annualized industry-wide costs of the interim final rule to large establishments of about $3.6 million, to small establishments about $12.5 million, and to very small establishments about $613,000.

The grand total of industry-wide annualized costs is $16.6 million. With the 50 percent downward adjustment discussed above, net benefits of $50.8 million at the median and ranging from $5.4 million at the 5th percentile to $60.4 million at the 95th percentile are to be derived from the interim final rule.

Paperwork Reduction Act

FSIS has reviewed the paperwork and recordkeeping requirements in this interim final rule in accordance with the Paperwork Reduction Act and has determined that the paperwork requirements respecting the regulations that may cause establishments to evaluate and revise their Sanitations SOPS, HACCP plans, and prerequisite programs have already been accounted for in the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems information collection approved by the Office of Management and Budget (OMB). The OMB approval number for the Pathogen Reduction/Hazard Analysis and Critical Control Point (HACCP) Systems information collection is 0583–0103.

The requirement that may cause establishments to test for *L. monocytogenes*, to document their testing protocols and their hold-and-test procedures, and the requirement for establishments that produce RTE products to provide FSIS with production volume information by product type and *L. monocytogenes* control alternative are new information collections.

Title: Listeria.

Type of Collection: New.

The paperwork and recordkeeping requirements in this interim final rule are awaiting approval by the Office of Management and Budget.

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this interim final rule in accordance with the Paperwork Reduction Act. Under this interim final rule, FSIS is requiring an information collection activity. FSIS is requiring that establishments that produce ready to eat product annually report the estimated production volume by product type and *Listeria* control alternative employed. FSIS is also publishing requirements for RTE establishments to conduct, and plans to ask them to report on, food-contact surface sampling. In addition, FSIS is establishing requirements that may cause some RTE establishments to hold and test product for *L. monocytogenes* and other indicator organisms.

Estimate of Burden: FSIS estimates that the time to collect and report the required information on the estimated volume of RTE product by product type and *Listeria* control method is one hour. The Agency estimates that it will take establishments 50 minutes to collect the information necessary to make the required estimates and 10 minutes to report the information by form.

FSIS estimates that it will take 25 hours to develop a microbiological sampling and testing plan to support the efficacy of the sanitation controls, including the development of test-and-hold procedures. The Agency estimates that it will take two hours to revise microbiological sampling and testing plans. And FSIS estimates that it will take an average of 30 minutes to conduct a food contact surface test and an average of 30 minutes to collect information on product samples for test and hold procedures.

Respondents: Meat and poultry product establishments that produce Ready to Eat product.

Estimated Number of Respondents: 4,975.

Estimated Number of Responses per Respondent: 10.

Estimated Total Annual Burden on Respondents: 154,243 hours.

Copies of this information collection assessment can be obtained from John O'Connell, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 112 Annex, 300 12th Street, SW., Washington DC 20250.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both John O'Connell, Paperwork Reduction Act Coordinator, at the address provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Government Paperwork Elimination Act (GPEA)

FSIS is committed to achieving the goals of the GPEA, which requires Government agencies, in general, to provide the public with the option of submitting information or transacting business electronically to the maximum possible extent. FSIS is making available to establishments affected by this interim final rule an electronic form by which they may provide the required production volume information. The form will be accessible on a special page on the FSIS Web site at *http://www.fsis.usda.gov*; log-on and authentication instructions will be provided. Each establishment's submission will be treated as confidential. Provision of this electronic form is expected to enable the Agency more efficiently to gather, and affected establishments to report, the needed information.

This electronic data collection is intended to meet Goal 4 of the e-Government strategy in the President's Management Agenda. The electronic filing option is provided to reduce data collection time and information processing and handling for the regulated industry and FSIS.

This electronic data collection is intended to be consistent with Goal 2 (enhancing collaboration with public and private sector organizations to develop and deliver USDA's mission) and Objective 2.4 of the Department's e-Government Strategic Plan in that it reduces time necessary for information collection and processing for both regulated establishments and FSIS. A further, related initiative, providing for use of electronic signatures and authentication, will be consistent with the Department-wide strategies and

policies to develop and implement e-signature and e-Authentication policies.

1. The interim final rule on *L. monocytogenes* control in ready-to-eat meat and poultry products contains a requirement for official establishments that prepare post-lethality exposed ready-to-eat meat and poultry products to provide FSIS at least annually with data on the volume of production of products they prepare in processes that are covered by the interim final rule. FSIS is developing a form by which to collect the data. The form will be made available to establishments in both paper and electronic formats. The electronic form will be available for use by affected establishments at all times after the rule becomes effective.

2. FSIS can use its existing information technology resources in the electronic data collection. That is, the Agency plans to use its existing database applications and server storage to house the data collection form and associated databases. FSIS estimates that no more than $1,000 in materials and 0.25 FTE annually at the level of a GS–13 or equivalent staff officer grade in FSIS'S Data Analysis Systems and Support Staff, Office of Policy and Program Development, will be required to administer the data collection.

FSIS is developing a centralized system known as the FSIS Automated Corporate Technology Suite (FACTS) for which approximately $15 million has been earmarked. The system will provide, among other things, facilities for accessing Agency electronic forms and for processing the data collected through such forms. The new production volume form can be integrated with FACTS.

3. FSIS plans to use e-signature and e-Authentication methods that are consistent with Department e-Authentication policy.

4. Regarding information security, FSIS plans to provide ordinary levels of protection for the production volume information obtained. Establishment-linked information will be treated as confidential and stored in password-protected databases and electronic systems to which only authorized personnel have access. Information in paper format will be stored under lock and key in file boxes or cabinets to which only authorized personnel have access. FSIS does not envision a need for sophisticated security or encryption systems to protect this information.

5. For the purpose of this information collection, FSIS does not foresee a need for telecommunications systems additional to those already operated by the Agency.

6. The interim final rule does not specifically address recordkeeping by establishments but only data reporting. The data collected will be stored in a protected database managed by FSIS.

XII. E. O. 12988 Civil Justice Reform

This interim final rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jursidicitons are preempted by the FMIA and the PPIA from imposing any marking, labeling, packaging, or ingredient requirements on federally inspected meat and poultry products that are in addition to, or different than, those imposed under the FMIA or PPIA. States and local jurisdictions may, however, exercise concurrent jurisdiction over meat and poultry products that are outside official establishments for the purpose of preventing the distribution of meat and poultry products that are misbranded or adulterated under the FMIA or PPIA, or, in the case of imported articles, that are not at such an establishment, after their entry into the United States. This proposed rule is not intended to have retroactive effect.

Administrative proceedings will not be required before parties may file suit in court challenging this interim final rule. However, the administrative procedures specified in 9 CFR 306.6 and 381.35 must be exhausted before any judicial challenge of the application of the provisions of this interim final rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

XIII. Additional Public Notification

Public awareness of all segments of policy development is important. Consequently, in an effort to better ensure that minorities, women, and persons with disabilities are aware of this interim final rule, FSIS will announce it and provide copies of this **Federal Register** publication in the FSIS Constituent Update.

The Constituent Update provides information on FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents/stakeholders. These include industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. The Constituent Update is available on-line through the FSIS Web page located at *http://www.fsis.usda.gov/OA/update/update.htm.*

The FSIS Constituent Update is issued via the USDA-FSISConstituentsListserv to over 400 organizations and individuals on a weekly basis. FSIS also issues other communications on the Listserv, including news releases, recall notices, and Constituent Alerts on important issues. Persons interested in subscribing to the Listserv can do so by completing a form at *http://www.fsis.usda.gov/OA/update/subscribe.asp.*

XIV. Final Regulations

List of Subjects in 9 CFR Part 430

Food labeling, Meat inspection, Poultry and poultry products inspection.

■ Accordingly, title 9, chapter III, of the Code of Federal Regulations is amended as follows:

■ 1. A new part 430 is added to read as follows:

PART 430—REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

Sec.
430.1 Definitions.
430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

Authority: 7 U.S.C. 450; 7 U.S.C. 1901–1906; 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

§ 430.1 Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes,* or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes,* in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an

antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called ''prerequisite'' because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

§ 430.4 Control of Listeria monocytogenes in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes.*

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) *Alternative 1.* Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *and* an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with § 417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(2) *Alternative 2.* Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product *or* an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes.* If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with § 417.4. The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes.*

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes,* its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) *Alternative 3.* Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an

indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes,* the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes.* The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with § 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with § 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.

Done in Washington, DC: June 2, 2003.

Garry L. McKee,

Administrator.

Note: The following appendix will not appear in the Code of Federal Regulations.

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.

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 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 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

[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.*

[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.*

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, 1,276 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.

BILLING CODE 3410–DM–P

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.

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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, cannot 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).

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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

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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 $((1 - .38) \times 1{,}712)$.

(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).

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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

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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 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 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 the FSIS can affect at federally inspected establishments is a potential maximum 78 deaths (24.4 × 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 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 × .5). This level would be somewhat higher if 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).

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[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.*

[5] The estimate is based on information from the A.C. Nielson Co. 2001 Consumer Expenditures 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.

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

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

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.

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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).

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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.

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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

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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.

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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 costs	14,351.3	42,390.6	0	56,741.9

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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).

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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			
Establishment 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 establishments	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

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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.

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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

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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			
	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 U.S. RTE MPP production cutback. Without such information, one can only say that higher industry compliance

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

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

Item	HACCP Establishment Size Category			Average
	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 percent 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 × 8.0); and, 3.1 fewer at the 95th percentile (0.133 × 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 × 136.7 × $10,300) + (0.95 × 136.7 × $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 × $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 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 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 (Pub. 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 U.S. 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

[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.* Amsterdam, the Netherlands: Elsevier Science Publishing Co., 1990, pp. 137–144.

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 (Tables 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 10 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.

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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

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