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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 430

[Docket No. FSIS-2014-0033]

RIN: 0583-AD53

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

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Affirmation of the interim final rule with amendments; request for comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is affirming, with changes and a request for comment, the interim final rule "Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products," which was published in the Federal Register on June 6, 2003. FSIS is making minor changes to the regulatory provisions in response to comments that the Agency received, on the basis of experience in implementing the provisions, and because the way FSIS obtains establishment profile information electronically has changed. FSIS is clarifying in the regulations that establishments may not release into

commerce product that has been in contact with Listeria monocytogenes (Lm)-contaminated surfaces without reprocessing the product. In addition, FSIS is removing the requirement for establishments to report production volume and related information to FSIS because the Agency now routinely collects this information through its Public Health Information System (PHIS).

DATES: Effective [INSERT DATE 90 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER]. Comments must be received on or before [INSERT DATE 60 DAYS FROM DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: FSIS invites interested persons to submit comments on the changes. Comments may be submitted by one of the following methods:

- Federal eRulemaking Portal: This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to <http://www.regulations.gov>.

Follow the on-line instructions at that site for submitting comments.

- Mail, including CD-ROMs, etc.: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Patriots Plaza 3, 1400 Independence Avenue SW, Mailstop 3782, Room 8-163A, Washington, DC 20250-3700.

- Hand- or courier-delivered submittals: Deliver to Patriots Plaza 3, 355 E. Street SW, Room 8-163A, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2014-0033. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Dr. Daniel L. Engeljohn, Assistant Administrator, Office of Policy and Program Development; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

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. FSIS also proposed to eliminate its regulations that require both RTE and not-ready-to eat pork and products containing pork to be treated to destroy trichina (Trichinella spiralis).

Finally, FSIS proposed environmental testing requirements for establishments to verify whether their processes were addressing Lm 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 the establishments are controlling the presence of Lm within their processing environments. Under the proposal, establishments that developed and implemented Hazard Analysis and Critical Control Point (HACCP) controls for Lm would have been exempt from these testing requirements.

Interim Final Rule

On June 6, 2003, FSIS published the interim final rule "Control of Listeria monocytogenes in Ready-to-Eat Meat and Poultry Products" (68 FR 34208). In the interim final rule, FSIS amended its regulations only in regard to the control of Lm in RTE products. The Agency decided to adopt these regulations before completing action on the other provisions of the proposed rule because of outbreaks of foodborne listeriosis, and because of recalls of meat and poultry products adulterated by Lm. FSIS plans to address the other proposed provisions in future Federal Register publications.

The interim final regulations remain in effect. Under these regulations, an establishment that manufactures post-lethality-exposed RTE meat or poultry products must control Lm in the processing environment through its HACCP plan or prevent contamination of products by the pathogen through sanitation standard operating procedures (Sanitation SOPs) or other prerequisite program. The regulations (9 CFR 430.4(b)(1)-(3)) identify three alternative means of controlling Lm: Alternative 1 -- use of a post-lethality treatment (e.g., steam pasteurization, hot water pasteurization, radiant heating, high pressure processing (HPP), ultraviolet treatment, infrared treatment, or drying) that reduces or eliminates populations of the organism and use of an antimicrobial agent (e.g., potassium lactate or sodium diacetate) or process (e.g., freezing) that suppresses or limits growth of the organism; Alternative 2 -- use of either a post-lethality treatment that reduces or eliminates Lm or an antimicrobial agent (Alternative 2a) or process that suppresses or limits growth of the organism (Alternative 2b); Alternative 3 -- use of only sanitation to control the organism. The regulations require an establishment that uses a post-lethality treatment for controlling Lm to validate the treatment's effectiveness and incorporate it in its HACCP

plan. Under the regulations (9 CFR 430.4(b)(1)-(3)), an establishment that uses an antimicrobial agent (Alternative 2a) or process that suppresses or limits growth of Lm (Alternative 2b), or that uses only a sanitation program (Alternative 3) for controlling the pathogen must include food-contact surface testing in its sanitation program.

Under the regulations, an establishment that produces hotdog or deli-meat products considered to be at high risk for Lm contamination and that uses only sanitation to control the pathogen must, after two tests of food-contact surfaces that are positive for Lm or an indicator organism under the conditions described in the regulation, withhold affected product from commerce until the food-contact surface contamination problem is corrected. The establishment may release the held product only after statistically valid sampling shows the product not to be adulterated with Lm, or after the product has been reworked using a process that destroys Lm (9 CFR 430.4 (b)(3)(ii)).

The regulations include requirements for proper documentation of an establishment's Listeria controls, the verification of those controls, and the availability of the documentation to FSIS personnel. In addition, the regulations require an establishment that produces post-lethality-exposed RTE products to provide FSIS, at least

annually, with estimates of annual production volume and related information on the types of products it processes under each of the Lm control alternatives (9 CFR 430.4(d)).

FSIS decided to establish the regulatory requirements for preventing Lm contamination of RTE meat and poultry products based on two studies on the public health risk posed by the pathogen in RTE food products. The first study, an FSIS-Food and Drug Administration (FDA) risk ranking of RTE food products, placed hotdog and deli-meat products among products that pose the highest risk in terms of listeriosis cases per annum.¹ The second study, a quantitative risk assessment by FSIS of Lm in deli meats, identified combinations of in-plant control measures that showed the greatest potential for reducing the public health risks posed by Lm.² The second study enabled FSIS to determine that the first Lm control alternative identified in the interim final rule - post-lethality treatment plus growth limitation or suppression - provided the greatest risk reduction potential, while the third alternative - sanitation only - provided the least.

¹ FDA/Center for Food Safety and Applied Nutrition; USDA/FSIS. September 2003. Quantitative Assessment of the Relative Risk to Public Health from Foodborne Listeria Monocytogenes among Selected Categories of Ready-to-Eat Foods. Washington, D.C.
<http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM197329.pdf>.

² USDA/FSIS. May 2003. FSIS Risk Assessment for Listeria monocytogenes in Deli Meats. Washington, D.C.
<http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F/ListeriaReport.pdf>.

In the regulations, FSIS advised establishments that it would conduct more testing at establishments if their Lm control measures provide less potential risk reduction than other available control measures. Thus, the regulations provide that FSIS will conduct more testing at an establishment that chooses alternative 2 and uses a post-lethality treatment of product than if it had chosen Alternative 1. Similarly, FSIS will conduct more testing at an establishment that chooses alternative 2 and uses an antimicrobial agent or process that suppresses or limits the growth of Lm than at an establishment that uses a post-lethality treatment (9 CFR 430.4(b)(2)(iv)). FSIS conducts more testing at an establishment that chooses Alternative 3 than at an establishment that has chosen Alternative 1 or 2 (9 CFR 430.4(b)(3)(iii)).

Finally, the regulations allow establishments that use post-lethality treatments or antimicrobial agents or processes that are effective in destroying Lm or in limiting its growth to declare this fact on the labels of their products (9 CFR 430.4(e)). The purpose of the voluntary 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.

On October 6, 2003, the Agency supplemented the interim final rule with the "FSIS Compliance Guideline: Controlling Listeria monocytogenes in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products" (the Compliance Guideline). The Agency also conducted a series of workshops on the interim final rule at several locations around the country during the pre-implementation period before October 6, 2003, when the interim final rule became effective. On January 10, 2014, FSIS made available an updated version of the Compliance Guideline is available on FSIS's Web site at <http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling-Lm-RTE-Guideline.pdf?MOD=AJPERES>.

Based on available data, FSIS is confident that it is successfully carrying out its mission to protect public health by enforcing safeguards designed to control Lm. In the 10 years since FSIS issued the interim final rule described above, the percent positive in FSIS testing for Lm in RTE products has decreased from 0.76 percent in CY 2003 to 0.34 percent in CY 2013. The Agency considers the RTE regulatory results to be an excellent indicator of the trends in pathogen presence in RTE products over several years. This downward trend shows that the interim final

rule has been effective in controlling Lm in RTE meat and poultry products. Therefore, FSIS is affirming the interim rule as final with only the minor changes discussed below.

Opportunities to Comment

Because some of the approaches to Lm control addressed in the interim final rule were novel, FSIS provided an 18-month comment period (69 FR 70051; December 2, 2004). FSIS also assembled a team of Agency experts to make a preliminary assessment of the interim final rule. FSIS announced in the Federal Register (69 FR 70051; December 2, 2004) that the report "Assessing the Effectiveness of the Listeria Monocytogenes Interim Final Rule" was available in the Agency's Docket Room and on line at

[http://www.fsis.usda.gov/wps/wcm/connect/4174b07e-8b39-4617-acdf-
adc38a249cd7/LM Assessment Report 2004.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/4174b07e-8b39-4617-acdf-
adc38a249cd7/LM_Assessment_Report_2004.pdf?MOD=AJPERES)

In addition, FSIS asked the National Advisory Committee on Meat and Poultry Inspection (NACMPI) to review the interim final rule and the assessment team's report and to make its own recommendations (69 FR 29124). NACMPI made recommendations on the assessment at its June 2-3, 2004, meeting. The Agency responded to the recommendations at the NACMPI meeting held on November 16-17, 2004 (69 FR 64902). NACMPI recommended that the assessment team focus

on the differences among small, very small, and large plants and assess the economic impact on very small and large plants. NACMPI also recommended that FSIS conduct focus groups to determine whether consumers are confused by the provisions for labeling statements explaining that product has undergone post-lethality treatments or has been treated with an antimicrobial. Finally, NACMPI recommended that FSIS determine whether the assumptions on product risk made in the FDA/USDA Quantitative Risk Assessment are accurate.

FSIS agreed to consider variables such as product types and the frequency of production, which reflect differences among small, very small, and large plants. The Agency also agreed to review whether the rule has caused firms, particularly small firms, to go out of business. FSIS also continued to assess the effects of the informational labeling statements allowed under the rule. However, FSIS stated that the informational labeling provision should remain in the final version of the Lm rule as an encouragement to industry to declare that products have undergone post-lethality treatments or have been treated with anti-microbial agents or processes to destroy Lm. FSIS agreed to assess the three alternatives in the rule and evaluate their effectiveness for risk mitigation.

NACMPI's recommendations and FSIS's responses can be viewed at

[http://www.fsis.usda.gov/wps/wcm/connect/d8be3905-5f3c-458d-a5e7-f5149457b20e/LM Assessment Response.pdf?MOD=AJPERES](http://www.fsis.usda.gov/wps/wcm/connect/d8be3905-5f3c-458d-a5e7-f5149457b20e/LM_Assessment_Response.pdf?MOD=AJPERES).

Finally, FSIS received comments on the impact of the interim final rule on small businesses from the Office of Management and Budget (OMB) in response to OMB's 2004 Draft Report to Congress on the Costs and Benefits of Federal Regulation (69 FR 7987; February 20, 2004). The commenters stated that FSIS underestimated the costs and overestimated the benefits of the interim final rule. The commenters stated that the rule should be rescinded or amended to replace the regulatory requirements for small and very small processors with a pre-HACCP regulatory environment. In response, FSIS stated that the Agency would consider all comments and respond to them in a final rule.

A summary of the comments and FSIS's response is reflected in the March 2005 OMB report "Regulatory Reform in the U.S. Manufacturing Sector," which is available at <http://www.whitehouse.gov/omb/inforeg/regpol/reports/congress>.

In developing this final rule, FSIS considered all comments received in response to the documents described

above. Based on information provided by comments, FSIS's experience enforcing the interim final regulations, and analysis of available data, FSIS has decided to affirm the provisions in the interim final rule with two minor changes. The minor changes are explained below and are discussed in more detail in the Agency's responses to comments.

Summary of Amendments to the Interim Final Rule

FSIS is clarifying that product that has tested positive for Lm or that has been in contact with an equipment surface that has tested positive for Lm is adulterated and may not be released into commerce. FSIS is also making explicit in 9 CFR 430.4(a), however, that the product may be reprocessed using a method that destroys Lm.

9 CFR 430.4(a) clearly states that "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." However, the wording of paragraphs 9 CFR 430.4(b)(2)(iii)(B), (b)(3)(i)(B), and (b)(3)(ii)(B) and (C) has led some establishments to question whether they may perform further confirmation testing after a finding of Lm in RTE product and then release the product into commerce. Therefore, FSIS removed from paragraphs 9 CFR 430.4 (b)(2)(iii)(B), (b)(3)(i)(B),

and (b) (3) (ii) (B) provisions concerning additional establishment testing in response to Lm results. As revised, the regulations will refer only to additional establishment testing in response to positive indicator organism results. In addition in paragraph 9 CFR 430.4 (b) (3) (ii) (C), FSIS has removed provisions that may suggest that establishments may "be able to release into commerce the lots of product that may have become contaminated with L. monocotogenes" because, as is stated in 9 CFR 430.4(a), such product is adulterated and cannot be released into commerce.

FSIS is also removing the requirement that establishments report production volume and related information to FSIS because the Agency now collects this information through PHIS.

In accordance with section 553 of the Administrative Procedure Act (5 U.S.C. 553), the Agency finds good cause for making these changes effective [INSERT DATE 90 DAYS AFTER PUBLICATION]. This rule provides minor conforming amendments to FSIS's regulations and imposes no new or substantive requirements on the public. For these reasons, FSIS has determined that notice and opportunity for public comment on these changes are unnecessary. However, FSIS is

providing the public with an opportunity to comment on these minor, conforming changes.

Comments and Responses

FSIS received comments from five trade associations that represent meat and poultry processors, two consumer organizations, an association that represents small businesses, an association that represents manufacturers, an organization that represents scientists, a very small establishment, and an individual consumer on the interim final and on the other opportunities for comment described above. Following are FSIS's responses to the issues that they raised.

Applicability of rule; exemption of certain products

Comment: Several commenters stated that certain classes of products should be exempt from the rule. For example, these commenters stated that products that are exposed to the environment but that receive a validated, post-packaging lethality, such as products that are cooked, repackaged, and then irradiated, thermally processed, or high-pressure processed in their final package, should be exempt from the requirements in the rule. These commenters stated that the fact that there was product exposure to the post-lethality processing environment during the repackaging operation that followed the initial cook should

not subject such a product to the Lm control rule. In addition, the commenters stated that, products that remain at a temperature lethal to Lm until the products are filled into the final packaging should be exempt.

Response: An establishment that produces post-lethality exposed RTE products is appropriately required to control Lm through HACCP or a sanitation program because an RTE product that is not free of pathogens, including Lm, can easily cause illness because it will not be subject to a lethality step before consumption. Therefore, FSIS is not exempting such post-lethality-treated products from the requirements in this rule.

Post-lethality exposed product may be at risk of contamination and thus needs to be subject to the requirements in this rule. However, a product that is not post-lethality exposed (not removed from the container in which it is processed) is not subject to the requirements in this rule.

Regarding HPP of RTE product, in most cases that FSIS is aware of, HPP is applied to an RTE product that was previously subject to a lethality treatment, such as cooking, and then was exposed to the environment before being packaged. Thus, HPP is considered a post-lethality

treatment that is subject to the Alternative 1 or Alternative 2 requirements of 9 CFR 430.4.

There may be cases in which a treatment is applied to a post-lethality exposed RTE product in such a manner that the product could no longer be regarded as post-lethality exposed and thus would be exempt from the interim final rule. For example, if HPP is validated to achieve at least a 5-log reduction of Lm and other pathogens of concern (e.g., Escherichia coli O157:H7 and Salmonella) for cooked uncured meat patties or at least a 7-log reduction in cooked chicken strips, the process would be considered to achieve full lethality, and the product would not be considered to be post-lethality exposed (see 9 CFR 318.23).

FSIS has explained in its Compliance Guideline (<http://www.fsis.usda.gov/wps/wcm/connect/d3373299-50e6-47d6-a577-e74a1e549fde/Controlling-Lm-RTE-Guideline.pdf?MOD=AJPERES>) that it considers certain RTE products as not post-lethality exposed; that is, they are not exposed to the environment after the lethality treatment and before packaging. They include fully cooked "cook-in-bag" product that is shipped from the establishment in an intact cooking bag, thermally processed commercially sterile products, and products that receive a

lethality treatment and are hot-filled at the lethality temperature.

A product that has undergone a lethality treatment and is hot-filled into packaging may be considered to be an RTE product that has not been post-lethality exposed if the temperature lethal to pathogens and the sanitary handling of the product are continuously maintained to the point where the product is packaged. In this situation, the establishment needs to have documentation on file showing that the lethality temperature and sanitary handling are maintained continuously from the point of lethality to the point of packaging.

Comment: A few commenters objected to the assessment team's statement that Lm is reasonably likely to occur in the production of RTE meat and poultry products. The commenters argued that the assessment team ignored the value of post-lethality treatments.

Response: In the assessment report, the assessment team was expressing a view that Lm is reasonably likely to occur in the absence of controls to eliminate or reduce it. Many in industry, Government, and academe share the view that Lm is ubiquitous in the RTE processing environment, and that a prudent establishment would maintain controls in its production process to prevent the contamination of its

food products. Establishments use post-lethality treatments because the pathogen is reasonably likely to occur in the product in the absence of the treatment. For this reason, the regulations require that an establishment that uses a post-lethality treatment include the treatment in its HACCP plan or Sanitation SOP or other prerequisite program (9 CFR 430.4(b)(1)(i)).

Comment: A few commenters suggested that the statements in the questions and answers accompanying FSIS Form 10,240-1 should be reflected in the final rule. According to one such statement on the questions and answers accompanying FSIS Form 10,240-1, products intended for further processing and labeled for further processing are not subject to the rule. According to another, products that otherwise would be considered RTE, but that are shipped to another establishment for use in a non-RTE product (e.g. frozen entrée), should not be subject to the rule.

Response: FSIS has addressed these issues in the Compliance Guideline. A product that is intended for further processing at another FSIS inspected establishment and that is labeled "for further processing" is not considered RTE and, therefore, is not covered by the rule. However, products that are commonly understood to be RTE,

such as cooked sausages subject to the standard of identity in 9 CFR 319.180, are commonly understood to be RTE and cannot be labeled for "further processing" as a non-RTE product. In addition, a product that otherwise would be considered RTE, but that is shipped to another FSIS inspected establishment for use in a non-RTE product, is not considered RTE and therefore, is not covered by the rule.

It should be noted that FSIS Form 10,240-1 was discontinued on September 30, 2011. As mentioned above, FSIS continues to collect the same information through PHIS.

Comment: One commenter asked FSIS to explain the criteria for determining when antimicrobial processes also act as post-lethality treatments. In particular, the commenter wanted FSIS to explain why products with a water activity (a_w) of less than 0.85 rather than of 0.92 or less will not support Lm growth.

Response: FSIS has addressed this issue in the Compliance Guideline. Low water activity limits the amount of water available to pathogens such as Lm and will not allow them to grow. An a_w less than or equal to 0.92 will not support the growth of Lm, and an a_w of 0.85 or less (the a_w for achieving shelf stability) can sometimes even reduce

Lm numbers. FSIS will consider an a_w of ≤ 0.85 at the time the product is packed to be a post-lethality treatment and to be an antimicrobial treatment if the establishment provides supporting documentation that Lm is reduced by at least 1-log before the product leaves the establishment, and that no more than 2-logs of growth of Lm occurs over the shelf life of the product.

Comment: One commenter asked FSIS to clarify for establishments the distinction between RTE and not-RTE products. The commenter stated that documentation for making the determination is not available for a number of products.

Response: In Attachment 1.2 of the Compliance Guideline, FSIS provides a chart that distinguishes three types of products, two not-RTE and one RTE. One type of not-RTE product is a product that contains a meat or poultry product ingredient that has not received a full lethality treatment sufficient to destroy pathogens (e.g., raw products, partially cooked products, or products that are irradiated or HPP-treated and do not achieve at least a 5-log reduction of Lm and other pathogens of concern). This type of not-RTE product could also be a product that has received an adequate lethality for Salmonella but is not defined by a standard of identity or bear a common or

usual name that consumers understand to refer to RTE product. The product also does not meet the definition of RTE in 9 CFR 430.1 (e.g., not-RTE ham). The other type of not-RTE product is a product that contains a meat or poultry component that has received a full lethality treatment for pathogens and that also contains non-meat or non-poultry components to which the intended user must apply a lethality treatment (e.g., a meal, dinner, or frozen entrée). An RTE product, on the other hand, may be a heat-treated or not-heat-treated shelf-stable product, a fully cooked, not-shelf-stable product (e.g., hotdogs), or a not-shelf-stable product containing secondary inhibitors (e.g., RTE sausage). The chart in the Compliance Guideline lists HACCP process categories for each product type, the applicability of safe handling labeling, and significant matters that the HACCP plan should address for the product and process.

Listeria control alternative requirements

Comment: A few commenters recommended that the determination of which Lm control alternative is being used at a given establishment should take into account documented processes applied at the establishment to which its RTE product is shipped. For example, the commenters stated that if an Alternative-3 product is shipped to an

establishment where it is subject to an Alternative 2-type of process, then FSIS should consider the product as an Alternative 2 product.

Response: The Compliance Guideline discusses situations in which an establishment implementing one type of Lm control to prevent contamination of its post-lethality exposed product ships the product to another establishment that applies the same or another type of Lm control. The determination of which Lm control Alternative requirements apply to the product would depend on the extent of documentation and documentation-sharing by each establishment, as well as on the product distribution controls actually applied by the establishments. If an Alternative-3 product is shipped to an establishment where it is subject to an Alternative 2-type of process, and this process is properly documented in the first establishment's HACCP system, FSIS would consider the product as an Alternative 2-type of product.

Verification sampling and testing

Comment: One commenter agreed with FSIS's recommendation that establishments hold all product tested by establishments until test results are known but urged FSIS to say more about when and how tests should be conducted (e.g., before or during production). The

commenter stated that FSIS needs to provide specific details and flow diagrams, with examples. FSIS also should provide a hold-and-test scenario flow chart.

Response: The Compliance Guideline includes recommendations on verification testing, methods to be used, recommended sampling plans, and a hold-and-test scenario flow chart. The Compliance Guideline also includes examples of verification sampling programs for the product classes that are subject to the interim final rule.

Establishments are required to hold or maintain control of RTE products that FSIS has tested for Lm and other pathogens, and RTE products that have passed over food-contact surfaces that FSIS has tested for Lm and other pathogens. In addition, establishments in Alternative 3 (who only use sanitation controls) are required to hold product after a second consecutive food-contact surface positive for Lm or an indicator organism until the establishment corrects the problem indicated by the test result (9 CFR 430.4(b)(3)(ii)(B)).

Establishments in Alternative 3 must sample and test the lots of product using a method that will provide a level of statistical confidence that the product is not adulterated (9 CFR 430.4(b)(3)(ii)(C)). FSIS recommends that establishments use the International Commission on

Microbiological Specifications for Foods (ICMSF) Tables. The ICMSF Tables provide examples of statistically-based sampling plans that are commonly used for demonstrating lot acceptance. The ICMSF Tables are included in the Compliance Guideline. FSIS also recommends that establishments collect samples at least three hours after the start of operations, if possible, to allow Lm to work its way out to the surface of the equipment. If establishments typically produce RTE product for less than three hours, then the samples can be collected less than three hours after the start of operations.

FSIS recommends that establishments in Alternatives 1 and 2a hold and test product after multiple contact surface positives for an indicator organism. The finding of three consecutive positive food contact surface samples increases the risk that the product is contaminated with Lm. If the establishment does not hold and test the product after the third positive, it should provide other support demonstrating that the product is not likely to be contaminated. The establishment should take preventative steps such as: increase its routine sampling for Lm; collect intensified samples to find sources of harborage and cross contamination; reassess its Sanitation SOPs to determine whether sanitation issues could be leading to

positive results; assess the effectiveness of its post-lethality treatment or antimicrobial agents and processes; or reassess its HACCP plan to determine whether the actions it is taking are effective in controlling Lm.

Comment: One commenter stated that FSIS verification sampling should be conducted after the use of Lm control techniques (such as Alternative 3 controls) that are more economically feasible than post-lethality treatments and the use of growth inhibitors. The commenter stated that FSIS should conduct risk-based inspection and data collection on risk factors in the establishment and should use sound statistical techniques in environmental sampling. The commenter also stated that intensified verification testing (IVT) is a return to the command-and-control mode of inspection that FSIS should avoid. (An IVT is an FSIS sample collection activity that the Agency may conduct when, in either FSIS or establishment testing, a surface that comes into contact with post-lethality exposed RTE product tests positive for a pathogen of public health concern. IVTs are performed with a "for cause" Food Safety Assessment (FSA) to provide an in-depth evaluation of food safety systems at the establishment. The FSA may find the vulnerability or the noncompliance that led to the positive result.)

Response: The regulations in 9 CFR Part 430 state that products and the processing environment under Alternative 3 are likely to be subject to more frequent verification testing by FSIS than products and the processing environment under Alternative 1 or 2. In fact, Alternative 3 products are sampled at a higher rate in the FSIS risk-based sampling code RTEPROD_RISK (9 CFR 430.4(b)(2)(iv) and (b)(3)(iii)).

FSIS agrees that inspection should be risk-based. To that end, FSIS has developed risk-based verification sampling that focuses the Agency's testing on those products or environments in a process where a problem is most likely to occur. As of August 1, 2013, FSIS combined its random ALLRTE and risk-based RTE001 product sampling projects into a single project called RTEPROD. The RTEPROD sampling project uses two project codes: RTEPROD_RAND for product samples selected randomly, and RTEPROD_RISK for post-lethality-exposed product samples selected based on risk. Under the RTEPROD_RISK project code, establishments are identified for sampling based on a risk-ranking algorithm, which takes into account the control alternative, the production volume, the type of product produced, and the establishment's sampling history.

FSIS also uses the Routine Lm Risk-based (RLm) sampling project. While RTEPROD involves sampling and testing of the RTE meat and poultry products themselves, the RLm program includes sampling and testing of products, product contact surfaces, and environmental surfaces. Thus, RLm provides a means of identifying establishments that present a higher risk of Lm contamination in the food processing environment before product contamination actually occurs.

A routine FSA is conducted at the establishment in conjunction with RLm sampling and testing. Under RLm, samples are scheduled using a FSA prioritization model, which takes into account levels of inspection, control alternative, and type of product produced. Starting in August 2009, RLm sampling was increased so that establishments that produce post-lethality exposed RTE product are sampled at least once every four years under this project.

FSIS also agrees that, to be successful, risk-based verification must be carried out on the basis of solid information. The IVT activity can be a valuable source of information for both the Agency and the inspected establishment when potentially serious problems are found in an establishment's food safety system. The results of

an IVT can be used to help the Agency focus its inspection resources where they are most needed and can help the establishment plan improvements in its food safety system. In this regard, the IVT does not constitute a return to a command-and-control system of inspection in which FSIS told the establishment explicitly what it had to do to produce a safe product. Rather, the IVT provides the information on which an establishment may base its own decisions on the most effective control measures to take.

Comment: While conceding that IVT may be appropriate in some circumstances, such as multiple Lm positives on product or food-contact surfaces, a few commenters strongly opposed the assessment team's recommendation that an IVT be performed for multiple contact or product positives for Listeria spp. or Listeria-like organisms. The commenters also urged the Agency not to penalize establishments for trying to actively detect and eliminate potential harborage areas but to verify that appropriate corrective actions have been taken. The commenters also questioned whether the Agency would have the resources necessary to conduct IVT each time an establishment surpasses arbitrary yearly limits, as recommended by the Agency's assessment team.

Response: The FSIS assessment team addressed the actions that the Agency should take with regard to Lm-

positive results from tests performed on official samples. It should be understood that every inspected establishment is required by regulation to operate under a HACCP plan and to take corrective actions whenever there is a deviation from critical limits for the CCPs identified in the plan. FSIS personnel are trained to take enforcement action only if there has been a violation of the regulations. If an establishment has found a deviation through its normal HACCP monitoring and verification activities and takes some corrective action based on its findings, the Agency has no regulatory grounds for taking enforcement action because of the deviation.

However, if the Agency has verification testing results or other information that an establishment may have shipped adulterated product, an IVT is one of a number of appropriate actions, including an enforcement action, that the Agency may take in the interest of protecting the public health. Repeated findings of Listeria spp. or Lm on food-contact surfaces or on product may lead to an enforcement action if FSIS determines that the establishment is not properly addressing insanitary conditions.

Comment: One commenter stated that the FSIS sampling program should be modified to provide baseline surveillance

information to permit progress to be gauged. The comment said that verification sampling should target the riskiest products, and that there should be a properly designed and conducted annual survey of RTE establishments.

On the results that were available in 2004, when the FSIS assessment team prepared its report, the commenter questioned why FSIS had found no difference among the prevalence levels of Lm in randomly sampled RTE foods (3 of 345 or 0.9%) and in RTE foods for which sampling was targeted (11 of 1,349 or 0.8%). (The results are presented in the "Agency Accomplishments" section of the assessment team's report.) The commenter recommended the reevaluation of establishment HACCP plans and Sanitation SOPs and other prerequisite programs in the event of an FSIS positive Lm sample in a product that supports the growth of the organism. The commenter said that uniform criteria for such reevaluation should be developed.

Response: FSIS's verification sampling and testing program for Lm is designed to focus Agency resources on those products and processes that may pose higher risks of adulteration.

Regarding the apparent similarity in Lm prevalence among RTE products that were sampled randomly and RTE products that were sampled according to risk, the Agency

found that, when both ALLRTE and RTE001 samples were scheduled in one month, often only the RTE001 products were collected. In addition, FSIS found that the highest-risk products produced by the establishment were often collected for the ALLRTE project, rather than products collected at random. FSIS determined that combining the ALLRTE and RTE001 sampling projects into the new RTEPROD project would reduce redundancy in sample scheduling and make the sample selection process more efficient. Under RTEPROD, the sampling project codes specify more clearly whether FSIS personnel should select samples randomly (RTEPROD_RAND) or based on risk (RTEPROD_RISK). In addition, FSIS personnel receive either a RTEPROD_RAND or a RTEPROD_RISK sampling request at most once per month per establishment (see FSIS Directive 10340.4, Verification Activities for the Listeria monocytogenes Regulations and the Ready-to-Eat (RTE) Sampling Program). FSIS personnel are not requested to collect both RTEPROD_RAND and RTEPROD_RISK samples in one month to avoid overlap and to increase sampling efficiency.

Regarding the suggestion that establishment HACCP plans and prerequisite programs be reevaluated in the event of an Lm-positive product test, such a reevaluation may be necessary depending on the circumstances of the positive test. If an establishment made such a finding in the

course of testing that was part of its HACCP verification procedures, the establishment would follow the corrective actions procedures in its HACCP plan. If the establishment determined that a change affecting the validity of the hazard analysis had occurred, the establishment would reassess its HACCP plan. On the other hand, an Lm-positive test on an official FSIS RTE product sample might indicate that the establishment's HACCP system had failed to prevent the production of adulterated food. In that case, under the HACCP regulations, FSIS would have grounds for finding the establishment's HACCP system to be inadequate. In addition, if the establishment failed to take appropriate corrective action, as required by 9 CFR 417.3, FSIS would have further grounds for finding the establishment's HACCP system to be inadequate.

In the Compliance Guideline, FSIS has listed and explained the elements of adequate validation for post-lethality treatments and growth-suppressing or limiting formulations or processes.

Comment: One commenter noted that the rule did not have a uniform recordkeeping requirement for the results of environmental sampling. Sanitation SOP records are required to be kept for only six months, HACCP records from one to two years. The commenter requested that FSIS

explain that an effective environmental sampling program must provide for long-term trend analysis.

Response: Records that are generated under the Lm control regulations may be Sanitation SOP records, HACCP records, or other prerequisite program documentation and records. As the commenter points out, retention requirements apply to Sanitation SOP records and HACCP records. Prerequisite program documentation and records of activities conducted under the Lm control regulations affect hazard analysis decisions and are required to be maintained for at least two years under 9 CFR 417.5 because they are documents used to inform decisions in the establishment's hazard analysis.

FSIS agrees that it is important that an establishment analyze trends in product, food-contact surface, and environmental test results. In the Compliance Guideline, FSIS advises establishments to keep monitoring records, including test results, for use in evaluating their Sanitation SOPs. The monitoring records should be designed to show trends in the development of insanitary conditions. Establishments should review at least the previous month's testing results to determine whether a trend is emerging, or whether it is necessary to revise their sampling plans. Persistent problems may indicate the pathogen's presence in

niches in the processing environment. FSIS also advises establishments to adjust their testing frequencies on the basis of data that they have collected over time. FSIS is not, however, proposing to change its record retention requirements because the Agency believes that the requirements are adequate.

Comment: One commenter stated that while the interim final rule required establishments to verify the effectiveness of their Listeria control program through testing, they have no obligation to conduct such testing at any particular frequency, even if they produce high-risk products such as deli meats and hot dogs. The commenter argued that, without mandatory minimum testing frequencies, establishments simply cannot be assured that their controls are working effectively every day to control Listeria.

Response: After reviewing comments on the 2001 proposed rule (66 FR 12589) and the results of the FDA/FSIS risk ranking and the FSIS risk assessment, FSIS concluded that a mandatory testing frequency was not well-founded. The FDA/FSIS risk ranking and FSIS risk assessment showed that post-lethality interventions and formulation of RTE meat and poultry products with growth inhibitors was much more effective in preventing listeriosis than testing product or food contact surfaces. Therefore, FSIS is not

making changes to the regulations to require a minimum testing frequency for establishments.

Nevertheless, the Agency regards establishment verification testing of the processing environment and especially of food-contact surfaces to be important in monitoring the sanitary conditions under which post-lethality exposed RTE products are processed. Establishments that produce RTE products and that rely on sanitation procedures alone to control Lm (Alternative 3) should carry out effective verification procedures, including food-contact surface testing, to ensure that their controls are effective, and that the products are not contaminated. Such is the Agency's regard for the value of food-contact surface testing that the Agency has incorporated food-contact surface testing into its RLM sampling program that it is carrying out in RTE establishments.

Comment: One commenter stated that, even though the rule required establishments to make their own testing results available to FSIS inspection personnel upon request, nothing in the interim final rule imposed on establishments an affirmative obligation to disclose test results, particularly positive results, to FSIS at the time the results are obtained. The commenter argued that,

without immediate access to these data when a problem is first identified, inspection personnel may be unaware that there is a sanitation problem at a facility, that interventions are not working properly, or that those problems may be persistent and uncorrected.

Response: As the comment acknowledges, when FSIS personnel request testing records, the establishment is required to make them available (9 CFR 430.4(e)) so that FSIS personnel can complete the required verifications. From the verification results FSIS can know whether there is a sanitation problem at the establishment, whether antimicrobial interventions are working properly, whether a corrective action was appropriately taken to address a non-recurring problem, or whether there is mounting evidence of a persistent problem that must be corrected.

Changing the regulations to require immediate notification of FSIS when a positive test is obtained would not affect what either the establishment or FSIS is required to do with respect to product safety in response to the positive test result. Therefore, FSIS is not proposing to change the regulations in this respect.

Compliance guidance

Comment: A few commenters stated that the Agency should periodically update the Compliance Guideline. Also,

commenters stated that the Agency should make available to the industry guidance on acceptable procedures for evaluating the effectiveness of new post-lethality treatments and antimicrobial agents or processes.

Response: FSIS has updated the Compliance Guideline four times since the interim final rule published. The first update in October 2004 responded to comments and questions that FSIS received about the rule and addressed questions that participants asked during the workshops that the Agency held in preparation for the implementation of the interim final rule. The second update in May 2006 included new information on FSIS's risk-based sampling algorithm and acceptable procedures for evaluating the effectiveness of new post-lethality treatments and antimicrobial agents or processes. The third update in September 2012 provided updated technical information on the control alternatives and on how establishments could take corrective actions in response to positive results and new information on developing a listeria control program. The fourth update in January 2014 responded to comments and questions that FSIS received in response to the previous version. FSIS will continue to update the Compliance Guideline as necessary.

Labeling; consumer education

Comment: One commenter stated that the labeling claims about treatments that eliminate, suppress, or limit the growth of Lm could be misleading. The commenter argued that allowing companies to provide information about technologies, without also including safe handling instructions, may create further potential to mislead consumers, including susceptible groups, into a false sense of safety and lead to improper handling.

Response: Safe handling instructions are required if the meat or poultry component of a product is raw or partially cooked (i.e., not considered RTE), and if the product is destined for household consumers or institutional users (9 CFR 317.2(1) or 381.125(b)). All food products, including shelf-stable RTE products, must be handled with appropriate care to prevent product adulteration. Findings of a survey conducted by the International Food Information Council (IFIC), which is described in more detail in the response to the next comment, do indicate that label statements about processing for improved product safety may cause some consumers to feel safe about eating product after a "use-by" date. This could be a concern if the "use-by" date were a safety-based date.

FSIS believes, nevertheless, that the processed-for-safety statements can be made if they are adequately supported. Also, as the Agency's own assessment team has recommended, the Agency should give industry flexibility to develop labeling statements that are truthful and not misleading. FSIS will review and approve labels that bear such statements before they are used, as it approves all labels that make special claims. The Agency also will ensure that its food safety education materials for consumers include information about the labels and about Lm.

Comment: IFIC submitted the results of a study that it conducted in collaboration with FSIS. In the study, IFIC tested several different informational statements to determine the impact such labeling has on consumer perceptions of food safety. The IFIC survey found that, while food-safety information can assist consumers in the purchase, preparation, and handling of foods, the food-safety labeling messages that were tested may not achieve this goal. None of the statements tested performed better than control product labeling. Only a very small segment of the population of consumers in the study felt that enhanced food safety was an important reason to purchase a product. Most statements did not enhance consumer

perceptions of food safety, although the statements were likely to make consumers feel safe eating product after the "use by" date. Also, the results appeared to indicate that use of labels with certain food safety information may actually drive some consumers away from the product category.

Response: FSIS understands the challenge of providing consumers with useful and important food safety information on product labels. That is why the Agency is not requiring labeling statements about Lm controls but only permitting and encouraging their use.

Retail

Comment: A few commenters stated that FSIS should conduct research to determine the magnitude of retail-level contamination. A few commenters agreed with the assessment team finding that efforts to control Lm contamination at retail are warranted. The commenters stated that, in addition to training, there must be measurement, monitoring, and enforcement of best practices at retail. The commenters agreed with the assessment team's finding that regulatory strategies aimed at FSIS-inspected establishments may not be effective in reducing retail-level contamination. Another commenter strongly agreed with the assessment team's recommendation to educate and

train retail and food service personnel but noted that this matter is usually outside USDA/FSIS jurisdiction.

One commenter stated that additional training for retail staff is appropriate for reducing Lm contamination of RTE products at that level. The commenter also recommended the use of antimicrobial agents in products sold at retail. The commenter recommended that FSIS investigate the practicality of freezing or other practices during transport of RTE products. In addition, the commenter stated that the FSIS Lm control strategy should focus on preventing cross-contamination at the deli counter.

Response: State and local governments have chief responsibility for the administration of inspections and regulation of retail facilities on a regular basis. Although FSIS does not inspect retail establishments, it may visit them to ensure that the meat, poultry, and egg products that they sell remain safe for human consumption and are not adulterated or misbranded.

FSIS provides information, materials, and assistance to help State and local agencies to achieve food safety goals and conducts outreach programs that are aimed at retail and food service personnel. FSIS also participates with FDA in the development of the Food Code model

ordinance. The Food Code sets forth model standards that State and local public health authorities may adopt in their own regulatory programs for the retail sector.

To help minimize the public health burden of listeriosis, FSIS and the FDA conducted an interagency risk assessment to better understand the risk of foodborne illness associated with eating certain RTE foods prepared in retail delis and developed recommendations for changes in current practices that may improve the safety of those products. In 2013, FSIS and FDA made their findings available to the public in the "Interagency Risk Assessment--Listeria monocytogenes in Retail Delicatessens" (Interagency Retail Lm Risk Assessment), which is available on FSIS's Web site at <http://www.fsis.usda.gov/wps/portal/fsis/topics/science/risk-assessments>.

The agencies conducted the risk assessment to better understand how retail practices (e.g., temperature control, sanitation, worker behavior) influence the risk of listeriosis associated with eating meat, cheeses, and salads sliced or prepared in retail delicatessens. The risk assessment also examines how effective various interventions are in limiting the survival, growth, or cross contamination of Lm.

The risk assessment is based on observations of deli employees' work routines; concentrations of Lm on incoming products and in the deli environment; studies on the ability of Lm to spread in retail delis, such as from a slicer to food; and an existing dose-response model. The study was designed to apply to a range of deli establishments, from small independent operations to the deli departments in large supermarkets.

FSIS agrees that care should be taken in storage, handling, and distribution of RTE meat and poultry products, and that strict temperature controls are important in preventing the outgrowth of any Lm that may be present in products. Using the key findings of the Interagency Retail Lm Risk Assessment along with available scientific knowledge, the FDA Food Code, and lessons learned from controlling Lm in FSIS-inspected meat and poultry processing establishments, FSIS developed the "FSIS Best Practices Guidance for Controlling Listeria monocytogenes (Lm) in Retail Delicatessens," which provides practical recommendations that retailers can use to control Lm contamination and outgrowth in the deli. The best-practices guidance is available at

<http://www.fsis.usda.gov/wps/wcm/connect/29d51258-0651-469b-99b8-e986baee8a54/Controlling-LM->

[Delicatessens.pdf?MOD=AJPERES](#). FSIS encourages retailers to use the best-practices guidance to help ensure that RTE meat and poultry products in the deli area are handled under sanitary conditions and are not adulterated.

Risk Assessment

Comment: One commenter noted that the draft of the second risk assessment, initiated in early 2001, was not completed until February 2003 -- two years after publication of the proposed rule, which addressed control of Lm. The commenter stated that the Agency limited the new assessment to deli meats only (ignoring hot dogs and other high-risk meat and poultry products) and did not include sampling of non-food contact surfaces in the risk model. The commenter also stated that the risk assessment excluded consideration of whether the risk would be reduced if, in addition to other steps, final product testing was required. The final version of FSIS's risk assessment,³ released in May 2003, found that the minimal testing frequency in the proposed Listeria rule would result in a

³ FSIS, FSIS Risk Assessment for Listeria Monocytogenes in Deli Meats (May 2003) available at <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/97-013F/ListeriaReport.pdf>. A final version of the Joint FDA/FSIS risk assessment was released in September 2003. It included a number of revisions to and refinements of the draft assessment, but still classified both deli meats and unheated frankfurters as "Very High Risk." See FSIS/FDA, Quantitative Assessment of the Relative Risk to Public Health from Foodborne Listeria Monocytogenes Among Selected Categories of Ready-to-Eat Foods (Sept. 2003) available at <http://www.fda.gov/downloads/Food/FoodScienceResearch/UCM197330.pdf>.

small reduction in Listeria levels, and that a combination of interventions (sanitation and testing of food-contact surfaces, lethality interventions, and growth inhibitors) appeared to be more effective than any single intervention.

Response: The focus of the risk assessment was narrowed on the basis of available data. The available data on hotdogs was not sufficient to be included in a plant-to-table risk assessment. Moreover, deli meat was believed to be the vehicle in most listeriosis cases. From the 2003 FDA-FSIS Quantitative Assessment of the Risk of Listeriosis due to Selected Food Categories (FDA, 2003), the median number of cases of listeriosis per annum from deli meats was estimated to be 1598.7. For frankfurters (reheated and not reheated combined) the number of cases was estimated to be less than 31. For pâté and meat spreads, the estimated number of illnesses was less than 4, and for dry/semi-dry fermented sausages, the estimated number of illness was less than 0.1. Clearly, this document pointed to deli meats as the high-risk food category in 2003.

While FSIS is aware of the limitations of its model, the Agency has concluded that the model is adequate to inform decision-making based on the specific risk management questions posed by FSIS risk managers. A more

detailed model would require additional data. The Agency noted in the final version of the risk assessment that the data available in the published literature on Listeria in the processing plant environment are limited. In addition to data limitations, the limited time available and the intended use of the model dictated other restrictions on the scope of the assessment. While the risk model addressed only food-contact surfaces as the source of contamination by Lm, the Agency's risk assessors acknowledged that Lm contamination could arise from inadequate lethality treatment or from cross-contamination from non-food contact surfaces. The risk assessment also made simplifying technical assumptions, such as those regarding a generic food-contact surface, the distribution of Listeria on the surface, and the assumption of a generic product lot.

The comment that the model excluded the effect of product testing, however, is not accurate. The in-plant model incorporated, in addition to food-contact surface testing, product testing and pre- and post-packaging interventions and the effect of growth inhibitors (or product reformulation). The risk assessment describes the role of product testing in the model and discusses the probability of detecting Lm in product samples and the

contribution of information from such testing to the development of risk reduction measures.

FSIS is affirming the 2003 risk assessment without updates or changes.

Economic impact; effect on small establishments; regulatory reform

Comment: One commenter disagreed with the assessment team's finding that the interim final rule was not disproportionately affecting small establishments because the number of noncompliance records (NRs) that FSIS issued related to this rule to very small plants was twice that for large plants. Similarly, the commenter stated that FSIS issued more NRs to small plants than large. Another commenter stated that the assessment team's finding that FSIS issued most NRs to very small establishments evidences the need for a much stronger effort at compliance assistance to the small processor.

A few comments that were submitted in response to OMB's February 2004 solicitation of nominations for regulatory reform (69 FR 7987) argued that the Agency greatly underestimated the costs and overestimated the benefits of the interim final rule.

One commenter that responded to the OMB request asserted that the economic analysis of the interim final

rule understated the costs to small businesses, particularly to small and very small processing plants, and overstated the benefits of the rule. The commenter noted that FSIS estimated the annual cost of the rule to the industry in the range of \$16.6 million, and that benefits were in the range of \$44 million to \$154 million. However, the commenter estimated that the actual costs were closer to \$115 million per year. The commenter charged that for each of the "10,000 plants" (sic) that are subject to the rule, the true costs are closer to \$11,500 per year and over \$1.15 billion over ten years. According to the commenter, the costs reflect the purchase of new equipment, reconfiguration of plant facilities, accumulated interest of \$50,000 per plant, and estimated annual costs of \$6,500 for testing to ensure compliance and for consultants. The grand total then would be \$115,000 per plant.

The commenter asserted that the rule puts American firms at a competitive disadvantage with foreign firms, and that the burden of the rule is so great that some small and very small plants may cease operations.

The commenter did not present an alternative benefit estimate in dollar terms but asserted that FSIS based its estimates on data that the Centers for Disease Control and Prevention (CDC) gathered through 1997, while CDC data for

1996 to 2000 show a 38 percent decrease in incidence of, and mortality from, Lm. Also the commenter asserted on the basis of the Q&A provided with the 2003 FDA/FSIS joint risk assessment that FSIS used for the interim final rule that it is likely that the annual total cases were less than 1,500, with 300 deaths.

Another commenter recommended that FSIS review the compliance costs of the rule and increase the calculation of those costs to a more reasonable figure.

Response: The commenters misstated the regulatory impact analysis of the interim final rule on key points. For example, rather than 10,000 plants, as one commenter stated, the rule was estimated to affect 2,930 total Federal establishments. In actual fact, the rule affected 2,473 Federal establishments in 2006 and 2,307 Federal establishments in 2013. Thus, the comment, on that basis alone, increased the arguable costs of the rule.

The comment stated that the costs of new equipment, plant reconfiguration, testing, and outside expert technical assistance are a substantial burden on small plants that the Agency ignored in its analysis. However, the interim final rule did not require these plants to upgrade their operations. For this reason, such costs are not a direct effect of the rule. The regulatory impact

analysis estimated that the vast majority of very small plants, such as the one submitting the comment, would use Alternative-3 type controls (sanitation only) to control Lm instead of changing from Alternative 3 to Alternative 2 or 1. Costs for Alternative 3 are minimal because it only requires an establishment to control Lm through its sanitation program. An establishment would not need to purchase new equipment for post-lethality treatment or apply antimicrobial agents. Comparing FSIS PHIS data of calendar year (CY) 2013 and the baseline in the 2003 interim final rule, the Agency found that about 77 percent of the small and very small establishments that used alternative 3 still use alternative 3.⁴ The percentage increases from the baseline to CY 2013 for small and very small establishments using Alternative 2b, Alternative 2a, and Alternative 1 are 17 percent, 1 percent and 1.5 percent, respectively. Therefore, the costs the small and very small establishments would incur would mostly be those attributable to initial and on-going compliance with the sanitation program requirements of the rule.

As to the benefit estimates in the economic analysis of the interim final rule, these were based on the

⁴ Note that the composition, and the relative statistics of the RTE establishments subject to this rule changed somewhat between 2003 and 2013, So the comparisons are approximate, not exact.

potential risk reductions to be achieved through the adoption by industry of the Listeria control alternatives set out in 9 CFR 430.4. While the comment stated that the CDC data for 1996 to 2000 show a 38 percent decrease in incidence of, and mortality from, Lm, the comment did not take into account an "up spike" in listeriosis illness that occurred in 2002-2003 before the rule went into effect. Thus, when the rule was promulgated, there were a significantly higher number of illnesses to be averted than the comment considered. Finally, the benefit estimates in the interim final rule were based on the differences in the number of illnesses in the risk assessment model results under different scenarios. The risk assessment model estimated the number of illnesses using FSIS simulation models that assess how the in-plant contamination level transfers to the retail contamination level and then assessed the number of illnesses based on the dose-response relationship from the FDA/FSIS exposure retail-to-table model where all models were calibrated for deli meat.⁵

For these reasons, FSIS is affirming the basic conclusions reached by the Final Regulatory Impact Analysis that was submitted in support of the interim final rule.

⁵ For details of these models, see footnote 3.

Executive Orders 12866 and 13563, and the Regulatory Flexibility Act

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "non-significant" regulatory action under section 3(f) of Executive Order (E.O.) 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

FSIS is affirming the basic conclusions reached by the Final Regulatory Impact Analysis that was submitted in support of the interim final rule. The two changes do not affect the basic conclusions reached by the Final Regulatory Impact Analysis that was submitted with the interim final rule. FSIS is making two changes in this document, making clear in the regulation that products that have been in contact with a Lm contaminated surface would be adulterated if not reprocessed (9 CFR 430.4(a)) and

removing the requirement for establishments to report production volume and related information to FSIS because the Agency now routinely collects this information through PHS (9 CFR 430.4(d)). Neither change will cause establishments to change their practices to comply with the regulation. Therefore, there is no need to conduct a cost or benefit analysis to affirm the interim final rule.

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601-602), the rule will not have a significant economic impact on a substantial number of small entities in the United States.

Paperwork Reduction Act

There are no paperwork or recordkeeping requirements associated with this rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the Internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

Executive Order 12988

This rule has been reviewed under the Executive Order 12988, Civil Justice Reform. Under this rule: (1) all State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal

consultation under E.O. 13175. If a Tribe requests consultation, the Food Safety and Inspection Service will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

USDA Nondiscrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

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Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.) should contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this Federal Register publication on-line through the FSIS Web page located at:

<http://www.fsis.usda.gov/federal-register>.

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, Federal Register notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and

stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

List of Subjects in 9 CFR Part 430

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

For the reasons set forth in the preamble, FSIS is adopting as final the interim final rule that amended Title 9, Chapter III, of the Code of Federal Regulations and that was published at 68 FR 34208 on June 6, 2003, with the following amendments:

PART 430 - REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

1. The authority citation for part 430 continues to read as follows:

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.

2. Amend § 430.4 by:

- a. Revising paragraph (a).
- b. Revising paragraph (b) (2) (iii) (B).
- c. Revising paragraph (b) (3) (i) (B).
- d. Revising paragraphs (b) (3) (ii) (B) and (C).
- e. Removing and reserving paragraph (d).

The revisions read as follows:

§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 that is contaminated with *L. monocytogenes*. Establishments must not release into commerce product that contains *L. monocytogenes* or that has been in contact with a food contact surface contaminated with *L. monocytogenes* without

first reworking the product using a process that is destructive of L. monocytogenes.

(b) * * *

(2) * * *

(iii) * * *

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

* * * * *

(3) * * *

(i) * * *

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

* * * * *

(ii) * * *

(B) During this follow-up testing, if the establishment obtains a second positive test for 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) In order to release into commerce product held under this section, 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.

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Done, at Washington, DC: May 29, 2015.

Alfred V. Almanza,
Acting Administrator.

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