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**9 CFR Parts 301, 303, et al.
Performance Standards for the
Production of Processed Meat and Poultry
Products; Proposed Rule**

DEPARTMENT OF AGRICULTURE**Food Safety and Inspection Service**

9 CFR Parts 301, 303, 317, 318, 319, 320, 325, 331, 381, 417, and 430

[Docket No. 97-013P]

RIN No. 0583-AC46

Performance Standards for the Production of Processed Meat and Poultry Products

AGENCY: Food Safety and Inspection Service, Agriculture.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend the Federal meat and poultry inspection regulations by establishing food safety performance standards for all ready-to-eat (RTE) and all partially heat-treated meat and poultry products. The proposed performance standards set forth levels of pathogen reduction and limits on pathogen growth that official meat and poultry establishments must achieve in order to produce unadulterated products, but allow the use of customized, plant-specific processing procedures. The proposed RTE performance standards apply to all RTE meat and poultry products, which can be categorized as follows: Dried products (e.g., beef or poultry jerky); salt-cured products (e.g. country ham); fermented products (e.g., salami and Lebanon bologna); cooked and otherwise processed products (e.g., beef and chicken burritos, corned beef, pastrami, poultry rolls, and turkey franks); and thermally-processed, commercially sterile products (e.g., canned spaghetti with meat balls and canned corned beef hash).

Although FSIS routinely samples and tests some RTE products for the presence of pathogens prior to distribution, there are no specific regulatory pathogen reduction requirements for most of these products. The proposed performance standards will help ensure the safety of these products; give establishments the incentive and flexibility to adopt innovative, science-based food safety processing procedures and controls; and provide objective, measurable standards that can be verified by Agency oversight.

FSIS also is proposing environmental testing requirements intended to reduce the incidence of *Listeria monocytogenes* in RTE meat and poultry products. Specifically, FSIS is proposing to require establishments that produce RTE meat and poultry products to test

food contact surfaces for *Listeria spp.* to verify that they are controlling the presence of *L. monocytogenes* within their processing environments. Establishments that have developed and implemented HACCP controls for *L. monocytogenes* would be exempt from these testing requirements.

Finally, FSIS is proposing 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*). These requirements are inconsistent with HACCP and some will be unnecessary if FSIS makes final the proposed performance standards for RTE meat and poultry products.

DATES: Comments must be received on or before May 29, 2001.

ADDRESSES: Submit one original and two copies of written comments to FSIS Docket #97-013P, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12 St., SW., Washington, DC 20250-3700. All comments submitted in response to this notice will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Daniel L. Engeljohn, Ph.D., Director, Regulation Development and Analysis Division, Office of Policy, Program Development, and Evaluation, Food Safety and Inspection Service, U.S. Department of Agriculture (202) 720-5627.

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Appendix 1

I. Background

Under the Federal Meat Inspection Act (FMIA; 21 U.S.C. 601 *et seq.*) and the Poultry Products Inspection Act (PPA; 21 U.S.C. 451 *et seq.*), FSIS issues regulations governing the production of meat and poultry products prepared for distribution in commerce. The regulations, along with FSIS inspection programs, are designed to ensure that meat and poultry products are safe, wholesome, unadulterated, and properly marked, labeled, and packaged. In this document, FSIS is proposing to establish new pathogen reduction regulations for ready-to-eat (RTE) and partially heat-treated meat and poultry products. This proposed action is compelled by recent outbreaks of foodborne illness related to the consumption of adulterated RTE meat and poultry products, as well as the need to provide objective, measurable pathogen reduction standards that can be met by official establishments and compliance with which can be determined through Agency inspection.

II. RTE Meat and Poultry Products

RTE meat and poultry products are products that have been processed so that they may be safely consumed without further preparation by the consumer, i.e., without cooking or application of some other lethality treatment to destroy pathogens. Although many of these products, such as frozen pizzas or country hams, customarily are cooked or otherwise reprocessed by the consumer, they would be safe to eat, if unpalatable, without this further preparation.

RTE meat and poultry products can be either non-shelf-stable or shelf-stable. Non-shelf-stable, RTE products must be refrigerated until consumption to prevent the growth of both pathogenic and spoilage organisms. Shelf-stable products remain ready-to-eat under ordinary temperature and humidity conditions and, if the package integrity is maintained during holding, shipping,

storage, display at retail, and in the home, throughout the manufacturer's shelf-life determination. Throughout the shelf-life, shelf-stable products are safe to eat when unrefrigerated (at temperatures over 50 °F or 10 °C) without additional preparation. Thermally processed, commercially

sterile meat and poultry products are packaged in hermetically sealed containers (usually cans) and also remain shelf-stable under unrefrigerated conditions (over 50 °F or 10 °C).

For the purposes of this proposal, FSIS has divided ready-to-eat meat and poultry products into five categories,

based on the type of processing they receive: dried products; salt-cured products; fermented products; cooked or otherwise processed whole and comminuted products; and thermally-processed, commercially sterile products. Many of these products can be either shelf-stable or non-shelf-stable.

EXAMPLES OF RTE PRODUCTS

| | |
|--|--|
| Dried Products | Basturma, Pastirma, Basturmi. Beef Sticks. Carne Seca. Dried Beef. Dry Duck Breast. Meat/Poultry Jerky. |
| Salt-Cured Products | Cappicola. Coppa. Country Ham. Dry Cured Duck. Parma Ham. Prosciutto, Prosciutti. |
| Fermented Products | Alessandri (Dry Sausage). Apenino (Dry Sausage). Arles or D'Arles (Dry Sausage). Blockwurst (Semi-Dry Sausage). Cacciatore/Cacciatore (Dry Sausage). Cervelat. Cervelat, Soft. Chorizo. Lebanon Bologna. Pepperoni. Salami, Soft. Salami: Genoa, Italian, German. Summer Sausage. Thuringer. Thuringer, Soft. |
| Cooked or Otherwise Processed Whole or Comminuted Products | <i>Meat</i> Berliner (Cooked, Smoked Sausage). Bologna. Bratwurst, Cooked. Braunschweiger/Liver Sausage. Breakfast Link Sausage or Patties. Brown and Serve Sausage. Burritos. Cheese Smokies. Cheesefurter. Cheesewurst/Cheddarwurst. Chili. Chorizo. Cooked Beef. Cooked Ham. Cooked Pork in BBQ Sauce. Cotto Salami. Entrees/Dinners. Fleischkaese (Cured, Cooked Sausage). Frankfurters. Frozen Entrees/Dinners. Gyros. Meat Loaf. Meat Salads. Meat Soups, Frozen. Nem-Chua (Cooked, Pickled Ham with Shredded Pork Skin). Pasta with Meat Sauce. Pastrami. Pickled Pigs Feet in Vinegar. Pickled Sausages/Meat in Vinegar. Piroshki. Pork Barbecue. Pork Sausage Patties. Ravioli. Roast Beef. Roast Pork. Souise. |

EXAMPLES OF RTE PRODUCTS—Continued

| | |
|---|---|
| <p>Thermally-Processed, Commercially Sterile Products</p> | <p>Stews. White Hots. Wieners.</p> <p><i>Poultry (Includes Products Containing any Amount of Poultry).</i></p> <p>Chicken Burritos. Chicken BBQ. Chicken Bologna. Chicken Breast. Chicken Franks. Cooked Poultry. Cooked Poultry Rolls. Corn Chowder with Chicken. Entrees/Dinners. Poultry Loaf. Poultry Patties. Poultry Rolls. Poultry Salads. Poultry Soups, Frozen. Turkey BBQ. Turkey Franks. Canned Spaghetti with Meat Balls. Canned Corned Beef Hash. Canned Ham. Canned Chicken Salad. Canned Soups with Meat or Poultry.</p> |
|---|---|

FSIS is proposing to require that the processing of each of these types of products achieve specific levels of pathogen reduction, as well as control over the growth of target pathogens so that they do not exceed specific levels. These levels are the performance standards. Establishments also would be required to maintain these levels of pathogen reduction and pathogen growth in their products, under normal handling conditions, until their products reach the consumer.

FSIS already has established pathogen reduction performance standards specific to certain types of not-shelf-stable, RTE meat and poultry products. On January 6, 1999, FSIS published a final rule in the **Federal Register** (FSIS Docket No. 95-033F; 64 FR 732) that established performance standards for RTE roast beef, corned beef, and cooked beef, all “fully-cooked” RTE poultry products, and partially-cooked meat patty and poultry products. Those standards are consistent with and, in fact, incorporated into the more comprehensive group of standards proposed in this document.

III. Performance Standards and HACCP

Under the regulations in 9 CFR 417, FSIS requires each official meat and poultry establishment to develop and implement a Hazard Analysis and Critical Control Point (HACCP) system, a science-based process control system for food safety that promotes systematic prevention of biological, chemical, and physical hazards. Establishments are responsible for developing and

implementing HACCP plans that incorporate the controls necessary and appropriate to produce safe meat and poultry products. HACCP is a flexible system that enables establishments to tailor their control systems to the needs of their particular plants and processes. Performance standards can be usefully and seamlessly incorporated into HACCP systems.

When developing a HACCP plan, an establishment must conduct a hazard analysis to identify and list the physical, biological, or chemical food safety hazards reasonably likely to occur in the production process for a particular product and the preventive measures necessary to control those hazards. The establishment then must identify the critical control points (CCPs) in each of its processes. A CCP is a point, step, or procedure in a food process at which control can be applied to ensure that the occurrence of a food safety hazard is prevented, eliminated, or reduced to an acceptable level. Next, the establishment must establish critical limits for the preventive measures associated with each identified CCP. A critical limit is the maximum or minimum value to which a hazard must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard. Critical limits are most often based on process parameters such as temperature, time, water activity, pH, or humidity. Significantly, critical limits must be designed to satisfy relevant FSIS regulations, including performance standards.

Therefore, performance standards are an integral part of the HACCP systems in official meat and poultry establishments. HACCP provides the framework for industry to set up science-based process controls. Performance standards tell establishments what those controls need to achieve for their HACCP plans to be effective and provide a necessary measure of accountability for achieving acceptable food safety. Performance standards and HACCP provide meat and poultry establishments with the incentive and flexibility to adopt innovative, science-based processing procedures and controls; ensure safety for consumers; and provide objective, measurable standards, compliance with which can be determined through Agency inspection.

IV. The Proposed Performance Standards

A. Lethality

For each category of RTE product, FSIS is proposing at least one lethality performance standard. The term “lethality” refers to a required reduction in the number of specific pathogenic organisms. Further, FSIS is proposing lethality performance standards that reflect the destruction of “reference” organisms, i.e., microorganisms whose elimination or reduction most often indicates the elimination or necessary reduction of other pathogens of concern.

In this proposed rule, for all RTE products except thermally-processed, commercially sterile products, the lethality performance standards are

expressed as probabilities of remaining numbers of the reference pathogen in 100 grams of finished product after a successful lethality treatment is, or treatments are, applied to hypothetical "worst case" raw product. The lethality performance standards also are expressed as the number of decimal reductions of the reference pathogen required to achieve those probabilities

in hypothetical worst case products. These decimal reductions are expressed as "x-log₁₀", meaning that the expected relative reduction of the reference organism would be a factor of 10^x. FSIS has tentatively concluded that effecting these specific reductions ensure even a worst case product would present no health risk to consumers.

For all RTE meat and poultry products, other than thermally processed, commercially sterile products, FSIS is proposing to require that processing achieve one of the following probabilities that that no more than small numbers of *Salmonella* would remain in any 100 gram sample of a finished product made from worst case product:

| >0 surviving | >1 surviving | >2 surviving | >3 surviving | >4 surviving |
|--------------|--------------|--------------|--------------|--------------|
| 39.4 | 9.06 | 1.45 | 0.177 | 0.0174 |

Although an establishment's processing would be required to achieve these probabilities that there will be few, if any, remaining pathogens in finished product, any detectable levels of viable *Salmonella* in RTE product would render that product adulterated.

Alternatively, official establishments may employ processes validated to achieve specific levels of reduction of *Salmonella* organisms throughout their finished, RTE meat and poultry products: 6.5-log₁₀ throughout finished, RTE meat products and 7-log₁₀ throughout finished, RTE products containing any amount of poultry. The probabilities in Table 1 are derived from statistical models of hypothetical worst case meat and poultry products that have been successfully processed to achieve 6.5-log₁₀ and 7-log₁₀ reductions in *Salmonella*, respectively. A hypothetical, worst case raw meat product would contain 6.2-log₁₀ of *Salmonella* per hundred grams; a hypothetical, worst case raw poultry product would contain 6.7-log₁₀ of *Salmonella* per hundred grams. See the section entitled "Derivation of the Proposed Lethality Performance Standards" for further discussion.

The Agency has selected *Salmonella* as the reference organism for most RTE meat and poultry products because: (1) It is prevalent in raw poultry, beef, and pork; (2) it causes a high incidence of foodborne illness; and (3) foodborne illness associated with *Salmonella* is severe. See the section entitled "Selection of the Reference Organisms" for additional discussion of how FSIS determined the lethality performance standards and the target pathogen for each type of RTE meat and poultry product.

Because destruction of reference organisms may not always result in the elimination or necessary reduction of other pathogens of concern, FSIS also is proposing to clarify in the regulations that establishments must also reduce other pathogens and their toxins or toxic metabolites to the levels necessary to

prevent product adulteration. It is the responsibility of the establishment to ensure that the final product is safe. If FSIS were to find certain viable pathogens in a RTE product at levels considered dangerous, even in product otherwise free of the reference pathogen, it would consider that product to be adulterated.

FSIS is not proposing any specific lethality performance standards in addition to those that target the reference pathogen, *Salmonella*, except for fermented RTE products that contain beef. Within its hazard analysis, each establishment will be responsible for determining which other pathogens might survive processing and then implementing the appropriate control measures. FSIS requests comment on whether it should enumerate, in its regulations, lethality performance standards for other pathogens and toxins that can pose hazards to specific products or within specific processing contexts.

FSIS is proposing an additional lethality performance standard for all fermented RTE products that include any amount of beef, except thermally-processed, commercially sterile products. The Agency is proposing to require that establishments that produce these products implement processes that result in the following probabilities that, at worst, only minute amounts of *E. coli* O157:H7 organisms would remain in any 100 gram sample of a finished product made from worst case product:

TABLE 2.—PROBABILITY (%) OF *E. COLI* O157:H7 SURVIVING IN 100 GRAMS OF FINISHED PRODUCT MADE FROM WORST CASE PRODUCT

| >0 surviving | >1 surviving |
|--------------|--------------|
| 22.2 | 2.67 |

Although an establishment's processing would be required to achieve these probabilities of remaining pathogens in finished product, any detectable levels of viable *E. coli* O157:H7 in RTE product would render that product adulterated.

FSIS also is proposing that, alternatively, establishments may employ processes validated to achieve a 5.0-log₁₀ reduction of *E. coli* O157:H7 throughout fermented products containing beef. The probabilities in Table 2 are derived from statistical models applied to hypothetical worst case beef products that have been processed to achieve a 5-log₁₀ relative reduction in *E. coli* O157:H7. A hypothetical, worst case raw product that contained any amount of beef would contain 4.4-log₁₀ of *E. coli* O157:H7 per hundred grams. See the section entitled "Derivation of the Proposed Lethality Performance Standards" for further discussion.

The Agency is proposing this lethality performance standard in addition to the *Salmonella* standard for fermented products that contain beef for several reasons. In 1994, there was an outbreak of foodborne illness linked to *E. coli* O157:H7 in fermented beef sausages. Also, these products may not be fully cooked before fermentation and fermentation creates an acidic environment in which *E. coli* O157:H7 can survive.

Also, the FSIS Office of Public Health and Science (OPHS) recently sponsored a study entitled "Risk Assessment of the Public Health Impact of *Escherichia coli* O157:H7 in Ground Beef" (Ref. 1, available for viewing by the public in the FSIS Docket Room). The draft risk assessment shows that levels of *E. coli* O157:H7 in cattle represents a risk to consumers of ground beef and that unless there is a significant intervention on the farm or during processing, the risk is likely to remain. This draft risk assessment is discussed further under the sections entitled "Derivation of the

Proposed Lethality Performance Standards” and “Fermented Products.”

Cattle and sheep may carry *E. coli* O157:H7 in the intestinal tract at the time of slaughter. However, among commercially-prepared meat products, only those that contain beef have been implicated in a number of foodborne illnesses associated with this pathogen. Therefore, in regard to meat and poultry products, the Agency is proposing this standard only for fermented products that contain beef.

FSIS is not proposing this performance standard for fermented poultry products that do not contain beef. *E. coli* O157:H7 has been found to colonize the ceca of chickens and has been isolated from retail poultry in the United States (Ref. 2, available for viewing by the public in the FSIS Docket Room). However, FSIS has never found the pathogen in raw or ready-to-cook samples of poultry obtained from processing establishments. FSIS requests comment as to whether it should also apply this standard to RTE fermented poultry products that do not contain beef, as well as to RTE fermented meat products that do not contain beef.

FSIS is proposing performance standards for thermally-processed, commercially sterile meat and poultry products that are similar to these lethality standards but derived somewhat differently. See the section “Thermally-Processed Commercially Sterile Products” for a complete discussion.

Compliance With the Lethality Performance Standards

To meet the proposed lethality performance standards, establishments would need to employ processes validated either to achieve the proposed decimal reductions of pathogens throughout a finished product or that result in one of the stated probabilities that only small numbers of reference organisms would remain viable in a worst case finished product. To develop criteria for evaluating the effectiveness of processes that achieve one of the proposed probabilities, it will be necessary for the processor to define, using associated statistical criteria, the expected characteristics of the treated product after processing, assuming certain product conditions before processing. For example, an establishment would need to specify that the probability of there being more than x surviving organisms in the finished product is no more than p , given that the worst case pre-processed product contained at least y organisms.

By codifying acceptable probabilities of remaining reference organisms in finished product, FSIS would be allowing establishments to employ processes that achieve varying levels of lethality, therefore providing processing flexibility while ensuring product safety. By also proposing specific lethality performance standards in the regulations, FSIS provides clear performance standards to establishments that may not have the resources to derive an alternative lethality or the ability to demonstrate that their process achieves a specific probability that no more than a certain number of reference organisms might exist in the finished product.

As explained above, FSIS has tentatively determined that processes that achieve the proposed lethality performance standards will process hypothetical, worst case raw product into finished, RTE product that poses no health risk to the consumer and is thus safe. In reaching this tentative conclusion, the Agency made conservative assumptions concerning the actual lethality achieved throughout the product. The Agency acknowledges that it might be possible for producers to demonstrate scientifically that these lethality assumptions or the Agency’s defined worst case would not be applicable for their particular processing situation. An establishment could then design a process with lethality values that are different from those provided in this rule, but that would still yield a product that meets the final conditions equivalent to those achieved by the specific levels of pathogen reduction contained in the lethality performance standards.

An establishment developing an alternative lethality treatment or treatments and assuming an initial product condition other than the worst case would need to include in its HACCP plan scientific data and statistical validation that would justify the assumed initial conditions and verify that these would remain constant over time. For example, an establishment may be able to demonstrate that the number of *Salmonella* is not uniformly distributed throughout a particular type of product. The establishment also might demonstrate that because of husbandry and slaughter practices, the worst case product processed within an establishment differs from the worst case scenarios developed for this rule. Demonstrations of initial product conditions solely by statistical means would likely be insufficient to ensure that processes that employ alternative

lethalities will result in product that meets the performance standards.

Generally, an establishment will need to demonstrate in its HACCP plan how its lethality treatment results in a finished product equivalent to that provided by compliance with the probabilities set out in this proposal. The establishment will need to demonstrate the relationships between the lethality treatments and the specific characteristics of a product, such as physical and chemical properties. This demonstration could involve the use of heat transfer equations and should account for all variables that would affect lethality (e.g., size of product, humidity, density, thermal conductivity, specific heat, shape, product composition, and strain of organism).

Finally, establishments employing alternative lethalities will need to demonstrate, within their HACCP plans, that they have validated their processes as being effective in ensuring product safety. Section 417.4(a)(1) of the HACCP regulations sets forth the “initial validation” requirements for establishments under HACCP:

Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCPs, critical limits, monitoring and record keeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

FSIS explains the derivation of the proposed lethality performance standards in the following section. A technical paper (Ref. 3, available for viewing by the public in the FSIS Docket Room and on the Internet.¹) explaining the derivation of the lethality performance standards also is available. Establishments are encouraged to use this paper when developing alternative lethalities. In the paper, FSIS explains the methodology used to calculate the probability of remaining *Salmonella* organisms in treated product.

Notably, with any final action, FSIS will provide compliance guides that give explicit processing instructions and time/temperature combinations proven to achieve the proposed decimal reductions of pathogens. Small and other establishments that do not have the technical resources to demonstrate that they are meeting the proposed

¹ http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/95-033F_tech%20paper.pdf

performance standards may use these compliance guides to develop their HACCP systems. FSIS has published compliance guides for meeting the lethality and stabilization performance standards already set forth in its January 6, 1999, final rule, has posted these documents to the FSIS web page (<http://www.fsis.usda.gov>), and has made the documents available free of charge via the Constituent Update (see section XIV Additional Public Notification) and the FSIS docket room. FSIS expects to make additional draft guidance documents available after publication of this proposed rule and as information becomes available in order to provide establishments with guidance for safely manufacturing RTE meat and poultry products. These draft guidance materials will be clearly identified as guidance materials and not as regulatory requirements. These guides would be applicable to the processing of many of the RTE meat and poultry products governed by these proposed regulations. FSIS plans to update these guides soon in accordance with ongoing Agricultural Research Service studies. Where possible, FSIS will base its compliance guides on existing industry practices and requests comment and information regarding processing that has been shown to meet the proposed performance standards.

Derivation of the Proposed Lethality Performance Standards

Salmonella

To derive the proposed lethality performance standards for *Salmonella*, FSIS first determined the levels of *Salmonella* in a hypothetical worst case raw product of a fixed weight. The hypothetical "worst cases" for *Salmonella* and *E. coli* O157:H7 were derived using data from FSIS's Nationwide Microbiological Baseline Data Collection Program surveys (Ref. 4, available for viewing by the public in the FSIS Docket Room). The baseline surveys conducted by FSIS were designed to provide estimates of the national prevalence and levels of selected bacteria of public health concern. *Salmonella* was one of the pathogens specifically addressed in all of the baseline surveys for the various classes of products. The baseline surveys were conducted over a specified period of time ranging from a half year to a full year. The baseline surveys were used to establish the pathogen reduction performance standards for *Salmonella* that were included as a component of the Pathogen Reduction-HACCP final rule of July 25, 1996 (61 FR 38806). The performance standards for *Salmonella*

that were established as part of the Pathogen Reduction-HACCP final rule differ from the proposed lethality performance standards for *Salmonella* included as part of this proposed rulemaking.

The *Salmonella* performance standards for the Pathogen Reduction-HACCP final rule are designed as follows: they are applicable to establishments that produce raw products; FSIS collects and tests samples from raw product; the results of the raw product samples are reported to the establishment by FSIS after a specified number of samples are collected over time; and a positive result for *Salmonella* in raw product generally does not result in an adulteration determination. In contrast to this design, the *Salmonella* lethality performance standards of this proposed rule are designed as follows: they are applicable to establishments that produce ready-to-eat products (not raw product); the establishment may sample and test samples of RTE product as part of its verification activity associated with the production of RTE product and any testing by FSIS is conducted as part of the Agency's verification activity; and a positive result for *Salmonella* in RTE product does result in an adulteration determination. The premise and use of the lethality performance standards for *Salmonella* in this proposed rule are unchanged from those previously contained in the recent final rule for RTE products (64 FR 732, January 6, 1999). Consequently, the baseline surveys were used in the design of two separate performance standards: one performance standard identifies the prevalence of *Salmonella* in raw product over a specified period of time; the other performance standard (addressed as part of this proposed rule) identifies the expected reduction in the level of *Salmonella* in RTE product in a specified lot of product. Since these two performance standards apply to different types of establishments (i.e., the former applies to establishments producing raw product; the latter applies to establishments producing RTE product), they are not duplicative standards nor do they directly relate to each other. The only commonality between these two performance standards for *Salmonella* is that they are both derived from the same baseline surveys. The level of *E. coli* O157:H7 in raw products also was assessed in the same baseline studies as were used to determine the level of *Salmonella* in raw products.

Using the national baseline survey information to establish the levels of selected bacteria of public health

concern (e.g., *Salmonella*), the Agency then determined levels of lethality that would limit the probability of any remaining *Salmonella* or *E. coli* O157:H7 in finished product produced from worst case raw product. FSIS made conservative but reasonable assumptions concerning measurement error and distributions of organisms throughout the product. These assumptions are fully discussed in the technical paper (Ref. 3, available in the FSIS Docket Room and at the FSIS web page <http://www.fsis.usda.gov>). However, the assumptions are generally based on the following which are further discussed below: the number of organisms recovered from frozen samples; the sensitivity of the detection methodology; the confidence level of measurement variability; and the serving size. Thus, worst case levels in product are not expected to actually occur, provided products are handled appropriately before lethality treatments. The derived worst case levels are hypothetical constructs meant to represent upper limits of possibilities for raw product produced under appropriate, normal manufacturing conditions. These conditions include maintaining the raw product at or below temperatures known to prevent growth of *Salmonella* and most other pathogenic organisms (e.g., at or below 40 degrees Fahrenheit). In addition, they include processing the raw product into RTE product quickly before the raw product's surface temperature becomes elevated for sufficient amounts of time to allow *Salmonella* and most other pathogenic organisms to multiply exponentially. FSIS believes that under these conditions, processes that satisfy the performance standards established as a result of this rulemaking will be safe.

The Agency used the most probable number (MPN) method for measuring levels of *Salmonella* in the FSIS surveys of meat and poultry products. The MPN measurements were made on frozen samples. The calculations used to determine the number of organisms for the worst case product take into account non-recovery of organisms in frozen samples.

For *Salmonella*, the Agency assumed a 30 percent recovery of organisms from frozen samples (Ref. 3, available for viewing by the public in the FSIS Docket Room). The expected recovery is a function of how quick and long the sample was frozen. Based on FSIS experience with samples, the approximate detection limit for recovery of *Salmonella* is 0.5 cells per gram in 25-gram frozen samples. This means that there is a high probability that a 25-

gram sample with 13 organisms would be found positive. For the purposes of this regulation, the Agency assigned a 99% probability that a 25-gram sample with 13 *Salmonella* cells would test positive. Even if one organism were recovered, the sample result would be positive, so that the probability of a positive sample result can be expressed as $1\tau^{13}$, where τ is the theoretical probability of a single injured or uninjured *Salmonella* organism not being recovered. With this assumption, for frozen samples, τ is approximately 70%, that is, there is a 70% probability that a single organism would not be recovered. Thus, there is a 30% recovery of *Salmonella* cells.

To account for measurement variability, the Agency calculated the 97.5 percent upper confidence limit associated with the measured MPN value (Ref. 3, available for viewing by the public in the FSIS Docket Room). FSIS did not use the average level of *Salmonella* reported for the various classes of product. Rather, in order to determine the highest estimate for the level of *Salmonella* in raw products, FSIS took the raw data, not the calculated average, and computed a number at the 97.5 percent upper confidence level. Using this upper limit, the Agency then computed the upper limit for 143 grams of raw product. The Agency used 143 grams of raw product as the basis for its calculations because after cooking, assuming a 70 percent yield, 143 grams would result in approximately 100 grams (3.5 ounces) of cooked product.

The Agency used the high MPN value for ground chicken (the highest MPN value measured for poultry products) from the FSIS national baseline surveys² to determine the proposed

lethality for *Salmonella* for all RTE products containing poultry, other than thermally processed, commercially sterile products. For ground chicken, the upper 97.5 percent confidence limit for the highest measured MPN value of 2300 MPN per gram for *Salmonella*, assuming a 30 percent recovery, is approximately 37,500 cells/gram, which, when multiplied by 143 grams totals approximately 6.7-log_{10} cells. Therefore, the level of *Salmonella* organisms in a hypothetical worst case raw product would be greater than 6.5-log_{10} but just less than 7.0-log_{10} . Consequently, to provide a margin of safety and to use either a whole or half integer lethality, FSIS is proposing to require a reduction in viable *Salmonella* of 7.0-log_{10} , which is 0.3-log_{10} above the worst case level, throughout RTE products that contain poultry, other than thermally processed, commercially sterile products. The consequence of this choice is that, for a hypothetical "worst case" product, the probability of surviving *Salmonella* organisms is 39.4%, assuming that the distribution of the number of survivors is binomial with number parameter equal to the number of organisms in the worst case and the probability parameter equal to $1/10^x$ where x is the required decrease in viability.

Alternatively, an establishment may use a processing procedure validated to achieve the probabilities in Table 1 above that no more than specific amounts of *Salmonella* would remain in any 100 gram sample of a finished, hypothetical worst case product. As stated above, these probabilities would result in hypothetical worst case poultry products that had been successfully processed to achieve a 7-log_{10} reduction in *Salmonella*.

To determine the proposed lethality for RTE meat products that do not contain poultry, other than thermally processed, commercially sterile products, the Agency used the high MPN value for whole beef (the highest MPN value measured for all meat products): 240 MPN/cm². To translate this value to a level per gram, FSIS assumed that, for a worst case level, a cut of meat is 0.8 cm and that the specific density of beef is approximately 1.1 grams/cm³ (slightly lower than average) (Ref. 3, available for viewing by the public in the FSIS Docket Room). These factors are for practical purposes equal to 1, so that the MPN/cm² values

requirements would be the same and the high value of the combined data set would be used for both species A and B. For the products and pathogen considered in this proposed regulation, the criteria for combining data depend upon the prevalences and the high values.

are assumed to estimate the level per gram of product. Thus, for the worst case derivation, the starting value is 240 MPN/g.

The 97.5 percent upper confidence limit, assuming a 30 percent recovery, is 4100 cells/g. Because samples for the whole product surveys consisted of pooled tissue from 3 different carcass sections, and the prevalence was low (less than 3 percent), the Agency assumed that the high value used for determining the worst case product is 3 times that of the measured MPN value. Thus, the 97.5 percent upper confidence limit is multiplied by 3 and then multiplied by 143 grams. The resulting number of organisms for the worst case product is approximately 6.2-log_{10} . Therefore, to provide the same margin of safety as provided for with poultry products, the proposed required lethality is obtained by adding 0.3 log_{10} to the worst case level of 6.2 log_{10} . Thus, FSIS is proposing to require either a relative reduction in viable *Salmonella* of 6.5-log_{10} throughout finished, RTE meat products, or alternatively, one of the probabilities listed above in Table 1. FSIS has not specified the probability of worst case product actually occurring since the worst case was a hypothetical construct based, in part, on a high confidence level of the maximum observed level of microorganisms in a statistically designed national baseline. In addition, FSIS made additional assumptions that FSIS believes to be conservative. All the assumptions regarding the derivation of the worst case are contained in the technical paper (Ref. 3, available in the FSIS Docket Room and at the FSIS web page, <http://www.fsis.usda.gov>). FSIS requests comments regarding these assumptions.

E. coli O157:H7

After a 1994 outbreak of illnesses caused by *E. coli* O157:H7, FSIS recommended that producers of fermented RTE products that contain any amount of beef validate their processes to achieve a 5.0 log_{10} lethality of *E. coli* O157:H7 (see additional discussion under *Fermented Products*). This recommended lethality was based on a report submitted to FSIS (The Task Force on Technical Issues Arising from the National Advisory Committee for Microbiological Criteria for Foods (NACMCF)). The 5-log_{10} relative reduction was derived by adding 1 log_{10} as a safety margin to an assumed worst case of 4.0 log_{10} that was recommended by the NACMCF. If this lethality were applied in a product containing 10^4 cells per gram, then it would be expected that a single cell would remain. However, the conclusion that a

² While the numbers of samples in the FSIS national surveys are rather large, the largest MPN value, as an estimate of large densities of pathogenic organisms, from a statistical perspective, may have substantial statistical variation. Thus, to reduce differences in required lethality reductions caused by statistical variation, data sets of different species were combined if warranted by consideration of the prevalences and possibly the geometric means of the levels of the organisms for these species. The high value of combined data sets was used for determining the hypothetical worst case for these species. The criteria used for combining data sets of different species are easier stated as the converse of criteria for when data sets would not be combined and thus the lethality requirements for these species would be different. The criteria for determining when lethality requirements for two species, A and B, are different are: For a given type of product, the lethality requirement for species A is larger than that of species B if (1) the high MPN value for species A is larger than that of species B, and (2) the prevalence for species A is larger than that of species B, or the prevalences are approximately equal and the geometric mean for species A is larger than that of species B. Otherwise, the lethality

single *E. coli* O157:H7 cell per 10 grams (or a possible 10 cells per 100 grams) remaining in the product adequately prevents foodborne disease is in question. Some researchers now believe that low numbers of *E. coli* O157:H7 cells ingested are sufficient to cause foodborne disease (Ref. 5, available for viewing by the public in the FSIS Docket Room).

Presented in chapter 5 of the OPHS risk assessment are results of a derivation of the possible number of *E. coli* O157:H7 cells in combo bins of 2000 pounds or approximately $10^{5.96}$ grams (Ref. 1, available for viewing by the public in the FSIS Docket Room). The highest number associated with a non-zero probability is 10^7 cells for which an upper bound probability of occurrence is 0.002% (1/50,000). As discussed above in the derivation of the proposed lethality requirements, the Agency considers the number of cells in 143 grams of raw product, accounting for a possible 70% yield when the product is processed. A bin with 10^7 cells implies that the expected number of cells in 143 grams of raw product would be about $3.2 \log_{10}$ cells per 100 grams. The assumptions used in deriving this number assume that the *E. coli* O157:H7 cells present are uniformly distributed throughout the bin, so that the $3.2 \log_{10}$ represent an average or expected number of cells per 143 grams of product. It is clearly possible that there would be in some 143-gram portion more than $3.2 \log_{10}$ *E. coli* O157:H7 cells. Thus, a worst case level should be larger than $3.2 \log_{10}$ *E. coli* O157:H7 cells.

To derive worst case levels for *E. coli* O157:H7 for the purpose of determining a performance standard, the Agency applied the algorithm, described above for *Salmonella*, using information presented in OPHS risk assessment. This risk assessment presented results of MPN analyses from the Agency's microbiological baseline surveys of bovine carcasses (Ref. 1, available for viewing by the public in the FSIS Docket Room). In total, out of about 4,000 samples, 4 samples were found positive. For each positive a matching sample was analyzed using the MPN procedure. Of the 4 analyzes, 2 were found positive. The highest reported MPN value was 0.93 cells/cm², which, as described above, is assumed to represent level per gram value, or 0.93 MPN/gram. A 97.5 percent upper confidence limit for this value is 3.7 cells/cm². FSIS did not use the average level of *E. coli* O157:H7 reported for the various classes of product. Rather, in order to determine the highest estimate for the level of *E. coli* O157:H7 in raw

products, FSIS took the raw data, not the calculated average, and computed a number at the 97.5 percent upper confidence level.

The samples used for determining *E. coli* O157:H7 levels in the FSIS surveys were frozen. In the OPHS risk assessment, information concerning the recovery rate is given. It is stated in the report that nine 25-gram samples of ground beef were inoculated with 0.7 *E. coli* O157:H7 organisms per gram, and that eight of these samples subsequently were detected as positive. In determining the possible recovery for *E. coli* O157:H7 cells in a sample that is subsequently frozen, FSIS assumes that the actual number of cells in a specified 25-gram sample is a random variable, n , following a Poisson distribution, $f(n, \lambda) = e^{-\lambda} \lambda^n / n!$, with expected value $\lambda = 17.5$. If τ is the probability of not recovering a given single cell, then the probability of detecting the presence of *E. coli* O157:H7 in a 25 gram sample, is, $\pi = \sum (1 - \tau^n) f(n, \lambda) = 1 - e^{-\lambda(1 - \tau)}$. Thus, the probability of recovering a given cell is $1 - \tau = -\ln(1 - \pi) / \lambda$. From nine samples, eight were detected positive, so that a 97.5% lower confidence bound for π is 0.6635. Using this value for π , the derived value for $1 - \tau$ is 0.062, representing the recovery. For the worst case level, the 97.5 percent upper bound, 3.7 cells/cm², is divided by 0.062 to derive 59.45 cells/cm².

As described above for deriving the worst case levels for *Salmonella* in beef, the measured levels are multiplied by 3, to account for the fact that samples from the bovine FSIS baseline surveys consisted of a composite from 3 sections of the carcass, and for a worst case derivation, FSIS assumes that all the cells existed in one of the three sections. Thus, for the worst case level, the 59.45 cells/cm² is multiplied by 3, and then multiplied by 143 grams to derive an approximate 4.4 \log_{10} cells for the worst case level.

The above derivation indicates that the "worst case" level of 4.4 \log_{10} cells per 143 grams is greater than the highest expected level of 3.2 \log_{10} cells per 143 grams derived in the OPHS risk assessment. Consequently FSIS will use the 4.4 \log_{10} as the "worst case" level.

To provide the same margin of safety as provided for with *Salmonella* in poultry and red meat products, the lethality is obtained by adding 0.3 \log_{10} to the worst case level of 4.4 \log_{10} . However, foodborne illness associated with *E. coli* O157:H7 might be more severe than that associated with *Salmonella*, as testified to by the severity of many reported cases in children and senior citizens. Also, as stated above, some researchers believe

that low numbers of ingested *E. coli* O157:H7 cells are sufficient to cause foodborne illness. Furthermore, there is only a small amount of data from the Agency's microbiological baseline survey: four samples, of which only two were positive. This number of samples does not provide a high degree of confidence in the magnitude of the higher levels that might exist. Consequently, FSIS is requiring that processors of fermented products containing beef achieve a higher probability of no surviving cells of *E. coli* O157:H7 in treated worst case products than that required for *Salmonella*. Specifically, FSIS is proposing a 5- \log_{10} lethality, which can be obtained by adding 0.6 \log_{10} to the "worst case" level (instead of 0.3 \log_{10} added for *Salmonella*). The probability of no surviving *E. coli* O157:H7 cells given a "worst case" level of cells is about 78% (instead of 61% for *Salmonella*).

FSIS also examined measured levels of *E. coli* O157:H7 found in suspect lots of hamburger identified in foodborne disease outbreaks (Refs. 6 and 7, available for viewing by the public in the FSIS Docket Room). Direct count determinations were as follows: 50, 100, 5100, and 6200 colony forming units (CFU) per gram. Because of the possibility that the high *E. coli* O157:H7 levels represent product that has been abused and thus are not representative of product produced in an establishment and used in RTE product, FSIS could not, with complete justification, use these values for determining a required lethality. However, these results do suggest that a lethality of at least 5- \log_{10} is needed to help ensure an *E. coli* O157:H7 free RTE product.

The derivation for the proposed lethality of *E. coli* O157:H7, in using only a slightly higher probability of no surviving cells compared to that used for deriving the proposed lethality for *Salmonella*, assumes only a slightly greater public health concern for *E. coli* O157:H7. However, foodborne illness associated with *E. coli* O157:H7 might be significantly more likely than that associated with *Salmonella*. As mentioned above, some researchers now believe that low numbers of *E. coli* O157:H7 cells ingested are sufficient to cause foodborne disease. This belief also is reflected in the recent OPHS draft risk assessment regarding *E. coli* O157:H7 in ground beef (Ref. 1, available for viewing by the public in the FSIS Docket Room). The dose response model used in this report allows the possibility of a 1% probability of illness when a random selected consumer ingests a

single cell; and when, ingesting 10 cells, the probability of illness could be as high as 10%.

Consequently, FSIS may need to require that processors of fermented products containing beef achieve a higher probability of no surviving cells of *E. coli* O157:H7 in treated worst case products. For example, if the proposed lethality were 5.5 log₁₀, the probability of no surviving *E. coli* O157:H7 cells in the hypothetical worst case would be 92.4% instead of 77.8%; if the proposed lethality were 6.0, then the probability of no surviving *E. coli* O157:H7 cells would be 97.5%.

Since the number of sample results from which the worst case was derived is small, there is not a high degree of confidence in the magnitude of the higher levels of *E. coli* O157:H7 that might exist. Further information may require FSIS to adjust the worst case level and thus the required lethality, accordingly. It is important to note, however, that a fermentation process offers an extra degree of safety compared to a heat process, given the same lethality. Unlike ordinary cooked RTE products, the physio-chemical environment within fermented products is hostile to the survival of pathogens. Thus, within an ordinary cooked RTE product, sublethally injured bacteria may be able to resuscitate and then multiply when the temperature rises. Within fermented sausages, most of which are shelf-stable, resuscitation is not possible. FSIS specifically requests comment on the proposed performance standard for the pathogen *E. coli* O157:H7 in fermented products containing beef.

FSIS has not specified the probability of worst case product actually occurring since the worst case was a hypothetical construct based, in part, on a high confidence level of the maximum observed level of microorganisms in a statistically designed national baseline. In addition, FSIS made additional assumptions that FSIS believes to be conservative. All the assumptions regarding the derivation of the worst case are contained in the technical paper (Ref. 3, available in the FSIS Docket Room and at the FSIS web page, <http://www.fsis.usda.gov>). FSIS requests comments regarding these assumptions.

Selection of the Reference Organisms

An explanation of how the Agency established the proposed reference organisms for each category of RTE product, other than thermally processed, commercially sterile products, follows.

Dried Products

The pathogens associated with dried (but not fermented) RTE meat and poultry products are *Salmonella*, *Listeria monocytogenes*, *Staphylococcus aureus*, *E. coli* O157:H7 and *Trichinella spiralis*. *T. spiralis* is only associated with pork and game products. There are a limited number of studies on the reduction of pathogens during the processing of dried meat and poultry products.

J. A. Harrison and M. A. Harrison surface-inoculated one-third of a beef jerky strip (15 × 1.5 × 1.5 cm.) with 0.1 ml of a 10⁸ CFU/ml cell suspension each of *L. monocytogenes*, *Salmonella typhimurium*, and *E. coli* O157:H7 (Ref. 8, available for viewing by the public in the FSIS Docket Room). Results show that higher log reductions of the three pathogens were obtained when beef jerky was preheated to 160 °F and when curing agents were added. In general, *L. monocytogenes* was more resistant to the treatments. However, after 10 hours of drying at 140 °F, the populations decreased to undetectable levels, resulting in a 5.5 to 6.0 log reduction of the three pathogens. After storage at 25 °C for 8 weeks, none of the pathogens were detected. Subsequent challenge studies on inoculated ground beef jerky, with or without curing agents, heated or unheated, showed that *Salmonella spp.* was in general more resistant than *L. monocytogenes* to the integrated process. However, after 6 hours of drying at 140 °F, *L. monocytogenes* and *Salmonella* had about the same population reduction in preheated samples (Refs. 9 and 10, available for viewing by the public in the FSIS Docket Room).

These studies show that the time and temperature of drying and other variables, such as the use of beef strips or formed ground beef jerky, the addition of curing agents, and preheating before drying, will affect the reduction of pathogens. Lethality of pathogens in dried products is achieved by dehydration to a water activity (a_w) level that inhibits their growth. Preheating or precooking and the addition of curing agents facilitate and add to the lethality factor.

In 1995, a salmonellosis outbreak was associated with commercially produced beef jerky linked to three *Salmonella* serotypes (Ref. 11, available for viewing by the public in the FSIS Docket Room). The CDC Morbidity and Mortality Weekly Report (MMWR) report stated that the New Mexico Department of Health investigated five outbreaks of salmonellosis associated with locally produced beef jerky from 1966 to 1988

and one outbreak of staphylococcal food poisoning associated with beef jerky in 1982. Also according to the MMWR, four other states reported foodborne disease outbreaks associated with the consumption of locally produced or homemade jerky from beef, bear, or cougar meat. The outbreaks were caused by *T. spiralis* and by nitrite poisoning.

The MMWR set out the recommendations of CDC for the prevention of bacterial growth in jerky production. CDC recommended rapid drying at high temperatures (i.e., initial drying temperature >155 °F (68.3 °C) for 4 hours, then >140 °F (60 °C) for an additional 4 hours), and decreased water activity (i.e., a_w = 0.86).

E. coli O157:H7 was implicated in one case in homemade venison jerky (Ref. 12, available for viewing by the public in the FSIS Docket Room). *L. monocytogenes* has not been reported to be associated with any foodborne illness attributable to the consumption of commercial jerky products. So, based on the epidemiological data and research studies on jerky, it does not appear that *E. coli* O157:H7 or *Listeria* represent serious hazards in commercially produced jerky. Consequently, FSIS chose *Salmonella* as the proposed reference organism for dried products.

If a process used to produce dried products achieves the proposed reduction in the number of *Salmonella* organisms, the number of *T. spiralis*, *E. coli* O157:H7, and *S. aureus* should also be reduced to safe levels because these organisms are generally less heat resistant than *Salmonella*. *L. monocytogenes* is a problem more often because of inadequate sanitation than inadequate processing. Under HACCP and Sanitation SOP requirements, establishments must ensure that their processing controls hazards in addition to *Salmonella*, such as *L. monocytogenes*, if they are reasonably likely to occur.

Salt-Cured Products

The microbiological stability (the lethality during processing) of salt-cured meats, such as salt-cured hams, is dependent on their low water activity, the presence of nitrite, and smoke applied between the salting and drying processes (Ref. 13, available for viewing by the public in the FSIS Docket Room). Lethality of pathogens in the salt-cured products is attained by low temperature salting and drying. Both of these processes reduce the water activity to levels that inhibit the growth of pathogens. The addition of nitrates or nitrites and smoke enhance the inhibitive effect of the process.

There were two salmonellosis outbreaks linked to salt-cured hams: Serrano variety cured ham in Spain and prosciutto ham in Italy (Refs. 14 and 15, available for viewing by the public in the FSIS Docket Room). Low levels of salt and relatively high water levels in some parts of the Serrano variety cured ham were judged to be the most probable cause of *Salmonella* growth and consequent illness. Aside from *Salmonella*, other pathogens of concern in salt-cured products are *S. aureus*, *L. monocytogenes*, and *T. spiralis*. The Agency is proposing to select *Salmonella* as the reference organism because outbreaks in salt-cured products have been associated with *Salmonella*. As with dried products, if the process used to produce salt-cured products achieves the proposed $6.5 - \log_{10}$ or $7.0 - \log_{10}$ reduction in *Salmonella* organisms, the number of these other pathogens should also be reduced to safe levels. In addition, establishments would have to ensure that processing also controls hazards other than *Salmonella*, including other pathogens, that are reasonably likely to occur.

Fermented Products

In late 1994, 23 cases of illness caused by the pathogen *E. coli* O157:H7 were reported in Washington State and northern California (Ref. 16, available for viewing by the public in the FSIS Docket Room). Epidemiological investigations by State and local health agencies associated the outbreak with the consumption of dry cured salami products. In October 1995, the Pennsylvania State Department of Health linked 26 cases of salmonellosis to the consumption of contaminated Lebanon bologna (Ref. 17, available for viewing by the public in the FSIS Docket Room).

After the 1994 outbreak of illnesses caused by *E. coli* O157:H7, FSIS met regularly with scientists from the Agricultural Research Service, representatives of the meat and poultry industry and members of the NACMCF to develop a policy for ensuring the safety of shelf-stable, RTE fermented sausages. This group developed several processing options that would ensure a $5 - \log_{10}$ relative reduction of *E. coli* O157:H7 in fermented sausages. In addition, FSIS approved a processing option developed by the Blue Ribbon Task Force on *E. coli* O157:H7 of the National Cattleman's Beef Association.

As explained previously, the $5 - \log_{10}$ reduction of *E. coli* O157:H7 in dry and semidry fermented sausages was originally based on the notion of adding a $1 - \log_{10}$ safety margin over an assumed

worst case of 10^4 CFU/gram in raw product. FSIS offered 4 options to either achieve the recommended $5 - \log_{10}$ relative reduction of *E. coli* O157:H7 or control for its presence in finished product: (1) Apply the cooking treatment in either 9 CFR 318.17 or 318.23, (2) apply a validated integrated heat treatment of equal lethality, (3) test product using ICMSF lot acceptance criteria, or (4) apply a validated $5 - \log_{10}$ relative reduction or process that results in less than 1 *E. coli* O157:H7 per 100 gram of finished product. The Blue Ribbon Task Force of the National Cattleman's Beef Association specifically addressed Option 2—a validated $5 - \log_{10}$ inactivation treatment. The Task Force focused on the processing parameters of heat and acid sensitivity of the organism. The processes and the resultant level of reduction of *E. coli* O157:H7 were summarized in a table and flow chart. In addition, the report recommended a fifth option, combination of sampling of raw ingredients and a $2 - \log_{10}$ lethality treatment, and described the remaining 3 options.

On August 21, 1995, FSIS wrote to establishments producing fermented sausages and strongly encouraged that they implement one of the validated processing options contained in the document to ensure the processing used achieves at least a $5 - \log_{10}$ relative reduction of *E. coli* O157:H7. While most establishments have implemented one of the processing options, not all have.

As discussed previously, in support of rulemaking, OPHS has sponsored a risk assessment of *E. coli* O157:H7 in ground beef (Ref. 1, available for viewing by the public in the FSIS Docket Room). The draft risk assessment presents data on the prevalence of *E. coli* O157:H7 among breeding herds and feedlots of cattle, and *E. coli* O157:H7 levels on carcass samples. This information shows that levels of *E. coli* O157:H7 in cattle represents a risk to consumers of ground beef, and that, unless there is a significant intervention on the farm or during processing, the risk is likely to remain.

In addition, because of the incidence of foodborne illness linked to *E. coli* O157:H7 in fermented sausages and because these products ordinarily are not fully cooked before being fermented (which creates a situation that may allow the survival of *E. coli* O157:H7), the Agency is proposing to include *E. coli* O157:H7, in addition to *Salmonella*, as a reference organism for fermented RTE meat and poultry products that contain beef.

Under this proposal, processing of fermented products that contain beef would be required to meet lethality performance standards for both *Salmonella* in § 430.2(a) and for *E. coli* O157:H7 in § 430.2(b). As discussed under the "Lethality" heading above, for fermented RTE meat and poultry products that contain beef, the Agency is proposing that processing achieve either specific probabilities of remaining organisms in 100 grams of finished product, or a $5.0 - \log_{10}$ relative reduction of *E. coli* O157:H7 throughout the product, which would achieve those probabilities in a hypothetical, worst case raw product. FSIS is not proposing this performance standard for fermented meat and poultry products that do not contain beef.

The Agency tests fermented sausage products for *Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, and staphylococcal enterotoxin. Isolation or detection of any of these pathogens and enterotoxin results in product recall and destruction of product. With the exception of *L. monocytogenes*, these pathogens and staphylococcal enterotoxin have been linked to foodborne illness associated with fermented sausage products. With regard to *S. aureus*, the production of a heat stable enterotoxin (staphylococcal enterotoxin) after it has achieved a density of at least 10^5 CFU/g rather than the bacterium itself is responsible for foodborne illness. Growth of *S. aureus* is inhibited by the competitive growth of lactic acid bacteria, such as lactobacilli and pediococci, which are often used in fermented sausage products (Refs. 18 and 19, available for viewing by the public in the FSIS Docket Room).

A suboptimally active fermentation culture or an initial large number of *S. aureus*, as has occurred when contaminated starter culture is used, may result in the growth of *S. aureus* and the production of enterotoxin. However, since 1980, the industry has implemented fermentation controls, and no repeat of the previous type outbreaks has occurred. Therefore, FSIS is not proposing *S. aureus* as a reference organism for these products.

L. monocytogenes is the most frequently isolated pathogen of those included in the FSIS monitoring program for fermented sausages. Despite its prevalence in fermented sausage products, no foodborne illnesses have been linked to *L. monocytogenes* in fermented sausages. Thus, the Agency is not proposing that *L. monocytogenes* be a reference organism for fermented sausages; however, if the Agency were to find *L. monocytogenes* in the finished

product, the product would be adulterated and subject to recall.

In a Lebanon bologna process, a 3- to 4-log₁₀ reduction of *Salmonella dublin* and a reduction of *Salmonella typhimurium* to undetectable levels was observed by the end of fermentation if starter culture was used (Ref. 20, available for viewing by the public in the FSIS Docket Room). Similarly, Bacus noted that contamination of fermented meat products with *Salmonella* most likely results from an inadequate lactic acid production or a highly contaminated raw product (Ref. 21, available for viewing by the public in the FSIS Docket Room).

Various studies have shown that fermentation and drying resulted in about a 2-log₁₀ reduction of *E. coli* O157:H7 (Refs. 22 through 24, available for viewing by the public in the FSIS Docket Room). In one study, Glass, et al., reported that *E. coli* O157:H7 decreased by about 2-log₁₀ CFU/g after fermentation, drying, and storage at 4 °C for 6 weeks following the end of an 18–21 day drying cycle for a fermented sausage formulation. In another, however, Faith et al., observed a 5- to 6-log₁₀ reduction of *E. coli* O157:H7 in pepperoni sticks following fermentation, drying, and 2 weeks of storage at an ambient (unrefrigerated) temperature of 21 °C.

In one of the few studies that compared the combined effect of fermentation and drying on both *Salmonella* and *E. coli* O157:H7, Ellajosyula, et al., observed that the reduction of *Salmonella* and *E. coli* O157:H7 in Lebanon bologna was less than 2- log₁₀ after fermentation to pH 4.7 (Ref. 22, available for viewing by the public in the FSIS Docket Room). In this study, *Salmonella* was equally or significantly (P<0.01) less resistant than *E. coli* O157:H7 to various combinations of pH levels achieved after fermentation and subsequent heating at 110 °F to 120 °F. Fermentation to pH 5.2 or 4.7 followed by heating at 110 °F to 120 °F for specified times (e.g., 110 °F for 20 hours or 120 °F for 3 hours) resulted in a greater than 7- log₁₀ reduction of both *Salmonella* and *E. coli* O157:H7. This study shows that a final heating step may be necessary to achieve the proposed reduction of both *Salmonella* and *E. coli* O157:H7 in fermented sausage products.

Salmonella and *E. coli* O157:H7 have been the cause of foodborne illnesses linked to fermented sausage products. Although, as noted above, *Salmonella* may be less resistant than *E. coli* O157:H7 to the processes for the different fermented meat products, it has not been demonstrated that

processes resulting in a 5.0-log₁₀ reduction of *E. coli* O157:H7 will result in a 6.5- log₁₀ or 7.0- log₁₀ reduction of *Salmonella* in meat and poultry products, respectively. Conversely, processes resulting in a 6.5- or 7.0- log₁₀ reduction of *Salmonella* have not been shown to produce a 5.0-log₁₀ reduction of *E. coli* O157:H7. Therefore, a process for fermented RTE products that contain beef must be validated for both pathogens.

Cooked and Otherwise Processed Whole or Comminuted Meat Products

As stated above, FSIS already has made final lethality performance standards for certain RTE meat products, including RTE cooked beef, corned beef, and roast beef. In this document, FSIS is proposing to extend these performance standards to all other cooked and otherwise processed (e.g., cured) meat products. Under this proposal, establishments would be required to employ processing validated to achieve specific probabilities (Table 1) that only small numbers of *Salmonella* organisms could remain in finished cooked or otherwise processed, whole and comminuted, RTE meat products. Alternatively, an establishment could use a process validated to achieve a 6.5-log₁₀ reduction of *Salmonella* throughout a finished RTE meat product.

As with cooked beef, corned beef, and roast beef, the primary pathogenic microorganism of concern in these other RTE meat products has been *Salmonella*. FSIS tentatively finds that the destruction of *Salmonella* in these products will result in the destruction of most other pathogens. FSIS is not proposing to require that any particular means be used to meet the lethality standard. Cooking, for example, would not need to be the sole means by which lethality would be achieved. Other applicable treatments, such as curing or other controls, could be used in combination with cooking to achieve the required lethality.

Meat Patties

In the proposal preceding the January 1999 final rule that established performance standards for certain RTE meat and poultry products, FSIS identified *Salmonella* as the target pathogenic microorganism in fully-cooked, uncured meat patties and proposed a 5-log₁₀ reduction in *Salmonella* as the lethality performance standard. FSIS made a tentative finding that a 5-log₁₀ reduction in *Salmonella* in cooked, uncured meat patties would effectively eliminate most other bacterial pathogens of concern. Notably,

compliance with the time/temperature requirements already contained in the regulations effectively achieved a 5-log₁₀ reduction in *Salmonella*.

However, FSIS did not make final the lethality performance standards proposed for RTE comminuted meat patty products. In the course of developing the final regulation, FSIS determined that a higher lethality was likely necessary to produce RTE, uncured meat patties that would pose no health risk to consumers. The Agency could find no conclusive information demonstrating that the distributions of bacteria on ground and whole product produced under normal manufacturing conditions would present comparatively higher or lower risks to consumers. Furthermore, most, if not all, RTE meat and poultry products will be manufactured from the same supply of raw product examined in the FSIS national baseline surveys. So, using performance standards that would render any hypothetical, worst case raw product safe should be applicable to all categories of RTE meat and poultry products.

Consequently, FSIS is proposing to require that establishments achieve a 6.5-log₁₀ reduction of *Salmonella* in all RTE meat products, including RTE meat patties. FSIS believes that many establishments are achieving this higher lethality already, either through a cooking step or a combination of treatments. Furthermore, new and innovative processing technologies, including irradiation of raw product, should allow establishments to achieve this lethality without significantly altering the quality of their products through overcooking.

Cooked and Otherwise Processed Whole or Comminuted Poultry Products

Again, FSIS recently made final lethality performance standards for all fully cooked, RTE poultry products, such as poultry rolls. In this document, FSIS is proposing to extend these performance standards to all other cooked and otherwise processed (e.g., cured) RTE poultry products. Under this proposal, establishments would be required to employ processing validated to achieve specific probabilities that only small numbers of *Salmonella* organisms could remain in finished cooked or otherwise processed, whole and comminuted, RTE products that contain any amount of poultry. Alternatively, an establishment could use a process validated to achieve a 7- log₁₀ reduction of *Salmonella* throughout a finished product.

The primary pathogenic microorganism of concern in these other

RTE poultry products has been *Salmonella*. FSIS tentatively finds that the destruction of *Salmonella* in these products will result in the destruction of most other pathogens. For example, *Campylobacter jejuni* was not selected as a reference organism in RTE poultry product, even though it is present at high levels in poultry, because it is generally recognized as being very sensitive to heat. As with the analogous meat products, FSIS is not proposing to require that any particular means be used to meet the lethality standard. For example, various treatments, such as curing or other controls, can be used in combination with cooking to achieve the required lethality.

B. Stabilization

In addition to lethality standards, FSIS is proposing that processing used to produce all RTE products, other than thermally processed, commercially sterile products, and processing used to produce partially heat-treated products, meet stabilization performance standards. The proposed stabilization standards require that establishments control their production processes to prevent the multiplication of spore-forming microorganisms. Stabilization is typically achieved through cooling a product after cooking. Specifically, the Agency is proposing to require that establishments producing these products ensure that there is no multiplication of toxigenic microorganisms, such as *Clostridium botulinum*, that potentially would create harmful toxins in the product, and that there is no more than a 1- \log_{10} multiplication of *Clostridium perfringens* within the product.

FSIS is proposing this performance standard because the means applied to products to bring about the lethality of certain microorganisms in RTE products, particularly heat treatment, can create a model environment for the multiplication of spore-forming bacteria. The processing for many RTE products includes a heat treatment. Spores of *C. botulinum*, *C. perfringens*, and other spore-forming bacteria can survive cooking and, in fact, can thrive in the warm product following cooking after competitive microorganisms, such as *Salmonella* or lactic acid bacteria, have been eliminated. Anaerobic, non-refrigerated conditions also facilitate multiplication and growth of these organisms.

Similarly, during processing, partially-heat treated meat and poultry products are partially cooked and then cooled, which creates a model environment for the growth of *C. perfringens*, *C. botulinum*, and other

spore-forming, toxigenic bacteria. Cooking by the consumer, retailer, or other end-user may not eliminate these bacteria or the toxins that they create in these products. Therefore, it is important that bacterial growth be controlled in these products to the extent possible before they reach the end consumer.

The stabilization performance standards are identical to the standards made final in the January 1999 performance standard rulemaking, cited above, for RTE products and partially-cooked poultry and meat patties. The purpose for imposing the no (zero) multiplication of *C. botulinum* standard was to ensure that harmful toxins would not be created in the product during cooling. Toxins are created only when there is multiplication of *C. botulinum*, or other spore-forming, toxigenic bacteria. When spores germinate and reach the outgrowth stage, even slight temperature abuse to the product can result in cell multiplication and, if there are sufficient numbers of cells, subsequent toxin formation. Thus, logically, ensuring no growth of these bacteria would provide the greatest amount of safety. Microscopic examination of cells can be used to determine whether cells have germinated and reached outgrowth stage.

The Agency requests comments on whether the *C. botulinum* standard should be no (zero) multiplication as proposed. The Agency also requests any data to support a tolerance in place of the proposed *C. botulinum* standard. The primary purpose for the zero growth standard is to ensure that harmful toxins will not be created in cooked product during cooling. If there were cell multiplication during cooling and sufficient numbers of cells, there could be subsequent toxin formation. Thus, ensuring no growth *C. botulinum* provides for the safety of the product with the greatest amount of confidence.

It is possible that there can be a small amount of *C. botulinum* growth within the time of a 1- \log_{10} relative growth of *C. perfringens*. If the relative growth of *C. botulinum* were greater than zero, but less than some small amount, the affected product could possibly be considered safe for consumption, provided it is also assumed that the initial levels of *C. botulinum* were not high. This assumption would be a reasonable one, since generally the levels of *C. botulinum* in raw meat are low. However, in this situation, the consequence of the low-level *C. botulinum* assumption being incorrect and of the possible toxin production would be severe.

It is possible that compliance with the proposed zero growth standard for *C. botulinum* could impose a significant burden on industry. Because there may be growth of *C. botulinum* during a 1- \log_{10} relative growth of *C. perfringens*, compliance with the proposed zero growth standard for *C. botulinum* could effectively require establishments to meet a more restrictive standard than that for *C. perfringens*. Further, demonstrating "no multiplication" by experiments (microscopic examination of cells to determine whether cells have germinated and reached outgrowth stage) could be expensive. Also, to the Agency's knowledge, there are not extensive data on which to build mathematical models for predicting the time before cell germination or outgrowth and using data from growth curves to develop predictive models for cell population growth is not propitious for demonstrating no multiplication. Usually with predictive growth models, it is very difficult or impossible to show a no occurrence event (zero-growth) with high probability. Consequently, FSIS requests comment on this issue, and data to support a possible relative growth tolerance in place of the zero growth proposed *C. botulinum* standard.

The proposed stabilization performance standard provides that any more than 1- \log_{10} multiplication of *C. perfringens* will adulterate the product for the following reasons: Viable counts of 10^5 or greater of *C. perfringens*/gram in finished product have been listed by the CDC as one criteria for incriminating *C. perfringens* as the causative agent of foodborne illness (Ref. 25, available for viewing by the public in the FSIS Docket Room), although foods responsible for *C. perfringens* outbreaks usually contain at least 10^6 vegetative *C. perfringens* cells per gram (Refs. 26 and 27, available for viewing by the public in the FSIS Docket Room). In the FSIS microbiological product surveys, some samples were found to contain more than 10^4 , but less than 10^5 , *C. perfringens*/gram. It is a conservative assumption with respect to public health that the great majority of *C. perfringens* in the raw product are spores. Heating activates the spores that, during the cooling, become vegetative cells that can multiply to hazardous levels. Given that there can be more than 10^4 *C. perfringens* (spores) per gram on raw product, it is possible that there could be as many as 10^4 vegetative *C. perfringens*/gram of these surviving, after cooking, in the product. Therefore, the Agency, using the aforementioned CDC criteria as an upper limit that should not be exceeded, has tentatively

determined that a limit of no more than 1 log₁₀ growth of *C. perfringens* is appropriate to ensure that there would be no more than 10⁵ *C. perfringens* per gram on the finished product after cooling.

An academic researcher recently suggested to the Agency that the stabilization performance standard for *C. perfringens* should apply only to the surface of intact, whole muscle, RTE products. This researcher stated that there is no data indicating that the interior of whole muscle products would ever contain *C. perfringens*. FSIS requests comment on this issue, as well as any relevant research data.

V. *Listeria monocytogenes*

L. monocytogenes grows at low oxygen conditions and 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 due to post-processing contamination. Consumption of food contaminated with *L. monocytogenes* can cause listeriosis, an uncommon but potentially fatal disease in newborns, the elderly, and persons with weakened immune systems, such as those with chronic disease, HIV infection, or persons taking chemotherapy for cancer. Listeriosis also is 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 serious illness or fetal death.

Each year, according to the FDA-FSIS draft risk assessment on *L. monocytogenes* (Ref. 28, available for viewing by the public in the FSIS Docket Room), the bacteria cause 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 indicates that the case-fatality rate varies by age, with a higher case-fatality rate among newborns (<1 year) and the elderly (>60 years). For a full discussion on case-fatality rate, refer to the “Baseline Number of Listeriosis Cases and Deaths and the Potential Benefits from the Proposed Rule” section in Appendix 1.

Since 1987, FSIS has conducted a microbiological testing program in which the Agency randomly samples, in-plant, RTE meat and poultry products produced in federally inspected establishments for *L. monocytogenes*, including cooked and fermented

sausages, cooked corned beef, sliced ham and luncheon meats, beef jerky, cooked uncurd poultry, and salads and spreads. FSIS treats RTE products in which *L. monocytogenes* is found as adulterated under the FMIA or the PPIA (21 U.S.C. 453(g) or 601(m)). This testing of approximately 7,000 RTE product samples per year for *L. monocytogenes* is an indicator of possible public health problems, but FSIS believes that more discriminating approaches are in need of development. (A comprehensive presentation on the FSIS testing program, entitled “FSIS Ready-to-Eat (RTE) Sampling in Transition,” is available from the FSIS Docket Room.)

During the late 1980's, *L. monocytogenes* emerged as a problem in deli meats and other processed food products. FSIS and the Food and Drug Administration (FDA) worked with processing plants to improve their procedures and emphasized the “zero” tolerance (no detectable level of viable pathogens permitted) for the pathogen in RTE products. Between 1989 and 1993, the rate of illness from *L. monocytogenes* declined 44 percent. This reduced incidence of foodborne listeriosis remained level until recently.

In the fall of 1998, state health departments and the CDC began investigating an increased number of reported cases of illness due to *L. monocytogenes*. CDC and state and local health departments identified the vehicle of transmission as hotdogs and possibly deli meats produced by one manufacturer under many brand names. On December 22, 1998, in response to reports of illness, the manufacturer voluntarily recalled specific production lots of these products that might be contaminated. Subsequently, CDC and FSIS investigators isolated the outbreak strain of *L. monocytogenes* from an opened and a previously unopened package of hotdogs manufactured by one plant. In addition, a different strain of the pathogen was isolated from unopened packages of deli meats produced at the same plant. CDC has since reported 101 illnesses, 15 adult deaths, and 6 stillbirths or miscarriages associated with this outbreak.

With this outbreak in mind, on May 7, 1999, the FDA, in consultation with FSIS, announced plans to conduct a risk assessment to determine the prevalence and extent of exposure of consumers to foodborne *L. monocytogenes* and to assess the resulting public health impact of such exposure (64 FR 24661). FDA and FSIS published this draft risk assessment for comment on January 19, 2001 (Ref. 28, available for viewing by the public in the FSIS Docket Room).

Significantly, it identifies certain RTE meat and poultry products, among the food products assessed, as posing a relatively high health risk of listeriosis to consumers because of potential RTE product contamination by *L. monocytogenes*.

In this document, FSIS is proposing regulatory requirements and considering other options to address the relatively high risk ranking of these RTE meat and poultry products. Significantly, the draft risk assessment was designed to estimate the predicted relative risk of serious illness and death that may be associated with consumption of different types of ready-to-eat foods. The draft risk assessment document, unlike more complete risk assessments, did not attempt to account for the level or sources of contamination of ready-to-eat meat and poultry products in a farm-to-table approach such as during processing in Federally inspected facilities. Rather, the draft risk assessment accounted for the retail foodborne exposure to human listeriosis (i.e., after the ready-to-eat product is out of the control of the Federal establishment). The data included in the draft risk assessment were gleaned from both international and domestic sources, with FSIS providing a substantial amount of data from its various microbiological programs associated with Federally inspected meat and poultry. The draft risk assessment was designed to address data only associated with listeriosis, providing a distinction between foodborne illness associated with mild, flu-like symptoms (referred to as listerial gastroenteritis) and severe and life-threatening outcomes (i.e., listeriosis). For this reason, some Federally inspected meat and poultry products were not addressed in the draft risk assessment (e.g., canned meat and poultry and partially- and fully-cooked meat patties). Except for the canned products and the meat patties, FSIS believes that the risk assessment addresses the remaining meat and poultry products contained in this proposed rule (i.e., frankfurters, dry/semi-dry fermented sausages, deli meats, and paté and meat spreads).

A. Proposed Requirements for Controlling *L. monocytogenes*

In the risk assessment, FDA and FSIS note that although pasteurization or cooking by an establishment will kill *L. monocytogenes*, there is risk of recontamination of RTE foods during processing, after the lethality is applied (Ref. 28, (Interpretive Summary, p. 24; Exposure Assessment, p. 24), available for viewing by the public in the FSIS

Docket Room). Significantly, FDA, FSIS and other authors point out, that deli meats in particular are most likely to be recontaminated by *L. monocytogenes* after cooking, during processing such as slicing (Ref. 28 (p. 167); Ref. 32; Ref. 33; all available in the FSIS Docket Room), although no data were available to distinguish between the risks of slicing product in a retail environment rather than an official establishment.³

FSIS is proposing to require that all establishments that produce RTE meat and poultry products conduct environmental testing of food-contact surfaces for *Listeria spp.*, after lethality treatment and before final product packaging, unless they have identified *L. monocytogenes* as a hazard reasonably likely to occur and so have incorporated into their HACCP systems one or more controls validated to eliminate it from their products. This testing will verify that an establishment's Sanitation Standard Operating Procedures (Sanitation SOPs) are preventing direct product contamination by *L. monocytogenes* after the lethality treatment, thus addressing the risk assessment assertion that RTE foods often are recontaminated by *L. monocytogenes* after lethality is applied.

After an establishment finds one of its food contact surfaces to be positive for *Listeria spp.*, it must take corrective actions defined in its Sanitation SOP that must include product testing, as well as any other activities that it deems necessary to determine and demonstrate that the affected lot or lots of product are not adulterated with *L. monocytogenes*. The establishment must 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.

Establishments that have identified *L. monocytogenes* as a hazard reasonably likely to occur in their HACCP plans and that have consequently established

CCPs for *L. monocytogenes* would be exempt from this mandatory testing requirement. For example, establishments that produce thermally processed, commercially sterile, hermetically-sealed (canned) products should be relatively unaffected by this proposed requirement. Neither should many other establishments that produce meat and poultry products that receive lethality treatment in their final packaging, such as beef cooked in an impervious bag. In most cases, these and similar establishments would need only to modify their HACCP plans to reflect that *L. monocytogenes* is likely to occur at some point during their processing, but their existing CCPs for lethality would eliminate the pathogen.

FSIS believes that *L. monocytogenes* contamination is reasonably likely to occur in the production of all RTE meat and poultry products. On May 26, 1999, FSIS published in the **Federal Register** a Notice advising manufacturers of RTE meat and poultry products of the need to reassess their HACCP plans to ensure that the plans are, in fact, adequately addressing *L. monocytogenes* (64 FR 28351). If this reassessment revealed that *L. monocytogenes* was a hazard reasonably likely to occur in an establishment's production process, the Notice stated that the establishment must address the hazard in its HACCP plan.

FSIS acknowledges, however, that there may be certain processing environments in which *L. monocytogenes* is not a hazard reasonably likely to occur. In such environments, verification through testing that the establishment's Sanitation SOP is controlling *Listeria spp.* would be necessary, at a minimum.

Notably, Tompkin, et al., have recommended plant-wide environmental testing that

* * * should focus on a non-pathogenic indicator such as *Listeria spp.* or *Listeria*-like organisms * * *, because these organisms will be found more frequently in the environment than *L. monocytogenes* and because test results are available more quickly.

(Ref. 29, available for viewing by the public in the FSIS Docket Room)

FSIS agrees, although the Agency is proposing to require only the testing of food contact surfaces. Were an establishment to find *Listeria spp.* on a food contact surface, that finding would be indicative of a sanitation problem that could cause product adulteration, even though the contaminant on the surface may not be *L. monocytogenes*.

FSIS is proposing to require that establishments without HACCP controls for *L. monocytogenes* test food contact

surfaces for *Listeria spp.* at one of the following frequencies, depending on establishment size:

- If the plant is large, at least four tests, per line, per month;
- If the plant is small, at least two tests, per line, per month;
- If the plant is very small, at least one test, per line, per month;

FSIS is proposing to employ the same Small Business Administration (SBA) size standards that it used to determine the implementation dates for its HACCP/Pathogen reduction final rule. Large establishments would be defined as all establishments with 500 or more employees. Small establishments would be defined as all establishments with 10 or more employees but fewer than 500. Very small establishments would be defined as all establishments with fewer than 10 employees or annual sales of less than \$2.5 million.

These frequencies ensure a very minimal amount of testing and, because they are progressive, mitigate some of the economic impact on small businesses. FSIS has not been able to correlate risk of product contamination with production volume or establishment size. However, assuming that large establishments produce a greater volume of product than do small establishments, and that a large insanitary establishment would be more likely to contaminate more product and thus pose more risk to the public health, FSIS is proposing to require large plants to test more often. Because these frequencies are not based on research but represent what the Agency believes to be minimal levels, FSIS requests comment on these proposed testing frequencies, their efficacy in preventing product adulteration, and the costs to industry. FSIS also specifically solicits information the current state of knowledge about the relationship between *Listeria spp.* on food contact surfaces and *L. monocytogenes* on the product; the appropriate timing of the test (pre-start-up or post-start up), seasonality and other risk based considerations that might be important in creating effective testing protocols; and, the testing methodologies that are currently available and the current practice and use of the tests by industry or others Agencies. FSIS will use the information to develop testing frequencies and methodologies that protect the public health, while providing flexibility to establishments. FSIS plans to hold one or more technical conferences during the comment period for this proposed rule, at which these testing issues and other can be discussed. FSIS plans to provide for discussion of the latest testing

³ Although pate and meat spreads also are identified in the draft FDA/FSIS risk assessment as having high predicted relative risk of causing listeriosis on a per serving basis, much of the reported foodborne outbreaks are associated with foreign populations. However, FSIS is aware of one foodborne outbreak in the U. S. involving pate produced in a federally inspected facility in 1999. In this outbreak, pate was prepared by cooking the product in open containers and then over-wrapped with film. Product was then distributed to multiple states and sold in gourmet shops. The pate was implicated as the food vehicle for *L. monocytogenes*. *L. monocytogenes* was cultured from an unopened package of pate at retail. FSIS was not able to determine whether *L. monocytogenes* was present in the unopened package as a consequence of underprocessing (i.e., inadequate lethality) or post-lethality contamination.

methodologies, including those used by other Federal Agencies and industry, as well as an ongoing ARS study on the testing of intact RTE product for *L. monocytogenes*.

FSIS is proposing to require that establishments take certain actions after food contact surfaces test positive for *Listeria spp.* After an establishment finds one of its food contact surfaces to be positive for *Listeria spp.*, it must take the corrective actions defined in its Sanitation SOP. According to § 416.15(a), Sanitation SOP corrective actions may include "procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s)."

The presence of *Listeria spp.* may be indicative of serious sanitation problems, especially if positive findings recur. Further, *Listeria spp.* positives on food contact surfaces indicate a potential for product adulteration by *L. monocytogenes*. Therefore, an establishment's corrective actions following a positive must include product testing and any other activities that it deems necessary to determine and demonstrate that the affected lot or lots of product are not adulterated with *L. monocytogenes*. The establishment must 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 acknowledges that some establishments would have to modify their Sanitation SOP corrective actions to include these elements.

FSIS requests comments on the proposed testing provisions and any data that would support the approach proposed. FSIS requests comments concerning whether *Listeria* positive test results on different food contact surfaces should be treated differently (e.g., positives on food contact surfaces that have undergone listericidal treatment versus other food contact surfaces). FSIS also requests comments on whether it should establish more specific requirements regarding product sampling and testing following a finding of *Listeria spp.* on a food contact surface. And, FSIS request comment on whether it should allow establishments that find *Listeria spp.* on a food contact surface to determine if the positive sample is in fact *L. monocytogenes* before having to initiate product testing.

If a sampled lot is found to be positive for *L. monocytogenes*, and is already in commerce, it will be subject to recall. Further, if product is found to be positive for *L. monocytogenes*, the

establishment likely will need to establish controls within its HACCP plan for *L. monocytogenes*. Also, reoccurring positives for non-pathogenic *Listeria spp.* may indicate that the establishment has a serious sanitation problem, even if *L. monocytogenes* is never found. FSIS enforcement action will vary depending on the establishment's efforts to correct its sanitation and processing problems and its disposition of affected product. FSIS acknowledges that establishments that develop one or more CCPs to control *L. monocytogenes* would not necessarily be testing for *Listeria spp.* to verify the efficacy of their Sanitation SOPs and requests comments on this issue.

The two provisions for *Listeria* control contained in this proposed rule (i.e., Sanitation SOPs and HACCP) require specific daily action regarding controls to ensure product is not adulterated. FSIS does not, at this time, consider control programs outside of Sanitation SOPs and HACCP to be sufficient for controlling hazards associated with post-lethality contamination with *Listeria* in the manufacturing of RTE meat and poultry products. Microbiological results and documentation of corrective and preventive actions generally are not provided to FSIS. FSIS has received a petition from a group of industry organizations regarding the issue of prerequisite programs. FSIS will address this issue separately from this proposed rule. In addition, FSIS will be further addressing this issue as part of its response to an Office of Inspector General report on HACCP implementation (Ref. 35, available in the FSIS Docket Room and at the FSIS web page, <http://www.fsis.usda.gov>).

With any final action FSIS will publish guidance to establishments regarding testing frequencies and methodologies and appropriate corrective actions following food-contact surface positives. FSIS also will publish guidance regarding available listericidal interventions establishments can implement as CCPs. FSIS expects to make draft guidance documents available after publication of this proposed rule and as information becomes available in order to provide establishments with appropriate guidance regarding sampling and testing to verify sanitation procedures. FSIS will consider comments on this draft guidance in developing any final regulations. These draft guidance materials will be clearly identified as guidance materials and not as regulatory requirements. FSIS expects to post these guidance materials to the FSIS web page (<http://www.fsis.usda.gov>) and will

make the documents available free of charge via the Constituent Update (see section XIV Additional Public Notification) and the FSIS Docket Room.

Eventually, FDA and FSIS may allow establishments to treat RTE products with ionizing radiation. If applied within a HACCP system, irradiation could eliminate *L. monocytogenes* from a RTE product. FSIS also is aware that industry is developing edible, antimicrobial coatings that could be applied to RTE meat and poultry after cooking or other lethality treatments. However, FDA has not yet approved any of these coatings for meat and poultry. FSIS also will make available its directives to inspection personnel that will explain how to verify whether an establishment has implemented a testing regime sufficient to verify the efficacy of Sanitation SOPs in preventing direct product contamination by *L. monocytogenes* prior to the effective date of any final regulation.

Finally, FSIS notes that on January 13, 2000, it received a petition from the Center for Science in the Public Interest (CSPI) requesting that FSIS require all establishments that produce RTE meat and poultry products to conduct environmental testing for *Listeria spp.* and product testing for *L. monocytogenes*. FSIS will respond to this petition completely along with other public comments submitted in response to this proposal. CSPI also requested that FSIS require RTE products produced by establishments without CCPs for *L. monocytogenes* to bear warning labels. FSIS discusses this request in the following section and also will respond more completely in any final action that stems from this proposal.

B. Shelf-Life and Labeling

In the petition discussed above, CSPI also requested that FSIS require establishments that have not incorporated microbial testing for *L. monocytogenes* into their HACCP plans to label their products so as to alert "consumers that the products may be contaminated and should not be eaten by at-risk consumers without reheating." FSIS will respond to this petition fully in any final action stemming from this proposed rule.

FSIS considered, but did not propose in this document, the option of requiring that the labeling of certain RTE meat and poultry products state the product's shelf-life, and that shelf-life be based on product safety ("use-by" date labeling). If after processing, a RTE product that could support growth of *L. monocytogenes* were to be

recontaminated by even a single cell of the pathogen, that cell could multiply during storage at refrigeration temperatures to levels that could pose a risk of illness to vulnerable individuals (e.g., pregnant women, the elderly, or the immunocompromised). "Use-by" date labeling may provide further reductions in risk of listeriosis if the labeling increases the likelihood that high-risk RTE products would be consumed before very low levels of *L. monocytogenes*, undetectable at the establishment, could grow to dangerous levels.

FSIS is not proposing to require "use-by" dates on the labels of any RTE products at this time because further information regarding the potential effects of use-by date labeling is needed. For instance, there is sparse information on current consumer understanding of use-by date labeling, the likelihood that consumer practices will change, and on the effect of changes in consumer behavior on listeriosis cases. Similarly, FSIS currently does not possess all the data necessary to assess the reduction in risk that will occur from this change. Also, FSIS does not have information concerning how use-by date labeling would affect the production and shipment patterns of labeled ready-to-eat meat and poultry products and the structure of the industry. FSIS requests comments on all of these issues and on the feasibility of requiring "use-by" date labeling on RTE meat and poultry products. Significantly, FDA and FSIS will present "use-by" date labeling issues to NACMCF for their review. FSIS has conducted a more thorough analysis of use-by date labeling in Appendix 1, Compliance with Executive Order 12866, under the "Alternatives" section.

Related to "use-by" date labeling is the issue of consumer preparation of hotdogs and similar RTE foods. In the draft risk assessment, FSIS and FDA state that "the factor that has the greatest effect on the predicted health impact of frankfurters is the extent of post-retail reheating by the consumer" (Ref. 28 (p. 161); Ref. 33; Ref 34; all available in the FSIS Docket Room). Obviously, testing for *L. monocytogenes* in the establishment will not directly affect consumer preparation of frankfurters or other RTE foods. However, if in-plant testing verifies that establishments are effectively preventing the contamination of frankfurters and other RTE products by *L. monocytogenes*, consumer preparation or handling of these RTE products will no longer be so inappropriately crucial to ensuring their safety. Furthermore, once FSIS is more

confident that establishments are adequately addressing the safety of their RTE products, especially for frankfurters and deli meats, throughout the shelf-life of their products, FSIS will consider modifying its consumer message to vulnerable populations and remove the current recommendation for these populations to either not consume these RTE products or to fully re-cook these products before consuming them.

Finally, as discussed below, FSIS is proposing that the labeling of RTE products state that the product requires refrigeration after opening, as applicable. Current regulations require that labels of perishable products include such instructions, but the Agency is proposing to expand the required label instructions to include RTE shelf-stable products that require refrigeration after opening. FSIS also considered proposing to change the "keep refrigerated" and the "refrigerate after opening" statements (see proposed in §§ 317.2(k) and 381.125(a)) to reflect the guidance developed by FDA on February 24, 1997 (62 FR 8248). In the guidance, these statements were modified to read "Important Must Be Kept Refrigerated to Maintain Safety" or "Important Must Be Refrigerated After Opening To Maintain Safety." FDA provided this guidance in response to the recommendations from the NACMCF, the National Food Processors Association, the Association of Food and Drug Officials, and the CDC regarding the labeling of foods that need refrigeration. FDA stated in this policy document that "[t]his guidance, which represents FDA's policy on adequate safe handling instructions for food, should reduce the likelihood of temperature abuse of certain foods by consumers, and it is intended to reduce the potential for foodborne illness and death." FSIS is not proposing to require these provisions because further information regarding the potential effects of this labeling is needed. FSIS requests comment on the statements and their appropriateness for RTE meat and poultry products which are not shelf stable.

VI. Thermally-Processed, Commercially Sterile Products

Thermally-processed, commercially sterile meat and poultry products generally have a water activity above 0.85 and have received a thermal process either before or after being packed in a hermetically sealed container. They are typically canned, although other types of packaging can be used. The thermal process renders the product shelf-stable and commercially sterile, that is, free of

microorganisms capable of growing in the product in nonrefrigerated conditions (temperatures over 50 °F or 10 °C), under which the product will be held during distribution and storage, until consumed.

Sections 318.300 to 318.311 and 381.300 to 381.311 of the regulations prescribe the exact means by which official establishments must produce thermally processed, commercially sterile meat and poultry products. These regulations include detailed requirements regarding containers and container closures, equipment specifications and operations, measurements and instrument calibration, recordkeeping and record review, corrective actions in the case of processing deviations, finished product inspection, personnel training, and product recalls. They also require that official establishments implement process schedules validated to render treated meat and poultry commercially sterile and shelf-stable. These process schedules must be developed or validated by processing authorities, persons or organizations with expert knowledge of thermal processing requirements for foods packaged in hermetically sealed containers.

Processors that produce thermally processed, commercially sterile meat and poultry products also must meet all other regulations applicable to meat and poultry establishments, such as sanitation and HACCP requirements. Significantly, however, under § 417.2(b)(3), FSIS exempts producers of thermally processed, commercially sterile products from addressing in their HACCP plans "food safety hazards associated with microbiological contamination." FSIS granted this exemption in response to comment on the proposal to require HACCP systems:

FSIS agrees that the microbial hazards associated with canned meat and poultry products are eliminated by complying with the regulations in 9 CFR Secs. 318.300–311 and 381.300–311. These regulations are based on HACCP concepts and provide for the analysis of thermal processing systems and controls to exclude microbial hazards. Accordingly, the final rule provides that HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the canning regulations. However, because the current regulations exclusively address microbial hazards, processors of canned meat, meat food and poultry products must develop and implement HACCP plans to address chemical and physical hazards that are reasonably likely to occur. (61 FR 38824)

The regulations governing the processing of thermally processed, commercially sterile meat and poultry products are, in a sense, a prescribed HACCP system that official establishments must implement along with controls to address other hazards not addressed in those regulations. Maintaining this prescriptive regulatory approach to a single category of meat and poultry products, however, is inconsistent with FSIS's other regulatory initiatives intended to grant industry maximum flexibility to innovate in processing, while clarifying industry's responsibility and accountability for the safety of meat and poultry products. Therefore, FSIS is proposing to replace the prescriptive regulations governing thermally processed, commercially sterile products with performance standards. FSIS is also proposing to remove §§ 320.2(b)(6) and 381.175(b)(3) because they refer to recordkeeping requirements in the canning regulations that FSIS is proposing to eliminate. FSIS has discussed this proposed action in previous documents, including the final rule that established the HACCP requirements:

The current canning regulations contain numerous prescriptive features, including extensive FSIS involvement in the decision making process, that are inconsistent with the philosophy underlying HACCP. In the advance notice of proposed rulemaking "FSIS Agenda for Change: Regulatory Review" (60 FR 67469; December 29, 1995), FSIS stated its intention to convert the canning regulations to performance standards, which are more consistent with HACCP.

(61 FR 38824)

FSIS is proposing lethality performance standards to ensure the elimination or control of the pathogen *C. botulinum* in thermally processed, commercially sterile meat and poultry products. FSIS also is proposing a revised requirement ensuring the commercial sterility of these products. This requirement is consistent with the existing shelf-stability/commercial sterility definitions in § 318.300(u) and 381.300(u) and the FDA regulations for commercial sterility of canned products contained in 21 CFR 113.3(e).

A. Lethality

FSIS is proposing different lethality performance standards, depending on whether the product is a low-acid product or a product in which pathogen growth is controlled by acidification or factors other than the thermal process. A low-acid, thermally processed, commercially sterile product is a canned or other hermetically sealed

product in which any component has a pH value above 4.6 and a water activity above 0.85. Such products include canned poultry and canned uncured meat products, such as beef stew and chili con carne, and certain canned cured meats, such as vienna sausages and corned beef. An acidified thermally processed, commercially sterile product is a canned product that has been formulated or treated so that every component of the finished product has a pH of 4.6 or lower, usually within 24 hours after the completion of the thermal process, but sometimes longer. Such products include spaghetti sauce with meat and meat with tomato sauce. In addition, there are some canned, hermetically sealed products in which pathogen growth is controlled by factors other than the thermal process, such as a heat treatment in combination with salt or nitrite (e.g., canned luncheon meat).

FSIS is proposing to require that an establishment's process for producing a low-acid canned product result in a probability of 10^{-9} or less that there are spores of *C. botulinum* in a container of the product that are capable of growing, assuming an initial load of ≤ 1000 spores per container. Alternatively, the establishment may achieve a 12- \log_{10} reduction of *C. botulinum*. A process carried out for a certain number of minutes at a given temperature that reduces *C. botulinum* by a factor of 12 decimal units, often referred to in the canning industry as a "botulinum cook," is one that meets a 12- \log_{10} standard, also known as a 12-D standard. A 12-D process has been demonstrated to be sufficient to destroy *C. botulinum* in a low-acid canned product. Under this proposal, the level of safety that a process other than a 12-D process would have to achieve would be a probability of 10^{-9} or less of any *C. botulinum* spores in a container of the product that are capable of growing, assuming an initial load of ≤ 1000 organisms.

The 12-D concept arose from studies on the thermal resistance of *C. botulinum* conducted in the early 1920's by scientists of the National Canners Association (predecessor of the National Food Processors Association). These scientists inoculated a phosphate buffer with spores of the most heat-resistant strain of the organism then known. They determined, by extrapolating from the exponential survival curve for the organism, the temperature and duration of the heat process necessary to reduce the population from 6×10^{11} spore/unit to less than one spore/unit. Subsequent studies on products inoculated with *C. botulinum* and other organisms

essentially confirmed the results of these studies.

These products undergo a botulinum cook to achieve an acceptable safety level. It should be noted that the intensity of the process is not related to the actual number of *C. botulinum* organisms that may be in the product. That number is usually very low in a meat product (less than a spore per kilogram). So the 12-D process provides a tremendous safety margin to consumers.

The level of safety achieved by a 12-D process in low-acid canned products is understood by thermal processing experts to be a 10^{-9} probability of any live botulinum organisms (Refs. 30–31, available for viewing by the public in the FSIS Docket Room). That means that the odds are one in a billion that a can is contaminated with the organism. This result is arrived at by assuming that a process that reduces botulinum spores by 10^{-12} —a 12-D process—is applied to a test pack of product inoculated with 10^3 spores per unit. The probability that any containers that are subjected to the process harbor spores capable of growing is 10^{-9} . Thus, FSIS is proposing to require that establishments producing low-acid products achieve a probability of 10^{-9} or less that there are spores of *C. botulinum* in a container that are capable of growing or a 12- \log_{10} reduction of *C. botulinum*.

FSIS is proposing to require that the processing of acidified low-acid products and of some cured products and other canned products in which pathogen growth is controlled by factors other than the thermal process, prevent multiplication of *C. botulinum*. For these products, processing (formulation and environment) must prevent growth rather than achieve any specific decimal reduction of *C. botulinum*. Therefore, there can only be one level of performance for acidified low-acid products and other thermally processed, commercially sterile products in which pathogen growth is controlled by factors other than the thermal process—prevention of *C. botulinum* multiplication. However, the prevention of multiplication can be achieved by a variety of methods.

Acidified low-acid meat and poultry products are generally acidified by ingredients, such as tomato sauce, or by additives, such as glucono-delta-lactone, which increase the acidity (i.e., lower the pH) of the products. The acidity of these products (pH at or below 4.6) is sufficient to prevent the germination of *C. botulinum* and other bacterial spores. The heat processing of these products does not include a botulinum cook or retort but is achieved at pasteurizing

temperatures below 100 °C. (212 °F.) and is sufficient to kill or inactivate molds, yeasts, and vegetative bacterial cells. This processing is important because, if canned acidified foods are contaminated by yeast or mold, the pH of the foods could be raised above 4.6, thus providing an environment for possible *C. botulinum* growth. These products—spaghetti sauce, for example—can be heat-treated before being placed in a container (i.e., hot-filled) rather than retorted and still achieve commercial sterility.

Other thermally processed, commercially sterile products can be rendered commercially sterile by a heat treatment in combination with other factors. For example, the shelf-stability of canned luncheon meat is a combined effect of heat treatment, the presence of nitrite and salt, and a low pre-processing level of *C. botulinum*. A 10-percent salt concentration or about 2 tenths of a percent of nitrite in the product formulation is usually considered sufficient to inhibit growth of the organism. The shelf-stability of dried meat-filled pasta results from a heat treatment and a water activity of less than 0.92 in the product. (Water activity is a measure of free moisture, or water available for microbial growth, in a food; the lower the number, the less moisture.) *C. botulinum* and other spore-forming organisms cannot grow at water-activity levels below 0.93. The heat treatment of these products destroys the vegetative cells of both pathogenic and nonpathogenic organisms, and the outgrowth of spores is prevented by the other inhibiting factors.

B. Commercial Sterility

FSIS also is proposing a specific requirement that all thermally processed, commercially sterile products, in fact, be commercially sterile and hermetically sealed. This requirement is consistent with the existing shelf-stability/commercial sterility definitions in § 318.300(u) and 381.300(u) and the FDA regulations for commercial sterility of canned products contained in 21 CFR 113.3(e). A commercial sterility requirement is necessary to protect against both food-safety-related and non-food-safety-related forms of contamination.

Product that has undergone more processing than necessary to protect health, but less than necessary for commercial sterility, is safe, but it may not be stable. The stability of the product is usually determined by incubating the product for a certain time at a given temperature (e.g., 10 days at 95±5°F), then sorting 100 percent of the

product to locate any swelling or abnormal-appearing containers. Products that are shown to have undergone less processing than necessary to protect health are potentially hazardous and are removed from commerce.

The proposed commercial sterility requirement would mean that the process for a canned product, in addition to reducing or inactivating *C. botulinum* spores, would have to ensure a reduction or inactivation of spore-forming organisms sufficient to guarantee commercial sterility. A process that ensures a 10⁻⁹ probability of contamination by *C. botulinum* spores will not provide the same probability of destruction of the most heat-resistant mesophilic (optimum growth, 20–45°C) anaerobes, such as *Clostridium sporogenes*, or thermophilic (optimum growth, 50–65°C) organisms, such as *B. stearothermophilus*. Recommended processes for preventing contamination by such nonpathogenic organisms typically ensure a probability of no spore-forming units in the range of 10⁻⁶. FSIS is proposing a general and not a quantitative standard for commercial sterility in this document but requests comment on whether a quantitative standard is necessary.

FSIS considers a commercial sterility standard to be appropriate, among other reasons, because the Agency is obligated under the statutes it enforces to administer programs aimed at preventing all forms of adulteration of meat and poultry products. The Agency's current thermal processing regulations are intended to ensure that canned and other thermally processed products are not adulterated.

Hermetic sealing of a container protects the product and prevents microorganisms or other potential contaminants from entering the container. If the container seal is inadequate, the product may no longer be microbiologically stable. *C. botulinum* or spoilage organisms could contaminate the product during container cooling or storage. The product could become adulterated because of spoilage, an economic concern, or because of *C. botulinum*, a public health concern. For this reason, FSIS considers appropriate, and is proposing, a hermetic sealing requirement. In § 430.5(c), FSIS is proposing that the seal be airtight to protect the contents of the container from the entry of microorganisms.

C. Training

Several industry groups and other interested parties have expressed reservations concerning any

replacement of the existing regulations for thermally processed, commercially sterile products with performance standards. The complexity of the canning process, as well as the virulence of *C. botulinum* toxin which can form in canned products, have been cited as reasons for maintaining the existing, prescriptive regulations. Significantly, FSIS is proposing to retain, in new § 430.5(d), the requirement that all operators of processing systems for commercially sterile meat and poultry products and container closure technicians be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for training supervisors of canning operations. FSIS specifically invites comment as to whether and in what form the existing requirements for thermally processed, commercially sterile meat and poultry products should be retained. If the Agency does replace the current regulations with the proposed performance standards, it plans to issue a revised version of the current regulations as compliance guides for industry.

VII. Elimination of *Trichina* Treatment Requirements

FSIS also is proposing to remove the provisions for the prescribed treatment of pork and of products containing pork to destroy *trichina* (*Trichinella spiralis*) under § 318.10. FSIS requires establishments to eliminate *trichina* from numerous RTE products under these regulations. If this proposal is made final, the specifically prescribed treatments will be unnecessary, since compliance with the proposed lethality performance standards should also render RTE products free of *trichina*.

With regard to heat-treated, RTE products containing pork, the required treatment to destroy *trichina* would no longer be needed because if the process used meets the proposed performance standards for *Salmonella*, the process should eliminate any live *trichina*. For dried, salt-cured, or fermented products, the implementation of the lethality requirements for *Salmonella* and *E. coli* 0157:H7 would also likely destroy *trichina*. However, because there are no published studies comparing the lethalities of *Salmonella* or *E. coli* 0157:H7 to the destruction of *trichina* in dried, salt-cured, or fermented products, the Agency cannot state with absolute certainty that the proposed lethalities for these products would also destroy any live *trichina*. Thus, if the establishment identifies *trichina* as a hazard reasonably likely to occur, the establishment would have to ensure that

the process used effectively eliminates this hazard.

Several products that are not RTE also must be treated to destroy *trichina* under § 318.10. FSIS is proposing to remove the *trichina* treatment provisions for these products because they represent overly prescriptive provisions that are contrary to HACCP. By removing these provisions for all products, the Agency would provide establishments with flexibility to determine whether they need to treat the products to eliminate *trichina*. If an establishment identifies *trichina* as a hazard reasonably likely to occur in a process, it must address *trichina* in its HACCP plan.

The Agency prescribes *trichina* treatment for certain not-RTE products that may be eaten rare or undercooked because of their appearance. These products may appear to have been cooked because they contain ingredients such as wine, paprika, or curing agents. Significantly, however, packages of raw meat and poultry products must bear the safe handling label. The safe handling instructions regulations (9 CFR 317.2(l) and 381.125(b)) require that all meat and poultry products that are not RTE bear safe handling instructions on the label. By following the "cook thoroughly" portion of the safe handling instructions, the consumer should eliminate possible bacterial contaminants and any *trichina* present in the product. According to the FSIS Meat and Poultry Hotline and industry sponsored consumer surveys, the perception that pork may be infected with *trichina* continues to be a common food safety concern to American consumers, so FSIS has some confidence that consumers will cook these products thoroughly.

FSIS is examining the need for future rulemaking to address these pork products and other similar non-pork products that may be eaten without adequate cooking because of their appearance. The Agency is considering requiring conspicuous labeling that would identify these products as not-RTE and provide more specific instruction to consumers regarding safe handling and preparation.

The requirements in § 318.10 for treating pork products that may contain *trichina* originated in the early part of the 20th Century. At that time *T. spiralis* was a serious foodborne problem caused by consumption of underprocessed products. In response, the USDA implemented rules that prescribed treatments, in part based on USDA research, to destroy *trichina* in RTE products. At the time these prescribed *trichina* treatments were implemented,

the causes of bacterial foodborne illnesses were not fully characterized or recognized. Thus, USDA was prescribing treatments to address the best-known foodborne hazard and believed a *trichina*-free product was indeed safe-to-eat. In subsequent decades, as other foodborne pathogens were recognized and characterized, these prescriptive regulations were not modified to address those hazards.

For example, other organisms may be biological hazards in pork, such as *Toxoplasma gondii* and *Taenia solium*. These organisms must also be eliminated from certain products, including RTE products, in order for the product to be safe. However, the Agency has not prescribed the methods of elimination of these and other similar potential hazards in pork. FSIS has determined that these and other hazards, like *trichina*, should be addressed under HACCP plans rather than through prescriptive regulations.

All establishments producing products containing pork should assess whether *trichina* is a hazard reasonably likely to occur in their processes. If it is, they should address this hazard in their HACCP plans. Establishments should assess whether the product should be treated for elimination of live *trichina*, whether special cooking instructions are necessary on the label of the product, or whether the safe handling label is sufficient to ensure that the product is cooked to temperatures necessary to eliminate any possible live *trichina*. The establishment's decision concerning whether to treat the product for *trichina* or to include special cooking instructions on the label may be based on how the consumer typically prepares the product or the likelihood of the product's being confused with a RTE product.

Establishments that produce pork products should consider whether their suppliers have taken measures to prevent *trichina* infection of their herds. FSIS has entered into an agreement with other USDA agencies, two pork processors, and the National Pork Producers Council to pilot test a program that will identify risk factors for *trichina* infection and certify production units that voluntarily adopt practices to reduce or eliminate those risks. Pork producers who wish to be certified will agree to implement management practices that prevent a herd from becoming *trichina* infected. Qualified accredited veterinarians, trained by the USDA Animal and Plant Health Inspection Service (APHIS), will audit production units to ensure that practices are being followed. APHIS will subsequently review audit findings and,

if satisfactory, issue a *Trichinae* Certification to the herd. In addition, APHIS will track the status of all certified herds and conduct spot audits to ensure program integrity. Herds owners must renew certification status every 15 months by satisfactorily completing another audit.

When pigs are submitted for slaughter as *trichina* certified, processors will check the APHIS database to ensure that the premises of origin are certified and in good standing. A representative sample of *trichina* certified pigs, as provided by the National *Trichina* Certification Program Standards, will be tested for the presence of *trichina* to ensure program integrity. FSIS will verify that processors properly check status of pigs, test samples as required, and maintain adequate animal identification and records. Any label claims that ultimately are made will be handled through the usual FSIS label approval process.

The pilot program began in August 2000 with the training of qualified accredited veterinarians and enrollment of pork producers. After the pilot is completed (in approximately one and a half years), the Certification program will be made available nationally to all pork producers and processors.

Finally, FSIS is also proposing to remove other referential and related provisions concerning required treatment to eliminate *trichina*. The Agency is proposing to remove all of the following additional provisions: A reference to the required *trichina* treatment in § 303.1(f); the requirement under § 319.106(b) that country ham products and dry cured pork shoulder be treated for the destruction of possible *trichina*; the requirement under § 319.145(a)(2) that when pork muscle tissue is combined with beef or veal, or both, in the preparation of certain Italian sausage products, it be treated for the destruction of possible live *trichina*; the record retention requirement under § 320.1(b)(7) concerning sample results and calculation results as required by processing procedures to destroy *trichina* in § 318.10(c)(3)(iv) (Methods 5 and 6); the provision in § 325.7(a) for including pork that has been refrigerated to destroy *trichina* in the category of products that require special supervision between official establishments under official seal; and the provision under § 331.5(a)(1)(ii) that any meat or meat food product is adulterated if it is a RTE pork product that has not been treated to destroy *trichina* as prescribed in § 318.10.

VIII. Other Proposed Revisions to the Regulations

FSIS is proposing that the labeling of RTE products state that the product requires refrigeration after opening, as applicable. Current regulations require that labels of perishable products include such instructions, but the Agency is proposing to expand the required label instructions to include RTE shelf-stable products that require refrigeration after opening.

Also, FSIS is proposing to remove the regulations under § 318.17, 318.23, and 381.150 that require establishments not operating under HACCP to develop process schedules for the production of roast beef, cooked beef, corned beef; fully-cooked, partially-cooked, and char-marked uncured meat patties; and fully-cooked and partially-cooked poultry products, respectively. Similarly, FSIS is proposing to remove the definitions for "process schedule" and "process authority" in Parts 301 and 381.1. These regulations were established by the January 1999 rulemaking that also established the pathogen reduction performance standards for these products. At that time, certain official meat and poultry establishments were not yet required to develop and implement HACCP systems. Therefore, with these process schedule requirements, FSIS intended to ensure that all establishments that developed customized processing systems to meet the performance standards also would develop a validated system of process control, similar to HACCP. As of January 25, 2000, all official establishments are required to develop and implement HACCP systems, so these process schedule requirements are no longer necessary.

IX. Scientific Information and Data Needs

FSIS has identified additional needs for scientific information and analytical data that if addressed could strengthen the scientific foundation of the rule. It is extremely important that the regulations be based on sound science and common sense measures that involve significant public comment. FSIS requests the specific information identified in this document. In the section, the major data needs are summarized.

In order to facilitate public input and gather additional information during the comment period for this proposed rulemaking, FSIS plans to hold public meetings and scientific conferences to discuss the proposed provisions, especially those that would require

certain establishments to conduct environmental testing for *Listeria spp.* FSIS also intends to present the proposed testing requirements and related scientific issues to the NACMCF for review.

Testing for *Listeria spp.*

In their recent draft risk assessment regarding *L. monocytogenes*, FDA and FSIS noted that there is an opportunity for recontamination of RTE foods by the pathogen during processing in the plant, after the lethality treatment is applied and before packaging (Ref. 28). Consequently, under the proposed regulations, each establishment that produces RTE meat and poultry products will be required to test food contact surfaces for *Listeria spp.* where product is handled after lethality but before final packaging, unless it has established a CCP for *L. monocytogenes* in its HACCP plan(s). The establishment and FSIS will use the test results to verify the efficacy of the establishment's Sanitation SOPs in preventing RTE product contamination by *L. monocytogenes*. If an establishment finds *Listeria spp.* on a food contact surface, it must take the corrective action(s) defined in its Sanitation SOPs, including: procedures to determine which lot or lots of product might have been affected; procedures to hold, sample, and test that product for *L. monocytogenes*; and procedures to dispose of affected product.

FSIS is confident that testing of food contact surfaces to verify that an establishment's Sanitation SOPs are eliminating *Listeria spp.* from food contact surfaces will result in sanitation improvements that will lead to reductions in the contamination of RTE meat and poultry products by *L. monocytogenes*. FSIS also is aware that its current testing of approximately 7,000 RTE product samples per year for *L. monocytogenes* is an indicator of possible public health problems, but that more discriminating approaches are in need of development. However, FSIS is not aware of any research that correlates specific amounts or types of testing with specific remedial actions or reductions in contamination and welcomes the submission of any data. FSIS also requests comment as to whether other types of environmental testing, regular product testing, or some combination may be more effective in detecting *L. monocytogenes* contamination problems.

FSIS has proposed required frequencies of testing that ensure very minimal levels of regular testing based on establishment size. FSIS is aware of no research linking volume of

production with the likelihood of product adulteration by *L. monocytogenes*, but has assumed that insanitary establishments producing higher volumes of RTE meat and poultry products would be more likely to adulterate more product and thus pose more risk to the public health. As a result, FSIS has proposed a progressive series of testing frequencies so as to protect consumers from adulterated product. These testing frequencies also should minimize the costs of testing accrued by small business. FSIS requests any data that may adjust this assumption, suggest specific testing frequencies, correlate contamination risk with volume of production, or indicate what types and frequencies of testing for *L. monocytogenes* are most effective in detecting insanitation and possible adulteration of RTE meat and poultry products. Also, FSIS request data regarding the relationship between *Listeria spp.* and *L. monocytogenes* and how that relationship should affect any required testing provisions; For example, does a food contact surface positive for *Listeria spp.* scientifically necessitate product testing and what would negative product test results mean?

FSIS also requests data regarding the costs and benefits of the proposed testing provisions, as well as other testing protocols. Considering the number of listeriosis cases and deaths probably attributable to the consumption of adulterated RTE meat and poultry products (see Appendix 1 for further discussion), FSIS believes the public health benefits that would result from mandatory environmental testing could easily exceed the costs of the testing. But, FSIS seeks any data correlating testing, reductions in establishment contamination, and consequent reductions in listeriosis that could be used to improve the Agency's cost/benefit analysis.

Lethality Performance Standards

FSIS is proposing lethality performance standards for the pathogens *Salmonella* and *E. coli* O157:H7 derived from the Nationwide Microbiological Baseline Data Collection Program. Using the positive samples in the baseline data, FSIS derived hypothetical worst case raw products and then determined the levels of pathogen reduction (lethality performance standards) that, if met, would render these worst case raw products ready-to-eat and unadulterated with a specific margin of safety. FSIS also translated the results of the application of the lethality performance standards into probabilities of

remaining pathogens in finished RTE, product. Consequently, an establishment that demonstrates that its incoming raw product is consistently less contaminated than the worst case could apply a lower lethality than proposed, as long as it achieves the corresponding probability of remaining pathogens in finished RTE product.

It is possible that better data is available for deriving hypothetical worst case products and corresponding performance standards. FSIS is unaware of any human health risk assessments that could be used to correlate changes in the performance standards with changes in public health benefits. Higher or lower lethality performance standards may be necessary in all or specific processing contexts. FSIS specifically requests any data that would support requiring different lethality performance standards to achieve certain public health benefits.

The lethality performance standards for *Salmonella* already apply to numerous RTE meat and poultry products and FSIS believes that many establishments that produce RTE products not now subject to the proposed standards already meet them. It is likely, however, that some establishments will have to alter their processing methods to meet the proposed standards, i.e., to achieve higher levels of lethality in their RTE products. Further, manufacturers of RTE meat patties now only are required to comply with time/temperature regulations that yield a lesser level of lethality than what FSIS is proposing for all RTE meat products. FSIS requests information on the costs meat patty manufacturers and other establishments may accrue if required to meet the proposed lethality performance standards for RTE meat and poultry products.

Stabilization Performance Standards

Also under the proposal, all RTE meat and poultry products, other than thermally processed, commercially sterile products, and all partially heat-treated products, must be processed so as to prevent multiplication of toxigenic microorganisms such as *C. botulinum* and to allow no more than 1-log₁₀ multiplication of *C. perfringens* within the product. Stabilization is commonly achieved by rapidly cooling product after cooking. It also can be achieved by the addition of a curing agent. These regulatory stabilization standards already apply to numerous RTE and partially-heat treated meat and poultry products.

Researchers have suggested to FSIS that there may be some inevitable

growth of *C. botulinum* during a 1-log₁₀ relative growth of *C. perfringens* and therefore compliance with the proposed zero growth standard for *C. botulinum* could in fact effectively require establishments to meet a more restrictive standard than that for *C. perfringens*. FSIS requests comment and scientific data relative to whether the Agency should revise the existing and proposed stabilization performance standard for controlling these two pathogens, as well as data on corresponding public health benefits.

X. Summary of the Proposed Rule

In summary, FSIS is proposing the following requirements governing the production of all RTE and partially heat-treated meat and poultry products:

- All RTE meat and poultry products, except for thermally-processed, commercially sterile products, must be processed to achieve a lethality performance standard that indicates a specific reduction in *Salmonella*.
- All fermented RTE meat and poultry products that contain any amount of beef, except for thermally-processed, commercially sterile products, must be processed to achieve an additional lethality performance standard that indicates a specific reduction in *E. coli* O157:H7.
- All RTE meat and poultry products, other than thermally processed, commercially sterile products, and all partially heat-treated products, must be processed so as to prevent multiplication of toxigenic microorganisms such as *C. botulinum* and to allow no more than 1-log₁₀ multiplication of *C. perfringens* within the product.
- The processing of RTE meat and poultry products must be validated to achieve the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent product adulteration. Further, processing must be validated to maintain the lethality and stabilization performance standards throughout product shelf-life under the conditions in which the food is stored, distributed, and held.
- All thermally-processed, commercially sterile meat and poultry products must be processed to either eliminate or control the growth of *C. botulinum*, depending on the pH of the product or other factors that affect the growth of that pathogen. These products also must be commercially sterile and the container in which the product is enclosed must be hermetically sealed.
- Each establishment that produces RTE meat and poultry products must test food contact surfaces for *Listeria*

spp. in order to verify the efficacy of its Sanitation SOP, unless it has incorporated one or more controls for *L. monocytogenes* into its HACCP plan. Testing frequency will be based on establishment size. Food contact surface positives for *Listeria spp.* will trigger mandatory product testing.

- The regulations in § 318.10 that require the elimination of *trichina* from pork products will be rescinded.

XI. Compliance With Executive Order 12866

This proposed action has been reviewed for compliance with Executive Order 12866. Because this proposed action has been determined to be economically significant for purposes of Executive Order 12866, the Office of Management and Budget has reviewed it.

FSIS is proposing to amend the Federal meat and poultry inspection regulations by establishing pathogen reduction performance standards for all RTE and all partially heat-treated meat and poultry products. FSIS also is proposing to require establishments that produce RTE meat and poultry products to conduct environmental testing for *Listeria spp.* to verify that they are controlling *L. monocytogenes* within their processing environments. Establishments that have developed and implemented HACCP controls for *L. monocytogenes* would be exempt from these testing requirements. Finally, FSIS is proposing to eliminate its regulations that require that both RTE and not-ready-to eat pork and products containing pork be treated to destroy *trichina*; these requirements are inconsistent with HACCP and some will be unnecessary if FSIS makes final the proposed performance standards for RTE meat and poultry products.

This proposed action is compelled by recent outbreaks of foodborne illness related to the consumption of adulterated RTE meat and poultry products, as well as the need to provide objective, measurable pathogen reduction standards that can be met by official establishments and compliance with which can be established through Agency inspection. Although FSIS routinely samples and tests some RTE products for the presence of pathogens prior to distribution, there are no specific regulatory pathogen reduction requirements for most of these products. And in regard to thermally processed, commercially sterile (most often canned) meat and poultry products, the proposed standards represent regulatory reform; they replace lengthy, prescriptive regulations with performance standards that provide the

same level of food safety, as well as increased flexibility for establishments to customize their processes under HACCP.

Appendix 1, published in this issue of the **Federal Register** immediately following this proposed rule, contains a preliminary analysis required under Executive Order 12866, including a discussion of the need for the proposed regulations, regulatory alternatives considered by FSIS, and a complete cost-benefit analysis. FSIS demonstrates in Appendix 1 why it believes that this proposed action would result in benefits.

In short, if the proposed regulations could achieve a complete elimination of listeriosis that results from the consumption of contaminated RTE meat and poultry products, the expected annual reduction in listeriosis cases and deaths would range from 1660 cases and 331 deaths (based the draft FDA-FSIS risk assessment and on 100 percent program effectiveness) to 167 cases and 35 deaths (based on two independent CDC studies and 100 percent program effectiveness). FSIS is uncertain about the effectiveness of its proposed testing requirements in reducing listeriosis and therefore unable to adequately quantify a range of benefits. FSIS intends to use comments and data received during the comment period and at the planned technical conference to refine the proposed regulations and to better estimate benefits. It is of course unlikely that the proposed regulations could achieve complete elimination of the listeriosis that results from contaminated meat and poultry, but FSIS believes that the benefits of the regulations would exceed the total costs of all of the proposed provisions.

The two main provisions of the proposed rule are: (1) Mandatory in-plant testing for *Listeria* and (2) *Salmonella* and *E. coli* O157:H7 performance standards firms must employ as measures of process control. Much of costs of these actions are associated with first-year, one-time validation pertaining to the achievement of the performance standards and with the incorporation of new information into plants' HACCP plans. These initial costs are projected at over \$6.5 million, while annual recurring costs are estimated at \$6.2 million. Benefits are expected to result from less contaminated product entering commercial channels due to increased sanitation efforts and in-plant verification through testing.

XII. 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 proposed rule will have a significant economic impact on a substantial number of small entities. As discussed in the regulatory impact analysis, FSIS estimates that the proposed performance standards may cost small and very small producers of jerky, hotdogs, luncheon meat and meat patties approximately \$5 million annually, about 71 percent of the total costs of compliance associated with these provisions.

FSIS considered not proposing to extend the performance standards to these products because of the possible disproportionate economic impact on small business. However, taking this alternative would result in a significant inconsistency in the Agency's public health policy. Most, if not all, RTE meat and poultry products are manufactured from the same supply of raw product examined in the FSIS national baseline surveys. So performance standards derived from this baseline should be applicable to all categories of RTE meat and poultry products, regardless of how they are processed. That is, all RTE products should be required to meet the same standard of safety.

The "Small Business Regulatory Enforcement Fairness Act of 1996" (P. L. 104-121) requires, among other things, that

For each rule or group of related rules for which an agency is required to prepare a final regulatory flexibility analysis under section 604 of title 5, United States Code, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as "small entity compliance guides". The guides shall explain the actions a small entity is required to take to comply with a rule or group of rules. The agency shall, in its sole discretion, taking into account the subject matter of the rule and the language of relevant statutes, ensure that the guide is written using sufficiently plain language likely to be understood by affected small entities. Agencies may prepare separate guides covering groups or classes of similarly affected small entities, and may cooperate with associations of small entities to develop and distribute such guides.

With any final action that stems from this proposed rulemaking, FSIS will publish compliance guides for small businesses. The guides will include detailed instructions on how to comply with the proposed performance standards for all categories of RTE meat and poultry products. Establishments that wish to use the guides may incorporate them into their HACCP plans. Because FSIS will base its

guidance on existing research and industry practices known to be effective, the Agency also will consider the processing instructions to be already validated. That is, establishment may follow the guidance without contracting for or conducting additional validation. FSIS believes compliance guides would significantly reduce the economic burden the proposed regulations could place on small businesses.

FSIS is examining other options to minimize the potential negative economic effects of these proposed regulations on small businesses, including staggering the effective dates for any final regulations, in consideration of establishment size. FSIS requests comment on other measures it could take to mitigate the economic impact of any final regulations.

FSIS also estimates that the direct cost of the mandatory environmental testing provision of the proposed rule will entirely fall on small and very small producers. Based on the preliminary analysis in Appendix 1, FSIS expects that they will incur approximately \$1.75 million annually (See Appendix 1 for details on the cost estimates).

Types of Entities and Production Affected by the Proposed Regulations

The 1997 Census of Manufacturers identifies 1630 establishments which could potentially be affected by the proposed rule. In Appendix 1 and for this analysis, these establishments are broken down into four broad groups that FSIS differentiated by the estimated costs of compliance with all of the proposed provisions. These groups are further broken down into sub-groups where appropriate. The main product groups (and sub-groups, if appropriate) are:

- *Group I:* Those entities that likely will incur the greatest costs and which are further broken down into: Sub-group 1: fermented, dried, and salt-cured RTE meat and poultry products; Sub-group 2: hotdogs and wieners; Sub-group 3: cooked meat and poultry patties; and, Sub-group 4: smoked hams and poultry luncheon meats;

- *Group II:* Those entities that likely will incur moderate costs and which are further broken down into three types of producers of cooked or otherwise processed meat and poultry products (either produced by a combo plant, meat or poultry processor);

- *Group III:* those entities that likely will incur minor costs (frozen dinners, pizza, and other similar meat and poultry products); and

- *Group IV*: those entities that likely will incur no costs (canned meat and poultry products).

Almost 60 percent of all the establishments that could be potentially affected by the proposed rule are classified as small (employing between 10 and 500 employees) (Table 3). Another 32 percent fall into the very small establishment category of employing fewer than 10 employees while the remaining 9 percent are classified as large (employing more than 500 employees).

The number of establishments, the types of products shipped, and value of shipments of these groups are summarized below in Table 3.

Most product groups and sub-groups exhibit a population distribution in which about 33% of firms are very small, 60% are small, and less than 10% are large. However, three product groups differ markedly: Group II, Sub-groups 2 and 3 and Group IV (rows 11, 12, and 15 in Table 3). Large establishments play an important role in Group II, Sub-group 2 (poultry processors of miscellaneous RTE products containing meat and poultry) making up 37 percent of all their numbers. As a consequence, the percentage contributions to their total numbers for both small and very small establishments are much lower than the

all-group averages. Canners (Group IV) also exhibit a much different population distribution than the average: they are dominated by small establishments, which lowers the presence of very small canning establishments. Finally, the percentage of very small combination slaughter/meat processing establishments in Group II, Sub-group 3 have almost as high a percentage of establishments as do the small establishments for all groups (55 percent of this sub-group consists of very small establishments while the percentage of small establishments drop to 48 percent).

TABLE 3.—NUMBER OF ESTABLISHMENTS BY SIZE WHICH MAY BE AFFECTED BY RTE RULE AND THEIR PROPORTION IN EACH PRODUCT GROUP

| Group and subgroup | Establishment size categories | | | | Total |
|--------------------|-------------------------------|-----------|------------|----------|-------|
| | VS | S | VS+ S | L | |
| I: | | | | | |
| 1 | 57 (38%) | 85 (57%) | 142 (95%) | 8 (5%) | 150 |
| 2 | 56 (34%) | 94 (56%) | 150 (90%) | 17 (10%) | 167 |
| 3 | 27 (36%) | 47 (62%) | 74 (98%) | 2 (2%) | 76 |
| 4 | 64 (34%) | 105 (55%) | 169 (89%) | 22(11%) | 191 |
| Sub-Total | 204 (35%) | 331 (57%) | 535 (92%) | 49 (8%) | 584 |
| II: | | | | | |
| 1 | 200 (36%) | 339 (62%) | 539 (98%) | 12 (2%) | 551 |
| 2 | 25 (15%) | 79 (48%) | 104 (63%) | 60 (37%) | 164 |
| 3 | 42 (55%) | 29 (38%) | 71 (93%) | 5 (7%) | 76 |
| Sub-Total | 267 (34%) | 447 (56%) | 714 (90%) | 77 (10%) | 791 |
| III | 35 (34%) | 62 (59%) | 97 (93%) | 7 (7%) | 104 |
| IV | 18 (12%) | 121 (80%) | 139 (92%) | 12 (8%) | 151 |
| Total | 524 (32%) | 961 (59%) | 1485 (91%) | 145 (9%) | 1630 |

Note: VS stands for "very small," S stands for "small," and L stands for "large."
Totals may not add due to rounding.

First-Year Total Direct Cost Impacts Across Establishment Size by Product Group

The total first year economic impacts (as estimated in Appendix 1) were broken down by product group and size. The percentages reported in Table 4 represent the impact on each product

group as a percentage of the total industry-wide impact. The distribution of the economic impacts is based on assumptions, explained in detail in Appendix 1, concerning which groups of industry will be affected by the proposed performance standards, which will be affected by the proposed *Listeria* requirements, and of those affected by

the *Listeria* requirements, which will choose to test for *Listeria spp.* and which will choose to develop CCPs for *L. monocytogenes*. Significantly, FSIS expects that large establishments would opt to develop CCPs for *L. monocytogenes*, but that many small and very small establishments will opt to test for *Listeria spp.*

TABLE 4.—POTENTIAL FIRST-YEAR TOTAL DIRECT COST IMPACTS ACROSS ESTABLISHMENT SIZES

| Group and subgroup | Across all product-types ¹ | | | | | | | |
|-------------------------|---------------------------------------|------|----------|------|----------|------|--------------------|------|
| | VS | | S | | L | | Total ² | |
| | 000's \$ | % | 000's \$ | % | 000's \$ | % | 000's \$ | % |
| I: | | | | | | | | |
| 1 | 942.5 | 7.4 | 3108.4 | 24.6 | 1847.4 | 14.6 | 5898.3 | 46.6 |
| 2 | 89.6 | 0.7 | 313.7 | 2.5 | 189.2 | 1.5 | 592.5 | 4.7 |
| 3 | 308.3 | 2.4 | 1235.7 | 9.8 | 399.2 | 3.2 | 1943.3 | 15.4 |
| 4 | 114.1 | 0.9 | 386.3 | 3.1 | 412.5 | 3.3 | 912.9 | 7.2 |
| Sub-Total Group I | 1454.5 | 11.5 | 5044.1 | 39.8 | 2848.3 | 22.5 | 9347.0 | 73.8 |

TABLE 4.—POTENTIAL FIRST-YEAR TOTAL DIRECT COST IMPACTS ACROSS ESTABLISHMENT SIZES—Continued

| Group and subgroup | Across all product-types ¹ | | | | | | | |
|--------------------------|---------------------------------------|------|----------|------|----------|------|--------------------|--------|
| | VS | | S | | L | | Total ² | |
| | 000's \$ | % | 000's \$ | % | 000's \$ | % | 000's \$ | % |
| II: | | | | | | | | |
| 1 | 307.5 | 2.4 | 1093.1 | 8.6 | 313.5 | 2.5 | 1714.2 | 13.5 |
| 2 | 59.7 | 0.5 | 313.1 | 2.5 | 575.4 | 4.5 | 948.2 | 7.5 |
| 3 | 64.3 | 0.5 | 99.2 | 0.8 | 70.4 | 0.6 | 234.0 | 1.8 |
| Sub-Total Group II | 431.6 | 3.4 | 1505.4 | 11.9 | 959.3 | 7.6 | 2896.3 | 22.9 |
| III | 58.4 | 0.5 | 213.3 | 1.7 | 144.6 | 1.1 | 416.3 | 3.3 |
| IV | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 | 0.00 |
| Total | 1944.5 | 15.4 | 6762.8 | 53.4 | 3952.3 | 31.2 | 12659.6 | 100.00 |

Note: VS stands for "very small," S stands for "small," and L stands for "large." Totals may not add due to rounding.

Matching up Percent of Establishments With Their Share of First Year Total Cost Impacts

The establishment data from Table 3 was broken down in a similar way as Table 4 above. That is, they were broken down by very small, small, and large size categories as a percent of the total number of establishments. This establishment population distribution (as reported in columns 3, 5, 7, and 9 in Table 5) was then combined with the distribution of the first-year industry-

wide direct cost impacts from Table 4 (as reported in columns 4, 6, 8, and 10 in Table 5). In effect, Table 5 pairs each product group's percent of total establishments with its share of total first-year industry-wide economic impact. For example, the bottom line in Table 5 reveals that very small establishments comprise 32 percent of all RTE establishments and absorbs 15.4 percent of total first-year industry-wide economic impact (as was reported in Table 4).

Table 5 reveals that large establishments, on an establishment basis, bear a disproportionate share of the total regulatory cost. That is, they constitute less than 10 percent of the establishments and yet absorb over 31.2 percent of the first year total direct cost impacts. Most of these impacts are incurred by large Group I establishments, mainly to satisfy the performance standard requirements of the proposed rule.

TABLE 5.—PERCENT OF TOTAL ESTABLISHMENTS AND THEIR SHARE OF FIRST-YEAR TOTAL DIRECT COST IMPACTS

| Group and sub-group | The percent of total establishments and total impact by establishment size | | | | | | | |
|---------------------------|--|--------|----------------|--------|----------------|--------|----------------|--------|
| | Very small | | Small | | Large | | All sizes | |
| | Establishments | Impact | Establishments | Impact | Establishments | Impact | Establishments | Impact |
| I: | | | | | | | | |
| 1 | 4 | 7.4 | 5 | 24.6 | 1 | 14.6 | 10 | 46.6 |
| 2 | 3 | 0.7 | 6 | 2.5 | 1 | 1.5 | 10 | 4.7 |
| 3 | 2 | 2.4 | 3 | 9.8 | 0 | 3.2 | 5 | 15.4 |
| 4 | 4 | 0.9 | 6 | 3.1 | 1 | 3.3 | 11 | 7.2 |
| Sub-Total Group I | 13 | 11.5 | 20 | 39.8 | 3 | 22.5 | 36 | 73.8 |
| II: | | | | | | | | |
| 1 | 12 | 2.4 | 21 | 8.6 | 1 | 2.5 | 34 | 13.5 |
| 2 | 1 | 0.5 | 5 | 2.5 | 4 | 4.5 | 10 | 7.5 |
| 3 | 3 | 0.5 | 2 | 0.8 | 0 | 0.6 | 5 | 1.8 |
| Sub-Total Group II | 16 | 3.4 | 28 | 11.9 | 5 | 7.6 | 49 | 22.8 |
| Sub-Total Group III | 2 | 0.5 | 4 | 1.7 | 0 | 1.1 | 6 | 3.3 |
| Sub-Total Group IV | 1 | 0.0 | 7 | 0.0 | 1 | 0.0 | 9 | 0.0 |
| Total | 32 | 15.4 | 59 | 53.4 | 9 | 31.2 | 100 | 100 |

Totals may not add due to rounding.

Per-Establishment Impact Estimates

FSIS realizes that the proposed rule has a unique impact on each establishment. Some establishments are already meeting the performance standards and some probably not; some establishments are conducting

environmental tests for *Listeria* and have a *Listeria*-related CCP; some do not. The following tables attempt to put the aggregate impact of the proposed rule on an individual establishment basis. This sheds additional light on the distributional impact across establishment size. By so doing, a

different picture on the relative impact on different size establishments comes into view. Keep in mind that the estimates below are made on an affected establishment basis, not on a purely product group average basis.

Performance Standards

For the 28 very small, 44 small, and 3 large establishments in Group I potentially affected by the proposed rule, performance standards may necessitate that these establishments incur an additional \$40,210, \$89,380 and \$630,140 per firm in the first year for each size establishment, respectively (Table 6).

Most of these expected expenditures reflect increased treatment costs. These per firm costs, multiplied by the number of affected firms, produce an industry-wide, first-year cost impact of approximately \$7.1 million (Table 6). The estimation of these costs is further explained in Appendix 1 in the sections entitled "A. Projected Costs Associated with Production Adjustments" and "B. Projected Costs Associated with Performance Standard Validation." FSIS acknowledges that due to a lack of available data, the total costs of the proposed performance standards may be underestimated. See the section in Appendix 1 entitled "Uncertainty: Cost Side" for further discussion of the uncertainty around these estimated costs.

Mandatory Testing Requirements:

Mandatory food contact surface 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 and the degree to which firms will be able to resolve their *Listeria*-related problems if they present themselves. Depending on the individual establishment, this provision of the proposed rule could necessitate small establishments incurring an additional \$5,000 (to establish a *Listeria*-related CCP) or an additional \$3,400 in environmental testing, and possibly as high as a \$6,200 cost to resolve any *Listeria*-related problems. Large establishments are expected to meet this requirement by either having or incorporating a CCP addressing *Listeria* in their HACCP plan at a cost of \$5000. Very small establishment could incur an additional \$5000 cost (in CCP validation) or an additional \$840 in environmental testing and possibly a \$3200 cost in resolving their *Listeria*-

related problems. Nineteen large establishments are expected to incur an \$81,900 to implement measures to resolve their *Listeria*-related problems.

Summary

In the aggregate, large establishments incur a disproportionate share of the total industry-wide impact. This result is due to the volume-based costs associated with performance standards. On an individual establishment basis, the proposed rule still presents a substantial potential cost increase for very small and small establishments. Efforts to reduce validation costs on CCPs addressing *Listeria* and performance standards could afford this group of establishments with great financial relief. The treatment costs related to the performance standards is also an important driver in this analysis: this cost estimate is based on limited information at this time. Also, the flexibility afforded producers by the proposed rule may mean that new, more cost-effective, technology may be adopted in a relatively short time period and lower these costs. Such assumptions could not be incorporated in this analysis at this time.

TABLE 6.—DISTRIBUTIONAL ECONOMIC COST OF PERFORMANCE STANDARDS IN PROPOSED RULE

| Group and sub-group | Per establishment cost impact (000's \$ per establishment) | | | | Number of establishments affected (number) | | | | Industry-wide impacts (000's \$) | | | | |
|------------------------|---|------|-------|-------|---|----|---|-----|-------------------------------------|--------|---------|----------|--|
| | VS | S | L | All | VS | S | L | All | VS | S | L | Total | |
| I: | | | | | | | | | | | | | |
| 1 | 45 | 100 | 650 | 108.4 | 19 | 28 | 3 | 50 | 854.15 | 2830.5 | 1731.6 | 5416.25 | |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.00 | 0 | 0 | 0.00 | |
| 3 | 30 | 70 | 550 | 68.4 | 9 | 16 | 1 | 25 | 267.30 | 1085.7 | 363.0 | 1716.00 | |
| 4 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.00 | 0 | 0.00 | 0.00 | |
| SubTotal Group I | 40.2 | 89.4 | 630.1 | 95.1 | 28 | 44 | 3 | 75 | 1121.45 | 3916.2 | 2094.60 | 7132.25 | |
| II: | | | | | | | | | | | | | |
| 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| III: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| IV: | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | |
| Total | 40.2 | 89.4 | 630.1 | 95.1 | 28 | 44 | 3 | 75 | 1121.45 | 3916.2 | 2094.6 | 7132.245 | |

Totals may not add due to rounding.

TABLE 7.—DISTRIBUTIONAL ECONOMIC COST OF ADDITIONAL TESTING ASSOCIATED WITH MANDATORY LISTERIA TESTING PROVISION IN PROPOSED RULE.

| Group and sub-group | Per establishment cost impact (000's \$ per establishment) | | | | Number of establishments affected (number) | | | | Industry-wide impacts (000's \$) | | | | |
|---------------------|---|-----|---|-----|---|-----|---|-----|-------------------------------------|-------|-----|-------|--|
| | VS | S | L | All | VS | S | L | All | VS | S | L | Total | |
| I: | | | | | | | | | | | | | |
| 1 | .84 | 3.4 | 0 | 2.1 | 46 | 43 | 0 | 88 | 38.3 | 142.8 | 0.0 | 181.1 | |
| 2 | .84 | 3.4 | 0 | 2.1 | 45 | 47 | 0 | 92 | 37.6 | 157.9 | 0.0 | 195.5 | |
| 3 | .84 | 3.4 | 0 | 2.1 | 22 | 23 | 0 | 45 | 18.1 | 79.0 | 0.0 | 97.1 | |
| 4 | .84 | 3.4 | 0 | 2.1 | 51 | 53 | 0 | 104 | 43.0 | 176.4 | 0.0 | 219.4 | |
| II: | | | | | | | | | | | | | |
| 1 | .84 | 3.4 | 0 | 2.1 | 160 | 170 | 0 | 330 | 134.4 | 569.5 | 0.0 | 703.9 | |
| 2 | .84 | 3.4 | 0 | 2.5 | 20 | 40 | 0 | 60 | 16.8 | 132.7 | 0.0 | 149.5 | |
| 3 | .84 | 3.4 | 0 | 1.6 | 34 | 15 | 0 | 48 | 28.2 | 48.7 | 0.0 | 76.9 | |
| III | .84 | 3.4 | 0 | 2.2 | 28 | 31 | 0 | 59 | 23.5 | 104.2 | 0.0 | 127.7 | |

TABLE 7.—DISTRIBUTIONAL ECONOMIC COST OF ADDITIONAL TESTING ASSOCIATED WITH MANDATORY LISTERIA TESTING PROVISION IN PROPOSED RULE.—Continued

| Group and sub-group | Per establishment cost impact (000's \$ per establishment) | | | | Number of establishments affected (number) | | | | Industry-wide impacts (000's \$) | | | |
|---------------------|---|-----|---|-----|---|-----|---|-----|-------------------------------------|--------|-----|--------|
| | VS | S | L | All | VS | S | L | All | VS | S | L | Total |
| IV | 0 | 0 | 0 | 0.0 | 0 | 0 | 0 | 0 | 0 | 0 | 0.0 | 0 |
| Total | .84 | 3.4 | 0 | 2.1 | 405 | 420 | 0 | 825 | 340.0 | 1411.2 | 0.0 | 1751.2 |

Totals may not add due to rounding.

TABLE 8.—DISTRIBUTIONAL ECONOMIC COST OF HACCP VALIDATION ASSOCIATED WITH LISTERIA MONOCYTOGENES CONTROLS IN PROPOSED RULE

| Group and sub-group | Per establishment cost impact (000's \$ per establishment) | | | | Number of establishments affected (number) | | | | Industry-wide impacts (000's \$) | | | |
|--------------------------|---|-----|-----|-----|---|-----|----|-----|-------------------------------------|-------|--------|--------|
| | VS | S | L | All | VS | S | L | All | VS | S | L | Total |
| I: | | | | | | | | | | | | |
| 1 | 5.0 | 5.0 | 5.0 | 5.0 | 6 | 14 | 4 | 24 | 28.5 | 70.8 | 20.00 | 119.3 |
| 2 | 5.0 | 5.0 | 5.0 | 5.0 | 6 | 16 | 9 | 30 | 28.0 | 78.3 | 42.50 | 148.8 |
| 3 | 5.0 | 5.0 | 5.0 | 5.0 | 3 | 8 | 1 | 12 | 13.5 | 39.2 | 5.00 | 57.67 |
| 4 | 5.0 | 5.0 | 5.0 | 5.0 | 6 | 18 | 11 | 35 | 32.0 | 87.5 | 55.00 | 174.50 |
| Sub-Total—Group I | 5.0 | 5.0 | 5.0 | 5.0 | 20 | 55 | 25 | 100 | 102.0 | 275.8 | 122.50 | 500.30 |
| II: | | | | | | | | | | | | |
| 1 | 5.0 | 5.0 | 5.0 | 5.0 | 20 | 57 | 6 | 83 | 100.0 | 282.5 | 30.0 | 412.5 |
| 2 | 5.0 | 5.0 | 5.0 | 5.0 | 3 | 13 | 30 | 46 | 12.5 | 65.8 | 150.0 | 228.3 |
| 3 | 5.0 | 5.0 | 5.0 | 5.0 | 4 | 5 | 3 | 12 | 21.0 | 24.2 | 12.5 | 57.7 |
| Sub-Total—Group II | 5.0 | 5.0 | 5.0 | 5.0 | 27 | 75 | 39 | 14 | 133.5 | 372.5 | 192.5 | 698.5 |
| III | 5.0 | 5.0 | 5.0 | 5.0 | 4 | 10 | 4 | 17 | 17.5 | 51.7 | 17.5 | 86.7 |
| IV | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 5.0 | 5.0 | 5.0 | 5.0 | 51 | 140 | 67 | 257 | 253 | 700 | 332.5 | 1285.5 |

Numbers may not add due to rounding.

TABLE 9.—DISTRIBUTIONAL ECONOMIC COST OF PRODUCTION EFFECT 1 AND 2 ASSOCIATED WITH THE MANDATORY LISTERIA TESTING PROVISIONS IN PROPOSED RULE

| Group and sub-group | Per establishment cost impact (000's \$ per establishment) | | | | Number of establishments affected (number) | | | | Industry-wide impacts (000's \$) | | | |
|--------------------------|---|------|-------|------|---|-----|----|-----|-------------------------------------|-------|---------|---------|
| | VS | S | L | All | VS | S | L | All | VS | S | L | Total |
| I: | | | | | | | | | | | | |
| 1 | 2.7 | 5.4 | 85.5 | 8.65 | 8 | 12 | 1 | 21 | 21.53 | 64.3 | 95.80 | 181.63 |
| 2 | 3.0 | 5.9 | 61.6 | 10.6 | 2 | 13 | 2 | 23 | 23.96 | 77.5 | 146.71 | 248.17 |
| 3 | 2.5 | 4.8 | 111.6 | 6.8 | 4 | 7 | 0 | 11 | 9.41 | 31.9 | 31.20 | 72.51 |
| 4 | 4.4 | 8.3 | 116.1 | 19.4 | 9 | 15 | 3 | 27 | 39.1 | 122.4 | 357.50 | 519.00 |
| Sub-Total—Group I | 3.3 | 6.4 | 92.0 | 12.5 | 29 | 46 | 7 | 82 | 94 | 296.1 | 631.21 | 1021.31 |
| II: | | | | | | | | | | | | |
| 1 | 2.6 | 5.1 | 168.8 | 7.7 | 28 | 47 | 2 | 77 | 73.1 | 241.1 | 283.5 | 597.7 |
| 2 | 8.7 | 10.4 | 50.6 | 24.8 | 4 | 11 | 8 | 23 | 30.44 | 114.5 | 425.4 | 570.34 |
| 3 | 2.6 | 6.5 | 82.7 | 9.3 | 6 | 4 | 1 | 11 | 15.1 | 26.3 | 57.9 | 99.3 |
| Sub-Total—Group II | 3.2 | 6.1 | 71.1 | 11.4 | 37 | 63 | 11 | 111 | 118.64 | 381.9 | 766.8 | 1267.34 |
| III | 3.5 | 6.6 | 129.7 | 13.8 | 5 | 9 | 1 | 15 | 17.4 | 57.4 | 127.1 | 201.9 |
| IV | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Total | 3.2 | 6.2 | 81.9 | 12.0 | 71 | 118 | 19 | 207 | 230.02 | 735.4 | 1525.20 | 2490.65 |

Totals may not add due to rounding.

XIII. Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. States and local jurisdictions are preempted by the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (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 and 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 and 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.

If this proposed rule is adopted, administrative proceedings will not be required before parties may file suit in court challenging this rule. However, the administrative procedures specified in 9 CFR 306.5 and 381.35 must be exhausted prior to any judicial challenge of the application of the provisions of this proposed rule, if the challenge involves any decision of an FSIS employee relating to inspection services provided under the FMIA or PPIA.

XIV. Risk Analysis

Section 304 of the Federal Crop Insurance Reform and Department of Agriculture Reorganization Act of 1994 (P.L. 103-354) requires any regulation published by USDA concerning human health, safety, or the environment, and having an annual economic impact of at least \$100 million in 1994 dollars, contain a risk assessment and cost-benefit analysis. The risk assessment and cost-benefit analysis must be "performed consistently and use reasonably obtainable and sound scientific, technical, economic, and other data." The USDA Office of Risk Assessment and Cost-Benefit Analysis (ORACBA), also established by the 1994 Act, must ensure that major rules include such analyses.

Although the initial costs of compliance with the proposed regulations may be less than \$100 million, they also may exceed \$100 million. FSIS estimates that over an undetermined, but relatively short period of time, the benefits of the regulations also should exceed this amount. In the economic analysis required under E. O. 12866, FSIS estimates that after 10 years, 868 to 8,632 cases of listeriosis may be eliminated as a result of this rule (see Appendix 1). Consequently, FSIS believes that the proposed regulations are subject to the Reorganization Act requirements for a risk assessment and cost-benefit analysis.

FSIS and ORACBA have agreed that the cost-benefit and economic impact analyses that FSIS has performed for this proposed rule, as required by E.O. 12866 and the Regulatory Flexibility Act, satisfy the cost-benefit analysis requirements of the Reorganization Act. Regarding the required risk assessment, FSIS is presenting several different documents to support different provisions of the proposed regulations.

To support the proposed lethality performance standard for the elimination of *E. coli* O157:H7 from fermented RTE products that contain beef, FSIS cites its draft "Risk Assessment of the Public Impact of

Escherichia coli O157:H7 in Ground Beef" (Ref. 1, available for viewing by the public in the FSIS Docket Room). As discussed above, this document shows that levels of *E. coli* O157:H7 in cattle represent a risk to consumers of ground beef, and that, unless there is a significant intervention on the farm or during processing, the risk is likely to remain. Use of this draft risk assessment to develop the performance standard for fermented products containing beef is discussed above in detail in the sections "Derivation of the Proposed Lethality Performance Standards" and "Fermented Products."

To support the other proposed lethality performance standards, except for the lethality standards applicable to commercially sterile meat and poultry products, and to support the proposed stabilization performance standards, FSIS used its Nationwide Microbiological Baseline Data Collection Programs and Nationwide Federal Plant Microbiological Surveys (Ref. 3, available for viewing by the public in the FSIS Docket Room), as well as its technical analysis of those surveys (Ref. 2, available for viewing by the public in the FSIS Docket Room). Within the technical analysis, FSIS developed models using the baseline and survey data to define a worst case raw product (the highest initial levels of *Salmonella* found in the data from the microbiological surveys), and then calculate the probability distribution for the number of surviving *Salmonella* organisms in 100 grams of finished product for various specific lethality reductions. Lethality performance standards then were selected that provided low probabilities of surviving organisms in finished worst case product. Most, if not all, RTE meat and poultry products will be manufactured from the same supply of raw product examined in the FSIS national baseline surveys. So, using performance standards that would render any hypothetical, worst case raw product safe should be applicable to all categories of RTE meat and poultry products.

To support the proposed environmental testing requirements for *Listeria spp.*, FSIS uses the draft interagency risk assessment concerning foodborne *Listeria monocytogenes* (Ref. 28, available for viewing by the public in the FSIS Docket Room). As discussed above in the section entitled "Proposed Requirements for Controlling *L. monocytogenes*," this draft risk assessment indicates that many of the meat and poultry products affected by these regulations (deli meat, frankfurters, meat and poultry-based

deli salads, and pâté) pose relatively high risks to consumers because of potential recontamination by *L. monocytogenes* after lethality is applied and before final product packaging.

XV. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. FSIS provides a weekly FSIS Constituent Update via fax to over 300 organizations and individuals. In addition, the update is available on line through the FSIS web page located at <http://www.fsis.usda.gov>. The update is used to provide information regarding 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. The constituent fax list consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals that have requested to be included. Through these various channels, FSIS is able to provide information to a much broader, more diverse audience than would be otherwise possible. For more information or to be added to the constituent fax list, fax your request to the Congressional and Public Affairs Office, at (202) 720-5704.

XVI. Paperwork Requirements

Paperwork Requirements

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995, the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB).

Abstract: FSIS has reviewed the paperwork and recordkeeping requirements in this proposed rule in accordance with the Paperwork Reduction Act. Establishments producing RTE product would make modifications to their HACCP plans. Also, establishments that produce RTE product and who do not identify *L. monocytogenes* as a hazard reasonably likely to occur, must perform tests for *Listeria spp.* to verify that their Sanitation SOPs are preventing direct contamination or adulteration of product. Establishments would need to maintain these results. The proposed revisions to the labeling requirements in §§ 317.2 and 381.125 would effect generically approved labels and so do not constitute a paperwork burden.

Estimate of Burden: FSIS estimates that 1,630 establishments will produce paperwork and recordkeeping as a result

of this rulemaking. Because the Agency does not know how an establishment will decide to implement certain requirements of this rule, that is some may modify their HACCP plans and others may chose to test product, FSIS used the total of 1,630 to make its burden estimates for each paperwork and recordkeeping activity. The Agency estimates that it will take 8 hours for an establishment to reassess their HACCP plans for a total burden of 13,040 hours. The Agency estimates that an establishment will spend about 5 minutes a day (250 days) completing 1 monitoring record for each new CCP for a total burden of 33,958 hours and 2 minutes a day filing the resulting record for a total of 13,583 hours. FSIS assumes each establishment will develop one new CCP. For an establishment testing products for *Listeria* spp., FSIS estimates it will take an establishment 30 minutes a day to collect the information and file the records for a total of 203,750 hours.

Respondents: Meat and poultry product establishments.

Estimated Number of Respondents: 1,630.

Estimated Number of Responses per Respondents: 502.

Estimated Number of Responses: 818,260.

Estimated Total Annual Burden on Respondents: 264,708.

Copies of this information collection assessment can be obtained from Lee Puricelli, Paperwork Specialist, Food Safety and Inspection Service, USDA, Room 109 Cotton Annex, Washington, DC 20250-3700.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information including the validity of the method and the assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on those who are to respond; including through use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology. Comments may be sent to Lee Puricelli, see the address above, and to the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) Washington, DC 20253. A comment to OMB is best assured of having its full

effect if OMB receives is within 30 days of publication of this proposed rule.

VII. References

The following sources are referred to in this document. All have been placed on display in the FSIS Docket Room (address above) and may be seen by interested persons between 8:30 a.m. and 4:30 p.m., Monday through Friday.

1. FSIS Office of Public Health and Science, "Draft Risk Assessment of the Public Health Impact of *Escherichia coli* O157:H7 in Ground Beef, 2000.
2. Ahmed, N. M., D. E. Conner, and D.L. Huffinan, "Heat-resistance of *Escherichia coli* O157:H7 in meat and poultry as affected by product composition," *Journal of Food Science*, 60(3): 606-610, 1995.
3. FSIS, "Lethality and Stabilization Performance Standards for Certain Meat and Poultry Products: Technical Paper," 1998.
4. FSIS, Microbiological Baseline Data Collection Program reports and Microbiological Surveys, 1994-1996.
5. American Gastroenterological Association, "Consensus Conference Statement: *Escherichia coli* O157:H7 Infections-An Emerging National Health Crisis, July 11-13, 1994," *Gastroenterology*, 108(6):1923-1934, 1995.
6. Wells, J. G., et al., "Laboratory Investigation of Hemorrhagic Colitis Outbreaks Associated with a Rare *Escherichia coli* Serotype," *Journal of Clinical Microbiology*, 18:512-520, 1983.
7. Todd, E.C.D., et al., "Rapid Hydrophobic Grid Membrane Filter-Enzyme-Labeled Antibody Procedure for Identification and Enumeration of *Escherichia coli* O157 in Foods," *Applied Environmental Microbiology*, 54:2536-2540, 1988.
8. Harrison, J.A. and M. A. Harrison, "Fate of *Escherichia coli* O157:H7, *Listeria monocytogenes*, and *Salmonella typhimurium* during preparation and storage of beef jerky," *Journal of Food Protection*, 59:1336-1338, 1996.
9. Harrison, J. A., M. A. Harrison, and R.A. Rose, "Fate of *Listeria monocytogenes* and *Salmonella* species in ground beef jerky," *Journal of Food Protection*, 60:9:1139-1141, 1997.
10. Harrison, J. A., M. A. Harrison, and R.A. Rose, "Survival of *Escherichia coli* O157:H7 in ground beef jerky assessed on two plating media *Journal of Food Protection*," 61:11:13., 1998.
11. CDC, Morbidity and Mortality Weekly Report, 44:785-788, 1995.
12. Keene, W.E., et al., "An outbreak of *Escherichia coli* O157:H7 infections traced to jerky made from deer meat," *Journal of the American Medical Association*, 277:15:1229-1231, 1997.
13. Tompkin, R. B., "Microbiology of ready-to-eat meat and poultry products," pp. 89-121, in *Advances in Meat Research*, volume 2, A. M. Pearson and T.R. Dutson, eds., AVI Publishing Co., Westport, CT., 1986.
14. Gonzalez-Helva, M.A., M.F. Gutierrez, and M.C. Mendoza, "Diagnosis by a combination of typing methods of a *Salmonella typhimurium* outbreak associated with cured ham," *Journal of Food Protection*, 59:426-428, 1996.
15. Mete, R., R. R. Fichera, and P. Chierchini, "Episodio di tossinfezione alimentare da *Salmonella* C2 trasmessa da prosciutto," *Nuovi Annali d'Igiene e Microbiologia*, 38:219-224, 1987.
16. CDC, Morbidity and Mortality Weekly Report, 44(9):157-160, 1995.
17. FSIS Epidemiology and Emergency Response Program, "Outbreak Report: *Salmonella* in Lebanon Bologna," May 22, 1996.
18. Haymon, L.W., "Fermented sausage," pp. 237-245, in *Industrial Microbiology*, 4th Edition, Prescott and Dunn, eds., AVI Publishing Co., Westport, CT., 1982.
19. Tatini, S. R., "Influence of food environments on growth of *Staphylococcus aureus* and production of enterotoxins," *Journal of Milk Food Technology*, 36(11):559-563, 1973.
20. Smith, J.L., et al., "Survival of *Salmonella dublin* and *Salmonella typhimurium* in Lebanon bologna," *Journal of Milk Food Technology*, 38(3):150-154, 1975.
21. Bacus, J., "Processing procedures to control *Salmonella* and *E. coli* in fermented sausage products," *Food Australia*, 49(11):543-7, 1997.
22. Ellajosyula, K.R., et al., "Destruction of *E. coli* O157:H7 and *Salmonella typhimurium* in Lebanon bologna by interaction of fermentation pH, heating temperature and time," *Journal of Food Protection*, 61(2):152-157, 1998.
23. Faith, N.G., et al., "Viability of *Escherichia coli* O157:H7 in pepperoni during the manufacture of sticks and the subsequent storage of slices at 21, 4 and -20C under air vacuum and CO₂," *International Journal of Food Microbiology*, 37:47-54, 1997.
24. Glass, K.A., et al., *Applied Environmental Microbiology*, Fate of *Escherichia coli* O157:H7 as affected by pH or sodium chloride and in fermented, dry sausage, 58(8):2513-2516, 1992.
25. Labbe, R., "*Clostridium perfringens*," pp. 210 and 213, in *Food borne Bacterial Pathogens*, M. Doyle (ed.), Marcel Dekker, Inc., New York, 1989.
26. Hauschild, A., "Criteria and Procedures for Implicating *Clostridium Perfringens* in Food-borne Outbreaks," *Canadian Journal of Public Health*, 66:388-392, 1975.
27. McClane, B.A., "*Clostridium Perfringens* Enterotoxin: Structure, Action, and Detection," *Journal of Food Safety*, 12:237-252, (1992).
28. Center for Food Safety and Applied Nutrition, FDA, and FSIS, "Draft Risk Assessment of the Public Health Impact of Foodborne *Listeria monocytogenes*," January 19, 2001.
29. Tompkin, R. Bruce, et al., "Guidelines to Prevent Post-Processing Contamination from *Listeria Monocytogenes*," *Dairy, Food, and Environmental Sanitation*, 8:552, 1999.
30. Pflug, I.J., T.E. Odlaug, "A review of z and F values used to ensure the safety of low-acid canned food," *Food Technology*, 32:63-70, 1978.
31. Pflug, I.J., "Calculating F_T values for heat preservation of shelf-stable, low-acid

canned foods using the straight-line semilogarithmic model," *Journal of Food Protection*, 50:608-620, 1987.

32. Beumer, R. R., Mc C. te Giffel, E. de Boer, and F. M. Rombouts. 1996. Growth of *Listeria monocytogenes* on sliced cooked meat products. *Food Microbiology* 13: 333-340.
33. Centers for Disease Control and Prevention. 1999. Update: Multi-state outbreak of listeriosis—United States, 1998-1999. *Morbidity and Mortality Weekly Report* 47(50): 1117-1118.
34. Anderson, G., Contra Costa County Health Department, San Francisco Department of Public Health, L. Mascola, G. W. Rutherford, M. S. Rados, R. Hutchenson, P. Archer, P. Zenker, C. Harvey, J. D. Smith, and CDC. 1992. Update: Foodborne listeriosis—United States, 1988-90, pages 251, 257-258, *Morbidity and Mortality Weekly Report*.
35. Office of Inspector General, USDA. June 2000. FSIS Implementation of HACCP, Report No. 24001-3-At.

XVIII. Proposed Regulations

List of Subjects

9 CFR Part 301

Meat inspection.

9 CFR Part 303

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 317

Food labeling.

9 CFR Part 318

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 319

Food grades and standards, Food labeling, Frozen foods, Meat inspection, Oils and fats.

9 CFR Part 320

Meat inspection, Reporting and recordkeeping requirements.

9 CFR Part 325

Meat inspection, Reporting and recordkeeping requirements, Transportation.

9 CFR Part 331

Intergovernmental regulations, Meat inspection.

9 CFR Part 381

Poultry and poultry products inspection, Reporting and recordkeeping requirements.

9 CFR Part 417

Meat inspection, Poultry and poultry products inspection, Reporting and recordkeeping requirements.

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:

PART 301—DEFINITIONS

1. The authority citation for part 301 would continue to read as follows:

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

2. Section 301.2 would be amended by removing the definitions for "Process authority" and "Process schedule."

PART 303—EXEMPTIONS

3. The authority citation for part 303 would continue to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

4. In § 303.1(f), the second sentence would be removed.

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

5. The authority citation for part 317 would continue to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

6. In § 317.2, paragraph (k) and the introductory text of paragraph (l) would be revised to read as follows:

§ 317.2 Labels: definition; required features.

* * * * *

(k) Packaged products which require special handling to maintain their wholesome condition must have prominently displayed on the principal display panel the statement: "Keep Refrigerated," "Keep Frozen," "Perishable Keep Under Refrigeration," or "Refrigerate after Opening," as applicable, or such similar statement as the Administrator may approve in specific cases. Products that are distributed frozen during distribution shall bear the statement on the shipping container: "Keep Frozen." The consumer-size containers for such products that are thawed prior to or during display for sale at retail shall bear the statement "Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated." For all perishable canned products the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for containers having a net weight over 3 pounds, the statement shall be in upper case letters at least one-half inch in height.

(l) Safe handling instructions shall be provided for: All meat and meat products of cattle, swine, sheep, goat, horse, or other equine that do not meet the requirements contained in 9 CFR 430.2 and 430.3(a), except as exempted under paragraph (l)(4) of this section.

* * * * *

PART 318—ENTRY INTO OFFICIAL ESTABLISHMENTS; REINSPECTION AND PREPARATION OF PRODUCT

7. The authority citation for part 318 would continue to read as follows:

Authority: 7 U.S.C. 138f, 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

8. Section 318.10 would be removed and reserved.

9. Section 318.17 would be removed and reserved.

10. Section 318.23 would be removed and reserved.

11. Subpart G (§§ 318.300 through 318.311) would be removed.

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

12. The authority citation for part 319 would continue to read as follows:

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

13. In § 319.106, paragraph (b) would be removed; paragraph (c) would be redesignated as paragraph (b); and paragraph (d) would be redesignated as paragraph (c).

14. In § 319.145, paragraph (a)(2) would be amended by removing the third sentence.

PART 320—RECORDS, REGISTRATION, AND REPORTS

15. The authority citation for part 320 would continue to read as follows:

Authority: 21 U.S.C. 601-695; 7 CFR 2.18, 2.53.

16. In § 320.1, paragraph (b)(6) and (b)(7) would be removed; paragraph (b)(8) would be redesignated as (b)(6); paragraph (b)(9) would be redesignated as (b)(7); paragraph (b)(10) would be redesignated as (b)(8); and paragraph (b)(11) would be redesignated as (b)(9).

PART 325—TRANSPORTATION

17. The authority citation for part 325 would continue to read as follows:

Authority: 7 U.S.C. 450, 1901-1906; 21 U.S.C. 601-695; 7 CFR 2.17, 2.55.

18. In § 325.7, paragraph (a) would be amended by removing the phrase, "pork that has been refrigerated to destroy *trichina*,".

PART 331—SPECIAL PROVISIONS FOR DESIGNATED STATES AND TERRITORIES; AND FOR DESIGNATION OF ESTABLISHMENTS WHICH ENDANGER PUBLIC HEALTH AND FOR SUCH DESIGNATED ESTABLISHMENTS

19. The authority citation for part 331 would continue to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.17, 2.55.

20. In § 331.5, paragraph (a)(1)(ii) would be amended to remove the phrase, “or it is a ready-to-eat pork product which has not been treated to destroy *trichinae* as prescribed in § 318.10 of this subchapter for products at federally inspected establishments; or”.

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

21. The authority citation for part 381 would continue to read as follows:

Authority: 7 U.S.C. 138f, 450; 21 U.S.C. 451–470; 7 CFR 2.18, 2.53.

22. Section 381.1 would be amended by removing the definitions for “Process authority” and “Process schedule.”

23. In § 381.125, paragraph (a) would be revised to read as follows:

§ 381.125 Special handling label requirements.

(a) Packaged products which require special handling to maintain their wholesome condition must have prominently displayed on the principal display panel the statement: “Keep Refrigerated,” “Keep Frozen,” “Perishable Keep Under Refrigeration,” or “Refrigerate after Opening,” as applicable, or such similar statement as the Administrator may approve in specific cases. Products that are distributed frozen during distribution shall bear the statement on the shipping container: “Keep Frozen.” The consumer-size containers for such products that are thawed prior to or during display for sale at retail shall bear the statement “Previously Handled Frozen for Your Protection, Refreeze or Keep Refrigerated.” For all perishable canned products the statement shall be shown in upper case letters one-fourth inch in height for containers having a net weight of 3 pounds or less, and for

containers having a net weight over 3 pounds, the statement shall be in upper case letters at least one-half inch in height.

* * * * *

24.–25. In § 381.125, the introductory text of paragraph (b) would be amended by removing the phrase “§ 381.150(a) or that have not undergone other processing that would render them ready-to-eat” and by adding the phrase “9 CFR 430.2 and 430.3(a)” in its place.

26. Section 381.150 would be removed.

27. In § 381.175, paragraph (b)(3) would be removed; paragraph (b)(4) would be redesignated as (b)(3); paragraph (b)(5) would be redesignated as (b)(4); and paragraph (b)(6) would be redesignated as (b)(5).

28. Subpart X (§§ 381.300 through 381.311) would be removed and reserved.

PART 417—HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

29. The authority citation for Part 417 would continue to read as follows:

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

§ 417.2 Hazard Analysis and HACCP plan.

30. Paragraph 417.2(b)(3) would be removed.

PART 430—PERFORMANCE STANDARDS

31. A new Part 430 would be established to read as follows:

PART 430—PERFORMANCE STANDARDS FOR READY-TO-EAT AND PARTIALLY HEAT-TREATED PRODUCTS

Sec.

430.1 Definitions.

430.2 Lethality.

430.3 Stabilization.

430.4 Testing for *Listeria spp.*

430.5 Thermally-processed, commercially sterile products.

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

§ 430.1 Definitions.

Acidified product. A commercially sterile and hermetically sealed product

that has been formulated or treated so that every component has a pH value of 4.6 or lower within 24 hours after completion of the thermal process unless a longer time has been validated as safe.

Commercial sterility. The condition achieved by the application of a heat, irradiation, high-pressure, or other process, alone or in combination with other ingredients or treatments, to render the product free of microorganisms capable of growing in the product at nonrefrigerated conditions (over 50 °F or 10 °C) at which the product is intended to be held during distribution and storage.

Fermented product. A meat or poultry product that is made ready-to-eat by the process in which bacterial enzymes act on organic substrates, such as carbohydrates, resulting in the production of acid (the lowering of product pH) and microbial inhibition.

Low acid product. A commercially sterile and hermetically sealed product in which any component has a pH value above 4.6.

Ready-to-eat product. A meat or poultry product that can be safely consumed without cooking or application of some other lethality treatment to destroy pathogens.

Worst case product. For purposes of the lethality requirements contained in § 430.2(a)(1), worst case raw poultry contains 6.7-log₁₀ of *Salmonella* in any 143 gram sample and worst case raw meat contains 6.2-log₁₀ of *Salmonella* in any 143 gram sample; for purposes of the lethality requirements contained in § 430.2(b)(1), worst case raw beef contains 4.4-log₁₀ of *E. coli* O157:H7 in any 143 gram sample.

§ 430.2 Lethality.

(a) (1) Processing of any meat or poultry product, except a thermally-processed, commercially sterile product, for the purpose of rendering that product ready-to-eat, must be validated to achieve probabilities no greater than the following that *Salmonella* organisms would remain in any 100 gram sample of finished product, assuming that incoming raw product is worse case product. Any detectable level of viable *Salmonella* organisms adulterates ready-to-eat meat and poultry products.

| >0 surviving | >1 surviving | >2 surviving | >3 surviving | >4 surviving |
|--------------|--------------|--------------|--------------|--------------|
| 39.4% | 9.06% | 1.45% | 0.177% | 0.0174% |

(2) Official establishments that do not wish to demonstrate that their

processing results in probabilities no greater than the probabilities in

paragraph (a)(1) of this section may instead employ processing validated to

achieve either a 6.5- \log_{10} reduction of *Salmonella* throughout a finished, ready-to-eat meat product, or, a 7- \log_{10} reduction of *Salmonella* throughout a finished ready-to-eat product that contains any amount of poultry. Any detectable level of viable *Salmonella* organisms adulterates ready-to-eat meat and poultry products.

(b)(1) In addition to meeting the standard in paragraph (a), of this section processing of any fermented meat or poultry product that contains any amount of beef, except a thermally-processed, commercially sterile product, for the purpose of rendering that product ready-to-eat, must be validated to achieve probabilities no greater than the following that *E. coli* O157:H7 organisms would remain in any 100 gram sample of finished product, assuming that incoming raw product is worst case product. Any detectable level of viable *E. coli* O157:H7 organisms adulterates ready-to-eat meat and poultry products.

| >0 surviving | >1 surviving |
|--------------|--------------|
| 22.2% | 2.67% |

(2) Official establishments that do not wish to demonstrate that their processing results in probabilities no greater than the probabilities in paragraph (b)(1) of this section may instead employ processing validated to achieve a 5- \log_{10} reduction of *E. coli* O157:H7 throughout a finished, ready-to-eat meat or poultry product that contains any amount of beef. Any detectable level of viable *E. coli* O157:H7 organisms adulterates ready-to-eat meat and poultry products.

(c) Processing of all ready-to-eat meat and poultry products, other than thermally processed, commercially sterile products, also must be validated to achieve the reduction of other pathogens and their toxins or toxic metabolites necessary to prevent product adulteration.

(d) Processing of all ready-to-eat products, other than thermally processed, commercially sterile products, must be validated to maintain the lethality performance standards throughout product shelf-life under the conditions in which the food is stored, distributed, and held.

§ 430.3 Stabilization.

(a) For all ready-to-eat meat and poultry products, other than thermally processed, commercially sterile products, processing must prevent multiplication of toxigenic microorganisms such as *Clostridium botulinum* and allow no more than 1-

\log_{10} multiplication of *Clostridium perfringens* within the product.

(b) For all meat and poultry products that receive a heat treatment but that are not ready-to-eat, processing must prevent multiplication of toxigenic microorganisms such as *C. botulinum* and allow no more than 1- \log_{10} multiplication of *C. perfringens* within the product.

(c) Processing of all ready-to-eat products, other than thermally processed, commercially sterile products, and products that are heat-treated but not ready-to-eat, must be validated to maintain the stabilization performance standards throughout product shelf-life under the conditions in which the food is stored, distributed, and held.

§ 430.4 Testing for *Listeria* spp.

(a) Each official establishment that produces one or more ready-to-eat meat or poultry products, but that has not identified *Listeria monocytogenes* as a hazard reasonably likely to occur within the HACCP plan for its ready-to-eat product and consequently established one or more controls for *L. monocytogenes* to be implemented after lethality treatment is complete, must test food contact surfaces, on which product is handled after lethality treatment but before final packaging, for *Listeria* spp. at one of the following frequencies depending on establishment size:

(1) If the plant is large (500 or more employees), at least four tests, per line of ready-to-eat product, per month;

(2) If the plant is small (10 to 499 employees), at least two tests, per line of ready-to-eat product, per month;

(3) If the plant is very small (fewer than 10 employees or annual sales of ready-to-eat products less than \$2.5 million), at least one test, per line of ready-to-eat product, per month.

(b) Results of the testing required in this section are to be used by official establishments to verify that their Sanitation Standard Operating Procedures (Sanitation SOPs), as required under 9 CFR part 416, are preventing direct contamination or adulteration of product. Results must be made available to FSIS personnel for review. In the event of a positive test result, establishments must take corrective actions under 9 CFR 416.15(a) and (b) that include the following procedures to determine and demonstrate that the affected lot or lots of product are not adulterated with *L. monocytogenes*:

(1) Procedures to determine which lot or lots of product might have been affected;

(2) Procedures to hold, sample, and test that product for *L. monocytogenes*; and

(3) Procedures to dispose of affected product.

§ 430.5 Thermally processed, commercially sterile products.

(a) For a low-acid product that receives thermal or other sporicidal lethality processing, that processing must be validated to achieve a probability of 10^{-9} that there are spores of *C. botulinum* in a container of the product that are capable of growing, or, a 12- \log_{10} reduction of *C. botulinum*, assuming an initial load of ≤ 1000 spores per container.

(b) For acidified products or products in which pathogen growth is controlled by factors other than thermal or other sporicidal processing, the processing must be validated to prevent multiplication of *C. botulinum* in the food under the conditions in which the food is stored, distributed, and held.

(c) The product must be processed to achieve commercial sterility and the container in which the product is enclosed must be hermetically sealed so as to be airtight and to protect the contents of the container against the entry of microorganisms during and after processing.

(d) All operators of processing systems for commercially sterile meat and poultry products and container closure technicians shall be under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for training supervisors of canning operations.

Done in Washington, DC on February 16, 2001.

Thomas J. Billy,
Administrator.

The following is an appendix to the preamble of the Proposed Rule.

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

Appendix 1

Executive Order 12866—Preliminary Analysis

This proposed action has been reviewed for compliance with Executive Order 12866. Because this proposed action has been determined to be economically significant for purposes of Executive Order 12866, the Office of Management and Budget has reviewed it.

Proposed Action

FSIS is proposing to amend the Federal meat and poultry inspection regulations by establishing pathogen reduction performance standards for all ready-to-eat (RTE) and all partially heat-treated meat and poultry

products. FSIS also is proposing to require establishments that produce RTE meat and poultry products to conduct food contact surface testing for *Listeria spp.* to verify that they are controlling *Listeria monocytogenes* within their processing environments. Establishments that have developed and implemented HACCP controls for *L. monocytogenes* would be exempt from these testing requirements. Finally, FSIS is proposing to eliminate its regulations that require that both RTE and not-ready-to eat pork and products containing pork be treated to destroy *trichina*; these requirements are inconsistent with HACCP and some will be unnecessary if FSIS makes final the proposed performance standards for RTE meat and poultry products.

Need for the Rule

This proposed action is compelled by recent outbreaks of foodborne illness related to the consumption of adulterated RTE meat and poultry products, as well as by the need to provide objective, measurable pathogen reduction standards that can be met by official establishments and compliance with which can be established through Agency inspection. Although FSIS routinely samples and tests some RTE products for the presence of pathogens prior to distribution, there are no specific regulatory pathogen reduction requirements for most of these products (e.g., there are no existing lethality requirements for products such as hotdogs similar to the lethality performance standards for roast beef). Except for cooked meat patties (which currently have prescriptive time and temperature requirements for lethality), roast beef products (which have the new lethality performance standards), cooked poultry (which have the new lethality performance standards), and canned meat and poultry (which have the current prescriptive process requirements), the remaining RTE meat and poultry products do not have regulation-specified criteria for establishing safe processes other than the products must not be adulterated. Therefore, to ensure the safety of these products, FSIS is proposing performance standards for RTE and partially heat-treated meat and poultry products.

The Sanitation Standard Operating Procedures (SOPs) and HACCP regulations were intentionally written to allow the regulated industry flexibility in the design of their procedures. FSIS is adding, through this proposed rule, minimum criteria to be addressed to prevent post-lethality contamination. In the Sanitation SOPs, the proposed requirements will ensure that establishments maintain minimal specific records and take specific action. If the establishment determines that a hazard is reasonably likely to occur, then the HACCP regulations will be addressed via CCPs and related performance standards, controls, and records.

Performance standards are an integral part of the HACCP systems in official meat and poultry establishments. HACCP provides the framework for industry to set up science-based process controls. Performance standards tell establishments what those controls need to achieve for their HACCP plans to be effective and provide a necessary

measure of accountability for achieving acceptable food safety. The proposed performance standards will provide meat and poultry establishments with the incentive and flexibility to adopt innovative, science-based processing procedures and controls; ensure safety for consumers; and provide objective, measurable standards, compliance with which can be determined through Agency inspection. Therefore, FSIS believes that developing HACCP systems around verifiable, objective performance standards is the most effective way for establishments to consistently produce safe, unadulterated meat and poultry products. Furthermore, by proposing performance standards for pathogens whose destruction results in the destruction of most or all other pathogens of concern, FSIS provides a reference for establishments to use in gauging the efficacy of their HACCP systems.

The proposed food-contact surface testing requirements are compelled by the recent *L. monocytogenes* outbreak attributed to contaminated hotdogs and the recent interagency draft risk assessment¹ concerning *L. monocytogenes*, which shows that there is significant opportunity for recontamination of RTE meat and poultry products during processing in the plant, after the lethality is applied. These data indicate that many establishments that produce RTE meat and poultry products are not effectively implementing Sanitation SOPs so as to prevent direct contamination of RTE meat and poultry products by *L. monocytogenes*. Therefore, FSIS is proposing to require that all establishments that produce RTE meat and poultry products conduct environmental testing of food-contact surfaces for *Listeria spp.*, after lethality treatment and before final product packaging, unless they have identified *L. monocytogenes* as a hazard reasonably likely to occur and so have incorporated into their HACCP systems one or more controls validated to eliminate it from their products. This testing will verify that an establishment's Sanitation SOPs are preventing direct product contamination by *L. monocytogenes* after the lethality treatment, thus addressing the draft risk assessment assertion and other research findings that RTE foods often are recontaminated by *L. monocytogenes* after lethality is applied.

In regard to thermally processed, commercially sterile (most often canned) meat and poultry products, the proposed standards represent regulatory reform; they replace lengthy, prescriptive regulations with performance standards that provide the same level of food safety, as well as increased flexibility for establishments to customize their processes under HACCP. *Market Failure.* Market failure occurs here because consumers cannot identify (and reward) those firms that both supply RTE products and implement the desired food safety safeguards and consequently shift consumption away from suppliers of products that may present a threat to public

health. These lower cost firms may not apply the most effective pathogen prevention methods and could be supplying a product that could lead to illness or death. Two main problems exist in many cases: lack of definitive cause and effect between consumption of the product in question and the illness or death (information gathering of epidemiological evidence) and difficulty in identifying the source of the original contamination (technical trace-back capabilities). Clearly, no individual consumer who may be stricken with a foodborne illness would have the means to overcome these two problems. The proposed rule tries to remedy this market failure. This is particularly true at this time with respect to *L. monocytogenes*.

Baseline

The most recent year in which both listeriosis cases and economic background information on the affected industries are available is 1997. The baseline analysis assumes that if no regulatory-induced producer actions took place, these baseline values would persist annually over a 10-year period. The analysis then proceeds by introducing only those changes that are projected to occur as a result of provisions of the proposed rule. Once these provisions come into effect, benefits accrue in the form of gradually reduced annual numbers of listeriosis cases and deaths, while costs are registered in the form of higher compliance and operating costs. This *ceteris paribus* assumption (all else held constant while allowing for a change in one variable at a time) and use of a static baseline avoids the thorny issue of forecasting the nature and magnitude of non-regulatory induced industry and food safety changes over this period not related to changes in regulatory requirements. Both the *ceteris paribus* assumption and the static baseline are standard analytical techniques used in economic analysis.² Section A discusses the nature of the industries likely affected by the proposed rule (numbers and size of establishments and type of products produced). This discussion is followed by a discussion of the current regulatory environment that these establishments operate within. Section C presents the baseline level of listeriosis cases and deaths which anchors the expected benefits of the proposed rule.

A. The Nature of the Industries Affected and Current Industry Practices

The 1997 Census of Manufacturers identifies 1630 establishments that could be affected by the proposed rule. For this analysis, these establishments are broken down into four broad groups differentiated by the estimated costs of compliance with all of the proposed provisions. The groups that would incur the greatest costs include establishments that may have to revise their HACCP plans and Sanitation SOPs in order to comply with both the proposed performance standards and testing requirements. The number of establishments,

¹ Center for Food Safety and Applied Nutrition, FDA, and FSIS, "Draft Risk Assessment of the Public Health Impact of Foodborne *Listeria monocytogenes*," January 19, 2001.

² Samuelson and Nordhaus, Economics, 16th Edition, McGraw Hill Publishers, 1998.

the types of products shipped, and value of shipments of these groups are summarized below (Table 1). The total value of shipments of all of the products in 1997 totaled around \$28 billion.³

These groups are further broken down into sub-groups where appropriate.

The main product groups (and sub-groups, if appropriate) are:

Group I, those entities that likely will incur the greatest costs and which are further broken down into:

Sub-group 1, RTE fermented, dried, and salt cured meat and poultry products;

Sub-group 2, RTE hotdogs and wieners; Sub-group 3, RTE frozen meat and poultry patties; and,

Sub-group 4, RTE smoked hams and poultry luncheon meats;

Group II, those entities that likely will incur moderate costs and which are further broken down into:

Sub-group 1, meat processing establishments that make RTE boiled hams, other sausages, and other frozen or cooked meats, such as barbecue pork;

Sub-group 2, poultry processors that make RTE jellied goods and other processed

poultry products, including pâté and spreads; and

Sub-group 3, combo plants who produce both RTE meat and poultry;

Group III, those entities that likely will incur minor costs; representative products include RTE frozen dinners, pizzas, and other frozen meat and poultry products; and

Group IV, those entities likely will incur no costs; representative products include RTE canned meat and poultry products.

TABLE 1.—NUMBER, TYPE OF MEAT AND POULTRY PRODUCTS (MPP'S) SHIPPED, AND VALUE OF PRODUCT SHIPMENTS BY ESTABLISHMENT GROUPING, 1997

| Group—subgroup | Number of MPP's (% of total) | Value of shipments in millions (% of total) | Combo plants that slaughter and process meat (% of total) | Processors (% of total) | | | Examples of MPP's shipped |
|----------------|------------------------------|---|---|-------------------------|--------------|-------------|--|
| | | | | Meat * | Poultry | Others ** | |
| I-All | 584 (36%) | 10537 (37%) | 77 (5%) | 421 (26%) | 86 (5%) | 0 | Fermented, acidified, dried, salt-cured products, hotdogs, meat patties, and luncheon meats. |
| I-1 | 150 (9%) | 1590 (6%) | 28 (2%) | 122 (7%) | 0 | 0 | [Fermented] dry or summer sausage, salami, cured smoked sticks, Lebanon bologna, pepperoni, chorizo, poultry mortadella, chicken/turkey salami; [Dried] beef jerky, dried beef or pork sticks, dried beef slices, carne seca, basturma, soujouk, manneh dry duck breast, poultry jerky; [Salt cured] country cured ham, coppa, cappicola, prosciutto, pancetta, dry cured duck; [others] pickled pigs feet, pickled meat/sausages, chorizo with added vinegar, Hickory farm beef sticks. |
| I-2 | 167 (10%) | 2365 (8%) | 18 (1%) | 112 (7%) | 37 (2%) | 0 | Frankfurters and wieners, turkey and chicken franks. |
| I-3 | 76 (5%) | 528 (2%) | 0 | 76 (5%) | 0 | 0 | Sausage or meat and poultry patties, fully cooked, uncured meat patties. |
| I-4 | 191 (12%) | 6054 (21%) | 31 (2%) | 111 (7%) | 49 (3%) | 0 | Pastrami, bologna, roast beef, bratwurst, bockwurst, poultry and meat roll products. |
| II-All | 791 (49%) | 12539 (44%) | 76 (5%) | 551 (34%) | 164 (10%) | 0 | Otherwise processed meat and poultry products. |
| II-1 | 551 (34%) | 4883 (17%) | 0 | 551 (34%) | 0 | 0 | Beef burritos, corned beef, chili, frozen entrees and meat soups, breakfast link, meatballs, ravioli, pork and beans, some poultry rolls, other cooked poultry, pâté, meat and poultry spreads, turkey BBQ, uncured meat products, i.e. beef stew. |
| II-2 | 164 (10%) | 6696 (24%) | 0 | 0 | 164 (10%) | 0 | |
| II-3 | 76 (5%) | 960 (3%) | 76 (5%) | 0 | 0 | 0 | D. |
| III | 104 (6%) | 2979 (11%) | 0 | 0 | 0 | 104 (6%) | Frozen pizza with meat toppings; frozen entries. |

³ These data were extrapolated from the 1997 Census of Manufacturers. The actual data reported over \$30 billion in shipments, involving 1320 establishments, but did not account for several important factors: specific volumes of product

shipments with meat and poultry, i.e., pizza, dinner entries, canned product shipments with meat and/or poultry; scant information on size distribution; and many missing values for important product classes. In general, about 80 percent of these

establishments produce mostly cooked and otherwise processed meat and poultry products; the other 20 percent produce fermented, acidified, dried, salted cured, and canned meat and poultry products.

TABLE 1.—NUMBER, TYPE OF MEAT AND POULTRY PRODUCTS (MPP'S) SHIPPED, AND VALUE OF PRODUCT SHIPMENTS BY ESTABLISHMENT GROUPING, 1997—Continued

| Group—subgroup | Number of MPP's (% of total) | Value of shipments in millions (% of total) | Combo plants that slaughter and process meat (% of total) | Processors (% of total) | | | Examples of MPP's shipped |
|----------------|------------------------------|---|---|-------------------------|-----------|-----------|---|
| | | | | Meat * | Poultry | Others ** | |
| IV | 151 (9%) | 2165 (8%) | 0 | 26 (2%) | 4 (-%) | 121 (7%) | Canned products such as canned Poultry spreads and spaghetti sauce. |
| Total ... | 1630 | 28220.0 | 153 (9%) | 998 (61%) | 254 (16%) | 225 (14%) | All of the Above. |

* These processors make product from received meat carcasses and/or slaughter and process.

** Others include canners, frozen food makers, and other prepared food manufacturers.

Group I

Within Group I, 150 establishments produce fermented, dried, and salt cured meat and poultry products (Sub-group 1). These establishments make up nine percent of the total number of establishments potentially affected by this proposed rule and ship out about six percent of the total value of shipments. Over eighty percent of these establishments are processors, over 95 percent of who employ fewer than 500 employees.

The second sub-group within Group I consists of 167 establishments that make wieners and frankfurters. Eleven percent of these establishments are combo plants, 67 percent are meat processors, and 22 percent are poultry processors.

The third sub-group of 76 establishments within Group I produce meat patties, some partially or fully cooked; all are classified as meat processors by the Census. Almost all (98 percent) employ fewer than 500 employees.

The final sub-group in Group I consists of 191 establishments that make pastrami, bologna, roast beef, bratwurst, bockwurst, smoked hams and picnics, and smoked poultry. Fifty-eight percent of the establishments are meat processors; 16 percent, meat and poultry combo plants; and 26 percent, poultry processors. Overall, eighty-nine percent are small to mid-sized processors.

Group I also can be broken down into groups by type of processing and whether they produce meat or poultry products. As a whole, 87 percent (507) are processors (421 meat and 86 poultry processors). Ninety-eight percent of the meat processors are made up of either very small (employing fewer than 10 employees) or small (employing more than 10, but fewer than 500 employees) operations, with 36 percent being very small and 62 percent being small operations. Only 2 percent of the establishments are considered large (employing more than 500 employees). Poultry processors are structured somewhat differently with 15 percent, being very small; 49 percent, small; and, 36 percent, large. Combining both meat and poultry processors gives a slightly different picture of the structure of processing with 32 percent classified as very small; 60 percent, small; and, 8 percent, large. The remaining 77 establishments (13 percent) in Group I are combo plants (which slaughter animals and

process meat products). On average, these establishments have a smaller scale of operation than the group as a whole, with 53 percent being very small; 38 percent being small; but 9 percent, being large.

Group II

These 791 establishments consist of just over 50 percent of the *total number* of establishments and produce about 45 percent of *total value* of product shipments (boiled hams, other smoked pork and poultry products, other sausages, jellied goods, and other meat and poultry products). Many of these products are used in the manufacture of other food products or sold to distributors for direct use by consumers. Seventy percent of these establishments are meat processors (551); 20 percent (164) poultry processors; and, 10 percent (76) combo plants.

Sub-group 1 of Group II is composed of the 551 meat processing establishments making boiled hams, other sausages, and other frozen or cooked meats, such as barbecue pork. Sixty-two percent (339) of these establishments are classified as small operations. Two percent (12 establishments) are large, while the remainder (36 percent or 200 establishments) are very small.

Sub-group 2 of Group II consists of the twenty-percent (164) of the establishments that are poultry processors. Forty-eight percent (79) of these establishments are classified as small operations. Fifteen percent (25) are very small, while 37 percent (60) are large operations. The main products produced by these establishments include jellied goods and other processed poultry products.

The remaining 10 percent (76) of the establishments in Group II are combo meat plants (Sub-group 3). Seven percent (5) of these establishments are classified as large operations, while the majority (55%) are very small and another 38 percent are small.

Group III

These 104 establishments make frozen dinners, pizzas, meat and poultry pies, and nationality foods containing meat and/or poultry. They make up roughly 7 percent of the total number of establishments and ship out over 10 percent of the total value of product shipments.

Group IV

These 151 establishments produce canned products that contain meat and poultry

products. These establishments make up over 9 percent of the total number of establishments and about 8 percent of the total value of shipments.

B. Current Regulatory Environment

Currently, all environmental testing for *Listeria* and the development of either a Sanitation SOP measure or CCP for *Listeria* is completely voluntary. Since 1987, FSIS has conducted a microbiological testing program in which the Agency randomly samples, in-plant, RTE meat and poultry products produced in federally inspected establishments for *L. monocytogenes*, including cooked and fermented sausages, cooked corned beef, sliced ham and luncheon meats, beef jerky, cooked uncured poultry, and salads and spreads. FSIS treats RTE products in which *L. monocytogenes* is found as adulterated under the FMIA or the PPIA (21 U.S.C. 453(g) or 601(m)).

A recent industry survey gives some indication on the extent of current environmental testing for *Listeria*.⁴ This survey was conducted to determine what types of actions establishments took in response to the FSIS **Federal Register** Notice of May 26, 1999 (64 FR 28351), asking establishments that produce RTE meat and poultry products to reassess their HACCP plans to determine if *L. monocytogenes* was a hazard reasonably likely to occur in their processing. Because the respondents to this survey represent only a small proportion of the total number of establishment that would be affected by the proposed regulations, the survey results may not reflect a representative sample of the total population. Nonetheless, these data represent the most comprehensive available that reflects current industry practices.

Approximately 308 establishments were contacted for the survey. Of 271 respondents, 67 percent had an end-product testing program for *Listeria* (88 percent of large plants, 64 percent of small plants and 27 percent of very small plants). Over 90 percent of the respondents conducted some type of

⁴ The industry survey was sponsored by: National Food Processors Association (NFPA), American Meat Institute (AMI), National Turkey Federation (NTA), National Chicken Council (NCC), National Meat Association (NMA), North American Meat Processors (NAMP), Southwest Meat Association (SMA), and American Association of Meat Processors (AAMP).

environmental testing (100 percent of large plants, 92 percent of small plants, and 41 percent of very small plants). These survey results suggests that most large establishments conduct both product and

environmental testing while many small and very small firms do not.
The industry survey also found almost all (97%) of the large establishments conducted at least some type of environmental microbiological testing before the

reassessment, but still, 39 of the 74 large establishments, 58 of 193 small establishments, and only one of 22 very small establishments added a CCP to their HACCP plan in response to the reassessment (Table 2).

TABLE 2.—ESTIMATED ESTABLISHMENTS ADDING LM CONTROL MEASURES AS A RESULT OF LM REASSESSMENT, SPRING 2000

| Firm size | Add CCP addressing LM | Total number of establishments | Percent Adding LM-related measures to their HACCP plans |
|------------------|-----------------------|--------------------------------|---|
| Large | 39 | 74 | 52.70 |
| Small | 58 | 193 | 30.05 |
| Very Small | 1 | 22 | 4.55 |
| Total | 98 | 289 | 33.91 |

Survey sponsored by: NFPA, AMI, NTF, NCC, NMA, NAMP, SMA, and AAMP.

The CCP addressing *L. monocytogenes* may or may not have included testing, but involved remedial type actions, such as increased use of disinfectants on processing surfaces. However, it does mean that more than half of the establishments had not included *L. monocytogenes* concerns in their

HACCP plan before reassessment even though microbiological testing was being conducted. Even after reassessment when these additional establishments identified *L. monocytogenes* concerns in their HACCP plans, microbiological testing programs were included in only 21 percent of the

establishments' HACCP plans (or in 15 establishments' HACCP plans) and 41 percent of the Sanitation SOPs of the establishments in this size category (Table 3, below).

TABLE 3.—PERCENT OF ESTABLISHMENTS SURVEYED WITH MICROBIOLOGICAL TESTING PROGRAMS AS PART OF EITHER THEIR SANITATION SOPs OR HACCP PLANS, SPRING 2000

| Firm size | SSOPs | HACCP | Either SSOP or HACCP |
|------------------------|-------|-------|----------------------|
| Large | 41 | 21 | 62 |
| Small | 41 | 24 | 65 |
| Very Small | 60 | 25 | 85 |
| Weighted Average | 43 | 23 | 66 |

Survey sponsored by: NFPA, AMI, NTF, NCC, NMA, NAMP, SMA, and AAMP.

Over 80 percent of the small establishments in the survey that conduct some type of environmental microbiological testing, did so prior to the reassessment. After reassessment, 58 out of the 193 small establishments added a CCP addressing *L. monocytogenes* to their HACCP plans. Microbiological testing was included as part of 24 percent of these HACCP plans. Microbiological testing was included in 41 percent of the Sanitation SOPs. Of the very small establishments, only one added a CCP addressing *L. monocytogenes* to their HACCP plan out of the 22 establishments surveyed. After reassessment, microbiological testing programs were part of 25 percent of the establishments' HACCP plans in this size category and 60 percent of the Sanitation SOPs of the establishments in this size category. In general, the survey results suggest that many establishments have identified *L. monocytogenes* as an important pathogen of concern and have included remedial measures in either their Sanitation SOPs or CCPs in their HACCP plans and that microbiological testing is more likely to be incorporated in Sanitation SOPs than as part of a CCP in a HACCP plan.

C. Baseline Number of Listeriosis Cases and Deaths and the Potential Benefits From the Proposed Rule

FSIS presents two baselines below for potential benefits from the proposed rule. The first baseline is derived entirely from the FDA-FSIS draft risk assessment. The second baseline is constructed from two independent CDC-based studies. FSIS' intent is to present a range of possible benefits.

Baseline 1

The baseline numbers of listeriosis cases and deaths are taken directly from the recent FDA-FSIS interagency draft risk assessment, mainly Appendix 9, Table 1. The FDA-FSIS draft risk assessment ranks 20 categories of foods and provides a rigorous, systematic assessment of the scientific knowledge to predict the relative public health impact of exposure to *L. monocytogenes*. The FDA-FSIS draft risk assessment shows that the following five factors affect the contamination levels at the time of consumption: (1) the frequency and extent of contamination at retail; (2) consumption habits; (3) the growth potential of *L. monocytogenes* in foods; (4) consumer storage practices; and (5) refrigeration temperatures. The results of the FDA-FSIS draft risk assessment estimates 2540 annual

median U.S. listeriosis cases of which 1659 (65.3 percent) are attributable to the consumption of RTE meat and poultry products.

The FDA-FSIS draft risk assessment not only provides the most recent and complete analysis on sporadic U.S. listeriosis cases by general product group, but it also provides insights into several commodities' relative risk rankings and their contribution to the total U.S. number of listeriosis cases. Deli-meats present the most prominent risk to all sub-populations (Intermediate Age, Elderly, and Perinatal), and are likely responsible for 1446 median U.S. listeriosis cases (58.9 percent of the U.S. total), or 88.9 percent of the listeriosis cases attributable to RTE meat and poultry products.

Other specific products within the meat and poultry product category identified by the FDA-FSIS draft interagency risk assessment as posing a risk related to listeriosis are: deli salads containing meat and poultry products (at the median, 3.8% of all listeriosis cases or 5.8% of listeriosis cases attributable to RTE meat and poultry products); frankfurters (at the median, 3.5 and 5.4 percent, of the total and all RTE meat and poultry products listeriosis cases, respectively); paté (at the median, 0.9 and 1.4 percent, respectively, for total and all RTE

meat and poultry products listeriosis cases); and, dry fermented sausage (at the median, 0.2 and 0.3 percent, respectively, for total and all RTE meat and poultry products listeriosis cases). The FDA-FSIS interagency draft risk assessment model anchors the

median number of listeriosis cases on epidemiologic surveillance data (FoodNet) without bounding the 5th and 95th percentiles of the estimated number of cases attributable to each product category. Table 4, based on the FDA-FSIS interagency draft

risk assessment, provides the total number of listeriosis cases across age groups for each product category for the 5th and 95th percentiles:

TABLE 4.—SUMMARY FDA-FSIS DRAFT RISK ASSESSMENT RESULTS CONCERNING TOTAL PREDICTED US LISTERIOSIS CASES OF FOODBORNE ORIGIN

| Product category | Statistics ¹ | | | Relative risk ranking ² | | | Etiologic fraction of cases attributed to each product category at the 5th and 95th percentiles ⁵ | | As a percent of total cases in their product class |
|---|-------------------------|--------|-------------------|------------------------------------|------|------|--|------|--|
| | 5th | 95th | Med. ⁴ | 1 | 2 | 3 | 5th | 95th | Med. |
| | | | | | | | | | |
| Smoked Seafood | 1 | 2464 | 33 | 6 | 6 | 7 | 1 | 1 | 61 |
| Raw Seafood | 0 | 35 | 0 | 17 | 20 | 17 | 0 | 0 | 0 |
| Preserved Fish | 0 | 300 | 3 | 13 | 13 | 13 | 0 | 0 | 6 |
| Cooked Crustaceans | 0 | 1415 | 18 | 9 | 8 | 9 | 0 | 1 | 33 |
| Total Seafood | 1 | 4214 | 54 | Vary | Vary | Vary | 1 | 2 | 100 |
| Vegetables | 0 | 7311 | 15 | 11 | 9 | 11 | 0 | 4 | 87 |
| Fruits | 0 | 900 | 2 | 16 | 14 | 14 | 0 | 1 | 13 |
| Vegetables/Fruits | 0 | 8211 | 17 | Vary | Vary | Vary | 0 | 5 | 100 |
| Dairy Products | 26 | 19481 | 523 | Vary | Vary | Vary | 28 | 12 | NA |
| Frankfurters | 3 | 6324 | 90 | 4 | 5 | 4 | 3 | 4 | 5 |
| Dry/Semi-Dry Fermented Sausages | 0 | 631 | 5 | 12 | 12 | 12 | 0 | 0 | 0 |
| Deli Meats | 50 | 98261 | 1446 | 1 | 1 | 1 | 55 | 59 | 87 |
| Pâté and meat spread | 1 | 1152 | 23 | 8 | 7 | 8 | 1 | 1 | 1 |
| Meat or Poultry Deli Salad ³ | 3 | 7146 | 96 | 2 | 3 | 3 | 3 | 4 | 6 |
| Total RTE Meat and Poultry Products | 57 | 113514 | 1660 | Vary | Vary | Vary | 62 | 68 | 100 |
| Non-Meat or Poultry Deli Salad | 5 | 21437 | 287 | 2 | 3 | 3 | 2 | 13 | NA |

¹ Horizontal summation of listeriosis cases across age group for each product category in Table 1, Appendix 9 of the FDA-FSIS interagency draft risk assessment (page 342).

² 1= Intermediate; 2= Elderly; and, 3=Peri-natal. The relative risk ranking is taken directly from Table V-3 of the FDA-FSIS interagency draft risk assessment (p. 108).

³ Meat deli salad estimate is based on FDA-FSIS draft risk assessment estimate of 26 deaths from deli salads and assuming that 25 percent is due to deli salads containing meat and poultry product's (their relative proportion of total deli salad consumption).

⁴ Med. = Median.

⁵ The etiologic fraction is calculated as the proportion of listeriosis cases associated with each product category at the 5th and 95th percentiles.

The number of listeriosis cases attributable to ready-to-eat meat and poultry products is 62% (1562 cases) at the 5th percentile and 68.0% (1727 cases) at the 95th percentile based on a median number of annual cases (2540 cases). This sensitivity about the median number of listeriosis cases attributable to meat and poultry products was calculated by summing the number of listeriosis cases attributable to each meat and poultry product category (frankfurters, dry and semi-dry sausage, deli meats, and pate and meat spreads) and 25% (based on one-fourth of all deli salad servings containing meat and poultry products, CSFII 1994-1996 survey data) of the deli salad category⁵ for the 5th and 95th percentile. The total number

of listeriosis cases attributable to meat and poultry products for each product category in the 5th percentile was divided by the total number of listeriosis cases for all RTE products at the 5th percentile. A similar calculation was done at the 95th percentile. These etiologic fractions of the number of listeriosis cases provide a plausible range for the estimated number of listeriosis cases attributable to RTE meat and poultry products.

FDA-FSIS interagency draft risk assessment reports results for three specific age groups: perinatal (which includes fetuses and newborns from 16 weeks after fertilization to 30 days after birth), elderly (which includes people 60 or more years of

age), and intermediate age (everyone else). The FDA-FSIS interagency draft risk assessment model predicts the number of deaths associated with each RTE food category. The estimated number of listeriosis cases presented in the FDA-FSIS draft risk assessment (Table 1, Appendix 9) is based on the assumption of an overall case-fatality rate of 0.20.⁶ This assumption is supported by a study of foodborne illnesses in the United States, Mead et al. (1999), which is based on published reports and unpublished CDC data, and is consistent with epidemiologic surveillance case-fatality data across all age groups (Table 5).

⁵ One-fourth of all deli salads consumed contain RTE meat and poultry products based on the 1994-1996 Continuing Survey of Food Intakes by Individuals used in the FDA-FSIS interagency risk assessment.

⁶ The number of neonatal deaths was multiplied by 2.5 to adjust the combined prenatal and neonatal deaths to a case-fatality rate constrained at approximately 20% in the FDA-FSIS interagency risk assessment. This adjustment was made to

account for underreporting of prenatal infections resulting in premature termination of pregnancy.

TABLE 5.—*LISTERIA* CASES BY AGE CLASS AND YEAR

| Age class | 1996 | 1997 | 1998 | 1999 | 1996–99 | % Cases | Perinatal adjustment factor |
|---------------------------|------|------|------|------|---------|---------|-----------------------------|
| 0–1, unadjusted | 8 | 5 | 10 | 12 | 35 | | 2.5 |
| Perinatal, adjusted | 20 | 13 | 25 | 30 | 88 | 20 | |
| 1–9 | 1 | 2 | 1 | 3 | 7 | 2 | |
| 10–19 | 3 | 1 | 2 | 1 | 7 | 2 | |
| 20–29 | 4 | 3 | 6 | 5 | 18 | 4 | |
| 30–39 | 6 | 9 | 13 | 7 | 35 | 8 | |
| 40–49 | 3 | 6 | 6 | 8 | 23 | 5 | |
| 50–59 | 4 | 9 | 13 | 16 | 42 | 10 | |
| >60 | 37 | 42 | 61 | 48 | 188 | 45 | |
| “Unknown” | 0 | 0 | 0 | 14 | 14 | 3 | |
| Totals | 78 | 85 | 127 | 132 | 422 | 100 | |

There is some uncertainty surrounding the assumed 20 case-fatality rate. The FDA-FSIS interagency draft risk assessment observes that if the susceptibility among the three age-based groups varies, then the ratio of serious illness to mortality may differ among these groups. This is consistent with epidemiologic data for *Listeria* mortality age distribution unadjusted for underreporting and misclassification of pre-natal cases. Other considerations include the fact that

epidemiologic surveillance data do not count unborn fetuses as deaths, but as miscarriages and stillbirths, which may contribute to underreporting within this age category (PHS, 1994).

The epidemiologic data also contains cases with an “unknown” age. In the 1999 data, there were 14 cases reported as “unknowns.” Epidemiologists at the FoodNet sites indicated that the “unknown” ages resulted

from database errors and are not a result of a systematic classification error.

Table 6 presents the *Listeria* mortality age distribution, unadjusted for the underreporting or misclassification of pre-natal cases (the “unknowns” age cases were not included in the data set). This unadjusted data suggests an overall case-fatality rate of 15%, and substantial variation of the case-fatality among the age categories.

TABLE 6.—*LISTERIA* MORTALITY AGE DISTRIBUTION, UNADJUSTED FOR UNDER-REPORTING OF PRE-NATAL CASES

| Age class (yrs) | Dead | Total cases | Mortality |
|-----------------|------|-------------|-----------|
| 0–1 | 1 | 23 | 4 |
| 1–9 | 0 | 4 | 0 |
| 10–19 | 0 | 6 | 0 |
| 20–29 | 0 | 13 | 0 |
| 30–39 | 1 | 28 | 4 |
| 40–49 | 3 | 15 | 20 |
| 50–59 | 4 | 26 | 15 |
| >60 | 29 | 140 | 21 |
| Totals | 38 | 255 | 15 |

Source: FoodNet 1996–98, unpublished CDC data.

While it is unlikely that all of the “unknown” age cases would be in the perinatal category due to National Health

Statistics standards for classification of fetal deaths, a bound for the largest possible case-fatality rate can be derived with the 14

“unknown” age cases in this age category as seen in Table 7.

TABLE 7.—*LISTERIA* MORTALITY AGE DISTRIBUTION, ADJUSTED FOR UNDER-REPORTING OF PRE-NATAL CASES

| Age class (yrs) | Dead | Total cases | % Mortality |
|-----------------|------|-------------|-------------|
| Perinatal | 15 | 37 | 41 |
| 1–9 | 0 | 4 | 0 |
| 10–19 | 0 | 6 | 0 |
| 20–29 | 0 | 13 | 0 |
| 30–39 | 1 | 28 | 4 |
| 40–49 | 3 | 15 | 20 |
| 50–59 | 4 | 26 | 15 |
| >60 | 29 | 140 | 21 |
| Totals | 52 | 269 | 19 |

While the estimated overall case-fatality rate of 19% is consistent with the Mead et al. (1999) estimate of 20%, uncertainty regarding the age-specific case-fatality rate due to misclassification and underreporting remain.⁷ Given disparate opinions on case-fatality rates by age group, it is difficult to come up with a point estimate for benefit of this rule based on available data. However, the following preliminary benefits analysis provides two point estimates based on two baseline approaches. It should be noted that there is considerable uncertainty in the benefits analysis below, which is recognized throughout this section and again addressed in the "Uncertainty" section.

Attaching Economic Value to the Number of Listeriosis Cases and Deaths

The listeriosis cases and deaths attributable to RTE meat and poultry products estimates derived from the FDA-FSIS draft risk assessment establish the number of lives lost and those temporarily hospitalized or unable to work as a result of illness. This cost may be measured in lost productivity and in medical costs incurred. The Economic Research Service has conducted research on the method. However, given many uncertainties, FSIS is not monetizing the values associated with reducing listeriosis cases and deaths. FSIS requests comment on

appropriate methods to value listeriosis cases and deaths.

Baseline 2

This second baseline derives the number of listeriosis cases and deaths from two independent studies: one by Olsen⁸ and one by Mead.⁹

The Olsen Study: Olsen estimated the number of cases and deaths from all foodborne diseases in several U.S. states and found that meat and poultry products were responsible for 8 to 20 percent of all foodborne cases and deaths, respectively (Table 8).

TABLE 8.—NUMBER OF U.S. FOOD BORNE DISEASE OUTBREAKS, CASES, AND DEATHS BY VEHICLE OF TRANSMISSION

| Year | All known food borne diseases | | | Meat and poultry products | | | Percent attributable to meat and poultry products | | |
|------------|-------------------------------|-------|--------|---------------------------|-------|--------|---|-------|--------|
| | Outbreaks | Cases | Deaths | Outbreaks | Cases | Deaths | Outbreaks | Cases | Deaths |
| | 1993 | 489 | 17477 | 9 | 28 | 1797 | 5 | 6 | 10 |
| 1994 | 653 | 16234 | 3 | 51 | 1804 | 1 | 8 | 11 | 33 |
| 1995 | 628 | 17800 | 11 | 35 | 1144 | 1 | 6 | 6 | 9 |
| 1996 | 477 | 22607 | 4 | 23 | 992 | 0 | 5 | 4 | 0 |
| 1997 | 504 | 11940 | 2 | 31 | 972 | 0 | 6 | 8 | 0 |
| Total | 2751 | 86058 | 29 | 168 | 6709 | 7 | 6 | 8 | 24 |
| 5-yr Avg. | 550 | 17212 | 6 | 33.6 | 1342 | 1 | 6 | 8 | 20 |

Source: Surveillance for Food borne Disease Outbreaks—United States, 1993–1997. Olsen, Sonja et al.— See tables 17 to 21.

If the percentage of listeriosis cases and deaths attributable to meat and poultry products is the same as the percentage attributable to foodborne diseases, the 8-percent estimate from the Olsen study can be used to estimate the number of listeriosis cases and deaths due to consumption of RTE meat and poultry products.¹⁰ This assumption may not be accurate. Olsen's study is a summary of reported foodborne

disease outbreaks. However, FoodNet surveillance data indicate that the majority of listeriosis cases are sporadic with no identified link to any other case. Furthermore, sporadic disease may reflect entirely different food vehicles, mechanisms, or sources of infection than those responsible for outbreaks.

With these reservations in mind, FSIS applied the 8-percent estimate from the

Olsen study to the Mead data (2500 cases and 499 deaths) for listeriosis (after developing a 5-year time series set of estimated listeriosis cases and deaths), which gave an average annual listeriosis case and death load of 186 and 38, respectively (Table 9). For example, the 1993 estimate of listeriosis cases and deaths was calculated by multiplying 0.08 times 2359 (189) and 0.08 times 745 (60), respectively for cases and deaths.

TABLE 9.—ESTIMATED NUMBER OF U.S. FOOD BORNE DISEASE CASES AND DEATHS: TOTAL FROM ALL PATHOGENS, TOTAL FROM LM, TOTAL FROM LM IN RTE MEAT AND POULTRY PRODUCTS (MPP'S) FOOD PRODUCTS AS DERIVED FROM A /COMBINATION OF THE MEAD-OLSEN STUDIES

| Year | Cases and deaths from all food borne diseases | | Listeriosis cases and deaths through food borne sources | | Listeriosis cases and deaths through MPP's | | Listeriosis cases and deaths through RTE MPP's | |
|--------------------|---|----------|---|--------|--|--------|--|--------|
| | Cases ¹ | Deaths | Cases | Deaths | Cases | Deaths | Cases | Deaths |
| | 1993 | 11796975 | 2700 | 2359 | 745 | 189 | 60 | 170 |
| 1994 | 10957950 | 900 | 2192 | 248 | 175 | 20 | 158 | 18 |
| 1995 | 12015000 | 3300 | 2403 | 911 | 192 | 73 | 173 | 66 |
| 1996 | 15259725 | 1200 | 3052 | 331 | 244 | 26 | 220 | 24 |
| 1997 | 8059500 | 600 | 1612 | 166 | 129 | 13 | 116 | 12 |
| Total ² | 58089150 | 8700 | 11618 | 2401 | 929 | 192 | 837 | 174 |
| 5-yr Avg. | 11617830 | 1740 | 2324 | 480 | 186 | 38 | 167 | 35 |

¹ It is assumed that the terms, illnesses as in Mead et al., and cases in Olsen et al., report, can be used interchangeably.

² May not add due to rounding.

⁷ Public Health Service, Medical Examiners' and Coroners' Handbook on Death Registration and Fetal Death Reporting. (Reprinted 1994).

⁸ Olsen, Sonja, et al., "Surveillance for Food borne Disease Outbreaks—United States, 1993–

1997," *Morbidity and Mortality Weekly Report*, March 17, 2000.

⁹ Mead, Paul S., et al., "Food-Related Illness and Death in the United States," *Emerging Infection Diseases*, 5:5, September–October, 1999.

¹⁰ Originally, deaths were calculated using the 0.276 estimate, but was found to produce an unrealistically high level of deaths. The 0.08 estimate produced results more in line with the number of listeriosis deaths reported by Mead.

Finally, the estimated number of cases and deaths due to listeriosis attributable to meat and poultry product consumption must reflect only that portion that is RTE. One method to do this is simply to assume that 90 percent of the meat and poultry product listeriosis cases and deaths are linked to RTE food products. Obviously this estimate is completely arbitrary. FSIS does not contend that this is an accurate depiction; therefore, FSIS solicits comments. Using this estimate, the number of listeriosis cases and deaths attributable to RTE meat and poultry product consumption is estimated at 167 and 35, respectively. Also, FSIS considered making an adjustment factor for the effectiveness of the provisions in the proposed rule. Again, FSIS is unsure how such an adjustment factor would be constructed, but recognizes that not all listeriosis cases and deaths could be totally eliminated by provisions in the proposed rule. FSIS requests comment on the efficacy of the proposed testing provisions.

Request for Comment

FSIS solicits comments and suggestions concerning the issues of the baseline number of listeriosis cases and deaths attributable to RTE meat and poultry products and the effectiveness of measures prescribed by the proposed rule. Notably, the recent FDA-FSIS draft risk assessment estimated that 65.3 percent of all U.S. listeriosis cases and deaths (or 1660 cases and 322 deaths per year) are attributable to the consumption of RTE meat and poultry products. The number of cases and deaths estimated by the FDA-FSIS draft risk assessment are 9.9 times greater than the estimated numbers obtained from the second baseline. FSIS welcomes comments and suggestions on the kinds of data and information needed to construct alternative baselines and sensitivity approaches to test baseline listeriosis cases and deaths and program effectiveness.

Projected Industry Costs

1. Mandatory Food Contact Surface Testing for *Listeria spp.*

FSIS is proposing to require that all establishments that produce RTE meat and poultry products conduct environmental testing of food-contact surfaces for *Listeria spp.*, after lethality treatment and before final product packaging, unless they have identified *L. monocytogenes* as a hazard reasonably likely to occur and so have incorporated into their HACCP systems one or more controls validated to eliminate it from their products. This testing will verify that an establishment's Sanitation SOPs are preventing direct product contamination by *L. monocytogenes* after the lethality treatment, thus addressing the risk assessment assertion that RTE foods often are recontaminated by *L. monocytogenes* after lethality is applied.

After an establishment finds one of its food contact surfaces to be positive for *Listeria spp.*, it must take corrective actions defined in its Sanitation SOPs that must include product testing, as well as any other activities that it deems necessary to determine and demonstrate that the affected lot or lots of product are not adulterated with *L. monocytogenes*. The establishment must 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.

Establishments can be expected to face at least three potential cost impacts due to mandatory food contact surface testing for *Listeria spp.* testing. These potential impacts could arise from: (1) the need to make major revisions in their HACCP plan(s); (2) additional verification testing; and, (3) the need to make major changes in their production process and/or production output mix.

The first and second impacts are closely related because the firms that elect to revise their HACCP plan to incorporate a CCP addressing *Listeria* will not be required to test for it at the prescribed level for those incorporating *Listeria* testing in the Sanitation SOPs. HACCP provides the opportunity for greater latitude in establishing more science-based verification approaches, which may include testing. Thus, some estimate on the number of firms expected to incorporate a CCP addressing *Listeria* as a result of this provision is necessary for this analysis to proceed. The higher this estimate, the higher will be the expected costs to validate needed HACCP modifications, and lower will be the expected costs of the proposed testing requirements.

The third impact stems from the decision by some establishments to drop certain RTE meat and poultry products (or drop out of production altogether). This decision would be due to persistently high rates of positive *Listeria spp.* food contact surface testing results and the subsequent increased amount of product being held while awaiting confirmation that positive food contact surface test results for *Listeria spp.* did not result in contaminated product.

This creates the prospect of an additional fourth potential impact: the potential increased cost associated with greater volumes of product held by establishments in a "test and hold" pattern. These costs are expected to be particularly relevant to those firms experiencing very poor testing results, presumably as a result of inadequate sanitation controls. These costs are discussed separately in the section entitled "C. Projected Costs Associated with Expected Production Adjustments." There, FSIS explains that establishments that encounter "Stage 2" and "Stage 3" type problems with

chronic *Listeria spp.* or *L. monocytogenes* contamination either incur substantial remediation costs or elect to exit RTE meat and poultry product production. FSIS lacks data to adequately estimate the volumes of product that establishments may have to test and hold and the resulting costs. See the section entitled "Uncertainty" for further discussion.

Each of the three cost impacts is discussed below.

A. Projected Costs Associated With HACCP Plan Validation

FSIS estimates that currently 397 establishments have a CCP addressing *Listeria* in their HACCP plan and that 257 additional establishments will do so as a result of the proposed rule. That is, the number of establishments with a CCP addressing *L. monocytogenes* is projected to increase nearly 65 percent as a result of this provision of the proposed rule (from 397 to 654). FSIS bases these estimates on judgment and information presented previously in the discussion on baseline industry practices. Main factors considered in FSIS's estimates pertaining to current and projected behavior related to firms' decision to modify their HACCP plans include:

- FSIS estimates that the percentage of the large establishments, excluding canners, that have a CCP addressing *L. monocytogenes* in their HACCP plans will increase from 50 to 100 percent (from 67 establishments to 133 establishments)¹¹ as a result of the proposed rule;
- FSIS estimates that the percentage of the small establishments, excluding canners, that have a CCP addressing *L. monocytogenes* in their HACCP plans will increase from 33 to 50 percent (from 280 establishments to 420 establishments) as a result of the proposed rule; and,
- FSIS estimates that the percentage of the very small establishments, excluding canners, that have a CCP addressing *L. monocytogenes* in their HACCP plans will increase from 10 to 20 (from 51 establishments to 101 establishments) percent as a result of the proposed rule.

The net results on the number of establishments with a CCP addressing *Listeria* in response to the proposed rule is given in Table 10 below. FSIS has excluded canners from total in the following table (resulting in a grand total of 1479: 1630 total minus 151 canners). FSIS expects that canners should only experience minimal costs from identifying that their existing CCPs already eliminate *L. monocytogenes* from their products.

¹¹ These numbers are derived from the total number of firms listed in Table 3 of section XII of the proposed rule preamble, "Compliance with Regulatory Flexibility Act of 1966."

TABLE 10.—SUMMARY OF CURRENT AND PROJECTED ESTABLISHMENT BEHAVIOR WITH RESPECT TO THEIR DECISION TO INCORPORATE A CCP ADDRESSING *L. MONOCYTOGENES*

| Item | Number of establishments | | Change |
|--|--------------------------|--------|--------|
| | Before | After | |
| Establishments that currently have or will develop a CCP addressing <i>L. monocytogenes</i> in their HACCP plan that also: | | | |
| Conduct food contact surface testing | 299 | 12 489 | 190 |
| Do not conduct food contact surface testing | 98 | 165 | 67 |
| Sub-total | 397 | 654 | 257 |
| Establishments without and that will not develop a CCP addressing <i>L. monocytogenes</i> in their HACCP plan that also: | | | |
| Conduct food contact surface testing | 645 | 825 | 180 |
| Do not conduct food contact surface testing | 437 | 0 | -437 |
| Sub-total | 1082 | 825 | -257 |
| Grand-Total | 1479 | 1479 | 0 |

The size distribution of establishments expected to modify their HACCP plans has important implications in the analysis on mandatory food contact surface testing. This analysis assumes that all large establishments are likely to incorporate a CCP addressing *L. monocytogenes* in their HACCP plans, while most small and very small establishments will not (instead relying on Sanitation SOPs to address *L. monocytogenes* and comply by mandatory testing). That is, larger establishments (who have the greatest volume, currently conduct a high volume of product and food contact surface microbiological testing and maintain CCPs addressing *L. monocytogenes*) will not be required to test, thus reducing the overall testing brunt of this provision. The current high numbers of large establishments with CCPs addressing *L. monocytogenes*, and the expectation that all remaining ones will modify their HACCP plans strongly influence this outcome.¹³ This leaves the smaller establishments to feel the brunt of mandatory food contact surface testing burden while at the same time, lowering the total level of testing needed to comply with the proposed rule.

One element that may increase the over-all cost of the HACCP modification component of mandatory testing at the prescribed frequency is if establishments need to modify more than one HACCP plan. Also, the relative of cost of testing versus developing a CCP would not be the only factor in an establishment's decision on how to comply with the proposed requirement. Unique

¹² This increase in this field is due to the number of establishments currently testing that choose to also develop a CCP in response to the rule. FSIS assumes that they will continue testing, so this number does not represent an increase in the number of establishments that test.

¹³ It must be kept in mind that although larger establishments will avoid mandatory testing at the prescribed frequency, nothing suggests that these establishments will discontinue their testing programs and jeopardize their product integrity. It is expected that the original product integrity be maintained through its own HACCP monitoring and verification activities and confirmed through FSIS verification of their HACCP plans.

aspects of ad establishment's processing system, as well as the relative risks posed by its products, may influence an establishment's decision. FSIS request comment on this issue.

FSIS has found that the costs associated with modification of HACCP plans can range from \$2,000 to \$20,000 per HACCP process. This cost depends on the efforts needed to draw up new CCPs (sanitation practices to limit levels of *L. monocytogenes* on incoming raw product and prevent recontamination after processing, lethality steps, or testing to validate and verify its controls); install monitoring equipment (thermometers and test kits) and; train labor to take additional samples and to keep records. The cost of \$5000 for the incorporation of a CCP addressing *L. monocytogenes* into an establishment's HACCP plan is used in cost projections for this analysis, regardless of size of establishment or number of HACCP plans per establishments. This cost is considered a one-time event (minimal recurring monitoring costs are assumed to result from the inclusion of a CCP addressing *L. monocytogenes*). Any additional costs associated with its' monitoring are subsumed in the over-all monitoring cost of the establishment's current HACCP plan(s). Industry-wide, these total one-time HACCP validation costs are estimated at \$1.285 million (\$5000 times 257 establishments). FSIS requests comment on this estimated total cost of HACCP plan modification.

B. Projected Costs Associated With Additional Testing

For those establishments not currently testing or that do not maintain a CCP addressing *Listeria*, FSIS tentatively concludes that food contact surface testing and Sanitation SOP controls will supply the same reassurance that *L. monocytogenes* is not a potential food safety problem as do regularly scheduled verifications of Sanitation SOPs. As was discussed, the proposed rule effectively exempts establishments from mandatory testing if: (1) they manufacture products whose processing destroys *L. monocytogenes* and/or eliminates any opportunity of recontamination, e.g.,

canners; or (2), if they previously identified *L. monocytogenes* as a hazard reasonably likely to occur and have incorporated one or more controls into their HACCP systems. These two conditions effectively exempts 151 establishments identified as canners and 397 establishments identified as currently having a CCP addressing *L. monocytogenes* in their HACCP plan. In addition, FSIS projects that an additional 257 establishments will elect to incorporate a CCP addressing *L. monocytogenes* into their HACCP plan, effectively avoiding this mandatory testing requirement. Thus, FSIS estimates that this provision will impose mandatory testing costs on 825 establishments (1630 - 151 - 397 - 257 = 825).

Nature of Testing (Areas to be tested, Frequency, and Consequences). All environmental tests will be made on food-contact surfaces (rather than non-food contact surfaces, such as floors and drains). Reliance on food contact surface testing is predicated on the logic that establishments, in the desire to minimize their chances of having a positive food product test, will use surface test results as a leading indicator of food product safety. Thus, no non-food product contact testing is required in this proposed rule change. Also, non-food product contact has not been found to be related with final product safety: "Areas where products are stored or processed are of lower priority because inadequately cleaned equipment in raw processing areas have not been associated with a problem of *Listeria monocytogenes* in finished product."¹⁴

The frequency of food contact surface testing is based on the following:

- (a) Four tests per active line¹⁵ per month for large establishments;

¹⁴ *Guidelines to Prevent Post-Processing Contamination from LM*, Tompkin, Scott, Bernard, Sveum and Gombas, Dairy, Food and Environmental Sanitation, August 1999, Vol. 19, No. 8, Pages 551-562.

¹⁵ Why lines? Many authorities recommend considering each product line as a critical control point. For example, "Each packaging line should be regarded as an independent unit for LM monitoring

Continued

(b) Two tests per active line per month period for small establishments; and, (c) One test per active line per month for very small establishments.

For purposes of this cost analysis below, FSIS used the following assumptions on the average number of operating lines per establishment: 2 lines for very small establishments; 4 lines for small establishments; and, 6 lines for large establishments.

These frequencies are intended to be the minimum level of food contact surface testing undertaken by firms. Greater frequency of testing by establishments (regardless of size) is encouraged by FSIS: FSIS policy states that the more the plant is testing, the less likely FSIS will include the plant's product in its end-product microbiological testing program(s) (FSIS Directive 10,240.2, Revision 1). This testing frequency incorporates the volume of production in two ways: (1) It assumes that the more an establishment produces, the more lines it has, and (2) the greater its size,

the more product is produced and thus, a need for higher weekly frequency as size increases.¹⁶ FSIS requests comment on these proposed testing frequencies.

Positive test results on food-contact areas will indicate a need to thoroughly clean the immediate working areas and equipment and re-test. Once a positive food contact surface is found, product samples will be tested for *L. monocytogenes*. The establishment must 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 and to correct and prevent further contamination appropriately.

The potential cost of mandatory testing is a function of the per-unit testing cost¹⁷ and of the number of establishments (and the number of lines that each establishment maintains) that are affected by this provision. Several testing firms were contacted concerning their testing kits for *Listeria spp.* The cost of these tests varied from \$10 to \$30, not including the costs for labor and shipping the material to the laboratory. One would

expect that the costs of in-house testing would be at least the amount charged by firms engaged in providing this service. A slightly higher cost of \$35 per test is used as the average cost of testing food-contact areas for *Listeria spp.* in this analysis to compensate for expenses associated with labor to conduct the test and shipping tests to laboratories for analysis.

The number of establishments that will face mandatory testing has been determined in the previous analysis. Recall that it found that all large establishments are expected to modify their HACCP plans and be exempt from mandatory food contact surface testing. The finding implies that only small and very small establishments will need to test to satisfy compliance of the proposed rule. FSIS estimates that 50,035 tests will be needed by these establishments (Table 11). The associated overall costs of these tests is estimated at \$1.75 million (\$35 times 50,035). This cost would be expected to recur annually.

TABLE 11.—SUMMARY OF NUMBER OF TESTS CONDUCTED BY ESTABLISHMENTS WITH AND WITHOUT CCPs ADDRESSING *L. MONOCYTOGENES*

| Item | Number of tests needed to meet compliance | | Change |
|--|---|---------------------|---------|
| | Before | After | |
| Establishments that currently have or will develop a CCP addressing <i>L. monocytogenes</i> in their HACCP plan that also: | | | |
| Conduct food contact surface testing | 39105 | ¹⁸ 67458 | +28353 |
| Do not conduct food contact surface testing | 8141 | 13594 | + 5453 |
| Sub-total 1 | 47246 | 81053 | + 33807 |
| Establishments currently without and that will not develop a CCP addressing <i>Listeria monocytogenes</i> in their HACCP plan that also: | | | |
| Conduct food contact surface testing | 63524 | 50035 | - 13489 |
| Do not conduct food contact surface testing | 20318 | 0 | - 20318 |
| Sub-total 2 | 83842 | 50035 | - 33807 |
| Grand-Total (1+2) | 131088 | 131088 | 0 |

C. Projected Costs Associated With Expected Production Adjustments

In addition to the above two expected industry costs (administrative costs related to incorporating a CCP addressing *L. monocytogenes* in their HACCP plans and increased food contact surface testing costs), some firms—across all size categories—may need to adjust their production process or facilities to comply with the proposed rule. One can view such adjustments as being on a continuum, from the most minor—and least costly—to the most radical—and costly—adjustments needed to remedy their *L. monocytogenes*-related control problem(s). Because measures vary greatly across establishments and product-types, it is

difficult to estimate the impact of eventual firm adjustments arising from this provision of the proposed rule.

For purposes of analysis, affected establishments are broken into four groups: those that are not expected to encounter any problems as a result of mandatory testing; those firms that are expected to encounter minor problems (Stage 1 problems); those firms that are expected to encounter more serious problems and higher costs to remedy their *L. monocytogenes*-related problems (Stage 2 problems); and, a small group that will drop certain products or drop production entirely due to persistent *L. monocytogenes* positive findings (Stage 3 problems). Based on the discussion that

follows, the number of establishments in each group was determined to be: 1,258 establishments that will not encounter any problems; 104 establishments that will encounter Stage 1 and 2 problems and 13 establishments that drop production of certain RTE meat and poultry products or drop out of the industry entirely (Table 12).

Steps to prevent *L. monocytogenes* contamination can take many forms: pre-operational (building and facility design; equipment design and maintenance) and operational (adequate attention paid by well-trained employees). Most establishments are assumed to follow the recommended guidelines in production,¹⁹ are already doing some testing (either food contact surface or

and control," *Guidelines to Prevent Post-Processing Contamination from LM*, pp. 551–562.

¹⁶The higher testing frequency for large establishments (once per week per line) also reflects the greater potential of large establishments to contaminate larger volumes of product than small and very small establishments.

¹⁷No adjustment is made to account for the degree to which plants currently test: the baseline discussion suggests that many firms are currently conducting some kind of environmental testing program.

¹⁸This increase in this field is due to the number of establishments currently testing that choose to

also develop a CCP in response to the rule. FSIS assumes that they will continue testing, so this number does not represent an increase in testing.

¹⁹*Guidelines to Prevent Post-Processing Contamination from LM*, 1999.

of products), and would not be expected to experience any increase in positive food contact surface testing results as a result of the proposed regulation changes. FSIS estimates that eighty-five percent²⁰ (1,258) of the establishments will incur no costs,

because these establishments already have taken steps to remediate problems with *L. monocytogenes* contamination in product. However, it is possible that these establishments may have future problems with environmental contamination by

Listeria spp. So, FSIS may have overestimated the number of establishments that will incur no future costs as a result of the proposed requirements.

TABLE 12.—NUMBER OF ESTABLISHMENTS AND ASSOCIATED COSTS OF POTENTIAL PRODUCTION ADJUSTMENTS WITH RESPECT TO MANDATORY LM TESTING

| Group/sub-group | Representative meat and poultry products | Problem category (by # of establishments) | | | | | Associated cost to control LM problem (000's \$) | Value of discontinued production on (mil \$) |
|-----------------|--|---|-------|-----|----|-------|--|--|
| | | None | Stage | | | Total | | |
| | | | 1 | 2 | 3 | | | |
| I-1 | Fermented; Dried; and, Salt cured Products | 127 | 11 | 11 | 1 | 150 | 181.6 | 5.9 |
| I-2 | Frankfurters and wieners | 142 | 12 | 12 | 1 | 167 | 248.1 | 23.6 |
| I-3 | Meat patties | 65 | 5 | 5 | 1 | 76 | 72.5 | 5.3 |
| I-4 | Luncheon meats | 163 | 13 | 13 | 2 | 191 | 519.0 | 60.5 |
| II-1 | Otherwise processed M&P RTE product by meat processors. | 468 | 39 | 39 | 5 | 551 | 597.7 | 48.8 |
| II-2 | Otherwise processed M&P RTE product by poultry processors. | 139 | 12 | 12 | 1 | 164 | 570.4 | 66.9 |
| II-3 | Otherwise processed M&P RTE product by combo plants. | 65 | 5 | 5 | 1 | 76 | 99.3 | 9.6 |
| III | Frozen dinners and pizzas | 89 | 7 | 7 | 1 | 104 | 201.9 | 21.6 |
| IV | Canned products | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Grand total | | 1258 | 104 | 104 | 13 | 1479 | 2490.5 | 252.2 |

Some establishments follow the recommended guidelines in production but, for any number of reasons, are expected to face difficulties in improving their *L. monocytogenes* testing results. Establishments that encounter Stage 1 problems would face only marginal difficulties in improving their *Listeria spp.* testing results. Seven percent of the establishments (104) are expected to fall into a this group. FSIS expects that these plants can reduce these positive findings by concentrating mainly on the pre-operational component of the business,²¹ perhaps taking more care in pre-operational sanitation and better training of and increased awareness by production personnel. Also, one could expect that some "quick-fixes" to equipment, such as finding the niches in equipment which may harbor *L. monocytogenes* and cleaning them thoroughly and more regularly, might greatly reduce their positive food contact surface testing results. Actions that are expected correspond roughly to the response by industry in a recent survey pertaining to what actions are taken by establishments when they exceed limits on results from environmental testing. These include:

- Enhance pre-operational and operational sanitation controls in production (262 out of 308 establishments that responded to the industry survey cited previously indicated

that this action was taken when allowable environmental testing results were exceeded);

- Implement an environmental monitoring program for *Listeria spp.* to verify that the control program is effective (241 out of 302 surveyed indicated that this action was taken when allowable environmental testing results were exceeded);

- Intensify training efforts on personnel (232 out of 302 surveyed indicated that this action was taken when allowable environmental testing results were exceeded);

- Purchase inputs from suppliers with a *L. monocytogenes* control program, and;
- Apply a validated listericidal process where appropriate.

FSIS expects that plants encountering Stage 1-type problems will face a \$2000 per line average "fix" for equipment and machinery. These efforts are expected to be effective and not involve any recurring cost. Across all affected establishments, such costs are expected to total \$0.7 million.

An additional 7-percent of all establishments (104) are expected to face significantly greater difficulty in improving their food contact surface *Listeria spp.* testing results: "Stage 2-type" problems that can not be solved simply by increased attention to pre-operational sanitation efforts. These

plants must instead concentrate on equipment and building re-design and other manageable "technical fixes". By their nature, these one-time efforts are more costly. Examples of the kind of efforts envisioned with these adjustments are: addition of post-processing pasteurization equipment, re-designed drains, walls, and floor areas, especially in the post-processing rooms, and other major renovations to buildings and equipment.²²

FSIS expects that plants encountering Stage-2 type problems will face higher costs than establishments facing Stage-1 problems. Based on expenses incurred by the industry in taking similar steps in the early 1990's, FSIS estimates that such efforts could cost the affected establishments 0.1 percent of their gross sales.²³ Some product losses from these firms are expected due to greater amounts of product held from commercial channels because of positive food contact surface tests for *Listeria spp.* or positive product test results for *L. monocytogenes*.²⁴ Such product losses are expected to diminish after 6 months. Thus, such temporary production drops and possible disruptions are not considered throughout this analysis. FSIS request comment on the costs of holding and testing product for *L. monocytogenes* contamination. Keeping this in mind, FSIS projects that the total expenses

²⁰ Further data analysis is needed to more accurately estimate this figure. The current estimate is based on MARCIS data on follow-up LM positive finding for only one year of data (1999). This first group of producers are assumed to represent the 85 percent of initial positive microbiological survey samples that quickly rectified their contamination problems in 1999. The latter stages reflect smaller and smaller percentages of the initial positive samples that required more and more follow-up tests because their test results persisted positive.

²¹ Some increase in sanitation supplies and materials are also expected.

²² Further examples can be found in: *Industry Perspectives on LM in Foods: Manufacturing and Processing*, Bernard and Sveum, Dairy, Food and Environmental Sanitation, Vol. 14, No. 3, Pages 140-143 (March 1994).

²³ Tappero, Jordan, Anne Schuchat, Katherine Deaver, Laurene Mascola and Jay Wanger, *Reduction in the Incidence of Human Listeriosis in the United States, Effectiveness of Preventive*

Efforts?, JAMA, April 12, 1995—Vol. 273, No. 14. This study actually put the costs at the range of 0.1 to 0.2 of annual industry sales.

²⁴ It is also acknowledged that increased numbers of positive environmental tests may result in increased numbers of positive product tests, leading in turn, to not only increased amount of product destroyed, but increased amounts of product that need to be held until results are complete and in the case of positives, increased amount of products that need to be reworked.

associated with Stage 2 corrective actions across the industry at \$1.7 million. In total, corrective actions associated for both Stage 1 and 2 type problems are expected to cost \$2.5 million in one-time costs.

A final group of plants is expected to face Stage 3-type problems: problems that establishments may perceive to be prohibitively costly to "fix" and/or not feasible to undertake without complete modernization or renovation. Without making the needed capital investments, their only option is to drop out of production. This may involve dropping just the RTE meat and poultry product component of their business or eliminating RTE meat and poultry products altogether.²⁵ FSIS estimates that one percent of all establishments (13) regardless of size category²⁶ will fall into this category. Resources, associated with the associated discontinued production, are expected to be absorbed by their next-best use, such as frozen not-RTE food and other food manufacturing. The value of the initial drop in production across the industry is estimated at \$252 million. Although firm numbers may drop by 1-percent, this initial drop in production would not be expected to persist over time. Market supplies would be expected to increase due to likely production increases by the remaining domestic establishments and possibly by increased imports of similar type meat and poultry products.

FSIS realizes that many of the technological "fixes" that many establishments may have to undertake are not scale-neutral (they favor increasing scale establishments). Thus, one may discover that small and very small establishments are

²⁵ It is misleading to attribute all of the reason for the one percent decline in firm numbers on the proposed rule. Some number of firms would have gone out of production due to competitive reasons and dynamics involved in industry technological change. Regardless of the regulatory environment, some level of technology will be adopted by some firms and not by others; in addition, technology may be made available to control LM in RTE food processing during the time frame of this analysis. If this technology is size-neutral, projections concerning industry response to the proposed regulation is problematic. On an optimistic note, impacts may be dampened considerably by such technology adoption. Examples of technology that is being developed (and may be scale-neutral) include: antimicrobial packaging, high pressure processing, irradiation, oscillating magnetic fields, pulsed electric fields, and UV light (Meat and Poultry, April 2000, *Post-processing pasteurization, Preventing recontamination requires an aseptic approach*). However, impacts may be greater if technology does not advance and Listeria control is more of a function of pre-operational prerequisites, like building re-design and layout. Due to the great amount of uncertainty related to this issue, no assumptions were made concerning these off-setting influences. However, the one-percent level was used to indicate that some number of plants may drop out of production as a result of the proposed rule.

²⁶ Given time, further analysis may reveal that the probability of such Positive Microbiological Survey Findings are associated with certain Meat and poultry products, plant age or size, or other major characteristic(s), i.e. season. Recall and other internal FSIS data were investigated and no single characteristic was found to explain MPSF occurrence and/or frequency.

disproportionately affected by this provision of the proposed rule. However, to ensure maximum food safety benefits from testing, FSIS is proposing to require industry-wide adoption. FSIS requests comments on expected impacts on small and very small establishments.

The total cost of mandatory food contact surface testing on this industry is estimated at \$5.53 million (\$1.28 million on HACCP plan modification, \$1.75 million on testing, and \$2.5 million in production adjustment costs).

2. Costs Associated With Lethality and Stabilization Performance Standards

This provision, as described in the provisions section, mirrors the recently published performance standards for the production of cooked beef, roast beef, cooked corned beef products, fully and partially cooked poultry products (64 FR 732). However, that rule did not apply to dried, fermented, and salt-cured RTE meat and poultry products. Fermented sausage makers were advised in the mid-1990's on methods to ensure food safety and most of these processors made changes to their production at that time; however, this is not known for sure. Also, the current proposed rule would increase the required level of pathogen reduction in meat patties. As such, processors of meat patties and the dried, fermented, and salt-cured RTE meat and poultry products are expected to feel the major impact from this provision of the proposed rule. FSIS expects that this provision may have two potential impacts on certain RTE meat and poultry product producers: (1) the need to make production changes to attain the higher performance standards and (2) the need to incorporate increased monitoring equipment and other means to validate that they are meeting the new performance standards.

A. Projected Costs Associated With Production Adjustments

The majority of the establishments that produce RTE meat and poultry products are not expected to be affected by the lethality and stabilization provisions of the proposed rule. Most establishments already may meet these requirements because they are identical to those in the final rule that established performance standards for the production of certain RTE meat and poultry products (64 FR 732). However, it is expected that one-third of the plants in Group I, Subgroup 1 (Dried, Salt-cured and Fermented Sausage makers) and one-third of Group I, Subgroup 3 (meat patty makers) will be affected by this provision of the proposed rule. FSIS estimates that these 75 establishments or less than 5 percent of the establishments in this industry produce about 441 million pounds of product.²⁷

FSIS expects that producers will adjust to higher performance standards by applying some additional heating or holding times to their products or by relying upon integrated

²⁷ Using an assumed average level of production for each establishment of 50, 5, and 2 million pounds for large, small, and very small establishments, respectively, in each affected subgroup times the number of affected establishments.

lethality involving multiple hurdles or accounting for come-up and come-down time. FSIS tentatively concludes that many establishments would meet the proposed performance standards using current procedures; however, the integrated cumulative lethality of these procedures may not have been fully assessed at this time. Individual establishments' costs could vary greatly depending on their need to purchase capital equipment, such as flash freezers for quicker cooling times, new heating equipment, etc., that may lead to increased costs in the short run, but lower operating costs and improved product in the long run. FSIS expects that most establishments will continue to produce their products in much the same way, but may increase their heating temperatures and holding times. In so doing, they are expected to experience somewhat reduced production line speeds, initially higher product rejection rates, and slightly lower annual production.²⁸

FSIS has only limited data to base its estimate for the impact of higher performance standard. Some anecdotal information suggests that some establishments, to attain the new lethality performance standards, may have to incur an additional cent per pound of product produced. This estimate implicitly incorporates the cost of reduced annual sales by the firm due to slower line speeds (and its implicit effect on lost value of production), equipment costs, and higher energy costs. At this time, this one-cent per pound cost is used in this analysis. FSIS uses this per-pound estimate and its estimate on affected poundage of product to project an aggregate annual recurring cost of \$4.4 million (\$0.01 times 441.1 million pounds).

B. Projected Cost Associated With Performance Standard Validation

The 75 establishments identified above are expected to need a one-time validation to determine if they are meeting the higher performance standards. FSIS estimates that these firms produce, at least, 545 specific product-types that would need lethality and stabilization validation. FSIS expects that the costs to validate the attainment of performance standards to be the same as the validation of a HACCP plan modification (\$5000). Thus, FSIS estimates that the overall cost to establishments to validate that they are attaining the higher performance standards for these products at \$2.7 million (545 times \$5000).

Projected Costs Associated With Label Changes. FSIS is proposing that the labeling of RTE products state that the product requires refrigeration after opening, as applicable. Current regulations require that labels of perishable products include such instructions, but the Agency is proposing to expand the required label instructions to include RTE shelf-stable products that require refrigeration after opening. For

²⁸ These implicit costs are associated with production drag—increased levels of recalls, higher rejection rates in production, slower production shifts, slower sales due to perceived poorer quality and such. Ideally they should be counted as a separate effect associated with a possible leftward shift in supply. At this time, there is not sufficient data to quantify this effect.

products that would be covered by this provision, FSIS estimates that the costs per label would be comparable to those for printing safe handling labels (\$0.0025 to \$0.05 per label if the information is included as part of their price label, and, \$0.01 per label if they developed separate labels) (see 58 FR 58924). FSIS requests comment on the costs and benefits of this labeling provision.

Projected Benefits From the Proposed Rule

All the benefits from this proposed rule are generated by producers' actions complying with the mandatory food contact surface *Listeria* testing and the HACCP plan provisions of the proposed rule.²⁹

Benefits are expected to accrue gradually over time. Although studies found in the literature suggests that *L. monocytogenes*

control measures take about 6 months to 2 years before they are successful, FSIS found no basis for what form this time path for benefits should take. However, FSIS wants to account for any lag in the effectiveness of producer actions and other factors that may affect the immediate realization of full benefits. FSIS uses the following time path for realization of benefits: 5% realization by the first year; 10%, by the second year; 15%, by the third year; 40%, by the fourth year; 50%, by the fifth year; 60%, by the sixth year; 70%, by the seventh year; 80%, by the eighth year; 90%, by the ninth year; and, 100% by year ten. FSIS requests comment and information regarding the realization of projected benefits.

Benefits are predicated on a chain of events: the proposed rule testing

requirements motivating establishments to maintain higher sanitation standards; the introduction of less contaminated product in commercial channels; and eventually, fewer listeriosis cases and deaths from the consumption of RTE meat and poultry products.

Mandatory environmental food contact surface testing forces producers to incur costs to recognize (and, if need be, to remedy) their contamination problems. These costs, and those related to performance standards, are made up of mostly one-time, first-year costs and low recurring annual costs. More than half (56 percent) is related to performance standards, not mandatory testing (44 percent). Still, FSIS expects that the benefits derived from mandatory testing results would exceed the costs of both provisions.

TABLE 13.—NOMINAL AND REAL COSTS OF THE PROPOSED RTE RULE AND ASSOCIATED LISTERIOSIS CASE REDUCTIONS AT 100 PERCENT EFFECTIVENESS—ALL RTE MEAT AND POULTRY PRODUCTS

| Year | Nominal cost (\$ million) | Real cost (\$ million) | Cases eliminated | |
|--------------|---------------------------|------------------------|--------------------------------|--------------------|
| | | | FDA-FSIS draft risk assessment | Mead-Olsen studies |
| 1 | 12.6 | 11.8 | 83 | 8.35 |
| 2 | 6.2 | 5.4 | 166 | 16.7 |
| 3 | 6.2 | 5.0 | 249 | 25.05 |
| 4 | 6.2 | 4.7 | 664 | 66.8 |
| 5 | 6.2 | 4.4 | 830 | 83.5 |
| 6 | 6.2 | 4.1 | 996 | 100.2 |
| 7 | 6.2 | 3.8 | 1162 | 116.9 |
| 8 | 6.2 | 3.6 | 1328 | 133.6 |
| 9 | 6.2 | 3.3 | 1494 | 150.3 |
| 10 | 6.2 | 3.1 | 1160 | 167 |
| Total | 68.1 | 49.3 | 8632 | 868.4 |

¹ The year-end discount rate used is 7.0 (OMB, Circular No. A-94, updated January 2000).

Alternatives

Executive Order 12866 requires that FSIS identify and assess alternative forms of regulation. FSIS considered one alternative to all of the proposed regulations and five alternatives to the proposed testing requirements. These are discussed below.

1. No Action

The Agency considered not requiring the proposed performance standards for RTE meat and poultry products. Small and very small establishments may incur most of the costs of the proposed extension of the existing performance standards to all RTE meat and poultry products. There are currently performance standards for certain not-shelf-stable RTE meat and poultry products (RTE roast beef, corned beef, all "fully-cooked" RTE poultry products, and partially-cooked meat patty and poultry products). However, there currently are no performance standards specific to jerky, meat hotdogs, and luncheon meat and the current requirements for meat patties effect a lethality less stringent than that which is proposed.

FSIS considered not proposing to extend the performance standards to these products because of the possible disproportionate economic impact on small business. However, taking this alternative would result in a significant inconsistency in the Agency's public health policy. Most, if not all, RTE meat and poultry products are manufactured from the same supply of raw product examined in the FSIS national baseline surveys. So, performance standards derived from this baseline should be applicable to all categories of RTE meat and poultry products, regardless of how they are processed. All RTE products should be required to meet the same standard of safety. FSIS will publish compliance guides and possibly take other actions to mitigate the economic effects of any final rule on small businesses.

In general, some members of the meat and poultry industry believe that regulatory performance standards are unnecessary or redundant, considering that FSIS already requires all meat and poultry establishments to develop and implement HACCP systems. FSIS believes, however, that developing HACCP systems around verifiable, objective performance standards is the most effective way for establishments to consistently

produce safe, unadulterated meat and poultry products. Furthermore, by proposing performance standards for pathogens whose destruction results in the destruction of most or all other pathogens of concern, FSIS provides a reference for establishments to use in gauging the efficacy of their HACCP systems. FSIS, therefore, is proposing pathogen reduction performance standards that can be incorporated into HACCP systems, rather than requiring that establishments rely upon HACCP alone.

FSIS considered not revising the prescriptive canning and *trichina* treatment requirements for certain pork products. However, these provisions of the proposed regulations represent regulatory reform and streamlining efforts. The regulatory safety standards for commercially sterile products and for pork products would be unaffected by this proposal. FSIS also considered not requiring testing for *Listeria*. However, without some regulatory requirements addressing *Listeria*, many establishments will continue not to regard *L. monocytogenes* as a post-lethality hazard reasonably likely to occur and not take steps through Sanitation SOPs or HACCP to ensure the safety of their products. FSIS tentatively concludes that

²⁹ Recall that the benefits from producers complying with the higher performance standards

are not quantified at this time. Also, refer to the

uncertainty discussion for an explanation of factors that may lead to underestimation problems.

without defining required actions in either the Sanitation SOPs or HACCP, product will continue to test positive for *L. monocytogenes* and outbreaks will continue to occur.

2. End-Product Testing

FSIS considered proposing to require testing of finished product for *L. monocytogenes* instead of the proposed food contact surface testing for *Listeria spp.* In short, FSIS does not believe that such end-product testing at levels high enough to ensure statistical confidence would be a practical means of ensuring that RTE meat and poultry products are not adulterated by *L. monocytogenes*. To determine that every lot of RTE product was not adulterated by *L. monocytogenes*, an establishment would likely have to test a significant portion of each lot and hold each lot until test results were confirmed.

Further, end-product testing to verify process control is antithetical to the notion of process control under the Agency's HACCP and Sanitation SOP regulations. Granted, FSIS is proposing to require product be held and tested in the event an establishment has a positive food-contact surface test result. But this proposed product testing is a measure every prudent establishment should take when it determines that its Sanitation SOP is ineffective and that product may have been produced under insanitary conditions and therefore may be adulterated. FSIS believes, based on the numerous recalls involving small quantities of RTE meat and poultry products and the fact that the majority of the recalls are initiated in small and very small establishments, that members of the meat and poultry product industry are not effectively ensuring that products are not adulterated. Thus, the Agency, in the interest of public health, opted to propose making mandatory food-contact surface testing for *Listeria spp.*

3. Mandatory Post-Lethality Interventions for *L. monocytogenes*

FSIS is aware of several establishments that currently apply a post-lethality steam pasteurization treatment to their RTE products, specifically to eliminate *L. monocytogenes*. FSIS allowed establishments to use antimicrobials specifically effective in preventing growth of *L. monocytogenes* in RTE products (i.e., sodium diacetate, potassium lactate, and sodium lactate, 65 FR 17128, March 31, 2000). Furthermore, in the future, other types of antimicrobial interventions that can be applied after lethality treatment and after packaging that can eliminate *L. monocytogenes* from RTE products may be available. For example, eventually, FDA and FSIS may allow establishments to treat RTE products with ionizing radiation. If applied within a HACCP system, irradiation could eliminate *L. monocytogenes* from a RTE product. FSIS also is aware that industry is developing edible, antimicrobial coatings that could be applied to RTE meat and poultry after cooking or other lethality treatments. However, FDA has not yet approved any of these coatings for meat and poultry.

FSIS considered requiring establishments to implement post-lethality antimicrobial

controls instead of testing food contact surfaces for *L. monocytogenes*. Obviously, however, since most of the needed technologies are not yet available or not yet approved, establishments would have a limited number of treatments to choose from and some may not be appropriate or useable in every processing system. Further, mandating the use of any specific technology would be counter the Agency's goal of granting establishments maximum flexibility to innovate and design customized processes capable of producing safe meat and poultry products. And, initially, many of these new technologies may be prohibitively expensive as they become available, especially for small businesses.

By proposing to exempt establishment with CCPs for *L. monocytogenes* from the required testing, FSIS is providing an incentive for establishments to implement these new technologies as they become available. Also, the proposed exemption will allow establishments to conduct testing instead of developing HACCP plan controls, if they find testing to be a more cost-effective means of preventing contamination of their RTE products by *L. monocytogenes* as result of insanitation.

4. Mandatory Food Contact Surface Testing for All Establishments That Produce RTE Products

Because *L. monocytogenes* is an environmental contaminant and often adulterates RTE products as a result of insanitation, FSIS considered requiring all establishments that produce RTE meat and poultry products to test for *Listeria spp.* as a way to verify plant sanitation, regardless of whether they have implemented HACCP controls for *L. monocytogenes*. However, if an establishment develops a new CCP or designates an existing CCP to control contamination of its products by *L. monocytogenes*, it will be taking process control actions that likely will include sanitation practices to limit levels of *L. monocytogenes* on incoming raw product, lethality steps to destroy *L. monocytogenes*, sanitation control steps to prevent recontamination, or testing to validate and then frequently verify that its controls are effective. FSIS believes that requiring these establishments to also conduct the mandatory testing for *Listeria spp.* would be unnecessary and redundant. Further, requiring all establishments that produce RTE products to conduct testing for *Listeria spp.* is expected to increase annual compliance costs from the estimated \$1.75 million in testing costs related to the specific provisions in the proposed rule to \$4.6 million. Again, these costs should be regarded as direct annual recurring costs associated with the minimum number of food contact surface testing estimated by FSIS.

5. Redesignation of Hotdogs and Other Products as Not-Ready-To-Eat

FSIS considered creating a new category of products for partially-cooked sausages and other products that no longer would be considered RTE. An establishment that redesignated its meat and poultry product as not RTE would not be required to conduct

the proposed testing for *Listeria spp.* nor meet any other regulatory requirements applicable only to RTE products. FSIS would require the establishment, however, to label its not RTE product with the safe handling instruction (9 CFR 317.2(l), 381.125(b)) and with cooking instructions similar to that for partially-cooked meat patties and poultry rolls (9 CFR 318.23 and 381.150).

The safe handling instruction is required for all products that have not undergone processing that would render them RTE and includes four labeling statements, including "cook thoroughly" along with a graphic illustration of a skillet. The cooking instruction is currently required for partially-cooked meat patties and poultry rolls, which need thorough cooking prior to consumption for safety. This cooking instruction states: "Partially-cooked: For Safety Cook until Well Done (Internal Meat Temperature of 160 degrees Fahrenheit)".

FSIS considers cooked meats, including those defined in 9 CFR 319.180 (Subpart G—Cooked Sausage) which include frankfurters, hotdogs, wieners, bologna, and similar products, to be RTE products. Ready-to-eat products should be safe to consume without any additional cooking or application of a lethality treatment by the consumer. More importantly, it is likely that most consumers also consider hotdogs and similar products to be RTE, and only apply a heat treatment to improve product palatability. Consumer behavior would have to be significantly modified to ensure that they are aware that an adequate cook for safety must be applied to these products.

Another consideration is that restaurants, including street vendors and quick-service operations, would have to treat these redesignated products as not-RTE. The current Model Food Code provides that RTE food taken from a commercially-processed intact package from a food processing plant shall be heated to a temperature of at least 140 degrees Fahrenheit for hot holding (FDA Food Code, section 3–403.11). The hot holding temperature is not intended to serve as the lethality treatment for the product, but only as a temperature sufficient to prevent multiplication of pathogens while the product is being held prior to sale. Thus, this industry would have to apply a higher minimum temperature and time combination to achieve the necessary lethality for safety.

FSIS does not have the data needed to estimate the costs that would result from the redesignation of certain hotdogs and similar products as not-RTE. Direct costs to industry would include: new labeling; the cost to retailers who be required to apply higher time/temperature combinations to the redesignated products; and possible loss of market share by firms that redesignate their products as not-RTE to firms that continue to produce RTE products. Other costs include consumer education and, most importantly, possible public health costs resulting from consumers inadequately cooking not-RTE products traditionally considered RTE and consequently contracting foodborne illnesses. It is likely that these costs would exceed the savings that industry would accrue from being exempted from the proposed testing requirements and other requirements

applicable to RTE products and FSIS has therefore rejected this alternative. FSIS does request comment, however, on these and related issues.

6. Require "Use-By" Date Labels on Certain RTE Meat and Poultry Products

FSIS considered, but is not proposing, requiring that the labeling of certain RTE meat and poultry products state the product's shelf-life, and that shelf-life be based on product safety ("use-by" date labeling) in addition to the proposed *L. monocytogenes* control measures. *L. monocytogenes* contamination is often a result of product manipulation, such as the slicing of deli meats or the peeling of hotdogs, after lethality treatments are applied. In the recent interagency draft risk assessment, FDA and FSIS have concluded that numerous RTE meat and poultry products that undergo post-lethality manipulation and that can support the growth of *L. monocytogenes* in their final packaging and under refrigerated conditions are at relatively higher risk of causing listeriosis.

Food contact surface testing does not address (1) the physical inability of current testing devices to detect minuscule amounts of *L. monocytogenes* in some finished RTE meat and poultry products after their manufacture and (2) the capability of *L. monocytogenes* to grow-out in certain products, even while being kept under refrigerated temperatures. Thus, process controls and food contact surface testing may not reduce risk sufficiently. Some small amounts of product, with non-detectable *L. monocytogenes* contamination levels, could continue to enter commercial food channels. Also, consumers may be improperly handling certain products. The main meat and poultry products of concern are deli meats and frankfurters—products which receive post-processing handling and manipulation and have been associated with past listeriosis outbreaks.³⁰ If consumers understood "use-by" dates and changed their behavior accordingly, "use-by" labels could help to ensure food safety through proper handling of RTE meat and poultry products and thereby reduce the risk of listeriosis. However, it is likely that consumer behavior would have to be significantly modified to ensure that they are understand "use-by" dating.

For most consumers who are healthy and safely handle their food, this low level of possible *L. monocytogenes* contamination does not pose a significant food safety hazard. However, this is not the case for high-risk individuals who may be severely harmed by *L. monocytogenes*, even by slightly contaminated RTE meat and poultry products. Increased mandatory food contact surface testing should reduce the likelihood of any *L. monocytogenes* contamination present in these products.

In the process, producers and marketers will likely alter their behavior with respect to product rotation in storage and marketing. There is sparse information regarding the

potential affects of this labeling, the likelihood that consumer practices will change, and on the effect of changes in consumer behavior on listeriosis cases. Similarly, FSIS currently does not possess all the information necessary to assess the reduction in risk that will occur from this change. Also, the "use-by" date labeling may give consumers a false sense of security.

Much uncertainty surrounds the potential costs and benefits of "use-by" dating. Little research has been done to address many issues regarding this alternative. For instance, what is the likely consumer reaction to "use-by" date labeling? What are the public health consequences? How would "use-by" date labeling potentially impact the production and shipment patterns of labeled RTE meat and poultry products and the structure of the industry? For example, will smaller operations benefit from a "use-by" date more than larger operations who must rely on larger sales areas which require longer product shelf life to penetrate the entire marketing area?

Further, much uncertainty surrounds expectations for increased consumer awareness by the high-risk sub-population of "use-by" date labeling. Assuming the awareness rates for the high-risk sub-population were the same as the general population, only 12.4 fewer annual listeriosis deaths would result from "use-by" dating (as opposed to 54).

Comment Request

FSIS requests comment on the feasibility of requiring "use-by" date labeling on certain RTE meat and poultry products, generally in regard to the public health benefits and the costs of such labeling, and specifically in regard to the following questions:

(1) What would be the most effective way to implement an "use-by" labeling scheme? Should FSIS propose to require that use-by dates be determined and validated within the producing establishment's HACCP plan? Or, should another alternative be used.

(2) What assumptions should be used about retailer and consumer behavior in determining a use-by date? Should the use-by date be determined under the assumption that retailers and consumers will follow any handling instructions contained in the labeling? Or, should the use-by date determination be based on a "worst case" assumption that products will be mishandled or temperature abused?

(3) What scientific and economic data are available regarding the shelf-life and safety of RTE meat and poultry products contaminated with *L. monocytogenes*? Are any studies of "use-by" date labeling efficacy available? FSIS is currently working with the Agricultural Research Service on a study to evaluate the shelf-life of hotdogs and is aware of other studies, but welcomes any additional information. FSIS would publish guidance regarding use-by dating before any final action becomes effective and would base this guidance on the latest science available.

(4) Should FSIS propose to require post-lethality *L. monocytogenes* interventions instead of "use-by" date labeling? FSIS is aware that in the future, certain types of antimicrobial interventions that can be applied after lethality treatment but before

packaging and that can eliminate *L. monocytogenes* from RTE products may be available. Eventually, FDA and FSIS may allow establishments to treat RTE products with ionizing radiation. If applied within a HACCP system, irradiation could eliminate *L. monocytogenes* from a RTE product. FSIS also is aware that industry is developing edible, antimicrobial coatings that could be applied to RTE meat and poultry after cooking or other lethality treatments. However, FDA has not yet approved any of these coatings for meat and poultry.

(5) What language would be most effective in informing consumers about "use-by" date labels? Would labeling such as "For safety, use-by * * *" be more effective? Should the labeling indicate anything regarding vulnerable populations? Should FSIS propose to allow for a variety of phrases? FSIS is aware that many RTE meat and poultry products already carry shelf-life labeling indicative of product quality. Would allowing different phrases result in consumer confusion? Would allowing quality and safety dates to appear on the same package result in confusion? Should FSIS propose to allow different dates based on handling instructions, for instance: one date if the consumer freezes the product, another if the consumer refrigerates the product?

Uncertainty

Benefits Side

The current level of benefits does not consider what technical obstacles exist that may reduce the effectiveness of the provisions in the proposed rule to actually reduce listeriosis cases and deaths. FSIS is uncertain about the effectiveness of its proposed testing requirements in reducing listeriosis, and therefore unable to adequately quantify a range of benefits. No research that directly looked into this subject was found in the literature. FSIS intends to use comments and data received during the comment period and at the planned technical conference to refine the proposed regulations and to better estimate benefits. It is of course unlikely that the proposed regulations could achieve complete elimination of the listeriosis that results from contaminated meat and poultry, but FSIS believes that the benefits of the regulations would exceed the total costs of all of the proposed provisions. The current baseline analysis does not consider any private sector benefits that may result from the proposed rule. The impact of fewer recalls, possibly smaller amounts of returned product with better labeling, fewer consumer complaints, and other reduced costs may benefit the establishments that thrive in the new regulatory environment.

The benefits in this analysis are calculated as if they accrue gradually over time. More research into this subject is needed. Although some research has shown that it would take six to eighteen months for industry LM-control efforts to show positive results, little research was found that looked into the time path for benefits.

Unquantified Benefits Resulting From Proposed Performance Standards

There are currently no performance standards specific to jerky, meat hotdogs, and

³⁰ Up to 92 percent of all listeriosis cases and deaths from RTE meat and poultry products, as calculated by FDA-FSIS RA, was attributable to the consumption of deli meats and frankfurters.

luncheon meat and the current requirements for meat patties effect a lethality less stringent than that which is proposed. Fermented sausage makers were advised in the mid-1990's on methods to ensure food safety and most of these processors made changes to their production at that time; however, this is not known for sure. As such, processors of meat patties and the dried, fermented, and salt-cured RTE meat and poultry products are expected to feel the major impact from the proposed rule. However, little is known about the production process for many dried and fermented products affected by this rule.

According to one study, *E. coli* O157:H7 causes 52 foodborne-related deaths per year. Nontyphoidal *Salmonella* causes 582 foodborne-related deaths per year (Mead, 1999). Some benefits are expected to be generated by fewer sicknesses due to the proposed *Salmonella* and *E. coli* O157:H7 performance standards that would be extended to certain RTE meat and poultry products that are not currently required to meet these performance standards. However, FSIS has not conducted a quantitative analysis of these benefits and requests comments and data on possible benefits resulting from the proposed requirements.

FSIS is replacing prescriptive provisions concerning thermally processed, commercially sterile meat and poultry products with performance standards. The proposed performance standards will ensure that this product continues to be safe. FSIS believes these proposed provisions would not impose any costs because producers could continue to follow the same procedures required under the current regulations. Producers may realize some benefit from the flexibility that will be allowed under the performance standard regulations if they adopt new innovative means of producing the product. However, FSIS could not estimate any benefits that may be derived from replacing these prescriptive provisions with performance

standards and requests comment on possible benefits that may be realized.

FSIS is proposing to eliminate its regulations that require both RTE and not-ready-to-eat pork and products containing pork be treated to destroy trichinae (*Trichinella spiralis*). FSIS believes that, even if these provisions are removed, pork products will continue to be safe from trichinae. For heat-treated, RTE products containing pork, the required treatment to destroy trichinae would no longer be needed because if the process used meets the proposed performance standards for *Salmonella*, the process should eliminate any live trichinae. For other products, if the establishment identifies *trichina* as a hazard reasonably likely to occur, the establishment would have to ensure that the process used effectively eliminates this hazard. If the prescriptive provisions concerning trichinae are removed from the regulations, producers may realize benefits if they determine *trichina* is not a hazard reasonably likely to occur or if they find new ways of treating their product for trichinae.

Cost Side

Over eighteen percent of the first 10 years' total cost of the proposed rule occurs in the first year of program implementation. These costs take the form of one-time outlays related to validation of (1) modifications to HACCP plans and (2) attainment of performance standards. FSIS anticipates that expected industry costs resulting from this proposed rule could be lowered substantially with assistance to deal with these one-time costs.

There may be some consumer welfare losses that result from lower production that may result from this proposed rule. Because some firms may lose market share for their RTE meat and poultry products, consumers may be provided with fewer RTE meat and poultry products in total and a more limited choice among RTE meat and poultry products. Comments are welcome concerning the extent to which this proposed rule may

affect the range of RTE meat and poultry products and other issues dealing with consumer choice.

The analysis of the costs associated with performance standards noted that the cost estimate used is highly uncertain, being based on information gathered in a pilot survey. An industry survey is underway and hopefully will address much of the uncertainty of production processes currently employed by producers of these products and their options when faced with higher performance standards. FSIS based the analysis on performance standards on very limited data, much of it received as part of a pilot survey. FSIS requests information concerning the production process for many of these dried and fermented products affected and the options that producers have in dealing with this provision.

Much uncertainty involves the break down of these results by size of establishment. As noted in this analysis and the Regulatory Flexibility Act section, an argument can be made that the proposed rule will disproportionately affect small entities. However, to the extent that validation costs (which can be considered more like fixed costs rather than variable costs) can be reduced, this effect will be minimized. Without these reductions, however, validation costs would tend to disproportionately affect small producers rather than large ones. Any research and assistance to make these needed validations and production adjustments as scale-neutral as possible could dampen the possible disproportionate impact on small entities.

Mandatory food contact surface testing could impose a need to build additional storage for suspected contaminated products to wait in a "test and hold" period. This may affect smaller operations more than larger ones. FSIS requests comments that address this issue.

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