COMPLIANCE GUIDELINES TO CONTROL *LISTERIA MONOCYTOGENES* IN POST-LETHALITY EXPOSED READY-TO-EAT MEAT AND POULTRY PRODUCTS

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SUMMARY OF GUIDANCE MATERIAL

This guidance document was developed to help establishments that produce ready-to-eat (RTE) meat or poultry products exposed to the processing environment after the basic lethality procedure (e.g., cooking) has been applied to comply with the requirements of the Food Safety and Inspection Service's (FSIS) *Listeria* interim final rule (*Listeria* rule). The *Listeria* rule establishes three alternative ways to address post –lethality contamination of *Listeria monocytogenes* (*L. monocytogenes*) in these products. Under Alternative 1, the establishment applies a treatment to the product after its exposure to the processing environment (post-lethality treatment) and uses a growth inhibitor (antimicrobial agent or process) to prevent the growth of *L. monocytogenes* in the product up to its declared shelf life. Under Alternative 2, the establishment can use either a post-lethality treatment or an antimicrobial agent/process to control *L. monocytogenes*. Alternative 3 requires the establishment to have a sanitation program controlling *L. monocytogenes* contamination in the processing environment and on the product.

The document gives guidance to establishments on how to determine whether their product is RTE (p.7), and on actions the establishments can take if the product is RTE and exposed to the processing environment after the basic lethality treatment. Information provided in the guidelines on the control methods required for Alternative 1, Alternative 2, and Alternative 3 can help establishments in choosing the alternative to choose for their products (pp.7-21).

In these guidelines, the Agency provides information on how to validate, document, and apply the post-lethality treatment and antimicrobial agent or process using, among other approaches, a challenge study, a peer reviewed article from a scientific journal, or a modeling program. The guidelines provide examples of challenge studies and links to guidance documents on how to conduct a challenge study and a shelf life study.

The guidelines also include a chart on growth limits for *L. monocytogenes* (p. 13). If an establishment uses pH, water activity, or temperature below the growth limits of this pathogen, it can be considered as using an antimicrobial agent or process.

The guidelines on sanitation include topics on possible sources of *L. monocytogenes* contamination, places in processing where contamination is likely to occur, general cleaning and sanitizing of the processing environment and equipment, methods to determine efficacy of cleaning and sanitizing procedures, controlling traffic especially between RTE and a non-RTE sections, employee hygiene, sanitizers that can be used, and food contact and environmental testing (pp. 25-45). The guidelines also include a section on how to determine whether the product should be considered deli meat or hot dog. They also provide an example of a test and hold scenario that would occur when an establishment test of a food contact surface is positive, and the product is held while corrective actions and retesting are conducted (pp. 44, 68-71).

The Agency has also included tables to show: 1) the recommended minimum log reduction of *L. monocytogenes* that is necessary for the post-lethality treatment to achieve to be considered under Alternative 1 and 2 (p.21); 2) the expected log suppression by the antimicrobial agent or process throughout the shelf life of the product (p. 21); and 3) the recommended frequency of testing food contact surfaces for the three alternatives (p. 42). The guidelines discuss how the establishment can receive reduced sampling from FSIS, labeling issues, information on new technologies and methods for testing food contact and environmental surfaces for *Listeria* spp., *Listeria*-like organisms and *L. monocytogenes*.

A. Introduction

Food Safety and Inspection Service (FSIS) developed Compliance Guidelines to help the establishments producing Ready-to-Eat (RTE) meat and poultry products, especially small and very small establishments, in their use of control methods for *L. monocytogenes* to comply with the requirements of 9 CFR 430. Their purpose is to show establishments how the control methods can, if used singly or in combination, prevent or eliminate *L. monocytogenes* contamination in the product during post-lethality exposure. Establishments can use the guidelines to choose control methods that are best suited to their processing. Some establishments may have already instituted their control methods, which they have verified to be effective in controlling the pathogen and may not need to change their methods to follow these guidelines. However, FSIS will make a determination on the effectiveness of the controls and establishment verification testing when deciding how FSIS will conduct its verification procedures in the establishment.

The interim final rule applies only to post-lethality exposed RTE meat and poultry products. Products containing both raw and cooked ingredients (e.g., a frozen entrée containing blanched vegetables and fully cooked meat) will not be considered RTE if: (1) the product label prominently indicates the need to cook the products for safety, and (2) there are validated cooking instructions. A frozen product to be cooked may be either RTE or not ready-to-eat (NRTE) unless a food standard of identity requires that the product be RTE. FSIS distinguishes between RTE and NRTE foods in Attachment 2.

This is the second update for these guidelines from the original document posted on the FSIS website on October 6, 2003. The first update in October 2004 responded to comments and questions that FSIS received about the rule and addressed questions that were asked during the workshops that the Agency held in preparation for the implementation of the interim final rule. This second update responds to additional questions and comments received. It also includes documents resulting from the Phase 1 activities for the risk-based verification for the rule. ***Added or revised sections are in color and in a different font.*** *The updated version includes:*

- *Summary of Guidance Material (p. 3)*
- *Discussion of reduced frequency of sampling by the Agency for some products (pp. 13 and 20)*
- *Adding the site for list of new technologies reviewed with "no objection" for use in establishments (p. 25)*
- *Modified the section (VII. 3.) on the testing of food contact and environmental services (p. 42) and modified the title (p. 1 and 42)*
- *Announcement of "Industry Best Practices for Holding Tested Products" (p. 46)*
- *Revision of section H.* ***Risk-Based Verification Testing Program*** *to describe current and projected risk-based verification program (p. 48)*

- *Attachment 3. Deleted the draft production volume form and replaced with the website link to the form (p.58)*
- *Attachment 6. Clarification on testing food contact surfaces (p. 71)*
- *Attachment 7. Procedures for the Evaluation of Establishment Control Programs for Listeria monocytogenes (p.76)*
- *Attachment 8. Guidance Derived from a Review of Comprehensive Food Safety Assessments Associated with Compliance (p. 99)*
- *Attachment 9. Links to guidelines for Validation(p. 102): "Guidelines for Conducting Listeria monocytogenes Challenge Testing of Foods" and "Considerations for Establishing Safety-Based Consume-by-Date Labels for Refrigerated Ready-to-Eat Foods"*

These guidelines will be updated periodically to include validated and other effective procedures as they become available.

B. Control of *Listeria monocytogenes* Using Three Alternatives

Listeria monocytogenes is a pathogen that is widely distributed in the environment such as plants, soil, animal, water, dirt, dust, and silage. Because *L. monocytogenes* may be present in slaughter animals and subsequently in raw meat and poultry as well as other ingredients, it can be continuously introduced into the processing environment. The pathogen can cross-contaminate food contact surfaces, equipment, floors, drains, standing water and employees. In addition, the pathogen can grow in damp environments and can establish a niche and form biofilms in the processing environment that are difficult to eliminate during cleaning and sanitizing. Other characteristics of *L. monocytogenes* that makes it a formidable pathogen to control are its heat and salt tolerance and its ability to grow at refrigeration temperatures and survive at freezing temperatures.

The lethality treatment received by processed ready-to-eat (RTE) meat and poultry products generally eliminates *L. monocytogenes*; however products can be re-contaminated by exposure after the lethality treatment during peeling, slicing, repackaging, and other procedures. Several outbreaks of foodborne illness resulting in hospitalization, miscarriage, stillbirth, and death have been linked to the consumption of deli meats and hotdogs containing *L. monocytogenes*. One of the most likely causes of *L. monocytogenes* contamination in these outbreaks was traced to post-lethality exposure and contamination by the pathogen. Deli and hotdog products are examples of RTE meat and poultry products that receive a lethality treatment to eliminate pathogens, but are subsequently exposed to the environment during peeling, slicing, and repackaging operations. If *L. monocytogenes* is present on the equipment used for peeling, slicing or repackaging, the pathogen can be transferred to the product upon contact. These products are examples of RTE meat and poultry products that can support the growth of *L. monocytogenes* during refrigerated storage. Since RTE products are consumed without

further cooking, if they are contaminated, there is a possibility of the occurrence of foodborne illness. The "FDA/FSIS Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods" (www.foodsafety.gov/~dms/lmr2-su.html) indicated that deli meats and hotdogs posed the greatest per serving risk of illness/death from *L. monocytogenes*.

RTE meat and poultry processing plants must include control programs for *Listeria monocytogenes* in their HACCP plans, Sanitation SOP or prerequisite programs to prevent its growth and proliferation in the plant environment and equipment, and prevent the cross-contamination of RTE products. The FSIS *Listeria* risk assessment (http://www.fsis.usda.gov/OPHS/lmrisk/DraftLm22603.pdf) indicated that the use of a combination of intervention methods to control *L. monocytogenes* in deli meats exposed to the environment after the lethality treatment has the greatest impact on lowering the risk of illness or death from *L. monocytogenes*. The Agency used these risk assessments as resources in developing the regulations to control *L. monocytogenes* in RTE meat and poultry processing.

The interim final rule for the control of *Listeria monocytogenes* (9 CFR 430) includes three alternative approaches that establishments can take in the processing of RTE meat and poultry products during post-lethality exposure. Under Alternative 1, an establishment applies a post-lethality treatment and an antimicrobial agent or process to control *L. monocytogenes*. Under Alternative 2, an establishment applies either a post-lethality treatment or an antimicrobial agent or process. In Alternative 3, the establishment does not apply any post-lethality treatment or antimicrobial agent or process. Instead, it relies on its sanitation program. Products produced under Alternative 1 and 2 are formulated and processed to eliminate *L. monocytogenes* and/or limit its growth if it is present. That means the number of organisms shall not increase during the product's shelf life to detectable levels, or levels which may result in a public health hazard. These alternatives provide greater control compared to Alternative 3 which involves only sanitation to control *L. monocytogenes*. Consequently, the rigor or stringency of the control methods decreases from Alternative 1 to 3. An establishment must identify which alternative their RTE product falls into based on its control program for *L. monocytogenes*. An establishment can choose to apply new control methods and subsequently move from one alternative to another; however, it must apply the control methods required for the specific alternative that it moved into. Each alternative has specific requirements with which the establishment must comply. A systematic table of the requirements for each alternative can be found in Attachment 1.

FSIS recognizes that establishments may be producing products that fall under different alternative control programs. These various products may best be covered in individual HACCP plans, though an establishment is free to adopt whatever program can best enable compliance. Conversely, products processed according to different alternatives, may by covered by a single HACCP plan. Products are grouped in a single HACCP plan when the hazards, CCPs, and critical limits are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and observed in practice. Thus, a single HACCP plan could cover hotdogs

formulated with and without antimicrobial agents (Alternative 2 and Alternative 3), provided that the HACCP plan clearly distinguishes any critical differences. In addition, if an establishment uses the same food contact surfaces (FCS) on the same production day (clean-up to clean-up) for products falling within two alternatives, the products should be treated as if they were in the higher risk category with respect to on-going verification by the establishment, including testing of product, food contact surfaces and the environment.

Products Covered by the *Listeria* rule:
Establishments should determine the alternatives to which it will adhere in its processes. The following steps can guide establishments in making this decision:

- Determine whether product is RTE or not RTE (NRTE)
  Resource 1 of the Directive and Attachment 2 of these Compliance Guidelines can guide the establishment in determining whether its product is RTE or NRTE. NRTE products are not covered by the rule.
- If the product is RTE, the establishment should determine whether the product is exposed to the environment after the lethality treatment (e.g., cooking) and before packaging. Examples of exposure to the environment after the lethality treatment are the following: 1) when product is removed from its cooking bag and re-packaged; 2) when product is removed from the cooking bag and sliced or cut-up and re-packaged; or 3) when product is peeled and repackaged; or when it is fermented or salt-cured or dried and smoked and packaged. (e.g., roast beef, cooked ham for slicing, hotdogs, fermented sausage, cured ham, and jerky).
- If the product is not exposed to the environment after the lethality treatment and before packaging, then the product is not covered by the *Listeria* rule. Examples of these products are fully cooked product in cook-in-bag that leaves the official establishment in the intact cooking bag; thermally processed, commercially sterile products; and products receiving a lethality treatment and hot-filled as long as the lethality temperature and sanitary handling are maintained during the period of time in which the product moves from the point of lethality to the point of packaging.
- If the product is post-lethality exposed, the establishment should determine the control methods it is using to control *L. monocytogenes* during the post-lethality exposure. The control methods used by the establishment will determine to what alternative the product can be categorized.

1. Alternative 1

Alternative 1 requires the use of post-lethality treatment (which maybe an antimicrobial agent or process) to reduce or eliminate *L. monocytogenes* <u>and</u> an antimicrobial agent or process to suppress or limit the growth of the pathogen. For RTE products that are cooked and then removed from their cooking bag and sliced, diced or repackaged, there is a risk of cross contamination from the equipment, conveyor belts and the processing environment. These products need to be aseptically processed and then repackaged under strict sanitary conditions to prevent contamination from *L. monocytogenes*.

a. *Post-Lethality Treatment*

Post lethality treatments such as steam pasteurization, hot water pasteurization, radiant heating and high pressure processing have been developed to prevent or eliminate post-processing contamination by *L. monocytogenes*. RTE products where post-lethality treatments were shown by studies to be effective in reducing the level of *L. monocytogenes* are whole or formed ham, whole and split roast beef, turkey ham, chicken breast fillets and strips, and sliced ham, sliced turkey, and sliced roast beef.

Post-lethality treatments can be applied as a pre-packaging treatment, e.g. radiant heating, or as post-packaging treatments, e.g., hot water pasteurization, steam pasteurization, and high pressure processing. Ultra violet treatment can be used either as a post-lethality treatment or antimicrobial agent or process depending on whether it eliminates, reduces or suppresses growth of *L. monocytogenes*. Some of the published studies on post-lethality treatments are reviewed in Attachment 4. Studies on post-lethality treatments showed reductions of inoculated *L. monocytogenes* from 1 to 7 $\log_{10}$ CFU/g depending on the product type, and duration, temperature and pressure of treatment. Higher log reductions were obtained when both pre-packaging and post-packaging surface pasteurizations were applied, and when post-lethality pasteurization was combined with the use of antimicrobial agents. Establishments should refer to the details of these studies if they want to use the intervention method in their processing. The guidelines will be updated to include studies or other methods as they become available.

Validation of Post-lethality Treatment

The post-lethality treatment that reduces or eliminates the pathogen must be included in the establishment's HACCP plan. The post-lethality treatment must be validated according to 9 CFR 417.4 as being effective in eliminating or reducing *L. monocytogenes* to an undetectable level, and the validation should specify the log reduction or suppression achieved by the post-lethality treatment and antimicrobial agents. Scott et al. (2005) developed guidelines for conducting challenge testing of foods for *L. monocytogenes* (Attachment 9). The effectiveness of the post-lethality treatments and antimicrobial agents must be verified, and establishments should make the verification results available to FSIS personnel upon request. FSIS expects the establishment's HACCP documentation to demonstrate that the post-lethality treatment is adequate to eliminate or reduce *L. monocytogenes* to an undetectable level. In cases of pre-packaging treatment, the establishment must be able to demonstrate how the level of contamination that may occur before packaging is eliminated.

An establishment can use available published research studies as reference for their validation provided these studies use the product type or size, the type of equipment, time, temperature, pressure and other variables used in the study in order to result in equivalent level of reduction of *L. monocytogenes*. An establishment that uses products, treatments or variables other than those used in the referenced studies must perform its own validation studies to determine the effective reduction of *L. monocytogenes* as a result of the post-lethality treatment or antimicrobial agent applied to the products. Some of the published studies use different products and report a range of levels of reduction of

L. monocytogenes. In this case, the establishment must validate the use of the post-lethality treatment or antimicrobial agent for its specific products. The establishment must specify the level of reduction achieved by the post-lethality treatment or antimicrobial agent applied in its validation to show that the product is safe. In the absence of published peer-reviewed paper that would contain information needed for validation, unpublished studies may be used provided there is supporting documentation that the data and analysis of results demonstrate that the specific level of application on specified products or range of products is effective to produce a safe product. In addition to the validation of the post-lethality treatment and antimicrobial agent, the establishment must verify its effectiveness by testing for *L. monocytogenes*.

Antimicrobial Process that Acts also as a Post-lethality Treatment

An example of an antimicrobial process that controls the growth of *L. monocytogenes* in the post-lethality environment is a lethality process that renders a RTE product shelf stable. Shelf stable products are formulated with salt, nitrites and other additives, and processed to achieve a water activity, pH and moisture-protein ratio that will reduce the level of *L. monocytogenes* and other pathogens during processing. In addition, the lethality treatment exerts a continuing bactericidal and bacteriostatic effect in the product, enabling the product to not support the growth of *L. monocytogenes* and other pathogens during the shelf life of the product at ambient temperatures.

Since products with water activity less than 0.85 will not support the growth of *L. monocytogenes* and can sometimes even cause *L. monocytogenes* death, FSIS will consider water activity of <0.85 at the time the product is packed to be a post-lethality treatment if there is a bactericidal effect (death of bacterial cells leading to a reduction in number) in the specific product, and the establishment has provided support documentation to document that the intended effect occurs prior to distribution of the product into commerce. In this case, the antimicrobial process could serve as both a post-lethality treatment and growth inhibitor. The establishment should have documentation on file (e.g., copy of a published report, challenge study) to demonstrate the effectiveness of the lethality treatment through the shelf life of the product. These shelf stable products can be classified in Alternative 1 if the requirements for this alternative are satisfied. The requirement that an antimicrobial process or product formulated with an antimicrobial agent suppress or limit growth throughout the commercial shelf life means that an establishment must have validated that the process or formulation does what is claimed. These validation records must be available to FSIS. Establishments must include in their HACCP plans the antimicrobial process used (e.g. drying, cooking/frying, or rendering) and the water activity achieved that renders the product shelf stable. Examples are shelf stable RTE jerky, country cured ham, pepperoni, dried soups, and pork rinds.

Pre-packaging Treatment as a Post-lethality Treatment

A pre-packaging treatment such as radiant heating can be used as a post-lethality treatment as long as it is validated to eliminate or reduce the level of *L. monocytogenes*. Since this is a post-lethality pre-packaging treatment, there is possible exposure to the environment after the treatment and before packaging. If there is separation between the treatment and packaging, then conditions have to be met to ensure a hygienic

environment to preclude contamination, or the post-lethality treatment would not likely be considered effective by FSIS. Some establishments may place the packaging machine right after the radiant heat treatment to reduce or eliminate this exposure. Support documentation must be made a part of the hazard analysis decision-making documents and validation data must be included in the HACCP plan. Studies have also shown that the use of pre-packaging treatment combined with a post-lethality treatment resulted in a higher log reduction of the pathogen.

Post-lethality Treatment Not a Critical Control Point (CCP) in the HACCP Plan

The rule states that *L. monocytogenes* is a hazard reasonably likely to occur for post-lethality exposed product unless there is a control measure incorporated in the HACCP plan, prerequisite program or Sanitation SOP. For Alternative 1 or Alternative 2 (post-lethality treatment) control measures, if a post-lethality treatment is used, it must be included in the establishment's HACCP plan as a CCP. FSIS encourages the use of any effective intervention for controlling *L. monocytogenes* contamination. However, if an establishment uses a post-lethality treatment for its product but does not incorporate the post-lethality treatment as a CCP, the post-lethality treatment cannot be used to justify Alternative 1 or 2 (post-lethality treatment). It could place the control measures for the operation in the Sanitation SOP or prerequisite program and the product can be categorized in Alternative 2 (antimicrobial agent) or Alternative 3.

Why an Antimicrobial Agent can be included in the HACCP Plan, Sanitation SOP or prerequisite program.

If an establishment chooses Alternative 2 and chooses to use an antimicrobial agent or process, the establishment can include the antimicrobial agent or process as a CCP in the HACCP plan, in the Sanitation SOP, or in a prerequisite program. The Agency gave establishments this flexibility because the Agency believes that how establishments choose to address control of *L. monocytogenes* will determine how they fit in the hierarchy. Antimicrobial agents or processes do not necessarily eliminate or reduce a food safety hazard from occurring but rather control for the hazard, by preventing or suppressing the growth of *L. monocytogenes*. A post-lethality process is applied at a specific step in the process that eliminates, reduces to an acceptable level, or prevents a food safety hazard, i.e., a critical control point. However, when the antimicrobial agent does eliminate or significantly reduce *L. monocytogenes*, it could be designated a CCP in the HACCP plan. On the other hand, if it only suppresses growth of *L. monocytogenes*, it could be addressed in the Sanitation SOP or other prerequisite programs.

Hot-packed products: edible oils and fats, lard, soups

Edible oils and fats resulting from a rendering process that processes them to 180º F and maintains at 160º F, with a water activity of less than 0.2 making them shelf stable are considered RTE. Rendering is intended to make this meat food product a ready-to-use ingredient in the preparation of other foods, e.g., edible tallow and lard are used as shortening. They do not require additional lethality treatment before being consumed. If these products are hot filled (as defined above) and packaged, they are not considered post-lethality exposed and therefore are not covered by the rule. However, these products would be considered NRTE and not covered by the rule if the process calls for partially

rendering animal fat for tallow or lard and then further processing or finished rendering in another plant.

Soups and other products that are cooked to eliminate pathogens and hot-packed in the final packaging material are RTE, but are not considered post-lethality exposed. Therefore the *Listeria* rule does not apply.

b. *Antimicrobial Agents or Processes*

Antimicrobial agents and processes must suppress or limit the growth of *L. monocytogenes* throughout the product shelf life i.e., the amount of time the product can be stored under specified conditions and still remain safe with acceptable quality. Antimicrobial agents were shown in research studies to reduce the levels of *L. monocytogenes*. These include lactates and diacetates added in the formulation and growth inhibitors in the immediate packaging material. These were shown to be effective in the control *L. monocytogenes* in RTE products such as hotdogs, bologna, cotto salami, and bratwurst.

Antimicrobial agents can be added to the product during formulation, to the finished product or to the packaging material to inhibit growth of *L. monocytogenes* in the post-lethality exposed product during its refrigerated shelf life. Lactates and diacetates are some antimicrobials added to the formulation of RTE meat and poultry products. Establishments should use antimicrobial agents that have been approved by FDA and FSIS for processed RTE meat and poultry products.

FSIS recently increased the permissible levels of sodium diacetate as a flavor enhancer and as an inhibitor of pathogen growth to 0.25 % (65 FR 3121-3123/2000). The rule also permitted the use of sodium lactate and potassium lactate in fully cooked meat, meat food products, poultry, and poultry food products, except for infant foods and formulas at levels of up to 4.8 % of total product formulation for the purpose of inhibiting the growth of certain pathogens. Approved antimicrobials for processed meat and poultry products can be found in 9 CFR 424.21 and in Directive 7120.1. The addition of antimicrobials in the formulation must be included in the ingredient statement of the label.

Studies on antimicrobials added to the packaging material or active packaging showed about 1-2 $\log_{10}$ CFU/g reduction of *L. monocytogenes* during the refrigerated shelf life of the products. Based on published studies, growth reduction or inhibition achieved by adding these antimicrobials to product formulation depends on a variety of factors, such as the level of antimicrobial agent added, product formulation and whether the agent was added during formulation or to the finished product. Depending on the amount of antimicrobials and other growth inhibitors added to the product formulation and other ingredients in the product, growth inhibition of *L. monocytogenes* was shown to range from 30 days to 120 days at refrigerated temperatures. Some published studies on antimicrobials are reviewed in Attachment 4. Establishments should refer to the details of the studies if they want to use the intervention method in their processing. A report of the National Advisory Committee for Microbiological Criteria for Foods gives guidance on

how to establish safety-based consume-by date labels for RTE foods, and can be found in Attachment 9.

An establishment that uses agents that inhibit *L. monocytogenes* on equipment and food contact surfaces in addition to using growth inhibitors in the product formulation can qualify the product for Alternative 2 using antimicrobial agents. Using these inhibiting agents on equipment and food contact surfaces can be considered as part of the sanitation program. These inhibiting agents applied to equipment and food contact surfaces must be GRAS and approved by FDA.

Antimicrobial Processes

Some RTE products with added salt, nitrites and other additives achieve a water activity, pH, or moisture-protein-ratio that will reduce the level of *L. monocytogenes* and other pathogens during processing and continue to inhibit the growth of the pathogens during the refrigerated shelf life. These products are not shelf stable because they need to be refrigerated during their shelf life, but because of the water activity and pH attained during the initial lethality treatment, these products may not support the growth of *L. monocytogenes* during its refrigerated shelf life. These products can be classified as using an antimicrobial agent or process. Examples of these products are RTE, not shelf stable fermented sausages and country cured hams.

Another antimicrobial process that controls the growth of *L. monocytogenes* in the post-lethality environment is freezing of RTE products. Freezing prevents the growth of any microorganisms in the product because their metabolic activities are arrested, but depending on the method and length of freezing and other factors, some microbial kill can also result. Like other microorganisms, *L. monocytogenes* is resistant to freezing. Once the product is thawed, metabolic activities of microorganisms may resume, depending on whether the microorganisms are killed, injured, or not affected at all. Therefore this antimicrobial process is only effective while the product is frozen. The requirement that a product remain frozen throughout its shelf life therefore excludes situations where a product is distributed frozen and then thawed and sold as a refrigerated product. If the product is thawed as part of the preparation process by the consumer, the product will be deemed to have been frozen throughout its shelf life. Labels of RTE frozen products contain cooking instructions for the frozen product and for thawed and refrigerated product, and instructions for thawing at refrigerated temperatures. Examples of frozen RTE products are fully cooked frozen chicken nuggets, fully cooked frozen chicken breast patties or fully cooked frozen dinners.

The chart below shows the growth limits for *L. monocytogenes*. These limits represent scientific consensus as to the temperature, pH, and water activity levels for *L. monocytogenes* (ICMSF, 1996). The pathogen can grow between the minimum and maximum levels. The pathogen cannot grow below the minimum growth limits and above the maximum growth limits. Establishments with processes that achieve levels below the minimum limits can use these as their control for the pathogen. Establishments that comply with the levels below the minimum growth parameters need not conduct further validation for their products to prove that growth of *L. monocytogenes* is not

supported throughout the shelf-life of the product. The Agency will conduct the least amount of verification, including sampling, within the Alternative on processes or products that have been demonstrated to not support any growth of *L. monocytogenes.* The establishment can place the attached reference on file in their control program documentation. However, the establishment should conduct on-going monitoring and verification activities to demonstrate that they are maintaining the conditions for pH, water activity, or temperature.

Growth limits for *Listeria monocytogenes* (ICMSF, 1996)

	Minimum	Optimum	Maximum
Temperature	-0.4 °C (31.3 °F)	37 °C (98.6°F)	45 °C (113 °F)
pH	4.39	7.0	9.4
Water activity	0.92	---	---

The antimicrobial agent or process that limits or suppresses *L. monocytogenes* must be included in the establishment's HACCP plan, or sanitation SOP, or other prerequisite program. The establishment must have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with 9 CFR 417.4. If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If the control measures for *L. monocytogenes* are contained in a prerequisite program other than a Sanitation SOP, the program must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment must include the program and the results produced by the program in the documentation that the establishment maintains as required in 9 CFR 417.5.

The establishment must include supporting documentation to show the effectiveness of the antimicrobials in suppressing or limiting *L. monocytogenes* in the HACCP plan, Sanitation SOP or prerequisite programs. An establishment can use published studies as reference for its validation and supporting documentation as long as it uses the same treatment variables as those used in the study. These variables include among others, specific antimicrobial agents and products, concentration, time and temperature of effectiveness. Use of antimicrobial singly or in combination, with different concentration and other variables, and for products not used in the studies must be validated or tested for their effectiveness. This must be validated for the HACCP plan, or documented in the Sanitation SOP or other prerequisite programs. The establishment must verify that the antimicrobial program is effective by testing product for *L. monocytogenes* and must verify that it does not cause the hazard analysis or the HACCP plan to be inadequate. That is, an effective prerequisite program will reduce the likelihood of occurrence of a hazard so that the product is safe. Based on such a program, an establishment could deem a hazard not reasonably likely to occur in its hazard analysis and therefore a CCP

for the hazard may not be needed. However, if the prerequisite program is not effective (or is not being followed), it means the hazard may become reasonably likely to occur. In such a case, the HACCP plan would be inadequate, since it does not include a CCP for the hazard. Accordingly, FSIS expects that establishments will routinely assess the effectiveness of the prerequisite programs and make any necessary adjustments to ensure that *L. monocytogenes* does not become a hazard reasonably likely to occur.

An establishment with products in Alternative 1 must maintain sanitation in the post-lethality processing environment in accordance with Part 416. The establishment must make available upon request to FSIS inspection personnel, the verification results that demonstrate the effectiveness of its controls, whether from carrying out its HACCP plan, or its Sanitation SOP, or other prerequisite program. The post-lethality processing environment encompasses all areas an exposed product goes through from the end of the lethality step to the time it is packaged. Should a post-lethality processing environment contact surface test positive, the establishment should investigate the potential source of the positive finding, take corrective actions to eliminate the source, and verify the effectiveness of the corrective actions. In certain situations, the source of *Listeria* may be the specific equipment that tested positive, such as a slicer. In other situations, such as a positive on a conveyor belt, the source may be a different location than the area tested.

FSIS considers a product to be adulterated if a food contact surface, such as a surface of equipment used in the production of the product, tests positive for *L. monocytogenes*. However, if a RTE post-lethality exposed product receives a post-lethality treatment (Alternative 1 or Alternative 2), that product which came in direct contact with a food contact surface that tested positive for *L. monocytogenes* would not summarily be considered adulterated. This is because the post-lethality treatment should have been validated and documented in the establishment's HACCP plan to be effective in eliminating or reducing *L. monocytogenes*. Without such validation and documentation, the establishment would have to present compelling argument for why the post-lethality treatment was effective for the Agency to conclude that the product is not adulterated. The product disposition would be made as part of the establishment's corrective actions under 9 CFR 417.3 or 416.15.

Establishments have been using prerequisite programs before in their processing operations, and the Agency has recently included the use of prerequisite programs as an option in another policy document. However, giving the establishment the option to include the antimicrobial agent or process in a prerequisite program in this rule is the first time prerequisite programs are recognized in codified regulations.

An establishment with products in Alternative 1 must have a post-lethality treatment that effectively reduces or eliminates *L. monocytogenes*, and an antimicrobial agent or process that suppresses any growth of the pathogen and extends the effect of the post-lethality treatment during the shelf life of the product. The Agency considers these treatments to be effective in controlling the pathogen resulting in a safe RTE product. If an establishment has an effective Sanitation SOP, any post-lethality contamination by *L. monocytogenes* would be very low, so the post-lethality treatment and the antimicrobial

will be able to reduce or eliminate this contamination. If there is gross contamination, the effectiveness of the treatments may be reduced or negated. Therefore the Agency is relying on the establishment's Sanitation SOP to prevent contamination with *L. monocytogenes*, and the post-lethality treatment and antimicrobials to further reduce or eliminate or suppress the pathogen.

Because of this combination of controls, the Agency is not requiring establishments to have a testing program for food contact surfaces. However, testing is recommended. Testing food contact surfaces in Alternative 1 could be minimal and primarily serve as a means to verify that the sanitary conditions in the establishment will not overwhelm the post-lethality treatment. A positive test on a food contact surface should trigger the establishment to review its sanitation program and post-lethality treatment to ensure that the treatment was properly applied for the product that came into contact with the positive. Furthermore, the establishment may determine that it is appropriate to conduct a product test after the post-lethality treatment to provide additional assurance that the treatment was effective. The establishments may test food contact surfaces for *L. monocytogenes*, or its indicator organisms, *Listeria* spp. or *Listeria*-like organisms periodically, to verify that their Sanitation SOP is effective. *L. monocytogenes* belongs to the *Listeria* genus or group and species (sp.) *monocytogenes.* The genus *Listeria* includes other species (spp.) in addition to *monocytogenes.* Therefore a positive test for *Listeria* spp. or *Listeria*-like organisms would indicate the potential presence of the pathogen. If these specific indicator organisms test negative, this is indicative that *L. monocytogenes* is not present. Aerobic plate counts (APC), total plate counts (TPC), and coliforms are not appropriate indicator organisms for *L. monocytogenes*. Results from these tests do not indicate the presence or absence of the pathogen, although they could provide a measure of general sanitation. Guidelines on sanitation procedures and food contact surface testing for *L. monocytogenes* or its indicator organisms, *Listeria* spp. or *Listeria*-like organisms, are found in section G-VII-3.

2. Alternative 2

An establishment that identifies its products in Alternative 2 must apply either a post lethality treatment <u>or</u> an antimicrobial agent or process that controls the growth of *L. monocytogenes*. Post-lethality treatments and antimicrobial agents and processes discussed above in the section on Alternative 1 can be used for Alternative 2. If an establishment uses a post-lethality treatment, it must have the post-lethality treatment in its HACCP plan and the treatment must be validated according to 9 CFR 417.4 as being effective in reducing or eliminating *L. monocytogenes* specifying the log reduction achieved by the post-lethality treatment. The effectiveness of the post-lethality treatment should be verified by testing the finished product for *L. monocytogenes,* and the verification results should be made available to FSIS personnel upon request. FSIS expects the establishment to conduct on-going verification of the CCP as detailed in its HACCP plan. The sanitary conditions likely will have a direct bearing on whether or not the post-lethality treatment is effective. If an establishment has a product identified in Alternative 2 and uses a post lethality treatment to control *L. monocytogenes* in its product, it is not required to test food contact surfaces in the post-lethality environment,

although it is recommended. However, FSIS most likely will conduct verification testing less frequently if the establishment tests food contact surfaces for *L. monocytogenes*, or its indicator organisms (*Listeria* spp. or *Listeria*-like organisms).

Under Alternative 2, an establishment that only uses an antimicrobial agent or process to control *L. monocytogenes* in its product must have the agent or process included in the establishment's HACCP plan, or sanitation SOP, or other prerequisite program. The establishment should have documentation in its HACCP plan, Sanitation SOP or other prerequisite program to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*. The establishment should document the log levels of the pathogen that the antimicrobial agent or process can suppress and the length of time under specific temperatures in days that the antimicrobial is effective. The establishment must validate and verify the effectiveness of its antimicrobial agent or process included in its HACCP plan in accordance with 9 CFR 417.4. The Agency expects that the use of post-lethality treatments or antimicrobial agents and processes, will prevent a significant increase in numbers of organisms during the product's shelf life to levels resulting in a public health hazard.

If the antimicrobial agent or process is in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with 9 CFR 416.14. If the control measures for *L. monocytogenes* are contained in a prerequisite program other than a Sanitation SOP, the establishment must ensure that the program is effective and does not cause the hazard analysis or the HACCP plan to be inadequate. The establishment should document its antimicrobial agent or process, its implementation and its verification results sufficiently in order to show that the HACCP plan is adequate in controlling the pathogen. The establishment must verify that the antimicrobials are effective by testing for *L. monocytogenes* and have the verification results whether from carrying out its HACCP plan, or Sanitation SOP, or other prerequisite program, available upon request to FSIS.

If an establishment produces a product under Alternative 2 by using an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* in its product, it should maintain sanitation in the post-lethality environment in accordance with part 9 CFR 416. The sanitation program must include testing for food contact surfaces in the post-lethality environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms (*Listeria* spp. or *Listeria*-like organisms). Studies on antimicrobials showed growth inhibition of *L. monocytogenes* if present at low levels of contamination during the shelf life of the RTE product. Antimicrobials were not shown to be effective at higher levels of contamination, so an effective sanitation program, which includes verification testing for food contact surfaces, should be implemented at the same time that antimicrobials are used.

The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms. It must include the frequency of testing and identify the size and location of the sample sites to be sampled. It must include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or its

indicator organisms is maintained. In addition, the establishment must identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for *L. monocytogenes* or its indicator organisms. The product produced with an antimicrobial agent or process will be subject to more frequent FSIS verification testing compared to a product using a post-lethality treatment to eliminate *L. monocytogenes*.

3. Alternative 3

Under Alternative 3, the establishment does not apply a post-lethality treatment or an antimicrobial agent or process to control the growth of *L. monocytogenes* in the post-lethality exposed product. An establishment producing this type of product must control the pathogen in its post-lethality processing environment through the use of sanitation control measures, which may be incorporated in the establishment's HACCP plan, Sanitation SOP or prerequisite program. Because the establishment is not relying upon a post-lethality treatment or an antimicrobial agent or process to control *L. monocytogenes*, the product will be subject to frequent FSIS verification testing compared to the other alternatives. Examples of products in this alternative are fully cooked meat and poultry that are packaged and refrigerated such as hotdogs, deli meats, chicken nuggets, or chicken patties that did not receive any post-lethality treatment or antimicrobial agent or process.

For this alternative, the establishment must maintain sanitation in the post-lethality processing environment in accordance with 9 CFR 416. The sanitation program must provide for testing food contact surfaces in the post-lethality processing area to ensure that surfaces are sanitary and free of *L. monocytogenes* or its indicator organisms. The testing program should include the frequency of testing, identify the size and location of the sample sites and include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or its indicator organisms is maintained. In addition, the establishment should identify the conditions under which the establishment will implement hold-and-test procedures following a positive test for *L. monocytogenes* or its indicator organisms on a food contact surface. Recommended testing frequencies are discussed in the Sanitation section G VII-1.

Moreover, an establishment that produces a deli product or a hotdog product must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or its indicator organisms on a food contact surface in the post-lethality processing environment are effective. The corrective action must indicate steps that the establishment will take to clean and sanitize the suspected food contact surfaces to eliminate the contamination. The effectiveness of the corrective action can be verified by follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and other additional tests in the surrounding food contact surface area as necessary. During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment

corrects the sanitation problem indicated by the test result. If the food contact surface is positive for *L. monocytogenes*, the affected product lot (product that had direct contact with the food contact surface) would be considered adulterated. Affected product (product or food contact surface tested positive for *L. monocytogenes*) must be recalled, if in commerce, and destroyed or reworked with a process that is destructive of *L. monocytogenes.* If the food contact surface is positive for *Listeria* spp. or *Listeria*-like organisms (indicator organisms), the affected products are not considered adulterated. Establishments may move production from an affected line provided the new production line does not include the food contact surfaces that tested positive for *L. monocytogenes* and the new food and non-food contact surface areas are tested.

In order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes* from the positive food contact surface, the establishment must sample and test the lots for *L. monocytogenes* or its indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The ICMSF (International Commission on Microbiological Specifications for Foods) statistical sampling plan is an example of a plan that some establishments have used (Attachment 5).

If the held product tests positive for *L. monocytogenes*, the sampled product lot is considered adulterated and must be withheld from commerce. The establishment must destroy the held product, or rework the held product using a process that is destructive of *L. monocytogenes*. The establishment must document the results of the testing and the disposition of the product. An example of a hold-and test scenario can be found in section G-VII-4 or in Attachment 6.

Products and the processing environment under Alternative 3 are likely to be subject to more frequent verification testing by FSIS than products and the processing environment in Alternative 1 or 2. This is because the products in Alternatives 1 and 2 are formulated and/or processed to reduce or eliminate *L. monocytogenes* or limit its growth in the RTE product and present a lower risk than products in Alternative 3 that do not have these interventions. Likewise, an establishment in Alternative 3 that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products because deli and hotdog products were ranked as higher risks for *L. monocytogenes* contamination in the FDA/FSIS risk assessment.

In determining the frequency of verification sampling, the Agency expects to take into consideration the level of pathogen reduction achieved by the post-lethality treatment, the growth inhibition achieved by the antimicrobial agent or process during the shelf life of the product, and the rigor of the sanitation and testing program, i.e., whether the sanitation and testing program exceeds the compliance guidelines.

<u>Products considered as deli and hotdog</u>

Like all RTE products exposed to the processing environment, deli and hotdog products that are exposed to the post-processing environment are subject to this rule. If the RTE

product is not exposed to the post-processing environment, it is not subject to this rule. Depending on the method that an establishment chooses to control *L. monocytogenes* contamination in its processing, deli and hotdog products may be in Alternative 1, 2, or 3.

Deli and hotdog products that receive a post-lethality treatment and antimicrobial agent or process fall under Alternative 1. An example is a hotdog that includes lactates or diacetates in the formulation and is steam pasteurized after repackaging.
Deli and hotdog products with antimicrobial agents such as lactates or diacetates added in the formulation, but with no post-process lethality treatment would fall under Alternative 2. Another example of an Alternative 2 product is a hotdog product that received only a post-lethality treatment such as being packaged in casings with an antimicrobial agent that reduces the level of *L. monocytogenes*. If an establishment does not use a post-lethality treatment or an antimicrobial agent or process in the processing of deli and hotdog products, these products would fall under Alternative 3.

Deli salads are also RTE post-lethality exposed, so they are covered by the rule. Deli meats that are used in salads receive additional handling after they are removed from their packages, and are mixed with other ingredients, thus exposing them to cross-contamination. An establishment producing deli salads with the meat and poultry components that receive a post-lethality treatment or antimicrobial agent needs to have supporting documentation showing that the antimicrobial action is sufficient to control *L. monocytogenes* in all the salad ingredients if they choose to have their product in Alternative 1 or 2. A deli salad with a final pH below 4.39 in all ingredients of the salad, (e.g. due to the salad dressing or other ingredients added) would fall under Alternative 2, using an antimicrobial agent.

A cook-in-bag product such as cooked ham or poultry roll that is shipped intact in its cooking bag is not covered by the rule. If the cook-in-bag product sold to a deli is not removed from the bag in the deli but sold to the consumer in the original cooking bag, then it is not considered post-lethality exposed, and therefore is not covered by the *Listeria* rule. It is also not considered a deli product because simply selling a product in a deli does not result in a product that is defined in 9 CFR 430 as a deli product. However, if it is sold to an establishment where it will be sliced and served in a sandwich or sold to the consumer, it is considered as a deli product.

Cooked chicken filets that are sliced or cut in strips, and frozen are covered under the rule since they are post-lethality exposed when sliced or cut. If these frozen products are shipped frozen, they fall under Alternative 2, using an antimicrobial process. If these products were refrigerated and shipped refrigerated, these will fall in Alternative 3.

C. Enhanced Level of Effectiveness of the Post-Lethality Treatment and the Antimicrobial Agent or Process

Products that receive a post lethality treatment achieving at least 2.0 log reduction of *L. monocytogenes* may likely be sampled less frequently by FSIS than products that receive a post-lethality treatment achieving <2.0 log reduction. Post lethality treatment achieving <1.0 log reduction will likely not be considered a post-lethality treatment for Alternatives

1 and 2 for purposes of the rule nor likely be eligible to apply for the labeling claim regarding enhanced protection from *L. monocytogenes* without supporting documentation that demonstrates this level of reduction provides a sufficient safety margin. In this case, the product will be viewed by the Agency as produced under Alternative 2 or 3, depending on whether the establishment uses an antimicrobial agent or process in addition to the post-lethality treatment

Likewise products receiving an antimicrobial agent or process that suppresses growth of *L. monocytogenes* such that there is 1.0 log or less increase during its shelf life may be expected to be sampled less frequently than products receiving an antimicrobial agent or process that allows the growth of *L. monocytogenes* by greater than 1.0 log increase during its shelf life. Use of an antimicrobial agent or process that allows more than 2.0 log growth increase during shelf life may not be considered an antimicrobial agent or process for Alternatives 1 and 2 for purposes of this rule unless there is supporting documentation that demonstrates that this level of growth provides a sufficient safety margin. In such cases, the product may be moved to a higher risk Alternative. In addition, products that allow greater than 1.0 log growth of the pathogen during its shelf life will not likely be eligible to apply for the labeling claim regarding enhanced protection from *L. monocytogenes*. In this case, the product may also be moved to a higher risk Alternative.

The Agency will do the least amount of verification, including sampling, within the Alternative, of 1) products that include processes using extrinsic and intrinsic characteristics of freezing below -0.4º C (31.3º F), pH below 4.39 or water activity below 0.92 and have been demonstrated to not support the growth of *L. monocytogenes*; and 2) products that are formulated to prevent the growth of *L. monocytogenes* in the event of a post-lethality contamination. This means that the effect of the antimicrobial agent/process is effective in limiting growth not only at the time of packaging and during the shelf life of the intact product but also in the event that the package integrity is compromised or the product is sliced at retail. The document should show validation and documentation of the effectiveness of the antimicrobial agent or process for these scenarios.

The chart below shows examples of levels of control that establishments could achieve with regards to post-lethality treatment and antimicrobial agent or process for Alternatives 1 and 2. Establishments should use these levels to base their minimum verification measures in determining the effectiveness of their controls.

Expected Levels of Control for Post-lethality Treatments and Antimicrobial Agents or Processes

	Levels of reduction or inhibition achieved to control *L. monocytogenes*		
	Higher Level[1]	Lower level[2]	Not Eligible[3]
Post-lethality Treatment (log_{10} reduction of *L. monocytogenes)*	=> 2 (equal to or greater than 2)	<2 (less than 2)	< 1 (less than 1)
Antimicrobial Agent or Processes (log_{10} allowed increase of *L. monocytogenes*)	<= 1 (less than or equal to 1)	>1 (greater than 1)	> 2 (greater than 2)

[1]Relatively less sampling by FSIS
[2]Relatively more sampling by FSIS
[3]Unless there is supporting documentation

D. Labeling

Antimicrobial agents that are added to RTE products, either to the formulation or to the finished RTE product, and those that are included in the primary packaging material of RTE products must to be listed in the ingredients statement of the product label. In addition, establishments that use a post-lethality treatment or an antimicrobial validated to effectively eliminate or reduce *L. monocytogenes*, or suppress or limit its growth in the product, can make claims or special statements on the labels of their products regarding the presence and purpose of use of the substances. The purpose of such claims is to inform consumers about measures taken by the processor to ensure the safety of the product and enable consumers to make informed purchase decisions. Such claims are voluntary and may be of value to consumers especially those in groups most vulnerable to foodborne illness. Processors need to document their validation of these claims. An example of a statement that can be made is: "Potassium lactate added to prevent the growth of *L. monocytogenes*." All labeling claims and label changes to add such claims must be submitted for evaluation and approval to the FSIS Labeling and Consumer Protection Staff.

Labeling Issues

Generic label approval and the new use of approved or listed safe and suitable antimicrobial agents. An establishment does not need to submit a label to the Agency for evaluation and approval when it adds an antimicrobial agent (e.g., sodium diacetate) that is approved or listed by FDA and FSIS as safe and suitable to a product formulation, provided the label can be approved in accordance with the generic labeling regulations in 9 CFR 317.5 and 381.133, (i.e., the product must have a standard of identity in Title 9 of the Code of Federal Regulations (CFR) or the Food standards and Labeling Policy Book and the labeling must not bear special claims, guarantees, or foreign language). All

ingredients including antimicrobial agents require declaration on the label. Establishments may submit for temporary approval to use existing stocks of labels with revised formulations (up to six months) in order to update and produce new labels.

Approval of labels bearing claims. As with all claims on labels, if there is a labeling claim about the use of antimicrobial agents or lethality treatments, the labels must be submitted to the Agency for evaluation and approval before use. Documents for validation of the effectiveness of the post-lethality treatment or antimicrobial agent must be included with the label application. An establishment cannot put labeling claims of enhanced protection on RTE products that are not post-lethality exposed, such as cook-in-bag that are opened only by the consumer, because these are not covered by the *Listeria* rule.

Antimicrobial agents in comminuted beef products. The standard of identity for ground beef, chopped beef, and their cooked versions, does not provide for the addition of ingredients with the exception of non-fluid condimental seasonings, e.g., salt, pepper. Therefore, these products cannot be formulated with or treated with antimicrobial agents that are classified as having a lasting technical effect, e.g., sodium lactate and sodium diacetate, unless these products are descriptively labeled to reflect the use of the antimicrobial agents. For example, if sodium lactate was added, the product name on the label should be "Ground Beef with Sodium Lactate".

However, for beef patties, which are standardized products, the regulations permit the addition of ingredients such as, antimicrobial agents. Therefore, comminuted beef products formulated with antimicrobial agents and other approved or listed safe and suitable food ingredients can be labeled as "beef patties" and can be generically approved if the labeling does not bear any special claims, guarantees or foreign language.

The labeling for other products with standards of identity that permit the addition of antimicrobial agents, e.g., luncheon meats, hotdogs, cooked whole muscle cuts (such as roast beef), may be approved in accordance with the regulations on generic label approval to reflect the addition of new, approved safe and suitable antimicrobial agents on labeling. The addition applies provided that no special claims or guarantees, foreign language, appear on such labels, per the generic labeling regulations.

Reclassification of products that are RTE as NRTE

Some products are expected to be lethality treated and RTE as shipped, as a matter of their common or usual identity, e.g., pates. Other products are defined by a standard of identity as RTE, that is, cooked, e.g., hotdogs. Some products are RTE based on labeling features, including Nutrition Facts, which declare nutrients in a product on a ready to serve or ready to eat basis. When these factors do not prevail, manufacturers may decide to reclassify products that have long been marketed as RTE products to NRTE products by doing the following:

(1) decide on the HACCP category that best fits their product based on the processing operations that are involved. In the situation where a product has been produced as a

RTE product and it is not a product that is defined by common or usual identity (e.g., pepperoni) or standard of identity (e.g., hotdog) as a lethality-treated (e.g., cooked/fermented/dried) product, the manufacturer can re-characterize their product in terms of HACCP category. The manufacturer would need to ensure that documentation exists to support the HACCP category selected by the establishment for the product and that the appropriate category is reflected in the HACCP plan and labeling records;

(2) generate data that validate the cooking instructions that must appear on the labeling of NRTE products (and include in all the alternative methods of cooking temperature that the product must reach, i.e., 160ºF) to ensure that consumers provide the lethality step. When the product has historically been viewed by the consumers as a “heat and eat” type of product, it is especially important for the establishment to make the distinction between the RTE product and the NRTE product. In addition, the “cooking instructions” should not be the same "heating" instructions that were previously used on labeling for the RTE products. Cooking instructions would need to include the internal temperature to which the product is expected to reach for the consumer to eat the product safely.

(3) assess the label to ensure that it adequately reflects the features that are necessary on the principal display panel to convey that the product is a ready to cook product, e.g., "cook and serve," "cook and eat," "cook thoroughly," as well as safe handling instructions. The basis for the Nutrition Facts declarations, e.g., serving size, must be on a ready-to-cook basis, not on a ready-to-serve basis (the company has to establish a ready- to-cook basis for serving size if the regulations do not provide one).

(4) consider whether the label for the product can be approved consistent with the regulations on generic label approval (i.e., it is a label for a standardized product and that bears no claims, special statements, guarantees, or foreign language) -- such labels would not need to be sent to the Agency to be evaluated and approved prior to use.

If a meat or poultry product that is processed to a time/temperature that traditionally is considered to attain a full cook but the intended use of the product is such that the product is intended to receive a lethality treatment by the consumer, the product does not have to be labeled as RTE unless the product is defined by a standard of identify as a RTE product (e.g., hotdogs, franks, pork with barbecue sauce, etc.). Such product may be identified as a NRTE product provided that the labeling and validated cooking instructions are adequate to discern that the product must be cooked for safety by the purchaser. An example of such product is a cooked <u>thick-sliced, center-cut ham slice</u> on which the labeling indicates that the product is ready to cook and for safety the product must be cooked to attain a minimum temperature.

On the other hand, a <u>thin sliced ham product in case-ready packaging</u> states that the product is ready-to-eat without additional cooking and which would not be required to bear preparation/cooking instructions. Both products may have been processed in the same manner in the Federal establishment but handled differently regarding controls for *L. monocytogenes*.

Furthermore, some establishments also add a "cooking" statement on the label on a fully cooked, RTE product for consumers to cook to a specific temperature. In this case, the establishment is adding heating rather than cooking instructions on the label in order to specify the temperature to which the product must be heated for palatability. In this case, the establishment does not need to have cooking instructions that have been validated to eliminate or reduce pathogens, nor does it need safe handling instructions on the label and the other requirements mentioned above.

E. Production Information Collection

An establishment that produces post-lethality exposed RTE products shall provide FSIS with estimates of annual production volume and related information for the types of meat and poultry products processed under Alternatives 1, 2, or 3 (9 CFR 430.4(d)). The establishment needs to provide the information at least annually, or more often, as determined by the Administrator. The Agency regards production volume as a more important risk factor than establishment size and therefore needs these data so that it can target its resources on higher volume operations in its verification program. FSIS will develop sampling frequencies for the establishments and the products based on these data. When sufficient data have been gathered (at least a year from implementation of the rule), the Agency expects to have the sampling frequency available to the establishments so that they will have an indication of how the risk of *L. monocytogenes* is tied to verification sampling.

The form by which to collect the data will be available to establishments in paper and electronic formats. An electronic form for this purpose will be available to the establishments at all times after the rule becomes effective. A sample form for the Production Information on Post-Lethality Exposed Ready-to-Eat Products collection can be found in Attachment 3.

F. New Technology Review

FSIS believes that the facilitation of the use of new technology represents an important means of improving the safety of meat, poultry and egg products. The Agency defines "new technology" as new, or new applications of equipment, substances, methods, processes, or procedures affecting the slaughter of livestock and poultry, and processing of meat, poultry and egg products. The Agency has an interest in new technology if new technology could affect product safety, inspection procedures, or inspection program personnel safety, or if it would require a waiver of a regulation. Substances used as new technology must also meet the requirements for safety and suitability under the Agency's food ingredient approval process. While FDA has the responsibility for determining the safety of food ingredients and additives, as well as prescribing safe use, FSIS has the authority to determine that new ingredients and new uses of ingredients are suitable for use in meat and poultry products.

The FSIS New Technology Staff reviews new technology that can be applied in meat, poultry, and egg processing and inspection to facilitate the introduction of the new technology in establishment or plant operations. New technology for use on post-lethality

RTE meat and poultry products to control the growth of *L. monocytogenes* should be sent to this office for review. FSIS issued the document on "Guidance Procedures for Notification and Protocol Submission of New Technology" (www.fsis.usda.gov/Regulations_&_Policies/New_Technologies/index.asp) to aid in the submission of application for review of new technology. New technologies received and reviewed by FSIS, which FSIS has "no objection" to their use in FSIS establishments are posted on the web site: http://www.fsis.usda.gov/regulations_&_policies/New_Technology_Table/index.asp.

G. Sanitation Guidelines for *Listeria monocytogenes*

Control of *L. monocytogenes* is a challenge to a processing plant's sanitation program. The pathogen can grow in a damp environment, attach to surfaces that come into contact with raw or finished product, establish a niche and form biofilms. The sanitation program should include cleaning and sanitizing procedures that have been proven effective for the particular operation, separation of raw and RTE processing areas, traffic control, employee hygiene, and equipment flow and design among others.

Proper and effective sanitation involves both cleaning and sanitizing, and verifying that the cleaning and sanitizing were effective. This involves developing and implementing written sanitation standard operating procedures (Sanitation SOPs). Sanitation SOPs could be viewed as the first step to designing a total system, including the HACCP plan that will prevent, eliminate, or reduce the likelihood of pathogenic bacteria from entering and harboring in the plant environment. The Sanitation SOPs as described in 9 CFR 416.12 through 416.16, give detailed requirements for developing and implementing the sanitation program, while 9 CFR 416.17 describes how FSIS will verify that each establishment is meeting the Sanitation SOP regulations. In brief, the regulations require the following:

- **Development of Sanitation SOPs (416.12)** – Each establishment must develop a written Sanitation SOP that describes all sanitation procedures that will be performed each day, before and during operations, with specific frequencies of each procedure and the responsible person for each task. It must also describe the cleaning process for all food contact surfaces, utensils, and equipment used to process your product(s). This document must be signed and dated by either the person responsible for the overall sanitation operations or a higher level employee in the establishment once it is implemented, and when any changes are made to the Sanitation SOPs.
- **Implementation of SOPs (416.13)** – All preoperational procedures identified in the Sanitation SOP must be done daily, before processing operations start. Each procedure must be performed at the specified frequency and they must be monitored daily.
- **Maintenance of Sanitation SOPs (416.14)** – Each establishment must routinely determine if the written Sanitation SOP is still effective in preventing direct product contamination and adulteration. If the Sanitation SOP is determined not

to be effective because of changes in equipment, utensils, facility, operations, or personnel, changes in the procedures must be made to reflect changes

- **Corrective Action (416.15)** – The appropriate corrective action(s) must be taken when it has been determined by FSIS or by an establishment employee that the written Sanitation SOP has failed to prevent direct product contamination or adulteration of product(s).
- **Recordkeeping Requirements (416.16)** – Daily records must be maintained that describe how the sanitation activities were implemented and monitored, and all corrective actions taken; these records must be initialed and dated. Both computer records and paper records are appropriate; however, additional controls may be needed to ensure the integrity of the electronic data.
- **Agency Verification (416.17)** – FSIS will verify the effectiveness and adequacy of the written Sanitation SOP's to ensure that they meet all of the regulatory requirements. This will be done by reviewing all records, direct observations, and microbial testing as deemed necessary.

In addition to the Sanitation SOP required by FSIS, the *Listeria* rule requires an additional sanitation program targeting *Listeria monocytogenes*.

I. General Cleaning and Sanitation Procedures

An example of equipment and processing room cleaning using eight steps is outlined below. Cleaning should be increased and intensified during periods of construction.

1. Remove waste material. Dry clean equipment, conveyor belts, tables, floors to remove meat particles and other solid debris. Some equipment such as slicers and dicers need to be disassembled so that parts can be cleaned thoroughly. Equipment may need to be cleaned and sanitized again after re-assembly.
2. Wash and rinse floor.
3. Pre-rinse equipment (rinse in same direction as product flow). Pre-rinse with warm or cold water – less than 140°F (hot water may coagulate proteins or "set soils").
4. Clean and scrub equipment. Always use at least the minimum contact time for the detergent/foam. Written instructions should be provided on the location of possible niches and the cleaning method to use. CAUTION: Live steam for cleaning is not acceptable at this step since it may bake organic matter on the equipment.
5. Rinse equipment (rinse in same direction as product flow).
6. Visually inspect equipment to identify minute pieces of meat and biological residues (repeat steps 3 and 4 if not clean visually or by testing such as with ATP bioluminescence).
7. Sanitize floor and then equipment to avoid contaminating equipment with aerosols from floor cleaning. Care should be taken in using high pressure hoses in cleaning the floor so that water won't splash on the already cleaned equipment. Use hot water, at least 180°F, for about 10 seconds to sanitize equipment. Sanitizers (e.g., chlorine, quaternary ammonia, etc.) may be more effective than

steam for *L. monocytogenes* control. If steam heating equipment in an oven or tarp, the target internal temperature is 160° F and hold for 20-30 min. Portable high-pressure, low volume cleaning equipment (131°F (55°C) with 20-85 kg/cm^2 pressure and 6- 16 liters/minute) can also be used.

8. Remove excess moisture. This can be done most safely and efficiently by air drying. Reduced relative humidity can speed the process. Avoid any possible cross-contamination from aerosol or splash if a method other than air drying (e.g., using a squeegee or towel) is used. If cross-contamination is suspected, repeat steps 4 – 7.

II. Determining the Effectiveness of Sanitation Standard Operating Procedures (Sanitation SOPs)

The establishment should determine if the cleaning and sanitizing procedures it uses are effective by visual examination or testing or both. Three examples of visual examination or visual examination and testing are described below.

1. Visual inspection of the equipment and environment. Visual inspection is the minimum means of determining the effectiveness of the sanitation SOPs. It can only detect observable contamination.
   a. Before the start of operation, visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria,.
   b. Record the results of the visual inspection.
   c. If any residue is noted, corrective action should be taken and recorded.
   d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
   e. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, after post-processing cleanup.
2. Visual inspection and use of ATP bioluminescence testing. Visual verification combined with ATP testing can determine both observable contamination and contamination from bacteria and meat/poultry residues that may not be visually detectable. The combined methods are more effective in determining the effectiveness of the sanitation SOP.
   a. The ATP test indicates the presence of both bacteria and meat or poultry residues and can be used to verify that no meat or poultry residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation. The ATP test is a rapid test and results are available immediately.
   b. Record the results of the ATP test and visual inspection.

c. If any residue is noted or observed visually or the ATP test indicates an insanitary condition, corrective action should be taken and recorded.
d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).

3. Visual inspection and total plate counts (TPC). Visual verification combined with TPC can determine both observable contamination and the level of bacterial contamination. Since TPC results are available in about 24 hours, and cannot be obtained at the time of inspection, its value lies in the measurement of the level of contamination. The level of contamination may assist the establishment in determining the source of contamination and the effectiveness of the sanitation SOP.
    a. Visually verify that no meat or product residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation.
    b. Use swabs or RODAC plates for sampling food contact surfaces, non-food contact surfaces (e.g., push-button on/off switches for the conveyor belt), and the processing environment.
    c. Record the results of the visual inspection.
    d. If any residue is noted, corrective action should be taken and recorded.
    e. Record the TPC when analysis is complete.
    f. The monitoring record should be designed to show any trends of insanitary conditions as determined by visual inspection or TPC. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
    g. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, again after post-processing cleanup.

III. Traffic Control

Controlling the movement of personnel and raw and finished products will help prevent cross-contamination of finished products by raw materials and personnel. The following are steps that can be taken for traffic control:

1. Establish traffic patterns to eliminate movement of personnel, meat containers, meat, ingredients, pallets and refuse containers between raw and finished product areas.
2. Control traffic into and within the RTE areas

    a. If possible, use air locks between raw and RTE areas.

b. Clean, dry floors are preferable to foot baths at the point of entry because effective concentrations of disinfectant are difficult to maintain and may become a source of contamination.
c. If foot baths are used:
   i) Wear rubber or other non-porous boots.
   ii) Maintain them properly,
   iii) Solutions should contain stronger concentrations of sanitizer than normally used on equipment
      (1) For example, 200 ppm iodophor, 400-800 ppm quaternary ammonia compound).
      (2) CAUTION: Chlorine is not recommended as it is too quickly inactivated esp. if cleated boots are used. The accumulation of biological material adhering to the cleats inactivate (or reduce) the bioavailability of chlorine and make it less effective. Monitor and maintain its strength if used.
   iv) Use a minimum depth of 2 inches.
d. Use foam disinfectant spray on floor for people or rolling stock entering the room.

3. Employees should not work in both raw and RTE areas, if possible. If they must work in both areas, they must change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear.
   a. Use different color smocks or helmets for raw and RTE areas so the workers and garments in the raw and RTE areas are readily distinguishable.
   b. Remove outer garments (e.g., smocks) when leaving RTE areas.

4. Do not allow employees who clean utensils and equipment for raw materials to clean RTE utensils and equipment, if possible. If not possible, there should be a time separation when utensils for raw processing/handling are cleaned after RTE. The tools to clean utensils and equipment for raw materials must be different than those used to clean RTE utensils and equipment. In either case, the intent is to prevent cross contamination of finished product.

5. Do not permit maintenance employees in RTE areas during operations if possible, primarily because they may cause direct product contamination or adulteration if they touch or lay their “dirty” equipment hands onto food contact surfaces. If not possible:

   a. Consider the need to cease operations until a full cleaning and sanitizing is done, <u>or</u>,
   b. Maintenance personnel must change outer clothing and any other soiled clothing, use separate tools for raw and RTE areas (or wash and sanitize tools and hands prior to entering RTE areas) and wear only freshly cleaned/sanitized footwear in such areas.

6. Use separate equipment, maintenance tools and utensils for the RTE and raw areas. If not possible, there should be a time separation between raw processing/handling and RTE processing in order prevent cross contamination of finished product.

7. Pallets can serve as a source of cross-contamination – pallets for raw materials should not be used in RTE areas or used for finished product.

8. Drains from the "dirty" or "raw" side should not be connected to those on the "clean" or "cooked" side.

9. There are instances when small establishments cannot separate the raw and cooked areas, or separate employees handling raw and cooked products by operating time. In this case, the establishment should plan to process cooked products first, then do a complete clean-up (thorough cleaning and sanitizing) of the processing area, processing and maintenance equipment, and personnel, and then do the raw products. The establishment's Sanitation SOP and their GMP or prerequisite program should address employee hygiene and traffic control during operation to prevent cross contamination and insanitary conditions.

10. Eliminate standing water which can facilitate the spread of *L. monocytogenes* into other areas of the plant. Sanitizer boluses can be used to sanitize standing water on a continuing basis.

IV. Employee Hygiene

Employee hygiene should be the responsibility of both the individual and management. The employee should be responsible for preventing contamination of food products and the management should be responsible for ensuring the employee is properly trained and maintains good practices.

1. Employee responsibilities and actions should include:

    a. Use a 20 second hand wash, allowing the soap suds to be in contact with the hands for this period of time, after using restroom facilities.
    b. Wash hands before entering the work area, when leaving work area, and before handling product.
    c. If gloves are worn:
        i. Gloves that handle RTE product must be disposable.
        ii. Dispose immediately and replace if anything other than product and food contact surface is touched.
        iii. Dispose of gloves when leaving the processing line.
    d. Remove outer clothing when leaving RTE areas.
    e. Do not wear RTE clothing inside restrooms or cafeterias.
    f. Do not store soiled garments in lockers.
    g. Do not eat in the locker room or store food in lockers because food may attract insects and vermin.
    h. Do not store operator hand tools in personal lockers. This equipment must remain in the RTE area at all times.

2. Management responsibilities should include:

a. Providing hand washing facilities at proper locations.
b. Ensuring the employee receives proper hygiene instruction before starting – use of hand soaps and sanitizers, no-touch dispensing systems, and boot and doorway sanitizing systems.
c. Developing a system for monitoring employee hygiene practices.
d. Developing a system for tracking the training, testing, and certification.
e. Retraining employees before placing back into production if they are absent from the job or have failed to follow acceptable hygiene practices. This will help ensure that the employees are following current, acceptable hygiene habits.

V. Sanitizers

Cleaning and sanitizing are vital to any effective sanitation program. Thorough cleaning should be followed by sanitizing. Generally, the cleaning step is to remove all waste materials and soils, and the sanitizing step is to destroy all microorganisms. Careful consideration should be given to selecting both cleaning and sanitizing solutions. It is important to use solutions that are compatible with the equipment materials, such as stainless steel or heavy plastics, and solutions that are effective in destroying the type of bacteria commonly associated with the type of products produced in the establishment. Rather than relying on a single sanitizer, rotating sanitizers will help prevent the development of microorganisms resistant to a particular sanitizer.

The concentration and application processes for all sanitizers approved for use in meat and poultry establishments are referenced in Title 21 Code of Federal Regulations (21 CFR), Part 178.1010. All cleaners and sanitizers commercially available should have at the minimum, the following information either on the label or available on a specification sheet that must accompany the product:

- ✓ Product Description
- ✓ To Use – Instructions on how to use the product
- ✓ Properties
- ✓ Safety Information

Additional information that is sometimes available includes:

- ✓ Benefits
- ✓ Quality Assurance Statements
- ✓ Effectiveness against *Listeria.*

Some manufacturers provide labeling in both English and Spanish, which makes the products more user friendly in various environments. At least one manufacturer also has commercially available color coded products that are easy to associate with a particular cleaning or sanitizing task.

Krysinski, L.J., (1992) evaluated the ability of chemical cleaning and sanitizing compounds to remove and/or inactivate surface adherent *Listeria monocytogenes* from stainless steel and plastic conveyor belts. With respect to the sanitizers, the study showed

that resistance of attached cells followed in descending order: polyester/polyurethane, and stainless steel. For the stainless steel, all of the sanitizers were effective in inactivating the adherent *Listeria monocytogenes* except chlorine and iodophor. None of the biocides were effective in sanitizing the surface of the polyester/polyurethane. The most effective sanitizers in these evaluations were acidic quaternary ammonia, peracetic acid, and chlorine dioxide. The cleaning agents used were effective in removing the attached *Listeria monocytogenes* for the stainless steel but not effective when used on the polyester/polyurethane chips. When the cleaning agents were followed by a sanitizer, reductions in the microbial load were observed. The study concluded that generally, acidic quaternary ammonia, chlorine dioxide, and peracetic acid were the most effective biocides on attached *Listeria monocytogenes*, less effective were the mixed halogens and acid anionics, and the least effective were chlorine, iodophors, and neutral quaternary ammonium compounds.

VI. Sources and Control of *Listeria monocytogenes* Contamination

Listeria monocytogenes may be introduced into the processing environment by construction (perhaps the single most important factor associated with outbreaks), the failure to control sanitation procedures, employee hygiene, movement of supplies and products, or other entry vectors (Mead, 1999; Perl, 2000). The bacterium may be brought in by incoming raw product, processing environment or by employees. It can be transferred from coolers, walls, floors, equipment and construction by direct or indirect contact with the product.

Dust generated by construction activities can move throughout the plant on air currents or be transferred by people or equipment traveling through the construction area into other areas of the establishment. A study by De Roin et al., (2003) showed that dust contaminated with *L. monocytogenes*, once in contact with meat surfaces can survive and grow. Construction or maintenance activities that can result in contamination with *L. monocytogenes* include removal of drains, removal of floor coatings, removal of a wall or ceiling that has absorbed moisture, movement of potentially contaminated materials through RTE areas or areas that directly connect with RTE processing areas, and exposure of areas typically not accessible for cleaning. Tompkin (2002) considers the potential of introduction of a new, more virulent strain of *L. monocytogenes* into the environment from an outside source or through disturbance of a harborage site (e.g., the process of replacing floor drains, walls or cooling units) as a greater concern.

The following are steps that should be taken to prevent contamination of product with *L. monocytogenes* after cooking:

1. Verify that cooking or other control measures will eliminate *L. monocytogenes*. Most meat products implicated in human listeriosis are contaminated with *L. monocytogenes* after these measures are applied. Undercooking product or other inadequately or improperly verified lethality treatments may introduce *L. monocytogenes* to food contact surfaces or the environment after cooking and before packaging.

2. Prevent contamination of food contact surfaces and prevent the formation and growth of *L. monocytogenes* in a niche, especially in areas after the lethality step. A niche is a harborage site within the plant that provides an ideal place for *L. monocytogenes* to establish and multiply. Factors involved in the formation of niches include equipment design, construction activities, operational conditions that move product debris into difficult to clean locations, mid-shift cleanup, high pressure during cleaning, and product characteristics that require excessive rinsing. Certain strains can become established in a processing environment for months or years. *L. monocytogenes* can be spread from these sites and re-contaminate food or food contact surfaces between the lethality step and packaging.

Examples of reservoirs and harborages of *L. monocytogenes* in RTE processing environment
Drains
Hollow rollers on conveyors
On-off valves and switches
Worn or cracked rubber seals around doors
Vacuum/air pressure pumps, lines, hoses
Cracked tubular rods on equipment
Air filters
Condensate from refrigeration unit
Floors
Standing water
Open or gulley drains
Ceilings and over head pipes
Overhead rails and trolleys
Chiller and passageway walls and doors
Chiller shelving
Roller guards
Door handles
Boots
Ice makers
Saturated insulation (wet or moldy)
Trolley and forklifts
Compressed air in-line air filters
Trash cans
Cracked hoses
Wet, rusting or hollow framework
Walls that are cracked, pitted, or covered with inadequately sealed surface panels
Maintenance and cleaning tools
Space between close fitting metal-to-plastic parts
Space between close fitting metal-to-metal parts

3. Examine routes taken by products from heat treatment, or other control steps to eliminate *L. monocytogenes*, to final packaging.

Typical sites that result in *L. monocytogenes* contamination
Filling or packaging equipment Solutions used in chilling food Peelers, slicers, shredders, blenders, brine chill, casing removal system, scales, or other equipment used after heating and before packaging Spiral or blast freezers Conveyors Bins, tubs, or other containers used to hold food for further processing

4. Frequently clean sites known to support *L. monocytogenes* using effective cleaning procedures. The following is a recommended frequency for cleaning and sanitizing processing equipment and the plant environment:

    a. Daily
        i. All processing equipment
        ii. Floors and drains
        iii. Waste containers
        iv. Storage areas
    b. Weekly
        i. Walls
    c. Weekly/monthly
        i. Condensate drip
        ii. Coolers
    d. Semiannually
        i. Freezers

5. Validate that the cleaning and sanitizing procedures are effective.

6. Maintain equipment and repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.

7. Implement a microbial sampling program to monitor and detect sources of *L. monocytogenes* in the environment. Environmental testing is more effective than product testing alone to monitor and detect *Listeria* in the environment. For positive test results, conduct intensified cleaning and other necessary corrective actions. Follow up with intensified and targeted testing of implicated sites.

8. Design a sampling scheme to locate a niche before *L. monocytogenes* becomes established.

    a. Determine the physical area to sample. Use prior experience with processing conditions and observation of cleaning and sanitizing procedures and equipment to determine the most likely source of contamination. For example, the use of high water pressure during cleaning may embed *L. monocytogenes* into parts of the equipment that are

hard to clean effectively. The cleaning and sanitizing procedures also should be monitored to assure that the established procedures are being followed. All surfaces of processing equipment should be sampled but with a bias toward those areas identified as possibly problematic.

b. Take 10 samples per line, with a maximum of 50 samples. The samples should include both food contact and non-food contact surfaces.

c. Review at least the last month of results to determine trends or to revise sampling scheme.

d. When a problem area is detected, take corrective action on the affected processing line as opposed to adjacent lines in the area. Target the area corresponding to the line associated with the findings for intensified cleaning. Contamination is usually line specific unless a vector in the system is present (e.g., an employee contaminates multiple sites; a common surface prior to splitting the lines is contaminated).

Equipment Design

Selecting the appropriate equipment (e.g., designs that facilitate cleaning and sanitizing, equipment that easily dismantled for cleaning, durability) enhances cleaning operations and helps to control *L. monocytogenes* in the plant environment. The following are recommended steps to take when selecting equipment:

1. If possible, develop a team (persons from Quality Assurance, Sanitation, Maintenance, and Production) to evaluate equipment before it is purchased or set specific requirements for plant equipment. The equipment should be easy to clean and sanitize and not have potential *L. monocytogenes* harborage sites, such as hollow rollers.

2. Have the equipment reviewed by a third-party expert if possible.

3. Select equipment designed to minimize sites on the exterior or interior where *L. monocytogenes* can grow.

4. Select equipment designed to enhance cleaning.

    a. All areas and parts should be accessible for manual cleaning and inspection or be readily disassembled.

        i. Closed conveyor designs are more difficult to clean. Equipment on the processing line should be as easy to clean as possible.

        ii. Avoid hollow conveyor rollers and hollow framing. If hollow material is used, have a continuous weld seal instead of caulk.

iii. Select food contact surfaces that are inert, smooth and non-porous.

b. Equipment should be self-draining or self-emptying.

5. Equipment evaluation

a. Thoroughly clean and sanitize equipment prior to using in production. Pathogens can live on surfaces that appear visually clean.
b. Operate the equipment for 90 days, then,
c. Disassemble to normal daily level, then
d. Evaluate visually and microbiologically as the equipment is completely disassembled.

6. Maintain equipment and machinery by adopting regular maintenance schedules.

a. Damaged, pitted, corroded, and cracked equipment should be repaired or replaced.

i. Repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.

ii. Use separate tools for RTE equipment only. Sanitize them before and after each use.

b. If compressed air is used, maintain and replace in-line filters regularly.

c. Use lubricants that contain listericidal additives such as sodium benzoate. *L. monocytogenes* can grow in lubricants that are contaminated with food particles.

e. Use the appropriate cleaners and sanitizers on surfaces or equipment.

7. Control the Environment During Construction
If possible, suspend operations during construction. Otherwise:

a. Dust from construction can be difficult to detect and control. Therefore, increased monitoring of product, food-contact surfaces, and the environment is recommended during and after these disruptive events.
b. Establish negative air pressure in the construction area in order to ensure that air does not flow from the construction area into the plant.
c. Temporary partitions can be established to protect the undisturbed areas of the plant from construction dust and debris.
d. Cover any construction debris when moving out of the construction area.
e. Do not move debris through RTE processing areas or areas that directly connect to RTE processing areas, if possible.
f. Schedule construction during non-processing hours.

g. Conduct intensified cleaning and monitoring of food contact and environmental surfaces.

8. Control the Environment After Construction

a. Schedule removal of all construction equipment, barriers, and final debris after production hours.
b. Perform a thorough clean-up and increased sanitation sampling at pre-operation inspection.
c. Continue intensified cleaning and monitoring of food contact and environmental surfaces until 3 consecutive negative tests on the food contact surfaces for 3 consecutive days.

VII. Verifying the Effectiveness of the Sanitation Program

Establishments can verify the effectiveness of their sanitation program by testing food contact surfaces (FCS) and other relevant environmental surfaces. This section includes a) recommended testing of food contact surfaces to verify the effectiveness of the sanitation program for each alternative from 9 CFR 430, b) a guide to testing for *Listeria* spp. or *Listeria*-lik*e* organisms, c) an example of a hold-and-test scenario, and d) an example of a Sentinel Site Program.

1. Food Contact Surface and Environmental Testing

The sampling frequencies for food contact surface (FCS) testing suggested below are recommended minimum frequencies. Sampling is required for Alternatives 2 (using antimicrobial agents or processes only) and 3, and recommended for Alternative 1. The sampling frequencies increase from Alternative 1 to Alternative 3 because the control program for *L. monocytogenes* decreases in intensity and effectiveness from Alternative 1 to 3. These frequencies should be increased if there is construction, change in the HACCP plan, roof leaks, or other events that could change or increase the probability of product contamination. Samples should be taken at least 3 hours after the start of operation or an appropriate time period after all parts of the food handling system are operational because the equipment has to be operational for seeding to occur. Establishments can also develop their own sampling plan based on their operations, or have a processing authority develop a sampling plan.

Generally, no more than 5 samples may be composited because when samples are composited, it becomes more difficult to trace the source of contamination. In addition, it is recommended that like or similar surfaces should be composited (e.g., food contact surfaces with other food contact surfaces, etc.). The individual locations for the composite sample should be noted to assist in determining the site of contamination to facilitate follow-up testing in case a positive is obtained. Environmental samples other than food contact surface samples should be sampled by the establishment. This will also assist the establishment in locating potential sources of contamination.

The establishment is encouraged to hold all products being tested until the test results are received. This will prevent exposure of the consumer to a potential food hazard. Retaining the product being tested also will eliminate the cost of a recall to the establishment.

a. Alternative 1 – Use of a post-lethality treatment and an antimicrobial agent or process that limits growth of *L. monocytogenes*.
   i. Conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least twice a year. This low frequency of testing is recommended because the post-lethality treatment and the antimicrobial agent and process are expected to reduce and inhibit the growth of *L. monocytogenes* in the product.
   ii. Sample at least 1 square foot area for each surface, if possible.
   iii. Record the test results.
   iv. If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like or organisms:
      (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
      (2) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot that came in direct contact with a food contact surface would not summarily be considered adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing *L. monocytogenes*, and documented in the establishment's HACCP plan.
      (3) Record the corrective actions taken.
      (4) Retest the food contact surface.
      (5) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms.
      (6) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode.

b. Alternative 2 - Use of a post-lethality treatment or an antimicrobial agent or process that limits growth of *L. monocytogenes*.
   i. If a post-lethality treatment is used, conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least quarterly. This recommended frequency is 2 times that for Alternative 1 because in this case, the product only receives one of the interventions.
      (1) Sample at least 1 square foot area for each surface, if possible.
      (2) Record the test results.

(3) If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms:
   (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
   (b) If the FCS test is positive for *L. monocytogenes*, the product that came in direct contact with a food contact surface would not summarily be considered adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing *L. monocytogenes*, and documented in the establishment's HACCP plan .
   (c) Record the corrective actions taken.
   (d) Retest the food contact surface.
   (e) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
   (f) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode.

ii. If an antimicrobial agent is used, conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least quarterly. (Sampling is required in this case).
   (1) Sample at least 1 square foot area for each surface, if possible
   (2) Record the test results.
   (3) Each time a FCS test positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.
   (4) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
   (5) If 3 consecutive tests of food contact surfaces are positive for *Listeria* spp. or *Listeria*-like organisms:
      (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
      (b) Record the corrective actions taken.
      (c) Hold the product.
      (d) Test product for *L. monocytogenes*.
      (e) Retest the food contact surface.
      (f) Repeat corrective action and testing until food contact surface test results are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
      (g) If the test results for the product are positive for *L. monocytogenes*,

(i) Recall the product, if already shipped, and
(ii) Destroy the product, or
(iii) Re-work the product with a process that is destructive of *L. monocytogenes*.

c. Alternative 3 – Use of sanitation control measures and testing to prevent contamination of product with *L. monocytogenes*. (Sampling is required in this case)

i. For establishments that produce non-deli or non-hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted once a month for large, small or very small volume establishments.

ii. For establishments producing deli and hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted at least four times per month per line for large volume establishments, two times per month per line for small volume establishments, and once per month per line for very small (or low) volume establishments.
FSIS regards production volume as a more important risk factor than establishment's size and intends to use volume as one of the primary triggers for when considering its verification activity. For now, regarding deli meat and hotdog operations, FSIS is considering the break point between high volume and low volume to be approximately 1.3 million pounds yearly, as derived from the RTE survey**.**

iii. Sample at least 1 square foot area for each surface, if possible.

iv. Record the test results.

v. If the first test result of a food contact surface is positive for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms, take corrective actions (as specified in the HACCP plan, Sanitation SOP or prerequisite program) and record.

vi. If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.

vii. Each time a FCS tests positive, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.

viii. For establishments producing hotdog or deli meat products, if the second test result of a food contact surface is positive for *L. monocytogenes*, *Listeria* spp., *Listeria*-like organisms:
(1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
(2) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
(3) Record the corrective actions taken.
(4) Hold the product (see hold-and-test scenario below and in Attachment 6).
(5) Test product for *L. monocytogenes* at a rate that provides a level of statistical confidence that the product is not adulterated.

(6) Conduct follow-up test of the food contact surface each day until the test result is negative for *Listeria* spp., *Listeria-like* organisms.
(7) At the same time, continue to hold each day's production lot until the test results for the food contact surfaces are negative.
(8) If the test results for the product are positive for *L. monocytogenes*,
  (a) Destroy the product, or
  (b) Re-work the product with a process that is destructive to *L. monocytogenes*.

ix. For establishments producing products other than hotdogs or deli meats, if the third consecutive test of food contact surfaces is positive for *Listeria* spp., or *Listeria-like* organism (sampling is required in this case):
  (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
  (b) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
  (c) Record the corrective actions taken.
  (d) Hold the product.
  (e) Test product for *L. monocytogenes*.
  (f) Retest the food contact surface.
  (g) Repeat corrective action and testing until food contact surface test results are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
  (h) If the test results for the product are positive for *L. monocytogenes*,
    (i) Destroy the product, or
    (ii) Re-work the product with a process that is destructive of *L. monocytogenes*.

For repeated FCS positives, the establishment should also conduct a comprehensive investigation to determine the cause and source of the contamination. This establishment should:

a. Review the cleaning and sanitizing procedures, including the types of cleaning agents.
b. Review traffic control patterns, equipment layout and adherence to employee hygiene procedures.
c. Locate niches
  i. Repeated, non-consecutive positives usually indicate the presence of a niche or harborage site for *L. monocytogenes*
  ii. Increase testing of the positive site including individual pieces of equipment to locate the source of the contamination
d. Thoroughly clean and sanitize the individual parts.
  i. Intense scrubbing is necessary to breakup or dislodge a biofilm.
  ii. A change of cleaning or sanitizing solutions may be indicated.

iii. Fogging of the equipment or room with a sanitizer such as quaternary ammonium compounds could be used if problems persist.

e. Reassemble and test again during operation until the FCS test negative on consecutive tests.

At the same time as the comprehensive investigation, the establishment should examine and review its HACCP plan, Sanitation SOP or its prerequisite program where the sanitation and testing programs are included, evaluate and determine if there is any design or execution flaw, and modify as necessary. The establishment should evaluate the cleaning or sanitizing procedure, the method of verifying that the procedures are performed as prescribed, employee hygiene practices, monitoring traffic patterns, equipment design, or change in processing conditions.

2. Expected Frequencies of Establishment Verification Testing of Food Contact Surfaces for Alternatives 1, 2 and 3

The chart below shows the frequencies of testing food contact surfaces that establishments in Alternatives 1, 2 and 3 should conduct for verification of the effectiveness of their sanitation program. Establishments should consider these frequencies when determining the level of *Listeria* control they believe is prudent in their establishments based on their operation and historical data. Those establishments assuming these levels of verification testing likely would be subject to more intense verification activity by FSIS, and their vulnerability regarding the scope of a recall likely is increased in situations where product in commerce is linked to their establishment. The scope of a recall is dependent, in part, upon the level and type of documentation that establishment maintains on the on-going effectiveness of their operation.

Expected Frequencies of Establishment Verification Testing of Food Contact Surfaces for Alternatives 1, 2 and 3.

	Food Contact Surface Testing	
	Higher Frequency	Lower Frequency
Alternative 1	> 2/year/line	2/year/line
Alternative 2	> 4/year/line	4/year/line
Alternative 3		
Non-deli, non-hotdogs	> 1/month/line	1/month/line
Deli, hotdogs:		
Very Small volume plant	> 1/month/line	1/month/line
Small volume plant	> 2/month/line	2/month/line
Large volume plant	> 4/month/line	4/month/line

3. Testing Food Contact Surfaces and Other Environmental Surfaces for *Listeria* spp. and *Listeria*-like Organisms

RTE meat and poultry establishments perform many different microbiological testing programs, including:

- **Testing for the presence of *Listeria* spp. or *Listeria*-like organisms.** These organisms are appropriate for use as indicators of *L. monocytogenes* because their presence indicates the possible presence of the pathogen. If tests for these organisms are negative, it is unlikely that *L. monocytogenes* is present. Tests for *Listeria* spp. or *Listeria*-like indicator bacteria are typically abbreviated versions of *L. monocytogenes* methods, terminated after enrichment and screening steps, but before *Listeria monocytogenes* is confirmed, specifically:

    - Tests for ***Listeria*** spp**.** organisms are rapid screening procedures involving genus *Listeria*-specific immunoassays, genetically-based or other rapid assays, in which a positive result is obtained but not confirmed as *Listeria monocytogenes*

    - Tests for ***Listeria*-**like organisms are typical cultural procedures in which potential positives are indicated by biochemical reactions in differential broth or plating media, but are not confirmed as *Listeria monocytogenes*

- **Testing methods to enumerate *Listeria* spp. or *Listeria*-like organisms.** Such methods are appropriate for enumerating the number, but are not sensitive enough for determining the presence or absence of these microorganisms, if present at low levels. Enumeration methods do not include an enrichment period, and therefore are not sufficiently sensitive for the requirements of a testing program designed to detect low numbers of organisms present. In addition, the surface area tested must be factored into the results in order to make a best estimate of the number of organisms present in that specified area. FSIS realizes that there may be circumstances when the establishment chooses to use such enumeration methods for their own purposes. Such techniques are important when trying to ascertain the likely level of contamination that comes into contact with RTE product. However, the establishment must provide scientific justification for any testing methods used for environmental testing, and a rationale for the conclusions derived from such testing.

- **Testing for aerobic plate counts (APC), total plate counts (TPC), coliforms, ATP etc.** Such tests are not appropriate indicators for *L. monocytogenes* as they cannot establish the presence or absence of this organism. Testing for these organisms is appropriate for monitoring the effectiveness of the sanitation procedures or the level of contamination during processing.

To ensure that any potential *Listeria* spp. or *Listeria*-like organisms are detected, it is necessary for the method used to provide the lowest possible limit of detection (*i.e.*, maximum sensitivity for detection) for these organisms. Testing methods meeting the following criteria are most likely to be suitable for this purpose:

- The method is used by a regulatory body or has been validated by a recognized independent body (*e.g.*, AOAC, AFNOR, ISO), using the FSIS *Listeria monocytogenes* qualitative method as a reference method. A validated method from a scientifically robust study using the FSIS *Listeria monocytogenes* qualitative method as a reference method is also acceptable but may be subject to FSIS review. The

validation procedure should be consistent with the goal of providing sensitive qualitative detection of environmental *Listeria*,
AND

- The method includes an enrichment period that allows for the recovery and resuscitation of any sub-lethally injured cells also allows for the outgrowth (multiplication) of very low numbers of *Listeria* to levels that can be detected by the test method. In general, direct-plating enumeration methods, which do not include a period for outgrowth of cells and cannot detect microorganisms at very low levels, are inappropriate for ensuring that *Listeria* contamination is not present on food contact or other environmental surfaces,
  AND
- The method must accommodate analysis of the entire sample sponge (or other sampling device), and all associated diluent, to maximize the possibility of detecting any cells that are present. By only analyzing a portion of the diluent or by not testing the sponge or swab, any *Listeria* remaining in the untested sample portion would not be represented, thereby decreasing the potential for detecting *Listeria* contamination. Quantitative methods, including direct-plating and most-probable-number methods, typically test only a portion of the diluent and so are inappropriate for ensuring *Listeria* are not present on food contact or other environmental surfaces.

The establishment is responsible for the choice of methods. It is the establishment's responsibility to share this guidance document with microbiological consultants and testing laboratories so that all parties understand what methods and sample test portions are appropriate for the intended purpose. Also, any methods used should be validated to ensure that they can reliably detect the presence of *Listeria* spp. or *Listeria*-like organisms on food contact and other environmental surfaces. In addition, the establishment should maintain documentation related to the selected testing procedure.

If an establishment chooses not to use a proven methodology for food-contact and other environmental-surface testing, it may be assuming a greater risk of allowing adulterated product into the marketplace, and therefore being confronted with recall requests and regulatory actions. Should FSIS question the suitability of the method employed by an establishment, it may choose to review the scientific basis for the sampling and testing procedures used. In such a circumstance, the establishment could be subject to focused verification checks, including review of recordkeeping, observation of production, and collection of product and environmental sampling for testing.

FSIS method for analysis and confirmation of *L. monocytogenes* and other FSIS microbiology laboratory methods are available and can be downloaded at http://www.fsis.usda.gov/Science/Microbiological_Lab_Guidebook

4. Hold-and-Test Scenario for Deli and Hotdog Products in Alternative 3

Assuming it takes to 3 days to obtain a test result for *Listeria* spp., or *Listeria*-like organisms:

Day 1 – Take food contact surface (FCS) samples

Day 4 –FCS sample (from Day 1) negative for *Listeria* spp. or *Listeria*-like organisms.

- ✓ Continue production as the corrective action appears to resolve problem and test FCS as scheduled.

If FCS sample positive (from Day 1) for *Listeria* spp. or *Listeria*-like organisms.

- ✓ Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
- ✓ Test FCS-- target most likely source of contamination, and additional tests in surrounding FCS area
- ✓ Continue production.

<u>Day 7 – Follow-up FCS sample (from Day 4) is negative for *Listeria* spp. or *Listeria*-like organisms</u>.

- ✓ <u>Continue production as the corrective action appears to resolve problem and test FCS as scheduled.</u>

If follow-up FCS sample (from Day 4) is positive for *Listeria* spp., or *Listeria*-like organisms.

- ✓ Take Corrective Action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ Hold and test Day 7 product lot (for *L. monocytogenes* or *Listeria* spp. or *Listeria*-like organisms).
- ✓ Continue production, hold product from the day's production

Day 8 –

- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 9 –

- ✓ Test FCS-- target most likely source of contamination, and take additional tests in surrounding FCS area
- ✓ Hold product from this day's production

Day 10 –

If FCS sample (day 7 sample) is negative for *Listeria* spp., or *Listeria*-like organisms.

- ✓ Continue production and hold product from days 7, 8, 9 and 10 until the results from Day 7 product testing and Days 8, 9, 10 FCS testing are available and found negative, unless there is compelling justification that affected products are not adulterated.
- ✓ Resume FCS testing according to frequency stated in sanitation program

If FCS sample (day 7 sample) is positive for *Listeria* spp., or *Listeria*-like organisms:

- ✓ Hold and test product from day 10 production.
- ✓ Test product from days 7, 8, 9, and 10 for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms
- ✓ Take corrective action
- ✓ Intensive cleaning and sanitizing
- ✓ Take FCS sample-- target most likely source of contamination, and additional tests in surrounding FCS area

Day 14 – If Day 7 product is positive for *L. monocytogenes*, destroy product, or rework product with a process that is destructive of *L. monocytogenes*. Recall product if already in commerce.
If product is positive for *Listeria* spp., verify that products (Days 7, 8, 9, 10), which may have been exposed to insanitary conditions are not adulterated by testing to provide compelling justification.

If the establishment tests FCS samples for *L. monocytogenes*, and the FCS test positive for the pathogen, the sampled lot is considered adulterated.

Every time there is a second or more (consecutive) follow-up FCS positive, product is held and tested for *L. monocytogenes*. Only product lots implicated with a second or more (consecutive) follow-up FCS positive are held and tested. Every time there is a product positive for *L. monocytogenes*, product is held, and destroyed or reworked with a listericidal process. Once the FCS testing is negative, implying that the corrective action is working, production is continued.

Repeated FCS positives would imply a critical sanitation problem and the establishment needs to conduct intensive testing and intensive cleaning and sanitizing. At the same time the establishment should investigate the cause and source of the contamination and review the documents where the sanitation and testing programs are included to determine if there are design or execution flaws. The establishment should have provisions in their sanitation and testing program for these kinds of situations.

A joint industry group has completed guidelines titled "Industry Best Practices for Holding Tested Products." This document was designed to encourage all establishments to hold products that are tested for adulterants until the results are received and to assist companies in developing best practices to ensure that they in fact do so. To obtain a copy of this document, visit the International HACCP Alliance website at the following address: http://haccpalliance.org/alliance/bestpractices.html

5. Sentinel Site Program Example

Some establishments have adopted a sentinel site program for the control of *L. monocytogenes* in RTE meat and poultry products. A sentinel site program is similar to traditional *Listeria* control programs – separate testing programs for the environment and food contact surfaces and increasingly aggressive corrective actions to eliminate *Listeria*

when it is detected. The distinctive characteristic of this control program is that in the case of a positive *Listeria* test result for a food contact surface area, the sanitation of that particular area will be included in the HACCP plan as a CCP. The CCP is removed when the establishment determines that the food safety hazard has been eliminated and is not reasonably likely to occur.

The CCP is the sanitation program for the particular site and food contact surface sampling as verification of the CCP. If a food contact surface or non-food contact surface tests positive for *Listeria* spp. or *Listeria*-lik*e* organisms, testing is intensified in the identified area.

If a non-food contact surface sampling site is found to be positive for *Listeria* spp. or *Listeria*-like organisms during routine monitoring, intensified sampling is initiated as soon as possible. Under intensified sampling, three samples per day (one each at pre-op, 1st shift, 2nd shift) are analyzed until a total of nine consecutive samples have been taken and are negative for *Listeria* spp. or *Listeria*-like organisms at that particular site. Swabs are analyzed for each day of production. If a sample finding is positive, testing of that site continues until nine consecutive samples are negative for *Listeria* spp. or *Listeria*-like organisms. Once nine consecutive samples are found negative, that site will be returned to routine sampling.

Similarly, the food contact surface site that initially tests positive for *Listeria* spp. or *Listeria*-like organisms will be placed under intensified testing. If nine consecutive samples under the intensified testing are negative for *Listeria*, that site is returned to routine monitoring. However, if the food contact surface tests positive under the initial intensified sampling, sanitation for that area is designated as a CCP, since *Listeria* would, at that point be considered a hazard not reasonably likely to occur. The site testing positive for *Listeria* would be considered a suspect harborage for *L. monocytogenes* and corrective actions taken. Testing becomes the verification step.

Intensified sampling under the CCP requires that 3 samples per day (one each at pre-op, 1st shift, 2nd shift) be taken until nine consecutive samples are negative for **both** *Listeria* spp. and *L. monocytogenes*. If a sample is positive for *Listeria* spp. but negative for *L. monocytogenes*, additional sampling days are added (3 samples per day) until nine consecutive samples are negative for both *Listeria* spp. and *L. monocytogenes*. All products that have contact with that particular site must be placed on hold pending test results.

If nine consecutive samples are negative for *Listeria* spp. and *L. monocytogenes*, the site can be returned to routine sampling. Product can be released when the line and production date receive negative test results for *L. monocytogenes*. Any sites testing positive for *L. monocytogenes* would require testing of the product.

Sentinel Site Program
Example Flowchart

1. Routine Environmental Sampling
    a. 5 samples/line/week
        i. 3 – food contact surface samples
        ii. 2 – non-food contact surface samples
        iii. *Listeria* spp.
2. Non-food Contact Surface Testing
    a. If negative for *Listeria* spp., continue Routine Environmental Testing
    b. If positive for *Listeria* spp., intensify sampling
        i. Collect 3 samples/site/day for 3 consecutive days for *Listeria* spp. (9 consecutive samples)
        ii. If 9 consecutive samples are negative for *Listeria* spp., return to Routine Environmental Sampling
        iii. If any sample is positive, continue sampling 3 samples/site/day until 9 consecutive samples are negative
3. Food Contact Surface (FCS) Testing
    a. If negative for *Listeria* spp., continue Routine Environmental Testing
    b. If positive for *Listeria* spp., intensify sampling
        i. Collect 3 samples/site/day for 3 consecutive days for *Listeria* spp. (9 consecutive samples)
        ii. If 9 consecutive samples are negative for *Listeria* spp., return to Routine Environmental Sampling
        iii. If any sample is positive, make sanitation for that site a CCP
4. CCP Testing
    a. Collect 3 samples samples/site/day for 3 consecutive days for *Listeria* spp. **and** *L. monocytogenes* (9 consecutive samples)
    b. If 9 consecutive samples are negative for *Listeria* spp. **and** *L. monocytogenes*, return to Routine Environmental Sampling and eliminate the CCP
    c. If a sample is positive for *Listeria* spp. but negative for *L. monocytogenes*
        i. Place product on hold
        ii. Release product if site and production date have negative results for *L. monocytogenes*
        iii. Continue testing until 9 consecutive samples are negative for *Listeria* spp. **and** *L. monocytogenes*, then return to Routine Environmental Sampling and eliminate the CCP
    d. If any sample is positive for *L. monocytogenes*, test the product for *L. monocytogenes*
        i. Reprocess or destroy product testing positive for *L. monocytogenes*

H. RISK-BASED VERIFICATION TESTING PROGRAM

Risk-Based Sampling. Before the implementation of risk-based verification sampling, samples were collected under sampling project codes ALLRTE (all RTE products – both post-lethality exposed and non-post-lethality exposed), RTERISK1 (product priority list based on FSIS Directive 10,240.4), and RTE001 (establishments are identified for sampling based on risk ranking). For ALLRTE, all establishments, regardless of plant

size, production volume, or process design had an equal chance of being sampled each fiscal year. Results from this project were unbiased to the extent that production practices were not addressed as they are in the other RTE verification sampling projects. Overall prevalence of the pathogens, for which FSIS tests, in all types of operations can be ascertained. FSIS randomly collected one sample of product at a time from an individual establishment and tested for pathogens of public health concern, namely, *Listeria monocytogenes*, *Salmonella* and *E. coli* O157:H7. Inspection program personnel carried out HACCP, Sanitation SOPs, and prerequisite program verification activities, including the review of records and laboratory results, to verify that establishment's are properly addressing the control of pathogens.

The implementation of the risk-based verification program consists of two phases. Phase 1 of the risk-based verification testing program was implemented in January 2005 with the issuance of FSIS Notice 61-04 announcing the RTE001 project for testing of post-lethality exposed ready-to-eat (RTE) meat and poultry products for *L monocytogenes*. Project RTE001 was designed to consider the Alternative (i.e., 1, 2. or 3 of 9 CFR 430.4) that the establishment selected for the production of post-lethality exposed products. That is, sampling was based on the risk of *Listeria* contamination of products produced under the three Alternatives. In Phase 2, this concept was expanded to include testing of food contact surfaces, environmental (non-food contact surfaces), and finished product. As more samples are taken for the RTE001 sampling project, sample project RTERISK1 will be discontinued. The ALLRTE project will still be continued in Phase 2.

In Phase 1, a checklist (Procedures for the Evaluation of Establishment Control Programs for *Listeria monocytogenes*, Attachment 7) was developed to evaluate the effectiveness of the post-lethality treatment, antimicrobial agent or process and the sanitation program used by the establishment to control *L. monocytogenes* in their post-lethality exposed RTE meat and poultry products. The checklist will be completed by Enforcement, Analysis and Investigative Officers (EAIO) whenever a Food Safety Assessment (FSA) is conducted.

Follow-up Sampling. When a sample taken under the sampling projects outlined above is found to be positive for a pathogen, FSIS will conduct follow-up verification testing after the establishment has taken its corrective and preventive actions. The follow-up sampling will be conducted under the Intensified Verification projects, as described below.

Intensified Verification Testing. These projects are designed for testing in any operation involving any RTE meat or poultry product, regardless of the establishment's control procedures, the production volume, etc., due to the production of adulterated product (i.e., the pre-shipment review has been completed), investigative purposes (e.g., as a result of an outbreak of foodborne disease), or concern that the establishment may not be properly controlling for pathogens. The projects may include instructions to Inspection program personnel to collect multiple samples. Intensified verification testing will include:

1. Increased frequency and number of samples taken for product testing (as compared to targeted verification testing), and the collection of environmental samples.

2. Increased FSIS record verification checks regarding the design and implementation of the food safety system.

These sampling projects will be scheduled by OFO through OPHS on a case-by-case basis.

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ATTACHMENT 1

CONTROL REQUIREMENTS for *LISTERIA MONOCYTOGENES*

Requirements	→ Increasing Risk Levels and Verification Testing →				
	ALTERNATIVE 1	**ALTERNATIVE 2**		**ALTERNATIVE 3**	
	Post-lethality Treatment AND Antimicrobial agent or Process	Post-lethality Treatment OR Antimicrobial agent or Process		Sanitation and Testing Program	
		Post-lethality Treatment	Antimicrobial Agent or Process	Non-deli, Non-hotdog	Deli or hot-dog product
Validate effectiveness of post-lethality treatment	X	X			
Document effectiveness of antimicrobial agent or process	X		X		
Sanitation Program Requirements			X	X	X
Testing food contact surfaces (FCS)			X	X	X
State testing frequency			X	X	X
Identify size and location of sites to be sampled			X	X	X
Explain why testing frequency is sufficient			X	X	X
Identify conditions for Hold-and-Test, when FCS (+)			X	X	X
Additional Sanitation Program Requirements					X
Follow-up testing to verify corrective actions are effective after 1st FCS (+)					X
If follow-up testing yields 2nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing.					X
Hold and test product lots for *L. monocytogenes* using sampling plan that provides statistical confidence. Release, rework or condemn products based on results. Document results and product disposition.					X

OTHER REQUIREMENTS

- Post-lethality treatments must be included in the HACCP plan.
- Antimicrobial agents must be included either in the HACCP plan, Sanitation SOP, or prerequisite program.

- Sanitation programs must be included either in HACCP plan, Sanitation SOP, or prerequisite program. If in the Sanitation SOPs or prerequisite program, there must be supporting documentation for the hazard analysis determination that this hazard is not reasonably likely to occur.
- Verification testing for sanitation in the post-lethality environment may be for *Listeria monocytogenes*, *Listeria* spp. *or Listeria*-like organisms.
- Product testing must be confirmed for *Listeria monocytogenes.*

- Establishment must maintain sanitation in the post-lethality environment per 9 CFR 416.
- If *L. monocytogenes* controls are in HACCP plan, establishment must validate and verify effectiveness per 9 CFR 417.4
- If *L. monocytogenes* controls are in Sanitation SOPs, their effectiveness must be evaluated per 9 CFR 416.14.
- If *L. monocytogenes* controls are in prerequisite programs, the program and results must be included in documentation required by 9 CFR 417.5
- Establishment must make verification results available to inspection program personnel.

ATTACHMENT 2
CHART OF RTE VS NRTE PRODUCTS

TYPE	CLASS	PROCESSING CATEGORY ISP CODE	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS/HACCP PLAN MAY ADDRESS
A product containing a meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for pathogens (i.e. raw or partially cooked product).	Not-ready-to-eat	• Raw Product Ground – ISP 03B • Raw Product Not Ground – ISP 03C • Not Heat Treated Shelf Stable – ISP 03E • Heat Treated –shelf stable – ISP 03F • Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H • Products with secondary inhibitors Not Shelf Stable – ISP 03I •	Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers. Use of Safe Handling Instruction (SHI) labeling required.	• Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., "Cook and Serve") but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as "needs to be fully cooked," "see cooking instructions," or "cook before eating." • Validation that: a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that has received a lethality treatment for pathogens in combination with non-meat/poultry components that need to receive a lethality treatment by the intended user. This includes meals, dinners, and frozen entrees.	Not-ready-to-eat	• Heat Treated but not Fully Cooked Not Shelf Stable - ISP 03H	Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.	• Validation that: a. The meat/poultry component received an adequate lethality treatment for pathogens. b. Cooking and preparation instructions on the product are sufficient to destroy pathogens. c. Instructions are realistic for the intended consumer. • Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., "Cook and Serve") but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as "needs to be fully cooked," "see cooking instructions," or "cook before eating." • If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.

A product containing a meat/poultry component that has received a lethality treatment for pathogens that may or may not be in combination with a non-meat/ poultry component that does not need to receive a lethality treatment by the intended user.	Ready-to-eat	• Not Heat Treated Shelf Stable – ISP 03E • Heat Treated Shelf Stable – ISP 03F • Fully Cooked Not Shelf Stable – ISP 03G • Products with secondary inhibitors Not Shelf Stable – ISP 03I	If the product is not shelf stable labeling such as keep refrigerated or frozen is required.	• See part 417 of the meat and poultry regulations.

ATTACHMENT 3

PRODUCTION INFORMATION ON POST-LETHALITY EXPOSED READY-TO-EAT PRODUCTS

The form can be accessed at:

http://www.fsis.usda.gov/Forms/PDF/Form_10240-1.pdf

ATTACHMENT 4

STUDIES ON POST-LETHALITY TREATMENTS

and ANTIMICROBIAL AGENTS

A. Studies on Post-lethality Treatments

(Mention of trade marks or commercial names does not constitute endorsement by USDA)

I. Steam Pasteurization and Hot Water Pasteurization

Post processing contamination of RTE meat and poultry is mostly confined to the surface. Pasteurization by steam and hot water acts on the surface microbial contaminants by the action of heat. Studies on surface pasteurization using steam or hot water were shown to be effective in reducing this contamination.

Studies by Murphy et al. (2003a) showed that post-cook hot water pasteurization and steam pasteurization resulted in a 7 $\log_{10}$ reduction of *L. monocytogenes* in inoculated vacuum packaged fully cooked sliced chicken. The reduction was effective when single – packaged breast fillets, 227 g- package strips and 454 g-packaged strips were heat treated at 90 C in a continuous steam cooker or hot water cooker for 5, 25 and 35 minutes respectively. These investigators developed a model called ThermoPro that could predict the thermal lethality of pathogens in fully cooked meat and poultry products during post-cook in-package pasteurization (Murphy et al., 2001, 2003b, 2003c). The model was developed using *L. innocua* and verified for *L. monocytogenes*.

II. Pre-Package Pasteurization and Post-Package Surface Pasteurization

Pre-package surface pasteurization treatment of fully cooked meat removed from their packaging wrap and inoculated with *L. monocytogenes* resulted in a 1.25 to 3.5 log reduction with a treatment time of 60-120 sec at 475 to 750º F air temperature (Gande and Muriana, 2003). Surface pasteurization was applied on cooked whole and split roast beef, whole corned beef, and whole and formed ham using a radiant oven. Pre-package pasteurization (60 sec) combined with post-package submerged water pasteurization using formed ham (60 or 90 sec), turkey bologna (45 or 60 sec), and roast beef (60 or 90 sec), resulted in a 3.2 to 3.9 log reduction for ham, 2.7-4.3 log reduction for bologna, or a 2.0-3.75 log reduction for roast beef. The level of reduction varied depending on the method of inoculation, type of product used, treatment temperature, and residence time.

Muriana et al., (2002) used a stainless steel water bath to submerge cooked RTE deli-style whole or formed turkey, ham and roast beef, removed from their package, inoculated with *L. monocytogenes* and vacuum packaged. Results show a 2-4 log decrease in the levels of L. monocyogenes in inoculated products post-cooked at 195-205º F for 2-10 min.

Treatment of processed foods with acidified sodium chloride (ASC) is another example of pre-packaging treatment. ASC is an antimicrobial agent that is approved for use on processed meat food products (unless precluded by standards of identity in 9 CFR 319) prior to packaging of the food for commercial purposes (21 CFR173.325 (f)). It is applied as a dip or spray at levels that result in sodium chlorite concentration of 500 to 1,200 ppm in combination with any GRAS acid at levels sufficient to achieve a pH of 2.5 to 2.9. It is approved as a secondary direct food additive, and considered as a processing aid, with very temporary or short term technical effect (bactericidal antimicrobial activity) after which it rapidly degrades to leave no long term residues or actives remaining (Kemp, Alcide Corp., personal communication, 2003). Because of this, it does not have to be included in the ingredient listing of the label. Marsden et al. (2000, unpublished), evaluated sodium chlorite (1,200 ppm) with 0.9% citric acid for its effectiveness in reducing *L. monocytogenes* on retail Little Smokies sausages. Results show that a water wash gave a 1.2 log cycle reduction of *L. monocytogenes*. An ASC dip for 15 sec provided a 1.0 log cycle reduction better compared to water wash. ASC exposure time of 30 sec gave 1.1 and 1.6 log cycle reductions over the water wash control, for spraying and dipping, respectively. Spray wash or dipping was found to be comparable in antibacterial effectiveness against *L. monocytogenes*.

III. High Hydrostatic Pressure Processing

High pressure processing (HPP) is one of the new technologies used for food processing. This technology provides a means of ensuring food safety for those products that are difficult to be heat treated due to organoleptic effects. HPP was shown to inactivate pathogens without any thermal or chemical effects and at the same time preserve the quality of the product. Raghubeer and Ting (2003) evaluated the efficacy of high hydrostatic pressure processing in inactivating *L. monocytogenes* in retail-packaged samples of sliced ham, turkey and roast beef obtained from a manufacturer and repackaged in 25-g portions. Results show that an inoculum of about 10^4 *L. monocytogenes* cocktail in these 3 products and HPP treatment at 87,000 psi for 3 minutes showed no recovery of *L. monocytogenes* after 61 days of storage at 34° F. There were no pressure-injured cells detected. There were no adverse organoleptic effects detected on the 3 HPP treated products during the 61-day shelf life study. No signs of spoilage were seen on all 3 products after 61 days of storage, and for 100 days for ham and turkey. According to the investigators, the normal shelf life of these products is 30 days, so the HPP treatment extended the shelf life of the products.

B. Studies on the Use of Antimicrobial Agents

I. Addition of Lactates, Acetates, Diacetates to Meat Formulations

Studies have shown that lactic acid and acetic acid have significant antimicrobial activity in broth and food systems. Sodium and potassium salts of these acids, when added to processed meat formulations are also known to potentially inhibit pathogenic bacteria especially *L. monocytogenes*. These antimicrobials inhibit growth of pathogens by

inhibiting their metabolic activities. Interest in these antimicrobials is in the growth inhibition of *L. monocytogenes* in post lethality exposed RTE meat and poultry products. Several studies used these antimicrobials to show their ability to inhibit growth of *L. monocytogenes* in different meat formulations.

Seman et al., (2002) developed a mathematical model capable of predicting the growth or stasis of *L. monocytogenes* in commercial cured meat products using a response surface method. The model can be used by manufacturers in the determination of the appropriate amounts of potassium lactate and sodium diacetate to be added to cured meat products that are organoleptically sensible and will not support the growth of *L. monocytogenes*. Thirty products were formulated by using a variety of raw material sources such as pork trimmings, trimmed turkey breast halves and four-muscle ham. Varying amounts of potassium lactate and sodium diacetate were added to the meat formulation and the meats were processed into different products. After chilling, the products were stripped of their casings, sliced into 25-g slices, placed into pouches, and inoculated with *L. monocytogenes* by applying to the surface of 100g of cured meat (four slices).

The results show that increasing amounts of potassium lactate syrup and sodium diacetate decreased the growth rate of *L. monocytogenes*, while increasing finished product moisture increased the growth rate. Sodium chloride content was not significant but was found to have a negative correlation to growth rate. The investigators provided a final regression equation predicting the growth of *L. monocytogenes* in cured RTE meat products stored at 4° C. The investigators used predictive model performance factors and a simple linear regression analysis to evaluate the model generated in this study. They verified the accuracy of the model by comparing with actual *L. monocytogenes* growth data from an independent challenge study conducted with four different commercial RTE meat products using similar storage conditions. Performance factors calculated and evaluated for control products (those not containing potassium lactate and sodium diacetate) indicated that on the average, the predicted growth of *L. monocytogenes* exceeded those of the observed values by about 24 %.

This study provided a useful model in determining the target amounts of potassium lactate and sodium acetate for cured meat product formulations to inhibit the growth of *L. monocytogenes*. The calculations would also require knowledge of the finished product sodium chloride and moisture contents. The investigators advised that this validated model is specific to the products designed for the study and the *L. monocytogenes* strains used. Testing of this model in other environments and with other *Listeria* spp., and to formulations that are outside the model's limits may result in different maximum growth rates. This study was used as the basis for the Opti.Form *Listeria* Control Model.

The Opti.Form *Listeria* Control Model is a unique tool to calculate the levels of lactate and diacetate required to retard the growth of *Listeria monocytogenes* in cured meat and poultry products. The model is based on the study detailed in the paper by Seman et al, 2002, above. The model, which is available on CD-Rom includes:

- instructions on how to use the model
- explanation on the development of the model

- information on the anti-microbial effect of lactate and diacetate
- lactates and diacetates and use of these products
- regulations and labeling
- literature references

To receive a free copy of the model on CD-Rom, call: 888-899 8229, E-mail pam@purac.com

Bedie et al., (2001) evaluated the use of antimicrobials, included in frankfurter formulations, on *L. monocytogenes* populations during refrigerated storage. Fully cooked and cooled frankfurters were inoculated with 10^3 to 10^4 CFU /cm^2 of *L. monocytogenes* after peeling and before vacuum packaging. Samples were stored at 4° C for up to 120 days and sampled for testing on assigned days. Results are as follows:

ANTIMICROBIAL	LEVEL (%)	*L. MONOCYTOGENES* GROWTH INHIBITION
Sodium lactate	3	70 days no pathogen growth
Sodium diacetate	0.25	50 days no pathogen growth
Sodium acetate	0.25, 0.50	20 days no pathogen growth
Sodium lactate	6	120 days no growth and reduced pathogen growth
Sodium diacetate	0.5	120 days no growth and reduced pathogen growth
Inoc. Control	0.0	Increased to 6 logs in 20 days

Note: Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

No pathogen growth refers to zero increase in the number of inoculated *L. monocytogenes* cells (bacteriostatic); while reduced pathogen growth refers to a decrease in the number of inoculated *L. monocytogenes* cells (bactericidal) in the product. In this study, tables showed the reduction varied with storage days, but was up to 1.0 log on some days. Antimicrobials were found to have no effect on pH except for sodium diacetate at 0.5 % which reduced the initial pH. Using the formulations and conditions in the study, establishments can add 3 % sodium lactate in the frankfurter formulation and obtain no growth of *L. monocytogenes* up to 70 days at refrigerated storage of 4° C. If the lethality treatment is adequate to eliminate *L. monocytogenes*, then the only probable source of *L. monocytogenes* would be from exposure of the product during peeling and repackaging. However, the establishment's sanitation program may keep the numbers to a very low level, and 3 % sodium lactate included in the formulation would inhibit the growth of *L. monocytogenes* during the product's refrigerated shelf life. Levels of sodium lactate at 6.0 % and sodium diacetate at 0.5 % showed a reduction of the pathogens, however these levels are above the permitted levels.

This study by Samelis et al., (2002) used similar treatments, processing and inoculation procedures and frankfurter formulations as the previous study described above. However, in this study combinations of antimicrobials were used, and in combination with hotwater treatment. Hot water treatment involved immersion of frankfurters, with two product links in a package to 75 or 80° C for 60 s. Storage at 4° C shows:

TREATMENT	LEVELS (%)	*L. MONOCYTOGENES* GROWTH INHIBITION
Sodium lactate	1.8	35-50 days no growth
Sodium lactate + sodium acetate	1.8 0.25	120 days no growth; 35-50 days growth reduction
Sodium lactate + Sodium diacetate	1.8 0.25	120 days no growth; 35-50 days growth reduction
Sodium lactate + Glucuno-delta-lactone	1.8 0.25	120 days no growth, 35-50 days growth reduction
Hot water treatment (80° C, 60 s) + Sodium lactate	1.8	Inoc. population reduced by 0.4-0.9 log CFU/cm^2 , and 50-70 days growth reduction by 1.1-1.4 CFU/ cm^2
Hot water treatment (80° C, 60 s)		Increase in growth to about 6-8 logs in 50 days
Inoculated Control, no treatment		Increase in growth to about 6 logs in 20 days and 8 logs thereafter up to 120 days

Note: Sodium lactate was used as a 3 % of a 60 % (wt/wt) commercial solution. Glucuno-delta lactone is approved as an acidifier, and a curing accelerator, but not as antimicrobial. Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

Glass et al., (2002) evaluated sodium lactate and sodium diacetate on wieners and cooked bratwurst containing both beef and pork supplied by a commercial manufacturer. Antimicrobial solutions used were sodium lactate and sodium diacetate singly or in combination at varying concentration. Wieners were repackaged in gas-impermeable pouches, then surface-inoculated with *L. monocytogenes* mixture on multiple areas of the surface of each link. Packages were vacuum-sealed and stored at 4.5º C for up to 60 days. Two types of cooked bratwurst from a commercial manufacturer were evaluated: bratwurst that was cured and naturally smoked and bratwurst that was uncured and unsmoked. Bratwurst was stored at 3 or 7° C for up to 84 days.
The surface treatment consisting of dipping wieners into solutions containing up to 6 % lactate and up to 3 % diacetate for 5 s did not delay pathogen growth, indicating that dipping wieners in the lactate/diacetate solutions is not an efficient way to apply the antimicrobials. However, the inclusion of lactates and diacetates in the formulation was found effective in inhibiting growth of *L. monocytogenes*. Results are as follows:

PRODUCT	Sodium Lactate (%)	Sodium diacetate (%)	*L. monocytogenes* levels (CFU/pkg)
Bratwurst uncured, unsmoked	3.4 2.0	0.1 0.0	Growth delayed for 4-12 weeks at 7 and 3°C storage, respectively. Growth delayed for 1-2 weeks at 7 and 3°C

Bratwurst cured, smoked	3.4 0.0	0.1 0.0	Growth inhibited for 12 weeks at 7 and 3°C Growth up to 1 log after 4 weeks at 7 and 3° C
Wieners	3.0 1.0	0.0 0.1	Growth inhibited for 60 days at 4.5° C Growth inhibited for 60 days at 4.5° C

Study by (Porto et al., 2002) used freshly processed peeled frankfurters in vacuum sealed packages obtained from a commercial manufacturer. Two formulations of links were used in the study: one with added 2 or 3 % potassium lactate and the other without added potassium lactate. Frankfurters were aseptically removed from their original package, repackaged, and inoculated with a mixture of *L. monocytogenes*. The packages were vacuum-sealed to 95 kPa and incubated at 4 and 10° C.
Results show that addition of 2 % or 3 % potassium lactate in frankfurters can appreciably enhance safety by inhibiting or delaying the growth of *L. monocytogenes* during storage at refrigeration or abused temperatures. The viability of the pathogen was influenced by pH, and the levels of lactate added, but not by the presence of indigenous lactic acid bacteria.

Potassium lactate (%)	Inoculum CFU/pkg	Storage temp °C)	Days Storage	*L. monocytogenes* levels (CFU/package)
2.0	20	4	90	Remained at about 1.6 log
3.0	20	4	90	Remained at about 1.4 log
3.0	500	4	90	Remained at about 2.4 log
0.0	20	4	90	Increased to about 4.6 log
0.0	500	4	90	Increased to about 5.0 log
2.0	20	10	60	Remained at about 1.4 log
3.0	20	10	60	Remained at about 1.1 log
0.0	20	10	60	Increased to about 6.5 after 28 days, declined to about 5.0 after 60 days
3.0	500	10	60	Remained at about 2.4
0.0	500	20	60	Increased to about 6.6 log after 40 days and declined to about 5.5 log after 60 days

II. Growth Inhibitor Packaging

Growth inhibitor packaging is an intervention, which delivers an active antibacterial agent to the surface of an encased sausage product. By incorporating this special coating onto the internal surface of cellulose casings, the antilisterial treatment is transferred to the surface of the processed meat/sausage during thermal processing. Upon removal of the casing, the treatment remains active on the meat surface, providing effective protection against inadvertent *Listeria* contamination during subsequent peeling and packaging processes. Growth inhibitor packaging used in conjunction with functional

HACCP and Good Manufacturing Practices provides the industry with one more tool in their intervention strategy to control the risk of pathogen contamination in ready-to-eat meat and poultry products.

Studies on meat formulations for hotdogs using NOJAX® AL™ showed that use of the casings provide a lethality hurdle to the growth of *Listeria monocytogenes*, not just an inhibitory effect. The lethality impact is delivered within the first hours/days of the sausage/hotdog package life. This impact is dependent on many variables but is generally in the range of 1 – 2 log kill of *L. monocytogenes* at high levels of inoculation. This performance has been observed in challenge studies conducted on hotdogs drawn from commercial full-scale trials at a number of commercial processing plants. In high inoculation trials, NOJAX AL has been combined with conventional growth inhibiting additives, and as expected, the lethality impact is obtained and then maintained throughout the product life cycle. In these same trials, without growth inhibiting additives, this casing produces lethality but in several weeks the remaining *L. monocytogenes* begin to grow.

NOJAX AL is available in the U.S. having approval by both FDA and USDA for its key component, nisin. This GRAS component must be included in the ingredient statement via a label change request to the FSIS Labeling and Consumer Protection Staff. Because this is a naturally derived polypeptide, there are storage and use-by criteria that will have to be adhered to by the user for maximum benefit. Casing shelf-life is about 60-90days with a not to exceed 85º F.

This technology can be applied to most hotdogs and sausages that are encased in cellulose casing. This casing intervention can be used in any instance were casing is used as a mold for processed meat and poultry during thermal processing. This would include cellulose, plastic, and possibly natural casing. As part of a manufacturer's decision to use this technology, benefits are: 1) no capital costs or new equipment; 2) no change in processing steps, plant reconfigurations or introduction of process bottlenecks—essentially processor transparent in all aspects of use except casing storage requirements; 3) no impact on flavor, texture, or package appearance, and 4) minor labeling change to ingredient statement
Since this is a surface treatment, cost will be proportional to the surface to volume ratio of the product: the larger the sausage diameter, the lower the cost per pound. In general, economic analyses put the cost of this lethality intervention at about 2-3 cents per pound of finished product, with a mid-range target price of 2.5 cents per pound for a traditional 10-to-the-pound retail pack of hotdogs.

Janes et al., (2002) investigated the effect of nisin added to zein film coatings (Z) coated onto cooked ready-to-eat chicken against *L. monocytogenes*. Cooked chicken samples inoculated with *L. monocytogenes* were dipped into Z dissolved in propylene glycol or ethanol, with or without added nisin (1,000 IU/g) and/or 1 % calcium propionate and stored at 4 C or 8 C for 24 days. After 16 d at 4 C, *L. monocytogenes* was suppressed by 4.5 to 5 log CFU/g with zein film coatings with nisin. The most effective treatment in the

study for controlling *L. monocytogenes* on the surface of ready-to-eat chicken was using edible zein film coatings containing nisin at a storage temperature of 4°C.

The use of film coatings in a processing plant would be to fully process the meat products then coat them with the films. Coating can be done by spraying or dipping the processed meat products and then allowing them to dry. Zein coatings on the meat products can be dried by circulating air around the meat product using a fan. Finally, the dried coated meat products can be packaged with the usual plastic film material and refrigerated. This study has not been tested in commercial poultry processing conditions.
Some general observations from the published studies on antimicrobials:

- Lactates, acetates and diacetates were found more effective in inhibiting growth of *L. monocytogenes* when used in combination than when used singly.
- These antimicrobials were found more effective when used to the maximum allowable concentration. However, higher concentrations of antimicrobials used in the formulation may affect the sensory qualities of the product, such as flavor and texture, which would necessitate sensory evaluation of treated products.
- When used in combination, the amount needed to inhibit growth may be reduced.
- These antimicrobials were found to have listeriostatic activity more than listericidal activity, i.e. they prevent growth of the pathogen more than reduce the number of cells of the pathogen, and therefore may not be effective against gross contamination of a product. The establishment's sanitation program should control gross contamination of the processing environment and equipment. Addition of antimicrobials would be effective only as part of the overall HACCP strategy.
- Including these antimicrobials in the formulation was found to be more effective in inhibiting listerial growth than dipping products in solutions of antimicrobials.
- The antimicrobial activity of lactates and diacetates when used singly or in combination is affected by the level of contamination of the meat product surface, and processing factors such as pH, moisture, water activity, fat, nitrite, salt content, time and temperature of storage, and packaging atmosphere.
- Application of the treatments used in these studies is limited to the formulations, products and treatments used in the studies. Applying these studies to other products and formulations may result in different rates of growth inhibition. Therefore the effectiveness of the antimicrobials used in these studies must be verified by the establishment for other processed meat products and other storage temperatures.
- Antimicrobials used in the formulation must have an effective antilisterial activity throughout the commercial shelf life of the product. Currently the targeted commercial shelf life of refrigerated cooked meat products in the U.S.A. is 75 to 90 days.
- Using post-packaging thermal treatments in addition to antimicrobials was found to increase the total antilisterial effects of the antimicrobials.
- These antimicrobials were found to be more effective in smoked products formulated with sodium nitrite, or in products stored at strict refrigeration temperatures.

- Use of these antimicrobials may be a cost effective antilisterial method that very small establishments can use.

References are found on pp. 48-49.

ATTACHMENT 5

Hold-and-Test Sampling for the FSIS LM Rule

Background

On June 6, 2003, FSIS published an interim final rule on the control of *Listeria monocytogenes* in ready-to-eat (RTE) meat and poultry products. Most processors of RTE products will have to conduct microbiological testing of product contact surfaces. The rule states that establishments using antimicrobial agents or processes under Alternative 2 and establishments producing non-hotdog or non-deli products under Alternative 3 must identify the conditions under which they will implement hold-and-test procedures. The rule describes the hold-and-test procedures to be followed by establishments producing hotdog and deli products under Alternative 3. Under alternative 3, an establishment producing a hotdog or deli product that obtains a positive for *Listeria monocytogenes* or an indicator organism such as *Listeria* spp. in follow up testing on food contact surfaces must hold lots of product that may have become contaminated by the food contact surface and must sample and test these lots before release into commerce. In addition, establishments producing RTE products must identify conditions under which the establishment will implement hold-and-test procedures following a positive test for *Listeria* spp. or *L. monocytogenes* on a food contact surface.

In response to NFPA questions, FSIS officials have indicated that the intent is not to set a minimum level of sampling, but rather to rely on the industry to identify what they individually or as a group consider to be reasonable and scientifically supportable. The Agency encouraged the industry to consider the ICMSF tables (International Commission on Microbiological Specifications for Foods. *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*. Kluwer Academic/Plenum Publishers, NY. 2002).

ICMSF Sampling Plans for *Listeria monocytogenes*

ICMSF categorizes microbial hazards according to risk – moderate, serious and severe. ICMSF ranks *L. monocytogenes* as either a serious hazard in foods for the general population or a severe hazard in foods for restricted populations (high risk groups). ICMSF describes 15 different cases of sampling plans, with sampling plan stringency based on degree of risk and the effect on risk of the conditions of use. Cases 10, 11 and 12 would apply to the serious category, and cases 13, 14, or 15 would apply to the severe category of microbial hazards. ICMSF considers cases 13, 14, and 15 to apply to foods intended specifically for highly susceptible individuals (e.g., hospitals and nursing homes) because a large proportion of the individuals would be potentially susceptible; thus, increasing the stringency of the sampling plans is appropriate. Cases 10, 11 and 12

apply to foods for the general population, where the proportion of susceptible individuals is much lower; thus, the overall risk of illness is reduced. Recent risk assessments have demonstrated that low levels of *L. monocytogenes* in food pose little risk, even for the highly susceptible population.

For cases 10 or 13, conditions of use reduce risk (e.g., the numbers of *L. monocytogenes* will decrease). For cases 11 and 14, conditions cause no change in the hazard (e.g., the organism cannot grow), and for cases 12 and 15, conditions may increase the risk (e.g., foods in which *L. monocytogenes* can grow are subjected to conditions that allow growth). Sampling plans for the cases are given in the table below, where n is the number of samples and c=0 means that none of the "n" 25-g samples can be positive for *L. monocytogenes*. The table also provides the sampling plan performance, assuming a log-normal distribution with a standard deviation of 0.8; lots having the calculated mean concentrations or greater will be rejected with at least 95% confidence. Each of these plans achieves assurance that *L. monocytogenes* is present at <1 in 25 g. It is recommended that the 25 g. sample be analyzed separately and not composited. However, if compositing is to be done, composites of 25-g portions should not exceed a total of 125 g. in order to maintain the sensitivity of the method of analysis.

Conditions reduce concern	**Conditions cause no change in concern**	**Conditions increase concern**
Case 10 n=5, c=0 Mean Concentration 1 cfu/32g	Case 11 n=10, c=0 Mean Concentration 1 cfu/83g	Case 12 n=20, c=0 Mean Concentration 1 cfu/185g
Case 13 n=15, c=0 Mean Concentration 1 cfu/135g	Case 14 n=30, c=0 Mean Concentration 1 cfu/278g	Case 15 n=60, c=0 Mean Concentration 1 cfu/526g

Where RTE products must be sampled (hold and test) under the rule, the number of samples (randomly selected) would be as specified for these cases based on the risk of the product and the intended consumers. Since deli and hotdog products are ranked as the top causes of foodborne illness, the establishment producing these products should select these products to be sampled first. Sampling starts after the establishment has conducted corrective actions that are specifically designed to find the most likely cause of the contamination and controls are put in place to prevent recurrence.

Case 10 n=5, c=0	Case 11 n=10, c=0	Case 12 n=20, c=0
Products with continued decline in population due to antimicrobial or other formulation considerations such as pH, a_w, etc. Products in Alternative 1	Products that limit growth (< 1 log) due to antimicrobial or other formulation considerations such as pH, a_w, etc. Products in Alternative 2	Products that support growth and that will be stored refrigerated for an extended period of time. Products in Alternative 3
Case 13 n=15, c=0	Case 14 n=30, c=0	Case 15 n=60, c=0
As for case 10, but where products are produced for a hospital or nursing home or other higher risk population Products in Alternative 1 intended for a hospital, nursing home or other higher risk population	As for case 11, but where products are produced for a hospital or nursing home or other higher risk population Products in Alternative 2 intended for a hospital, nursing home or other higher risk population	As for case 12, but where products are produced for a hospital or nursing home or other higher risk population Products in Alternative 3 intended for a hospital, nursing home or other higher risk population.

The number of samples recommended will be collected in 1 day and all affected products will be held during the testing period. Testing can be for *Listeria* spp. or *L. monocytogenes*. Any positive results from this follow-up testing (using the ICMSF approach) should lead to more significant investigations of the cause and of prevention before intensified follow-up testing. If samples tested positive for *Listeria* spp., the establishment should confirm for *L. monocytogenes* and if positive for *L. monocytogenes*, the product is considered adulterated. The establishment must conduct rigorous corrective actions, and other sanitation and HACCP type activities.

Establishments may send a letter or certification when they ship tested products to nursing homes, hospitals and other institutions with susceptible populations. Such a letter would indicate that product has been sampled and tested according to ICMSF recommendations. Establishments supplying nursing homes, hospitals and other institutions with the susceptible populations are expected to implement whatever additional controls and verification procedures are necessary to ensure that product is not adulterated.

ATTACHMENT 6

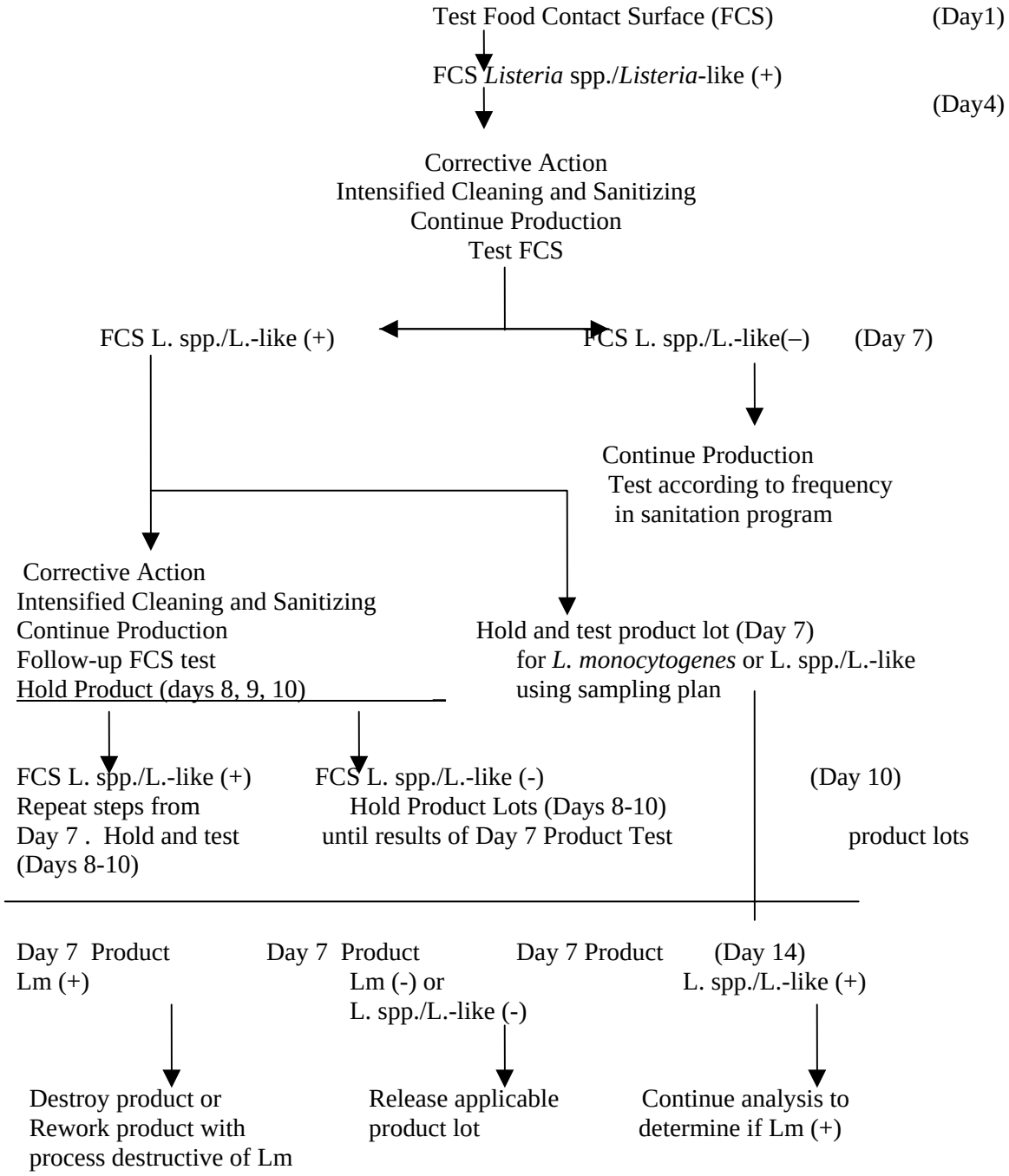
HOLD-AND-TEST SCENARIO FLOWCHART

The following flow chart is a most likely scenario for a hold and test situation. The flowchart illustrates what an establishment could do in case of a food contact surface (FCS) testing positive for *Listeria* spp. or *Listeria*-like organisms, and when a follow-up FCS test is positive. Establishments can design their own procedures or flowchart for their hold and test program. Repeated positive FCS test would imply an inadequate sanitation system or harborage of the pathogen and establishments should investigate and reassess their sanitation program, their equipment layout and design product flow to determine the cause of the contamination. For repeated food contact surface positives for *Listeria* spp. or *Listeria*-like organisms during the hold and test period, establishments can test associated product for *L. monocytogenes* based on a sampling plan.

This chart only addresses FCS testing with *Listeria* spp or *Listeria*-like organisms. If the establishment tests FCS for *L. monocytogenes* and the result is positive, product in the sampled lot is considered adulterated. The establishment can destroy the product or reprocess the product with a process that is destructive of *L. monocytogenes*.

ATTACHMENT 6

HOLD-AND-TEST SCENARIO FLOWCHART



FCS: food contact surface
L spp. or L.-like: *Listeria* spp. *or Listeria*-like organisms (test results available after 2 or 3 days)
Lm: *Listeria monocytogenes* (test results available after 6 or 7 days)

Enforcement strategy

Under 9 CFR 430, an establishment with deli and hotdog products in Alternative 3 must provide for testing of food contact surface (FCS). If the FCS tests positive for *L. monocytogenes* or *Listeria* Spp. or *Listeria*-like organisms, the establishment must conduct follow-up testing to verify its corrective actions. If during the follow-up testing another positive FCS occurs, the establishment must hold the applicable product lot if positive for *L*. spp. or *L*.-like, or destroy or rework with a process destructive of *L. monocytogenes* if positive for *L. monocytogenes*, and test the FCS until the establishment corrects the problem as indicated by the test result. In addition, the establishment must test held product lots for *Listeria monocytogenes* using a sampling plan that will provide a statistical level of confidence. The flowchart above shows a test and hold scenario which an establishment in this type of situation can use. The following section describes the likely action and reaction of inspection personnel during a hold and test situation.

Day 1, 4

The testing program and the test results for food contact and non-food contact surfaces should be available to inspection program personnel. In case of a FCS testing positive for L spp. or *Listeria*-like organism, inspection program personnel will verify that the establishment is performing the corrective actions as specified in the HACCP plan, Sanitation SOP or prerequisite programs, including any intensified cleaning and sanitizing. For deli and hotdog products in Alternative 3, inspection personnel will verify that the establishment is conducting follow-up testing for FCS to determine the effectiveness of the corrective actions, targeting most likely source of contamination and additional tests in surrounding FCS area, and recording all these.

Day 7

Results of the follow-up FCS tests are available on this day. If the FCS tests are negative, then the establishment continues with its normal production and sanitation program procedures. If the follow-up FCS tests are positive for *L. monocytogenes, Listeria* spp. or *Listeria*-like organisms, inspection program personnel will verify that the establishment is following its corrective action for a second FCS positive, including intensified cleaning and sanitizing. For deli and hotdog products in Alternative 3, inspection personnel will verify whether the establishment is holding the product produced that day and testing the product lot for *L*. spp or *L. monocytogenes*, and whether the establishment is conducting follow-up testing of FCS during each production, and holding all products until a negative follow-up FCS test is obtained. Products produced on days 8, 9 and 10 are held until the follow-up FCS test available after about 3 days is found negative. The interim rule states that products must be held until the problem is corrected as indicated by testing. For establishments in Alternative 3 producing deli and hotdog products, inspection personnel can cite the establishment if these procedures are not followed.

Days 8, 9, and 10

The presence of *Listeria* spp. or *Listeria*-like organisms on a food contact surface or on ready-to-eat (RTE) product is associated with the potential for an insanitary condition to exist. FSIS expects an establishment to develop a compelling justification for concluding that product produced on days in which insanitary conditions may have existed is not adulterated. Thus, FSIS would further expect that the establishment, on days 8-10 would conduct verification testing on the food contact surfaces to demonstrate that the potential insanitary condition was adequately redressed via the corrective and preventative actions. In addition, to further develop a compelling justification to support the establishment's decision, FSIS would expect a prudent establishment to also compile data on product testing to confirm and verify that the corrective and preventative actions were effective in preventing product from becoming adulterated.

Day 10

If Day 7 FCS Test is Positive

Inspection program personnel will verify that if the follow-up FCS test taken on Day 7 is positive, then the day's production lots of deli and hotdog products in Alternative 3 are held and tested for *Listeria* spp./*Listeria*-like or *L. monocytogenes* and the same procedures are followed as in the second FCS (+) test as in Day 7.

If FCS samples taken on day 7 are found positive for *L*. spp./*L*.-like on day 10, the establishment should hold and test product produced on days 8, 9 and 10 unless the establishment has supporting documentation to justify that product produced on days 8, 9 and 10 would not be contaminated with *L. monocytogenes*. The sampling plan must provide a level of confidence that each product is not contaminated with *L. monocytogenes*. Because of 3 consecutive positive FCS, the establishment should conduct intensive cleaning and sanitizing and reevaluate its sanitation program.

If FCS is positive for *L. monocytogenes*, affected product lots are considered adulterated. The establishment should also hold and test products produced on days 8, 9 and 10 because a FCS positive for *L. monocytogenes* shows that the corrective action may not have been effective in removing the contamination and products produced on succeeding days may also be contaminated.

If Day 7 FCS Test is Negative

If FCS samples taken on day 7 are found negative for *Listeria* spp./*Listeria*-like on day 10, the establishment should wait for the results of the FCS tests conducted on days 8, 9, and 10 as detailed above, and results of the Day 7 product test before releasing these products. Products produced on days 8 and 9 may be released without waiting for product testing results if the establishment has a compelling justification for concluding that products produced on those days are not adulterated.

Day 14

If day 7 product was found positive for *L. monocytogenes* on day 14, affected product lots produced on day 7 are considered adulterated. The establishment must destroy the product lots or rework them with a process destructive of *L. monocytogenes*. The establishment should continue holding product lots produced on days 8, 9, and 10 until results of products tests are available, unless the establishment has supporting

documentation for why product produced on days 8, 9 and 10 would not be contaminated with *L. monocytogenes*. Establishment should also test and hold product produced before day 7 and recall them if already in commerce or provide compelling evidence that product produced before day 7 was not adulterated.

For a product sample that tests positive for *L. monocytogenes*, inspection personnel will verify that the product lots affected are disposed properly, i.e., destroyed, or reworked with a process destructive to *L. monocytogenes*. Establishments should have supporting documentation that products lots produced before Day 7 are not contaminated with *L. monocytogenes,* so that these will not be included as adulterated.

A product that is positive for *Listeria*. spp. or *Listeria*-like is not summarily determined to be adulterated, although it can lead to a determination that an insanitary condition exists and without compelling documentation, the establishment may not be able to conclude that the product is not adulterated. This also indicates that corrective and preventative actions taken may not have been effective, or that the sanitation program is inadequate and ineffective and therefore, the establishment needs to take actions to prove otherwise. The establishment needs to have compelling documentation that the product is not adulterated and needs to determine that its sampling plan provides a level of confidence that each product is not contaminated with *L. monocytogenes*.

If the establishment is using a post-lethality treatment or antimicrobial agent and the product tests positive for *Listeria* spp., *Listeria*-like organisms, or *L. monocytogenes,* according to 417.6(e), the HACCP plan may be found inadequate. In determining whether the HACCP plan is inadequate, the Agency will take into account all available information and consider the entire situation. The cause and significance of a positive result varies from case to case depending on the circumstances of processing involved, and the pathogen found. FSIS will consider whether some or all products produced under the same or a substantially similar HACCP plan are affected, whether there have been other incidents of product contamination with the pathogen, and whether incidents of product contamination have been persistent or recurring. Establishments are required to take corrective and preventive actions in accordance with 9 CFR 417.3.

The Agency will expect the same rigor for testing and sanitation at the point that product testing is reached for products in Alternative 3 and in Alternative 2, using an antimicrobial agent or process. For products in Alternative 1, and in Alternative 2 using post-lethality treatment, if FCS is positive for *Listeria* spp. or *Listeria*-like organisms, product holding and testing may not be necessary as long as the post-lethality treatment is validated to reduce *L. monocytogenes* by at least 1 log, and the establishment verifies the effectiveness of the post-lethality treatment.

ATTACHMENT 7

PROCEDURES FOR THE EVALUATION OF ESTABLISHMENT CONTROL PROGRAMS FOR *LISTERIA MONOCYTOGENES*

FSIS is conducting an evaluation of the effectiveness of the post-lethality treatment, antimicrobial agent or process and the sanitation program used by establishments to control *Listeria monocytogenes* (LM) in their post-lethality exposed ready-to-eat (RTE) meat and poultry products. Results of this evaluation will be used to determine the risk of LM contamination and the frequency of risk-based verification sampling for LM.

This document includes procedures and questionnaires for evaluating an establishment's control measures for LM. The document also contains an Appendix that includes definitions, explanation of terms, and examples of validation studies with highlighted information that are important for control.

Background:

L. monocytogenes is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation Standard Operating Procedures (SOP) or other prerequisite program. 9 CFR Part 430 "Control of *Listeria monocytogenes* in Ready-to-Eat Meat and Poultry Products: Final Rule, June 6, 2003" with implementation starting on October 6, 2003, mandates establishment compliance with one of three post-lethality alternatives.

For establishments that produce RTE products that are post-lethality exposed, FSIS needs your assistance in providing information that will answer the following questions.

1. Has the establishment selected one of the three alternatives per 430.4(b) of the regulations?
2. For establishments electing to use Alternative 1, the following questions apply: (a) Does the establishment use a post-lethality treatment for product AND an antimicrobial agent or process that suppresses or limits the growth of LM? (b) How effective is that process?
3. For establishments electing to use Alternative 2, the following questions apply: (a) Does the establishment use a post-lethality treatment for product OR an antimicrobial agent or process that suppresses or limits the growth of LM? (b) How effective is that process?
4. For establishments electing to use Alternative 3, the following questions apply: (a) Does the establishment have a sanitation program that addresses testing of food contact surfaces: How effective is that program?

You will evaluate the establishment's level of effectiveness in implementing Alternatives 1, 2 and 3 through a set of questions for each Alternative. The set of questions for each Alternative are provided in separate Evaluation Sections in the Procedures. The Evaluation Sections are numbered I, II, III and IV. Step 4 in the **Instructions** matches each Alternative with the appropriate Evaluation Sections.

INSTRUCTIONS

(If you have any questions regarding this survey, please contact Amelia K. Sharar (202-205-0009, Amelia.Sharar@FSIS.USDA.gov) or Paul Uhler (202-205-0438, Paul.Uhler@FSIS.USDA.gov)

Step 1:

- Have the following documents ready and available for review: the establishment's HACCP plan, Sanitation SOP, and prerequisite programs addressing post-lethality exposed RTE product associated with 9 CFR 430.
- Use the establishment's completed FSIS Form 10, 240-1 as reference ONLY. Do not simply re-state what is on the form.

- For determination of risk-based verification testing, FSIS needs to have this evaluation completed without participation of establishment personnel. All information needed should be readily available for review, in accordance with HACCP requirements. FSIS will follow-up in circumstances in which there are significant discrepancies between these procedures and the information provided by the establishment on FSIS Form 10,240-1. NOTE: FSIS is not asking the establishment personnel to participate by responding to the checklist questions because FSIS has not sought approval from OMB to conduct such information gathering from industry. However, FSIS does have authority to assess and document the information relative to the checklist that is available as part of the establishment's food safety system FSIS can share with the establishment the checklist and the FSIS assessment that was completed as part of the checklist.

Step 2: Answer preliminary questions in "Guide to Selecting Evaluation Sections."

Step 3: Read through the evaluation sections and accompanying tables prior to completing the preliminary question related to the control programs for each applicable product(s):

Section I: Post-lethality Treatment (PLT)
Section II: Antimicrobial Agent or Process (AMAP)
Section III: Sanitation Program
Section IV: On-going Verification

Step 4: For each Alternative, use the following sections to rate the evaluation of that control program:
Alternative 1, use Section I, II, III and IV
Alternative 2 (PLT), use Section I, III and IV
Alternative 2 (AMAP), use Section II, III and IV
Alternative 3, Section III and IV

Step 5: Follow the instructions provided on how to score the establishment's validation and on-going verification documentation in your assessment for each product.

GUIDE TO SELECTING EVALUATION SECTION

PRELIMINARY QUESTIONS

Establishment Number: _____

1. Does the establishment produce post-lethality exposed ready-to-eat product covered by 9 CFR 430?

   ☐ YES

   ☐ NO (STOP, product is not covered by 9 CFR 430)
2. Did the establishment develop control measures that meet one of the three Alternatives for the product, as required in 9 CFR 430.4?

   ☐ YES

   ☐ NO (STOP and consult with front-line supervisor)
3. In the chart below, list the products covered by 9 CFR 430 and the Alternative chosen by the establishment.

   NOTE: There can be only one Alternative chosen for each product group. If needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430.

   Group the products that are controlled by the same Alternative and treatment. Use separate evaluation forms for products or product groups with unique situations, such as having the same

alternative and treatment but with different methods/sources of validation or with different log reduction or suppression. For example, for the same product in Alternative 2 using AMAP and the same antimicrobial agent used, such as hotdog treated with sodium lactate validated by a challenge study, and hotdog treated with sodium lactate validated using a modeling program, separate evaluation forms should be used.

Conduct one evaluation for each product group, using the questions in the appropriate Evaluation Sections for that group's Alternative (See Step 4 Instructions). Include the name of each product within the group in the entry for product name in the Preliminary Questions section. Complete as many Evaluation Sections to cover all products produced by the establishment that are associated with 9 CFR 430.

PRODUCT(GROUP) NAME	ALTERNATIVE

4. Complete the sections that correspond to the chosen alternative.

Alternative 1 (PLT and AMAP)	Sections I, II, III and IV
Alternative 2 (PLT only)	Sections I, III and IV
Alternative 2 (AMAP only)	Sections II, III, and IV
Alternative 3 (Sanitation)	Sections III and IV

SECTION I – Post-Lethality Treatment (PLT)

Product (Group) Name: _____
Post-lethality Treatment used: _____

For the following questions, please place an X in the appropriate response column.
(NOTE: If needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Rate and score responses using the scoring instructions at the end of these questions.)

Questions	**Yes**	**No**	**Not Sure**	**N/A**
1. Is the post-lethality treatment validated and documented? (*Note: See APPENDIX for examples of validation.*)				
2. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? (*Note: Examples of validation methods that can be used are challenge study for the product, published study, modeling program.)*				
3. If the critical variables have been identified for PLT, are they being applied in the HACCP plan in a similar manner?				
4. Is the product or product formulation used in the validation the same as or similar to the product or product formulation for which the establishment is using the PLT?				
5. Is the establishment using the PLT as described in the validation with regards to equipment and procedures?				
6. If the critical variables, product formulation, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? *(Note: Place an X on N/A if you answered "YES" to questions 2-5)*				
7. If the establishment did not conduct additional validation, did it provide any rationale to explain why the PLT is effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different? *(Note: Place an X on N/A if you answered "YES" to questions 2-5)*				
8. Did the establishment conduct an initial validation to test the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions as stated in the HACCP plan? (*This would be evident by data to demonstrate that the CCP was applied and the process was tested, e.g., product was tested prior to the treatment for presence/absence, and/or level of LM, and tested after the treatment for the same attributes in order to find low level of LM contamination using appropriate number of tests from randomly selected samples. Reliance only on tests with negative results after treatment is not considered product validation and should be marked as 'No'- not validated.*)				
9. Does the establishment have a rational basis or data to show that the reduction of LM by the PLT as described is sufficient to control the level of contamination of LM that may occur in the product? *(Example: evidence of actual reduction of LM contamination on product by PLT vs. level of contamination on food contact surface)*				
10. Do the information in the HACCP plan, Sanitation SOP and Prerequisite programs (e.g., Alternative, PLT, AMAP, log reduction, log suppression, FCS testing frequency, etc.) corroborate the information on the survey form (FSIS Form 10,240-1) that the establishment submitted? *(Note: If No, consult with the front-line supervisor and, if appropriate, inform the establishment and request it complete and submit a new Form 10,240-1 with revised information.)*				
11. Is the PLT treatment a pre-packaging treatment, i.e., the PLT is applied after				

Questions	Yes	No	Not Sure	N/A
environmental exposure but before re-packaging (e.g., infra-red treatment)? *(Note: If No, stop and rate this section)*				
12. If the PLT is a pre-packaging PLT, does the establishment have validated control measures in place to prevent recontamination after treatment and before re-packaging? (*Examples of control measures are: 1) aseptic packaging procedures; 2) packaging equipment located right after the PLT equipment; 3) use of antimicrobials; 4) positive air flow; 5) other environmental control program.*)				

You have completed this section. Please rate this section.

Rating:
Conclusive: Answered 'yes' for #1-5, 8-10, and 12 if 'yes' to 11
Substantiated: Answered 'yes' to #1-3 and [6 or 7], [8 or 9], and 12 if 'yes' to 11
Inconclusive: Answered 'no' or 'not sure' to any of the following #1- 3, [6 or 7], [8 or 9] and 12 if 'yes' to 11,

Use the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to applicable establishment PLT in Table 1.

Table 1: Features of a Validated Post-lethality Treatment
Table 1 gives numerical scores based on the method of validation and the log reduction achieved by the PLT. The more rigorous the validation method and the log reduction achieved by the PLT, the lower the risk, and the higher the scores. The risk of LM contamination goes down as the score goes from inconclusive to conclusive**.**
Using the result from Section I, circle the score provided (in parenthesis) for the appropriate feature and criteria. For example, if the establishment's PLT as documented in its HACCP plan was derived from a manufacturer challenge study and achieves 2 log reduction of LM, and the result from SECTION I is Conclusive, circle the score provided on the appropriate row (manufacturer challenge study and equal to or greater than 2 log reduction), which in this case is 10.

Control measure	**Feature**	**Criteria**[1]	**Inconclusive**	**Substantiated**	**Conclusive**
Post-lethality treatment	Challenge study for the product conducted by establishment or manufacturer	Less than 1 log reduction	(0)	(0)	(0)
		Equal to or greater than 1 log, but less than 2 log reduction	(0)	(3)	(5)
		Equal to or greater than 2 log reduction	(0)	(5)	(10)
	Published challenge study	Less than 1 log reduction	(0)	(0)	(0)
		Equal to or greater than 1 log, but less than 2 log reduction	(0)	(2)	(4)
		Equal to or greater than 2 log reduction	(0)	(4)	(8)
	Modeling Program	Less than 1 log reduction	(0)	(0)	(0)
		Equal to or greater than 1 log, but less than 2 log reduction	(0)	(1)	(3)
		Equal to or greater than 2 log reduction	(0)	(3)	(7)

[1] Criteria: Log reduction of *Listeria monocytogenes* (Lm)

SECTION II- Antimicrobial Agent or Process (AMAP)

Product (Group) Name: _____
Antimicrobial Agent or Process Used: _____

For the following questions, please place an X in the appropriate response column.
(NOTE: For products using extrinsic or intrinsic characteristics (freezing below -0.4º C (31.3º F), pH below 4.39, or water activity below 0.92), skip questions 4-11. Also, if needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Rate and score your responses using the scoring instructions at the end of these questions.)

Questions	Yes	No	Not Sure	N/A
1. Is the AMAP validated or tested, with documentation on file? (*Examples: challenge study, published study, modeling program. See Appendix) (Note: Select "YES" if extrinsic or intrinsic characteristics such as freezing below -0.4º C (31.3º F), pH below 4.39, or water activity below 0.92r are used.)*				
2. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, moisture, pH, water activity, etc.) used in the validation? (*Note: Examples of validation sources or documentation that can be used are challenge study for the product, published study, modeling program, extrinsic or intrinsic characteristics.)*				
3. If the critical variables have been identified, are they being applied in the application of the AMAP in the product?				
4. Is the establishment using the AMAP as described in the validation with regards to equipment and procedures?				
5. Is the product formulation used by the establishment the same or similar to the product or product formulation used in the validation study using the AMAP? *(Examples of product formulation factors: amount of antimicrobial agent used; species [e.g., beef, pork, chicken, turkey, etc.]; whether cured or uncured; amount of salt and moisture in finished product)*				
6. If the critical variables, product formulation, procedures or equipment used by the establishment are not exactly the same as those used in the validation, did the establishment conduct additional validation that demonstrated that the changes are effective? (*Note: Place an X on N/A if you answered "YES" to questions 2-5.*)				
7. If the establishment did not conduct additional validation, did it provide any rationale to explain why the treatment is effective and have the same impact even though the critical variables, product formulation, procedure or equipment are different? (*Note: Place an X on N/A if you answered "YES" to questions 2-5.*)				
8. Did the validation study or validation of the model include a shelf life study, i.e., determining the growth of LM during storage?				
9. Is the refrigerated shelf life (use by date on the label) shorter or the same as the recommended shelf life in the validation? *Note: Place an X on N/A if no shelf life on label.*				
10. Did the establishment initially test for the adequacy of the AMAP in inhibiting LM growth? (*Example: product was tested prior to the treatment for level of LM, and tested after the treatment and during the shelf life for the same attributes in order to find the presence of low level growth during shelf life using appropriate number of tests from randomly selected samples.*)				

Questions	Yes	No	Not Sure	N/A
11. Does the establishment have a rational basis or data to show that the level of growth allowed by the AMAP is sufficient to control LM growth in the product? *(Example: evidence of actual inhibition of LM growth on product by AMAP vs. level of contamination on food contact surface)*				
12. Do the information in the HACCP plan, Sanitation SOP and Prerequisite programs (e.g., Alternative, PLT, AMAP, log reduction, log suppression, FCS testing frequency, etc.) corroborate the information on the survey form (FSIS Form 10,240-1) that the establishment submitted? *(Note: If No, consult with the front-line supervisor and, if appropriate, inform the establishment and request it complete and submit a new Form 10,240-1 with revised information.)*				

You have completed this section. Please rate this section.

Rating:
Conclusive: Answered 'yes' to #1-5, 8-11. For products using extrinsic or intrinsic characteristics (freezing, pH, water activity), 'yes' answers to #1- 3, and 12.
Substantiated: Answered 'yes' to #1 and [5 or 6], and 8. For products using extrinsic or intrinsic characteristics, 'yes'answers to #1- 3.
Inconclusive: Answers with 'no' or 'not sure' to any of the following: #1, [6 or 7], and 8. For products using extrinsic or intrinsic characteristics, 'no' or 'not sure' answers to #1- 3.

Use the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to applicable establishment AMAP in Table 2.

Table 2. Features of an Effective Antimicrobial Agent/Process

This table gives numerical scores based on the method of validation and the log growth allowed by the AMAP. The more rigorous the validation method or the effectiveness and the lower the log growth allowed by the AMAP, the lower the risk, and the higher the scores.

Using the result from Section II, circle the score provided (in parenthesis) for the appropriate feature and criteria. For example, if the establishment's AMAP as documented in its control program is from a published study and allows 1 log growth of LM during the refrigerated shelf life, and the result from SECTION II is Substantiated, circle the score provided on the appropriate row (published study and 1 log growth),which in this case is 4.

Table 2

Control Measure	Feature	Criteria[1]	Inconclusive	Substantiated	Conclusive
Antimicrobial growth suppressing agent or process	Shelf-life study of the product using the antimicrobial agent or process	Less than or equal to 1 log	(0)	(5)	(10)
		More than 1 log but not more than 2 log	(0)	(3)	(5)
		More than 2 log	(0)	(0)	(0)
	Modeling program specific to the AMAP used in the product (e.g. Purac)	Less than or equal to 1 log	(0)	(5)	(10)
		More than 1 log but not more than 2 log	(0)	(3)	(5)
		More than 2 log	(0)	(0)	(0)
	Published study using an antimicrobial agent	Less than or equal to 1 log	(0)	(4)	(8)
		More than 1 log but not more than 2 log	(0)	(2)	(4)
		More than 2 log	(0)	(0)	(0)
	Extrinsic and Intrinsic characteristic	Frozen at <-4º C (31.3º F)	(0)	(5)	(10)
		Aw < 0.92	(0)	(5)	(10)
		pH < 4.39	(0)	(5)	(10)

[1] Criteria: Log growth of *Listeria monocytogenes* (Lm)

SECTION III- Sanitation Program

Product (Group) Name: _____

For the following questions, please place an X in the appropriate response column. Please note that the "N/A" response only applies to certain questions.

(NOTE: Review establishment Sanitation program or prerequisite program for the sanitation procedures used and the food contact surface (FCS) testing program (testing frequency, number of sites, hold and test, etc). If needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430). Rate and score responses using the scoring instructions at the end of these questions.)

A. Sanitation Procedures

Questions	Yes	No	Not Sure	N/A
1. Are employee hygiene procedures available in a written document?				
2. Are employees trained in hygiene procedures?				
3. Are gloves used properly (e.g., are they disposed of when leaving processing line and when touching anything other than product or food contact surface)?				
4. Are outer garments removed when leaving RTE area?				
5. Do the employees use a 20 second hand wash (or comparable method of sanitizing) before starting and returning to work?				
6. Are food and operator hand tools stored in a sanitary manner?				
7. Are traffic patterns established to eliminate movement of personnel between the raw and RTE areas or controlled to prevent cross-contamination?				
8. Are traffic patterns established to eliminate movement of equipment between the raw and RTE areas or controlled to prevent cross-contamination?				
9. Are the raw and RTE areas physically separated (e.g., by a wall, etc.)?				
10. If raw and RTE areas are not physically separated, is the potential for cross contamination minimized? *(Note: If 'yes' to question 9 above, place an X on N/A.)*				
11. Are different utensils used in the raw and RTE areas, or if different utensils are not used, are utensils washed and sanitized between raw and RTE processing?				
12. Are garments worn in RTE areas readily distinguished from those used in the raw areas?				
13. Are maintenance employees restricted from the RTE areas during operation or are hygienic practices followed if access is needed during operation?				
14. Do tools and equipment for maintenance used in the RTE area remain in the RTE area or are tools used in another area sanitized before use in another area?				
15. Are the thermometers, maintenance tools and equipment cleaned and sanitized before use?				
16. Are all materials for discard (trash and waste) removed at clean up (mid-shift, end-shift, etc.)?				
17. Is equipment cleaned at the end of operation to remove food and other debris? *(Note: In establishments conducting extended operations, clean-up operations may occur at a frequency of less than daily.)*				
18. Is equipment such as slicers and dicers with blades disassembled for thorough cleaning at the end of the operation*? (Note: If slicers or dicers*				

Questions	Yes	No	Not Sure	N/A
are not used, place an X on N/A.)				
19. Are equipment and floors sanitized after being rinsed?				
20. Is sanitizer for equipment and floors used in the concentration specified where used?				
21. Are operations discontinued during construction, or are the areas under construction or remodeling isolated to prevent contamination of other areas of operation? *(Note: Place an X on N/A only if there is no construction.)*				

B. Sanitation Testing

Questions	Yes	No	Not Sure	N/A
1. Does the sanitation program or prerequisite program provide for testing FCS in the post-lethality processing environment?				
2. Does the sanitation program or prerequisite program identify the conditions under which the establishment will implement hold-and-test procedures following a FCS test that is positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*?				
3. Does the sanitation program or prerequisite program state the frequency for testing?				
4. Does the sanitation program, prerequisite program or other recordkeeping system identify the location of sites for sampling?				
5. Does the sanitation program or prerequisite program identify the size of sites for sampling?				
6. Are the selected locations of the sites the most probable area for contamination?				
7. Is the size of the sampling area at least 1-square foot if surface allows?				
8. Are all possible FCS sampling sites identified?				
9. Does the sanitation program or prerequisite program explain why the testing frequency is sufficient to ensure effective control of *Listeria*-like, *Listeria* spp., or *L. monocytogenes*?				
10. If a FCS tested positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*, were the hold-and-test procedures implemented as written in the sanitation program? *(Note: If FCS tested negative, place an X on N/A.)*				
11. If FCS tested positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*, were measures taken to prevent recurrence? *(Note: If FCS tested negative, place an X on N/A.)*				
12. If FCS tested positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*, were corrective actions taken to identify and eliminate the source of contamination? *(Note: If FCS tested negative, place an X on N/A.)*				
13. If a FCS tested positive for *L. monocytogenes*, was the lot of product affected destroyed or reworked with a process that eliminates *L. monocytogenes*? *(Note: If FCS tested negative, place an X on N/A.)*				
14. Were the results of the product testing documented?				
15. Were non-FCS tested for *Listeria*-like, *Listeria* spp., or *L. monocytogenes*?				
16. Was follow up testing conducted on all non-FCS that tested positive for *Listeria*-like, *Listeria* spp. or *L. monocytogenes*? *(Note: Place an X on N/A only if there is no positive follow-up non-FCS test or no positive non-FCS test.)*				

Complete the next table only for an establishment that produces deli or hotdog product in Alternative 3. *(Questions reflect regulatory requirements for these products.)*

Questions	Yes	No	Not Sure	N/A
17. Was follow-up testing conducted on the FCS site that tested positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes* to verify that the corrective actions after an initial positive test on a FCS were effective? *Note: Place an X on N/A only if there is no positive follow-up FCS test.*				
18. Was follow-up testing conducted on the FCS area surrounding the FCS site that tested positive for *Listeria*-like, *Listeria* spp., or *L. monocytogenes* to verify that the corrective actions after an initial positive test on a FCS were effective? *Note: Place an X on N/A only if there is no positive follow-up FCS test.*				
19. If a second follow-up FCS tested positive for *Listeria*-like or *Listeria* spp. on follow-up testing, were lots of affected product held? *Note: Place an X on N/A only if there is no second follow-up positive FCS test.*				
20. If the second follow-up FCS tested positive for *Listeria*-like, *Listeria* spp. on follow-up testing, were the affected lots of product tested for *Listeria*-like, *Listeria* spp. or *L. monocytogenes*? *Note: Place an X on N/A only if there is no second follow-up positive FCS test.*				
21. If a second follow-up FCS tested positive for *L. monocytogenes* on follow-up testing, were the affected lots of product destroyed or reworked with a process that is destructive of *L. monocytogenes*? *Note: Place an X on N/A only if there is no second follow-up positive FCS test.*				
22. If the second follow-up FCS tested positive for *Listeria*-like or *Listeria* spp. on follow-up testing, did the sampling method and frequency provide a level of statistical confidence that ensured that each lot was not adulterated with *L. monocytogenes?* (e.g., is the sampling method and frequency based on a statistical sampling plan such as the ICMSF) *Note: Place an X on N/A only if there is no second follow-up positive FCS test.*				

You have completed this section. Please rate this section.

Rating:
Conclusive:

A. Sanitation Procedures
For **all establishments, "Yes" or "N/A"** answers to **all questions**

B. Sanitation Testing.
For **establishments producing deli or hot dog products under Alternative 3**:
Answered "Yes" to questions **1 to 9 and "Yes"** or **"N/A"** for questions **# 10 – 22**

For establishments **under Alternative 2 Choice 2 (AMAP),** or those producing **non-deli or non-hotdog products under Alternative 3:** Answered **"Yes"** to questions **1 to 9 and "Yes" or "N/A"** for questions **# 10 - 16**

For establishments producing **products under Alternative 1, or Alternative 2 Choice 1 (PLT)**: Answered **"Yes" or "N/A"** to **questions # 1-16**

Substantiated:

A. Sanitation Procedures.
For **all establishments, "Yes" or "N/A"** answers **to at least 17 of the 21 questions**

B. Sanitation Testing
For **establishments producing deli or hot dog products under Alternative 3:** Answered **"Yes"** to questions # **1 – 9,** except **6, 7, 8 and "Yes" or "N/A"** to questions **# 10- 22** except**15 and 16**.

For establishments producing **products under Alternative 2 Choice 2 (AMAP)** or **non-deli or non-hotdog products under Alternative 3**: Answered **"Yes"** to **questions # 1-14 except 6, 7, and 8**

For establishments producing **products under Alternative 1, or Alternative 2 Choice 1 (PLT)**: Answered **"Yes**" **or "N/A"** to **questions # 1- 14 except 6, 7, and 8**

Inconclusive:

A. Sanitation Procedures.
All establishments answered **"Yes" or "N/A"** to less than **17 of the 21 questions**

B. Sanitation Testing
For **all establishments producing deli or hot dog products under Alternative 3:** Answered **"No" or "Not Sure"** to any question **# 1- 22 excluding 6, 7, 8, 15 and 16.**

For establishments producing **products under Alternative 2 Choice 2 (AMAP), or non-deli or non-hotdog products under Alternative 3**: Answered **"No" or "Not Sure"** to any **questions # 1- 14 excluding 6, 7, and 8**

For establishments producing **products under Alternative 1, or Alternative 2 Choice 1 (PLT)**: Answered **"No" or "Not Sure"** to any **questions # 1- 14 excluding 2 -8**

Use the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to applicable establishment sanitation criteria in Table 3.

Table 3. Features of a Sanitation Program

Table 3 gives the numerical scores based on the rigor of the testing. Higher frequency of testing suggests more rigorous control, lower risk, and higher scores. These scores will be used in the risk-based verification model.

Using the result from Section III, circle the score provided (in parenthesis) for the appropriate criteria. To obtain the score, apply the conclusions obtained from the questions above (conclusive, substantiated, or inconclusive) to the applicable establishment sanitation control program listed in Table 3. For example, if the establishment's FCS testing is 1/line/month for Alternative 3 as documented in its control program and the result from the SECTION III was substantiated, circle the value in the space provided in the appropriate row, which is 3 in this example.

Control Measure	Feature	Criteria	Inconclusive	Substantiated	Conclusive
Sanitation	FCS testing frequency	Alt 1 (AMAP & PLT) <1/line/6 month	(0)	(1)	(2)
		Alt 1 (AMAP & PLT) 1/line/6 month	(0)	(4)	(6)
		Alt 1 (AMAP & PLT) >1/line/6 month	(0)	(7)	(10)
		Alt2 (AMAP or PLT): <1/line/3month	(0)	(0)	(0)
		Alt2 (AMAP or PLT): = 1/line/3month	(0)	(3)	(5)
		Alt2 (AMAP or PLT): >1/line/3month	(0)	(5)	(10)
		Alt 3: <1/line/month (non-deli, non-hotdog, or v sm. vol. deli or hotdog)	(0)	(0)	(0)
		Alt 3: = 1/line/month (non-deli, non- hotdog, or v sm. vol. deli or hotdog)	(0)	(3)	(5)
		Alt 3: >1/line/month (non-deli, non- hotdog, or v sm. vol. deli or hotdog)	(0)	(5)	(10)
		Alt 3: <2/line/month (sm. vol., deli or hotdog)	(0)	(0)	(0)
		Alt 3: =2/line/month (sm. vol., deli or hotdog)	(0)	(3)	(5)
		Alt 3: >2/line/month (sm. vol. deli or hotdog)	(0)	(5)	(10)
		Alt 3: <4/line/month (lg. vol., deli or hotdog)	(0)	(0)	(0)
		Alt 3: =4/line/month (lg. vol., deli or hotdog)	(0)	(3)	(5)
		Alt 3: >4/line/month (lg. vol., deli or hotdog)	(0)	(5)	(10)

SECTION IV- On-Going Verification System

Product (Group) Name _____

For the following questions, please place an X in the appropriate response column.

- If Alternative 1 was chosen for the product(s), complete sections A, B and C.
- If Alternative 2 using a PLT (choice 1) was chosen for the product(s), complete sections A and C only.
- If Alternative 2 using an AMAP (choice 2) was chosen for the product(s), complete sections B and C only
- If Alternative 3 was chosen for the product(s), complete section C only

(NOTE: Review establishment HACCP plan, Sanitation program or prerequisite program depending on the Alternative chosen for the product. If needed, please refer to the establishment's FSIS Form 10,240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Score responses using the scoring instructions at the end of these questions.)

A. Post-lethality Treatment (for Alternative 1, and Alternative 2 using PLT)

Questions	Yes	No	Not Sure	N/A
1. Is the PLT validation rating conclusive or substantiated (from SECTION I and Table 1)?				
2. Are CCPs, CLs or critical variables for the PLT reassessed annually or when a change may affect the hazard analysis or HACCP plan per 417.4(a)(3)?				
3. Is recurrence of positive product or FCS controlled at zero or prevented within the last 12 months? *(Note: If there is no positive product or FCS, place an X on N/A)*				
4. Are corrective actions conducted when CCP is not achieved? *(Note if CCP is achieved, place an X on N/A)*				
5. Are corrective actions conducted if positive products or positive FCS are found? *(Note if no positive products or FCS are found, place an X on N/A)*				
6. Does the establishment persist or succeed in determining the cause and source of the positive product or positive FCS? *(Note: If there is no positive product or FCS, place an X on N/A.)*				
7. Was the last Food Safety Assessment for cause (for *Listeria* rule non-compliance or positives) conducted in the establishment prior to implementation of the rule in October 2003? *(Note: If no assessment[(for cause, for Listeria] has ever been conducted, place an X on N/A.).*				
8. Was the last Intensified Verification Testing for the establishment conducted prior to implementation of the rule in October 2003? *(Note: If no IVT has ever been conducted, place an X on N/A.)*				

You have completed this section. Please rate and score for PLT (Table 4).

B. Antimicrobial Agent or Processes (for Alternative 1, and Alternative 2 using AMAP)

Questions	Yes	No	Not Sure	N/A
1. Is the rating for validation/effectiveness of AMAP conclusive or substantiated (from SECTION II and Table 2)?				
2. Are the CCPs, CLs (if AMAP is in the HACCP plan) or critical variables (if AMAP is in the SSOP or Prerequisite Programs) reassessed annually or when a change may affect the hazard analysis or HACCP plan per 417.4(a)(3)?				
3. Does the labeling of product shelf life agree with the shelf life determined from the AMAP study or model? (*Note: If the label does not*				

Questions	Yes	No	Not Sure	N/A
indicate a shelf life ,place an X on N/A				
4. Are corrective actions conducted when the CCP or critical variables are not achieved? *(Note if CCP or critical variables are achieved, place an X on N/A)*				
5. Are corrective actions conducted if positive products or positive FCS are found? *(Note: If there is no positive product or FCS, place an X on N/A)*				
6. Is the recurrence of positive product or FCS controlled at zero or prevented within the last 12 months? *(Note: If there is no positive product or FCS, place an X on N/A)*				
7. Does the establishment persist or succeed in determining the cause and source of the positive product or positive FCS? *(Note: If there is no positive product or FCS, place an X on N/A.)*				
8. Was the last Food Safety Assessment for cause (for *Listeria* rule non-compliance or positives) conducted in the establishment prior to implementation of the rule in October 2003? *(Note: If no assessment [for cause, for Listeria] has ever been conducted, place an X on N/A.)*				
9. Was the last Intensified Verification Testing for the establishment conducted prior to implementation of the rule? *(Note: If no IVT has ever been conducted, place an X on N/A.)*				

You have completed this section. Please rate and score for AMAP (Table 4).

C. Sanitation Program (for Alternative 1, Alternative 2 and Alternative 3)

Questions	Yes	No	Not Sure	N/A
1. Is the rating for effectiveness of the sanitation program conclusive or substantiated (from SECTION III and Table 3)				
2. Is the establishment following the sanitizing procedures as stated in its Sanitation SOP or prerequisite programs?				
3. Does the establishment follow procedures for taking at least the minimum number of samples at designated areas for FCS testing as described in its control program?				
4. Is recurrence of positive product or FCS controlled at zero or prevented within the last 12 months? *(Note: If there is no positive product or FCS, place an X on N/A)*				
5. Are sanitation corrective actions conducted promptly and effectively, e.g., when product or FCS tests positive?				
6. Does the establishment persist or succeed in determining the cause and source of the positive result? *(Note: If there is no positive product or FCS, place an X on N/A.)*				
7. Does the establishment use more rigorous sanitizing to prevent recurrence of positives? *(Note: If there is no positive product or FCS, place an X on N/A.)*				
8. Was the last Food Safety Assessment for cause (for *Listeria* rule non-compliance or positives) conducted in the establishment prior to implementation of the rule in October 2003? *(Note: If no assessment [for cause, for Listeria] has ever been conducted, place an X on N/A.)*				
9. Was the last Intensified Verification Testing for the establishment conducted prior to implementation of the rule in October 2003? *(Note: If no IVT has ever been conducted, place an X on N/A.)*				

You have completed this section. Please rate and score for Sanitation (Table4).

Rating:

A. Post-lethality Treatment

Conclusive: Answered 'yes' to # 1-2 and 'yes' or 'N/A' for # 3-8
Substantiated: Answered 'yes' to # 1-2 and 'yes' or 'N/A' to # 4-6
Inconclusive: Answers with 'no' or 'not sure' to # 1-2

B. Antimicrobial Agent or Process

Conclusive: Answered 'yes' to # 1-2 and 'yes' or 'N/A' for # 3-9
Substantiated: Answered 'yes' to # 1-2 and 'yes' or 'N/A' for # 3-5
Inconclusive: Answers with 'no' or 'not sure' to # 1-3

C. Sanitation Program

Conclusive: Answered 'yes' to #1-3 and 'yes' or 'N/A' for # 4-9
For establishments producing products under Alternative 1, and Alternative 2 (Choice 1, PLT), can be N/A in # 3
Substantiated: Answered 'yes' to # 1-3 and 'yes' or 'N/A' for # 4, 5 and 7
For establishments producing products under Alternative 1 and Alternative 2 (Choice 1, PLT), can be N/A in # 3
Inconclusive: Answers with 'no' or 'not sure' to # 1-2

Table 4. Features of an on-going verification system

Use the rating obtained from the questions above to establishment PLT, AMAP or Sanitation program as applicable**, and circle the score provided (in parenthesis)** .

Control measure	Feature	Criteria	Inconclusive	Substantiated	Conclusive
On-going verification system	Post-lethality treatment		(0)	(5)	(10)
	Antimicrobial agent or process		(0)	(5)	(10)
	Sanitation program		(0)	(5)	(10)

Add scores for PLT, AMAP or Sanitation depending on the control program that the establishment has.

APPENDIX

DEFINITION/EXPLANATION OF TERMS

Antimicrobial Agent
A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as LM, or that has the effect of suppressing or limiting growth of a pathogen such as LM in the product throughout the shelf life of the product (9 CFR430.1). Examples: potassium lactate, sodium diacetate, which limit the growth of LM.

Antimicrobial Process
An operation, such as freezing that is applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as LM, in the product throughout the shelf life of the product, (9CFR 430.1). Other examples are processes that result in a pH or water activity that suppresses or limits microbial growth.

Challenge Study
A study that documents the adequacy of control measures in a process. This involves inoculating the target organism (e.g., LM) into a product to determine the effect of control measures such as post-lethality treatment or antimicrobial agent or process on the reduction or growth of the organism. Challenge studies are usually performed in a laboratory to avoid the possible spread of contamination in an establishment. They are also performed under laboratory conditions, which means that the scale of the study is adjusted, based on the capacity of the laboratory (i.e. fewer products may be tested, and a water bath may be used rather than a hot-water pasteurizer). The number of organisms before and after the application of the control measure is counted to determine the effect of the control measure. The study determines the effect using different processing variables such as time, temperature, pressure, concentration, acidity, pH and others.
If challenge studies are used as supporting documentation by the establishment, it is important that they use product that has similar physical characteristics to that being produced by the establishment (i.e., pH, Aw, etc.) and processing (and intervention) steps that are similar to those utilized by the establishment. For example, for a post-lethality treatment like steam pasteurization or hot water pasteurization, the time and temperature of treatment similar to that used for the product itself may be critical components of a challenge study. For high pressure pasteurization, pressure is a critical variable. For the use of chemical additives as antimicrobial agents, pH, acidity, and concentration may be additional critical variables. Challenge studies used for validation may or may not be published in scientific journals, and can be 1) conducted for any product; 2) conducted for an establishment's specific product or processing; or 3) conducted by the manufacturer of an equipment or chemical additive for use in the processing of a product. Challenge studies conducted for an establishment's specific product or a manufacturer's equipment or chemical additives have the advantage of using the same formulation, procedure and critical factors of moisture, pH, time, temperature, pressure, etc. as those used in the establishment. However, most of these challenge studies are not published. Published studies have the advantage of being peer-reviewed before publication, but may not be specific for an establishment's product or processing.

Microbial Pathogen Computer Modeling (MCPM) Program
A modeling program is a mathematical model describing the growth characteristics of pathogens in foods subjected to different environmental (product factors such as pH, salt, phosphates, nitrites, and water activity, and extrinsic factors such as temperature and culture atmosphere) and processing conditions. Computer-based microbial modeling programs may be used to provide an estimate of the influence of each limiting agent or combination of agents during processing. A computer model is a predictive tool and must be evaluated in terms of relevance and validity to the product in question. An establishment should verify the model's predictions for the establishment's product and conditions of processing by conducting tests, such of product and food contact surfaces, to confirm whether conditions are adequately controlled, as predicted. Of note, some modeling programs may identify zero growth as allowing up to 1 log growth, as a consequence of measurement error. Establishments should be aware of this when relying upon such assumptions.

Products Covered by 9 CFR 430
All post-lethality exposed RTE meat and poultry
Examples: deli meat, hotdog, jerky, chicken nuggets

Products Not Covered by 9 CFR 430
Cook-in bag and shipped products
Hot-filled products
Partially cooked products
Commercially sterile, thermally processed products

Post-lethality Exposed Product
Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment (9 CFR 430.1). Examples of post-lethality exposed products: hotdogs after the casings are removed; cooked roast beef after removing the cooking bag.

Post lethality Processing Environment
The area in an establishment into which product is routed after having been subjected to an initial lethality treatment (CFR 430.1). Examples are the production area where hotdog casings are peeled, or products are sliced and re-bagged.

Post-lethality Treatment (PLT)
A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure (9 CFR 430.1). Examples: hot water pasteurization, steam pasteurization, high pressure processing.

Pre-packaging Post-lethality Treatment
This is a post-lethality treatment that is conducted prior to packaging. Most PLT are conducted after the product is repackaged. Because the PLT is applied before packaging, the product can be exposed to re-contamination after the treatment. The establishment has to include methods to demonstrate, with high confidence, that recontamination does not occur. Some of the methods include placing packaging right after the treatment by physically placing the packaging equipment next to the treatment equipment, having aseptic environmental controls, including micro-filtered air flow and positive/negative air pressure, as well as mechanisms for ensuring equipment does not become contaminated within the packaging room.

Published Study
A challenge or inoculated pack study conducted by scientists, subsequently reviewed by other scientists knowledgeable in the subject (peer-reviewed), before publishing in a scientific journal.

Shelf life Study
A shelf life study is one that measures the increase or decrease in the number of the target organism or pathogen during storage. For an antimicrobial agent or process (AMAP), a shelf life study is important because it determines the time (in days) at a slightly abusive refrigerated storage temperature (e.g., at 45 degrees Fahrenheit) that the number of LM increases, signifying growth. A slightly abusive temperature is used in order to ensure that if LM is present and viable, growth will occur and can be measured throughout shelf-life. This slightly abusive temperature also represents the worse-case conditions that could occur during cold-chain storage and handling.

Validation
Validation is a process of demonstrating that the HACCP system, if operated as designed, can adequately control identified hazards to produce a safe product. Validation consists of a scientific or technical justification or documentation of control, and an initial demonstration proving that the system will perform as expected. Validation can be derived from a challenge study, a published study from a peer-reviewed scientific journal, modeling program, data underlying published guidelines, or establishment data.

The documentation must identify the hazard and the pathogen, including the level of hazard prevention or pathogen reduction to be achieved, and all associated factors or conditions should identify which processing steps will achieve the specified reduction or prevention, and how these processing steps will be monitored. The scientific or technical basis should be related to the specific hazard or pathogen and should identify specific control parameters. The demonstration should be conducted in the plant using the parameters in the validation. As part of the demonstration, the establishment should observe, measure, and record results and should show that the plant can routinely meet the parameters in order to control the hazards.

EXAMPLES OF CHALLENGE STUDIES

When faced with a challenge study on file to document validation, it is important to look at the title and the abstract or summary first. The abstract at the beginning of the document always give the most important findings of the study. Look for the objective, the procedure or conditions used and the results. Sometimes the equipment used is also included in the abstract. The abstract usually gives the critical factors (e.g., time, temperature, pH, concentration, pressure), the initial level of pathogens or organisms and how these factors affected the level of pathogens or organisms, and whether there was reduction, suppression or no effect. For important information not found in the abstract, look or read the other sections of the document. The Materials and Methods section includes the microorganisms used and microbial inoculation method, post-lethality treatment procedure, and data analysis. The Results and Discussion section gives the results, tables, graphs, pictures, and the authors' explanation and discussion of the results. The Conclusions section gives the overall result of the study, conclusions based on the conditions of the study and recommendations. Sometimes the conclusions are included in the end of the Results and Discussions section.

The following are summaries of challenge studies for post-lethality treatment and antimicrobial agents taken from the Compliance Guidelines for the *Listeria* rule (FSIS website). The summaries include the conditions for post-lethality treatments or addition of antimicrobial agents and the resulting time, temperature pressure or concentration to control *L. monocytogenes*. The critical variables of time, temperature, pressure, concentration or pH, as well as the procedure or equipment that are bolded are the important information that needs to be determined when reading or scanning a challenge study. These variables are the ones used for the CCP and critical limit. Noting down the information gathered from the abstract or summary as shown for the first challenge study would help in determining if the establishment is using the same or similar procedure, equipment and critical factors as the challenge study.

A. Steam Pasteurization and Hot Water Pasteurization
(Important information for validation are bolded)

Studies by Murphy et al. (2003) showed that **post-cook hot water pasteurization and steam pasteurization** resulted in a **7 $\log_{10}$ reduction of *L. monocytogenes*** in surface inoculated vacuum packaged fully cooked chicken fillets and strips. The reduction was effective when **single –packaged breast fillets, 227 g- packaged strips and 454 g-packaged strips** were **heat treated at 90º C** in a **pilot-scale steam cooker or hot water cooker for 5, 25 and 35 minutes, respectively.**

Information gathered from the summary or abstract:
Post-lethality treatment: hot water pasteurization or steam pasteurization
Products: fully cooked chicken breast fillets and strips
Procedure: fully cooked products were surface inoculated with *L. monocytogenes*, vacuum packaged and pasteurized
Equipment used for the pasteurization treatment:
Steam pasteurization: pilot-scale steam cooker
Hot water pasteurization: pilot-scale hot water cooker
Temperature of pasteurization: 90 C
Reduction of *L. monocytogenes*: 7 log reduction
Products and time of pasteurization that resulted in 7 log reduction

Product	**Time of pasteurization (min)**
Single-packaged breast fillets	5
227g-package strips	25
454 g-packaged strips	35

Murphy, R.Y., L. K. Duncan, K.H. Driscoll, B.L. Beard, M. E. Berrang and J.A. Marcy. 2003. Determination of thermal lethality of *Listeria monocytogenes* in fully cooked chicken breast fillets and strips during post cook in-package pasteurization J. Food Protect 66:578-583.

B. High Hydrostatic Pressure Processing
(Important information for validation are bolded)

High pressure processing (HPP) is one of the new technologies used for food processing. This technology provides a means of ensuring food safety for those products that are difficult to be heat treated due to organoleptic effects. HPP was shown to inactivate pathogens without any thermal or chemical effects and at the same time preserve the quality of the product. Raghubeer and Ting (2003) evaluated the efficacy of high hydrostatic pressure processing in inactivating ***L. monocytogenes* in retail-packaged samples of sliced ham, turkey and roast beef obtained from a manufacturer and repackaged in 25-g portions.** Results show that an inoculum of about **10^4 *L. monocytogenes* cocktail in these 3 products and HPP treatment at 87,000 psi for 3 minutes showed no recovery of *L. monocytogenes* after 61 days of storage at 34° F.** There were no pressure-injured cells detected. There were no adverse organoleptic effects detected on the 3 HPP treated products during the 61-day shelf life study. No signs of spoilage were seen on all 3 products after 61 days of storage, and for 100 days for ham and turkey. **According to the investigators, the normal shelf life of these products is 30 days, so the HPP treatment extended the shelf life of the products.**

Raghubeer, E.V. and E.D. Ting. 2003. The Effects of high hydrostatic pressure (HPP) on *Listeria monocytogenes* in RTE meat products. Avure Technologies, Inc. Submitted for publication.

C. Studies on the Use of Antimicrobial Agents
(Important information for validation are bolded)

Bedie et al., (2001) evaluated the use of antimicrobials, included in frankfurter formulations, on *L. monocytogenes* populations during refrigerated storage. **Fully cooked and cooled frankfurters were inoculated with 10^3 to 10^4 CFU /cm^2 of *L. monocytogenes* after peeling and before vacuum packaging. Samples were stored at 4° C for up to 120 days and sampled for testing on assigned days.** Results are as follows:

ANTIMICROBIAL	**LEVEL (%)**	***L. MONOCYTOGENES* GROWTH INHIBITION**
Sodium lactate	**3**	**70 days no pathogen growth**
Sodium diacetate	**0.25**	**50 days no pathogen growth**
Sodium acetate	**0.25, 0.50**	**20 days no pathogen growth**
Sodium lactate	6	120 days no growth and reduced pathogen growth
Sodium diacetate	**0.5**	**120 days no growth and reduced pathogen growth**
Inoc. Control	**0.0**	**Increased to 6 logs in 20 days**

Note: Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

No pathogen growth refers to zero increase in the number of inoculated *L. monocytogenes* cells (bacteriostatic); while reduced pathogen growth refers to a decrease in the number of inoculated *L. monocytogenes* cells (bactericidal) in the product. In this study, tables showed the reduction varied with storage days, but was up to 1.0 log on some days. Levels of sodium lactate at 6.0 % and sodium diacetate at 0.5 % showed a reduction of the pathogens, however these levels are above the permitted levels.

Bedie, B. K., J. Samelis, J.N. Sofos, K. E. Belk, J. A. Scanga, and G. C. Smith . 2001. Antimicrobials in the formulation to control *Listeria monocytogenes* postprocessing contamination on frankfurters stored at 4° C in vacuum packages. J. Food Protect. 64:1949-1955

This study by Samelis et al., (2002) used similar treatments, processing and inoculation procedures and **frankfurter formulations** as the previous study described above. However, in this study **combinations of antimicrobials were used, and in combination with hot water treatment. Therefore this is a combination of post-lethality treatment and antimicrobial agent. Hot water treatment involved immersion of frankfurters, with two product links in a package to 75 or 80° C for 60 s. Storage at 4° C** shows:

TREATMENT	**LEVELS (%)**	***L. MONOCYTOGENES* GROWTH INHIBITION**
Sodium lactate	**1.8**	**35-50 days no growth**
Sodium lactate + sodium acetate	**1.8 0.25**	**120 days no growth; 35-50 days growth reduction**
Sodium lactate + Sodium diacetate	**1.8 0.25**	**120 days no growth; 35-50 days growth reduction**
Sodium lactate + Glucuno-delta-lactone	**1.8 0.25**	**120 days no growth, 35-50 days growth reduction**
Hot water treatment (80° C, 60 s) + Sodium lactate	**1.8**	**Inoc. population reduced by 0.4-0.9 log CFU/cm^2, and 50-70 days growth reduction by 1.1-1.4 CFU/ cm^2**
Hot water treatment (80° C, 60 s)		**Increase in growth to about 6-8 logs in 50 days**
Inoculated Control, no treatment		**Increase in growth to about 6 logs in 20 days and 8 logs thereafter up to 120 days**

Note: **Sodium lactate was used as a 3 % of a 60 % (wt/wt) commercial solution**. Glucuno-delta lactone is approved as an acidifier, and a curing accelerator, but not as antimicrobial. Sodium acetate is approved as a flavor enhancer, not as an antimicrobial agent.

Samelis, J. G.K. Bedie, J.N. Sofos, K.E. Belk, J.A. Scanga, and G.C. Smith. 2002. Control of *Listeria monocytogenes* with combined antimicrobials after post-process contamination and extended storage of frankfurters at 4° C in vacuum packages. J. Food Protect. 65: 299-307.

ATTACHMENT 8

GUIDANCE DERIVED FROM A REVIEW OF COMPREHENSIVE FOOD SAFETY ASSESSMENTS ASSOCIATED WITH COMPLIANCE WITH 9 CFR 430

Since 2004, FSIS conducted comprehensive Food Safety Assessments (FSA) by Enforcement, Investigations, and Analysis Officer (EIAO) in which the design and execution of the food safety systems were assessed, with a specific focus on *Listeria monocytogenes* in ready-to-eat (RTE) products. From June 2004 through September 2005, a total of 195 FSA reports directly related to 9 CFR 430, the *Listeria monocytogenes* regulations on post-lethality exposed RTE products, were further reviewed by the Office of Policy, Program and Employee Development. The OPPED review was performed in order to glean from the reports the design and execution features of the associated food safety systems that may have contributed to weak control measures. OPPED has summarized the significant features that may be helpful for the RTE industry, particularly small and very small establishments, in order for the industry to focus attention and enhance their control measures for *L. monocytogenes*.

Summary of Findings and Recommendations

The three failures common to most of the establishments reviewed from 2004 to 2005, regardless of the establishment-selected 9 CFR 430 control measure (i.e., Alternatives 2 or 3; there were no noted failures associated with Alternative 1), were: 1) not identifying *L. monocytogenes* in the hazard analysis; 2) not explaining how the food contact surfaces (FCS) were identified and selected and how the testing frequency was established; and 3) not providing hold and test procedures in the event of a *Listeria spp*. or *L. monocytogenes* finding by the establishment.

Alternative 2: In addition to the 3 failures common to most of the establishments mentioned above, some establishments selecting Alternative 2 did not identify the control method (e.g., freezing) used, provide supporting documentation for the control method, follow the written cleaning and sanitizing frequencies, or address and control condensation problems in processing areas where product is post-lethality exposed.

Alternative 3: In addition to the 3 failures common to most of the establishments mentioned above, some establishments selecting Alternative 3 were found to have a number of problems with designing and implementing a sanitation program to meet the requirements of 9 CFR 430, in addition to meeting the requirements of 9 CFR 416. Establishments that selected Alternative 3 for their products had problems with the sampling plan described in their sanitation program to control *L. monocytogenes*, such as its implementation, identifying the location and size of their sampling sites, failure to identify and incorporate all food contact surfaces in their program, failure to include non-food contact surfaces such as cooling racks, wire trays, cooler walls, and tubs used to hold open bags of RTE products as potential sampling sites.

Corrective Actions: For the three most common failures, the following corrective actions were identified and taken by many of the establishments and likely contributed to resolving regulatory enforcement actions:

1. *L. monocytogenes* is not identified in the hazard analysis as a hazard reasonably likely to occur.

> FSIS, through 9 CFR 430, believes that *L. monocytogenes* is a hazard reasonably likely to occur in post-lethality exposed RTE meat and poultry products. As such, the hazard analysis should list *L. monocytogenes* either as a hazard reasonably likely to occur or as a hazard not reasonably likely to occur. In either case, the associated control measures need to describe what control measures are in place to support this finding. This does not automatically mean that a critical control point is required. If the control measure does not eliminate, prevent, or reduce *L. monocytogenes* to an acceptable level, the controls can be addressed in the Sanitation SOP or other prerequisite program. The exception is that for application of a post-lethality treatment (as in Alternative 1 and

2), 9 CFR 430 requires the treatment to be identified in the HACCP plan only and not in the Sanitation SOP or other prerequisite program.

2. The sanitation program does not explain how the FCS were identified and selected and how the testing frequency was established.

If an establishment chooses either Alternative 2 or 3, the sanitation program for that establishment must provide for testing of FCS in the post-lethality processing environment, identify the frequency for testing, and provide an explanation of why the testing frequency is sufficient to ensure the effective control of *L. monocytogenes* or indicator organisms (430.4(b)(2)(iii)(A), (C), and (E) and 430.4(b)(3)(i)(A), (C), and (E)). Identifying the FCS is simply determining the surfaces to which the product is exposed post-lethality. In addition to the equipment surfaces that contact the product post-lethality, other FCS may include knives that are used to slice the product, thermometers inserted into the product after the lethality process, or other surface that compromises the product integrity. For the testing frequency, the establishment has the options of either setting and justifying their own testing frequency or using the testing frequency recommended in the Compliance Guidelines for the control of *L. monocytogenes*. Whether establishments use their own or the Compliance Guideline testing frequency, the establishment still needs to have a justification on file as part of the validation support for the food safety system that provides a rationale for why the selected level of testing frequency is sufficient to demonstrate that *L. monocytogenes* is appropriately controlled.

3. The sanitation program did not provide hold and test procedures in the event of a FCS testing positive *Listeria* spp.or *L. monocytogenes*.

If a FCS tests positive for *L. monocytogenes*, the product that came in contact with that surface is considered adulterated according to 9 CFR 430 and must be destroyed or treated with a process sufficient to destroy *L. monocytogenes*. In this case, a hold and test procedure would not be necessary for the lot in question. However, if the establishment or inspection program personnel have reason to believe that product lots other than those immediately identified may have become contaminated, the establishment should have hold and test procedures for the other product lots.

On the other hand, if a FCS tests positive for an indicator organism (e.g., *Listeria* spp. or *Listeria*-like organisms), the establishment producing products under Alternative 2 or non-hotdog or deli meat products under Alternative 3 must define conditions under which they will implement their hold and test procedures. Hold and test procedures for hotdog and deli meat products are described under 430.4(b)(3)(ii).

For other common deficiencies in program design, the following corrective actions were identified and taken by many of the establishments and likely contributed to resolving regulatory enforcement actions:

- The establishment fails to identify the post-lethality treatment or antimicrobial treatment or process.

  It is the responsibility of the establishment, not the Agency, to determine the Alternative that applies to their product. However, in doing so, the establishment must provide justification for their determination. Also, the effectiveness of the post-lethality treatment or antimicrobial agent or process must be validated. For example, an establishment cannot simply declare that a process is Alternative 1 or 2 if documentation isn't available on file with the food safety system to provide the rationale for how the treatment and/or process reduces the level of *L. monocytogenes* and/or suppress its growth.

- The establishment's post-lethality treatment is not validated or the establishment cannot provide supporting documentation for the effectiveness of the antimicrobial agent or process or the post-lethality treatment.

  Validation of the post-lethality process and documentation to support the effectiveness of the antimicrobial agent or process are requirements of 9 CFR 430(b)(1)(ii) and (b)(2)(ii). The supporting documentation can be a challenge study on the specific product, journal article on a process that is

used by the establishment, or the Compliance Guidelines with rationale to support the effect of the treatment or process. For the antimicrobial agents pH, water activity, and temperature, the Compliance Guidelines can be used as supporting documentation if these factors are below the levels listed that allow growth of *L. monocytogenes*.

- The establishment did not identify the location and size of FCS sampling sites.

  The location of the sampling sites should be determined in conjunction with the requirement to provide testing of FCS. Documenting the location of the sampling sites also assists in determining the thoroughness of the sampling plan. One square foot of FCS or non-FCS, if available, is the minimum area recommended for sampling in the Compliance Guidelines. A prudent plant could use the Compliance Guidelines as the minimum testing amount to ensure the effectiveness of their sanitation program while conducting on-going verification to demonstrate that the level and frequency of testing is sufficient to find insanitary conditions and, when found, adequately controlled to prevent product adulteration.

Failures in the implementation of *L. monocytogenes* food safety programs were attributable to either not implementing the program or not applying the program as written. Either case is comparable to not developing a program – the establishment cannot ensure the effectiveness of their control for *L. monocytogenes* or indicator organism in the post-lethality environment. Failures of program implementation noted in many of the establishments were: not following sampling programs as described in the establishment's plan including failure to test FCS or include all FCS, failure to document corrective actions; not isolating or separating the processing area from construction; and not following the written sanitization procedures.

Failures in implementation can be addressed by effective training the employees accompanied by supervision to ensure they are performing the tasks as described in the program. If an employee is observed to be incorrectly performing their tasks, re-training may be needed.

In responding to failures in program design or implementation, an establishment should not limit the corrective actions to just meeting the minimum requirements or recommendations. The establishments should strive to develop a program that is the most effective in controlling *L. monocytogenes* or an indicator organism. For example, one establishment responded by extending sample collection to food contact surfaces prior to the start of processing. This practice would provide the establishment with the effectiveness of their equipment cleaning and sanitizing measures to eliminate *L. monocytogenes* or indicator organism.

ATTACHMENT 9

GUIDANCE DOCUMENTS FOR VALIDATION

1. GUIDELINES FOR CONDUCTING *LISTERIA MONOCYTOGENES* CHALLENGE TESTING OF FOODS.
www.foodprotection.org/publications/TOCarchive/2005TOC/November2005.htm

2. CONSIDERATIONS FOR ESTABLISHING SAFETY-BASED CONSUME-BY DATE LABELS FOR REFRIGERATED READY-TO-EAT FOODS
www.fsis.usda.gov/ophs/nacmcf/2004/NACMCF_Safety-based_Date_Labels_082704.pdf

NACMCF. 2005. J. Food Protect. 68:(8):1761-1775