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

Table of Contents

A. Introduction

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. Its purpose is to show establishments what the control methods can achieve, if used singly or in combination, to prevent or eliminate *L. monocytogenes* contamination in the product during post-lethality exposure. Establishments can use the guidelines to determine 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 only 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 NRTE. FSIS distinguishes between RTE and NRTE foods in Attachment 2.

These guidelines were updated from the version posted on the FSIS website in June 2003. The updated version includes:

- growth limits for *L. monocytogenes* with regards to pH, temperature and water activity (p.9).
- section on levels of reduction of *L. monocytogenes* achieved by the post-lethality treatment and the levels of growth suppression of *L. monocytogenes* achieved by the antimicrobial agent or process that will likely be considered for Alternatives 1 and 2 for purposes of this rule, and the levels that will likely be eligible for application of labeling claim of enhanced protection for *L. monocytogenes* (p.14).
- chart of expected minimum levels of control for post-lethality treatments and antimicrobial agents or processes that establishments could achieve for Alternatives 1 and 2 from which establishments should base their minimum verification measures to determine the effectiveness of their controls (p. 15)
- information on new technology review (p.16)
- chart that shows the minimum frequency of testing food contact surfaces that an establishment in Alternatives 1, 2 and 3 could conduct for verification of the effectiveness of their sanitation program (p. 32).
- section on Projected Risk-Based Verification Testing Program (p.37)

The following were also added as attachments:

Attachment 1- Table of Control Requirements for *Listeria moncytogenes*
Attachment 2- Distinction Between RTE and NRTE products
Attachment 3- Production Information Collection sample Form
Attachment 4- Studies on Post-lethality Treatments and Antimicrobial Agents

Attachment 5- Using the ICMSF Sampling Plan
Attachment 6 - A schematic diagram and flowchart of a hold-and-test scenario.

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 plant, soil, animal, water, dirt, dust, and silage. Because *L. monocytogenes* can be found in slaughter animals and in raw meat and poultry and 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.

The lethality treatment received by processed ready-to-eat (RTE) meat and poultry products 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 and death have been linked to the consumption of deli meats and hotdogs containing *L. monocytogenes*. The cause 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 for safety, 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/lmrisk.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 cross-contamination of RTE products. The FSIS *Listeria* risk assessment (www.fsis.usda.gov/OPHS/lmrisk/DraftLm.22603) 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 references 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 or limit its growth (i.e., the number of organisms shall not increase during the product's shelf life to a level resulting in a public health risk, as well as detectable levels of the pathogen) should it be present, and provide the greater control compared to Alternative 3 which involves only sanitation to control *L. monocytogenes*. Consequently, the assurances of control of the pathogen decreases from Alternative 1 to 3, based on rigor or stringency of the control methods used by the establishment. 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 move from one Alternative to another; however, it must apply the control methods required for the specific Alternative. 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 hot dogs 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.

Alternative 1

Alternative 1 requires the use of post-lethality treatment (which maybe an antimicrobial agent) to reduce or eliminate *L. monocytogenes* and 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 environment. These products need to be aseptically processed and then repackaged under strict sanitary conditions to prevent contamination from *L. monocytogenes*.

Post-LethalityTreatments

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.

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 reducing or eliminating *L. monocytogenes* and the validation should specify the log reduction achieved by the post-lethality treatment and antimicrobial agents. The effectiveness of the post-lethality treatments and antimicrobial agents must be verified and have the verification results available to FSIS personnel upon request. FSIS expects the establishment's HACCP documentation would demonstrate that the post-lethality treatment will be adequate to reduce a level of contamination that has a potential to occur before packaging.

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 depending on whether it eliminates, reduces or suppresses listerial growth. Some of the studies on post-lethality treatments 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. The guidelines will be updated to include studies or other methods as they become available. 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.

An establishment can use available published research studies as reference for their validation provided it uses 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 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 their specific products. The establishment must specify the level of reduction achieved by the post-lethality treatment or antimicrobial agent applied in their validation. In the absence of published peer-reviewed paper that would contain information needed for validation, unpublished studies may be used provided the data and analysis of results included demonstrate that the specific level of application on specified products or range of products is effective at a specific level. Aside from validation of the post-lethality treatment and antimicrobial agent, the establishment must verify its effectiveness by testing for *L. monocytogenes*.

Antimicrobial Agents or Processes

Antimicrobial agents and processes must suppress or limit the growth of *L. monocytogenes* throughout the product shelf life - the amount of time the product can be stored under specified conditions and still remain safe with acceptable quality. Examples of antimicrobial agents shown to inhibit listerial growth are lactates and diacetates added in the formulation and growth inhibitors in the immediate packaging material. Some growth inhibitor packaging and some levels and combinations of antimicrobial agents were shown by research studies to reduce the levels of *L. monocytogenes*. RTE products where studies on antimicrobial agents were shown to be effective in the control *L. monocytogenes* are hot dogs, 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. Approved antimicrobial agents for processed meat and poultry products can be found in 9 CFR 424.21**.**

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 added during formulation or 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.

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 and does 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 listericidal effect in the specific product and the establishment has provided support documentation to document 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 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, and need to satisfy the requirements for this Alternative. The requirement that an antimicrobial process or product formulated with an antimicrobial 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. Examples of shelf stable RTE products are country cured ham, pepperoni, salami, and jerky.

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 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 is intended to exclude 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, 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 minimum growth limits represent the lowest levels below which the pathogen cannot grow. Establishments with processes that achieve levels below the minimum limits can use these as their control for the pathogen. Establishments that comply with these growth parameters need not conduct further validation for their products to prove that growth is inhibited to less than 1-log throughout the shelf-life of the product. 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, and temperature.

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

	Minimum	Optimum	Maximum
Temperature (°C)	-0.4	37	45
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 is required to maintain under 9 CFR 417.5.

The establishment can include the antimicrobial treatment that limits or suppresses *L. monocytogenes* in the HACCP plan, Sanitation SOP or prerequisite program and must show the effectiveness of the antimicrobials in suppressing or limiting *L. monocytogenes* in these programs. An establishment can use published studies as reference for its validation as long as it uses the same treatment variables as those used in the study. These variables include among others, specific antimicrobial agents, 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. Based on such a program, an establishment could deem a hazard not reasonably likely to occur in its hazard analyses and need not adopt a CCP for the hazard. 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 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, available upon request to FSIS inspection personnel. 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 and where that source is located, then 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.

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 to result in a safe RTE product. If an establishment has an effective Sanitation SOP, any post-lethality contamination by *L. monocytogenes* would be very small, 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 the pathogen.

Because of this combination of controls, the Agency is not requiring establishments to have a testing program for food contact surfaces. Testing food contact surfaces in Alternative 1 would be minimal and primarily 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 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 can 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 species (spp.) of microorganisms, 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. 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-CC.

Alternative 2

An establishment that identifies its products in Alternative 2 must apply either a post lethality treatment or an antimicrobial agent or process that controls the growth of *L. monocytogenes*. The establishment 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* and should specify the log reduction achieved by the post-lethality treatment. The effectiveness of the post-lethality treatment must be verified by testing for *L. monocytogenes* and have the verification results available to FSIS personnel upon request. FSIS expects the establishment to conduct via HACCP on-going verification of the CCP. 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. 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*. For antimicrobial agents and processes, the Agency expects that there will not be a significant increase in numbers

of organisms during the product's shelf life to a level resulting in a public health risk, as well as detectable levels of the pathogen. The establishment should document the log levels of the pathogen that the antimicrobial agent or process can suppress and the length of time 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.

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 inspection personnel.

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 must 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*.

Alternative 3

Under Alternative 3, the establishment does not apply either 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.

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 verification of the effectiveness of the corrective action can be shown 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 to ensure the effectiveness of the corrective actions. 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.

Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes* from the food contact surface, the establishment must sample and test the lots for *L. monocytogenes* 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 product tests positive for *L. monocytogenes*, the sampled product lot is considered adulterated and must be withheld from commerce. The establishment may 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-DD.

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.

For frequency of verification sampling, the Agency is expected 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.

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 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 suppresses 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 likely 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 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 Minimum Levels of Control for Post-lethality Treatments and Antimicrobial Agents or Processes

	Levels of reduction or inhibition achieved to control *L. monocytogenes*	
	Higher Level	Lower level
Post-lethality Treatment (log_{10} reduction of *L. monocytogenes)*	=> 2	< 2
Antimicrobial Agent or Processes (log_{10} allowed increase of *L. monocytogenes*)	<= 1	> 1

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.

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 has 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 draft 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/OPPDE/op/technology/guidance.pdf) to aid in the submission of application for review of new technology.

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 your 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.

I. General 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 at least use 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 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.

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. 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, before the start of operation.
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, since people or rolling stock enter 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, or,
   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.

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, tests taken, 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.

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

Some manufacturers provide labeling in both English and Spanish, which makes the products more user friendly in various environments. At least one manufacturer, Ecolab Inc., 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 organisms 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 peractetic acid were the most effective biocides on attached organisms, 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 constantly introduced into the processing environment by inadvertent actions of plant employees or other entry vectors. It may be introduced by incoming raw product, processing environment or by employees. 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*. Scientists believe that most meat products implicated in human listeriosis are contaminated with *L. monocytogenes* after these measures are applied. Undercooking product or other inadequate 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, operational conditions that move product debris into uncleanable 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
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
Drains
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 to eliminate *L. monocytogenes*, to final packaging.

Typical sites of *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 then product testing alone to monitor and detect Listeria in the environment.

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

    a. Use statistically designed sampling plans based on probability, such as those described in ICMSF 7 or Military Standards (MIL-STD-105E), or

    b. 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.

    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 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., 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.

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

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*-like organisms, c) an example of a hold-and-test scenario, and d) an example of a Sentinel Site Program.

AA. Food Contact Surface and Environmental Testing

The sampling frequencies for food contact surface (FCS) testing suggested below are recommended minimum frequencies. 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.

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 surfaces should be composited (e.g., food contact surfaces with other food contact surfaces, etc.). The sample 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.

1. 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 or 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) 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.
      (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.

2. 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) 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) 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.
(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) 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.
(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*.

3. Alternative 3 – Use of sanitation control measures and testing to prevent contamination of product with *L. monocytogenes*.
   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-off 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) 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.
   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 <u>*L. monocytogenes*,</u> *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) 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.
      (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:
(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. Consecutive or 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
iii. Use total plate counts (TPC) or other method of bacterial enumeration to determine the site of heaviest contamination. A higher TPC for one part of the equipment may indicate that site is a more likely source than another part. For example, higher counts on the screw holding the slicer blade than

the blade itself may indicate ineffective cleaning of the parts holding the blade and the possible development of a niche.

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 their HACCP plan, Sanitation SOP or their prerequisite program where the sanitation and testing programs are included, evaluate and see if there is any design or execution flaw, and modify as necessary. The establishment should evaluate the cleaning or sanitizing procedure, the method of determining that the procedures are performed as prescribed, employee hygiene practices, monitoring traffic patterns, equipment design, or change in processing conditions.

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

The chart below shows the minimum frequency 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 minimum 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 the minimum 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 Minimum Frequency 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

CC. Testing for *Listeria* spp. and *Listeria*-like Organism for Food Contact Surfaces and Other Environmental Testing

Listeria spp. or *Listeria-like* organisms are the indicator organisms to be used for *L. monocytogenes* because their presence indicates 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 tests for *L. monocytogenes*. Results from these tests do not indicate the presence or absence of the pathogen. However, testing for these organisms can be conducted in addition to the testing for *L. monocytogenes* or its indicator organisms to monitor the effectiveness of the cleaning procedures and level of contamination during processing. Any methodology used by a regulatory body or validated by a recognized body is acceptable. FSIS microbiology laboratory methods are available and can be downloaded at http://www.fsis.usda.gov/OPHS/microlab/mlgbook.htm

4. *Listeria* spp. testing
   i) The methodology must employ enrichment prior to *Listeria* spp. screening.
   ii) *Listeria* spp. screening is conducted from the enrichment using an immunoassay, nucleic acid assay, or equivalent *Listeria* spp.-specific technology.
   iii) The above enrichment and screening must be part of a method in use by a government agency (*i.e.*, FSIS or FDA) or validated by a recognized body (*e.g.*, AOAC, AFNOR, ISO, etc.) for the detection of *Listeria* spp. and/or *L. monocytogenes*. Specific validation for environmental sampling is encouraged but not a requirement at this time.
5. *Listeria*-like organism testing
   i) The methodology must employ enrichment prior to *Listeria-like* organism screening.
   ii) The *Listeria-like* organism positive screening result may be indicated by the presence of suspect *Listeria* spp. colonies after selective plating, or may be indicated by biochemical changes to screening broths (*e.g.*, Fraser Broth) that are consistent with the potential presence of *Listeria* spp.
   iii) The above enrichment and screening must be part of a method in use by a government agency (*i.e.*, FSIS or FDA) or validated by a recognized body (*e.g.*, AOAC, AFNOR, ISO, etc.) for the detection of *Listeria* spp. and/or *L. monocytogenes*. Specific validation for environmental sampling is encouraged but not a requirement at this time.
   iv) Aerobic plate counts, ATP assays and other indicator organism tests that do not specifically meet the above requirements may be employed by the establishment for supplemental sanitation testing. However, these tests do not meet the FSIS expectations for *Listeria* spp. or *Listeria-like* organism food contact and other environmental surface testing programs that may be conducted by the establishment.

DD. Hold-and-Test Scenario

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.

Day 7 – Second FCS sample (from Day 4) negative for *Listeria* spp. or *Listeria*-like organisms.

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

If second FCS sample (from Day 4) 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 product (for *L. monocytogenes*) for lot implicated in the positive FCS testing.
- ✓ 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 release product from days 7, 8 and 9 production
- ✓ 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 product from day 10 production.
- ✓ Test product from days 7, 8, 9, and 10 for *L. monocytogenes*
- ✓ 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 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 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) FCS positive, product is held and tested for *L. monocytogenes*. Only product lots implicated with a second or more consecutive 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.

EE. 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*-like organisms, testing is intensified in the area of the positive.

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* cannot 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 testing 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. PROJECTED RISK-BASED VERIFICATION TESTING PROGRAM

FSIS expects to begin this risk-based verification-type program after it has received production volume and related information from establishments operating in accordance with 9 CFR 430, sometime within the first year to 18 months after the effective date of October 6, 2003. For purposes of the verification testing program, FSIS is planning to group RTE products into at least four sampling projects for routine analysis:

#1 – Prevalence Verification Testing
#2 – RTE products in Alternative 1 under 9 CFR 430
#3 – RTE products in Alternative 2 under 9 CFR 430
#4 – RTE products in Alternative 3 under 9 CFR 430

Prevalence verification testing program. FSIS will direct Inspection program personnel to collect samples of any RTE product regardless of the control measures for pathogens,

compliance history, production, volume, etc. All establishments, regardless of plant size, production volume, or process design will have an equal chance of being sampled each fiscal year in sampling frame #1. Note*:* All Ready-to-Eat products whether post-lethality exposed *or not* will be sampled in this prevalence category. The sampling projects that cover the alternatives according to 9 CFR 430, only apply to post-lethality exposed product.

Results from this project will be unbiased to the extent that production practices are 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 collects one sample of product at a time from an individual establishment and tests for pathogens of public health concern, namely, *Listeria monocytogenes, Salmonella* and *E. coli* O157:H7. Inspection program personnel will carry 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.

Sampling Under Alternatives 1, 2, and 3 of 9 CFR 430. Until FSIS has actual production volume and associated data as a result of the information request contained within 9 CFR 430, for sampling frames #2, #3, and #4, FSIS will design the scheduling of sample requests using the best available data, that is, information voluntarily provided by establishments, data collected in a survey of RTE establishments in December of 2002, and the information available in the PBIS establishment profile.

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. FSIS will collect a sufficient number of samples from a subsequent lot or lots to provide a level of statistical confidence that the establishment has its production process under control. The follow-up sampling will be conducted under the Intensified Verification projects, and may include direct product contact surface and non-product contact surface sampling in addition to the product sampling.

Intensified verification testing projects. These projects are designed for testing in any operation involving any 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.