

## **Control of *Listeria monocytogenes*, Alternatives 1, 2, 3**

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

The lethality treatment received by processed ready-to-eat (RTE) meat and poultry products generally eliminates *L. monocytogenes*; however products can be recontaminated by exposure after the lethality treatment during peeling, slicing, repackaging, and other procedures. Several outbreaks of foodborne illness resulting in hospitalization, miscarriage, stillbirth, and death have been linked to the consumption of deli meats and hotdogs containing *L. monocytogenes*. One of the most likely causes of *L. monocytogenes* contamination in these outbreaks was traced to post-lethality exposure and contamination by the pathogen. Deli and hotdog products are examples of RTE meat and poultry products that receive a lethality treatment to eliminate pathogens, but are subsequently exposed to the environment during peeling, slicing, and repackaging operations. If *L. monocytogenes* is present on the equipment used for peeling, slicing or repackaging, the pathogen can be transferred to the product upon contact. These products are examples of RTE meat and poultry products that can support the growth of *L. monocytogenes* during refrigerated storage. Since RTE products are consumed without further cooking, if they are contaminated, there is a possibility of the occurrence of foodborne illness. The “FDA/FSIS Draft Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods” ([www.foodsafety.gov/~dms/lmr2-su.html](http://www.foodsafety.gov/~dms/lmr2-su.html)) indicated that deli meats and hotdogs posed the greatest per serving risk of illness/death from *L. monocytogenes*.

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

The interim final rule for the control of *Listeria monocytogenes* (9 CFR 430) includes three alternative approaches that establishments can take in the processing of RTE meat and poultry products during post-lethality exposure. Under Alternative 1, an establishment applies a post-lethality treatment and an antimicrobial agent or process to control *L. monocytogenes*. Under Alternative 2, an establishment applies either a post-lethality treatment or an antimicrobial agent or process. In Alternative 3, the establishment does not apply any post-lethality treatment or antimicrobial agent or process. Instead, it relies on its sanitation program.

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## Alternative 1

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

### **a. Post-Lethality Treatment**

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

Post-lethality treatments can be applied as a pre-packaging treatment, e.g. radiant heating, or as post-packaging treatments, e.g., hot water pasteurization, steam pasteurization, and high pressure processing. Ultra violet treatment can be used either as a post-lethality treatment or antimicrobial agent or process depending on whether it eliminates, reduces or suppresses growth of *L. monocytogenes*

Validation of Post-lethality Treatment The post-lethality treatment that reduces or eliminates the pathogen must be included in the establishment's HACCP plan. The post-lethality treatment must be validated according to 9 CFR 417.4 as being effective in eliminating or reducing *L. monocytogenes* to an undetectable level, and the validation should specify the log reduction or suppression achieved by the post-lethality treatment and antimicrobial agents.

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

Since products with water activity less than 0.85 will not support the growth of *L. monocytogenes* and can sometimes even cause *L. monocytogenes* death, FSIS will consider water activity of <0.85 at the time the product is packed to be a post-lethality treatment if there is a bactericidal effect (death of bacterial cells leading to a reduction in number) in the specific product, and the establishment has provided support documentation to document that the intended effect occurs prior to distribution of the product into commerce. In this case, the antimicrobial process could serve as both a post-lethality treatment and growth inhibitor. The establishment should have documentation on file (e.g., copy of a published report, challenge study) to demonstrate the effectiveness of the lethality treatment through the shelf life of the product. These shelf stable products can be classified in Alternative 1 if the requirements for this

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alternative are satisfied. The requirement that an antimicrobial process or product formulated with an antimicrobial agent suppress or limit growth throughout the commercial shelf life means that an establishment must have validated that the process or formulation does what is claimed. These validation records must be available to FSIS. Establishments must include in their HACCP plans the antimicrobial process used (e.g. drying, cooking/frying, or rendering) and the water activity achieved that renders the product shelf stable.

### **b. Antimicrobial Agents or Processes**

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

### **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*. Post-lethality treatments and antimicrobial agents and processes discussed above in the section on Alternative 1 can be used for Alternative 2. If an establishment uses a post-lethality treatment, it must have the post-lethality treatment in its HACCP plan and the treatment must be validated according to 9 CFR 417.4 as being effective in reducing or eliminating *L. monocytogenes* specifying the log reduction achieved by the post-lethality treatment. The effectiveness of the post-lethality treatment should be verified by testing the finished product for *L. monocytogenes*, and the verification results should be made available to FSIS personnel upon request. FSIS expects the establishment to conduct on-going verification of the CCP as detailed in its HACCP plan. The sanitary conditions likely will have a direct bearing on whether or not the post-lethality treatment is effective. If an establishment has a product identified in Alternative 2 and uses a post lethality treatment to control *L. monocytogenes* in its product, it is not required to test food contact surfaces in the post-lethality environment, although it is recommended. However, FSIS most likely will conduct verification testing less frequently if the establishment tests food contact surfaces for *L. monocytogenes*, or its indicator organisms (*Listeria* spp. or *Listeria*-like organisms).

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

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

### **Alternative 3**

Under Alternative 3, the establishment does not apply a post-lethality treatment or an antimicrobial agent or process to control the growth of *L. monocytogenes* in the post-lethality exposed product. An establishment producing this type of product must control the pathogen in its post-lethality processing environment through the use of sanitation control measures, which may be incorporated in the establishment's HACCP plan, Sanitation SOP or prerequisite program.

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

Moreover, an establishment that produces a deli product or a hotdog product must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or its indicator organisms on a food contact surface in the post-lethality processing environment are effective. The corrective action must indicate steps that the establishment will take to clean and sanitize the suspected food contact surfaces to eliminate the contamination. The effectiveness of the corrective action can be verified by follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and other additional tests in the surrounding food contact surface area as necessary. During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the sanitation problem indicated by the test result. If the food contact surface is positive for *L. monocytogenes*, the affected product lot (product that had direct contact with the food contact surface) would be considered adulterated. Affected product (product or food contact surface tested positive for *L. monocytogenes*) must be recalled, if in commerce, and destroyed or reworked with a process that is destructive of *L. monocytogenes*. If the food contact surface is positive for *Listeria* spp. or *Listeria*-like organisms (indicator organisms), the affected products are not considered adulterated. Establishments may move production from an affected line provided the new production line does not include the food contact surfaces that tested positive for *L. monocytogenes* and the new food and non-food contact surface areas are tested.

In order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes* from the positive food contact surface, the establishment must sample and test

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the lots for *L. monocytogenes* or its indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The ICMSF (International Commission on Microbiological Specifications for Foods) statistical sampling plan is an example of a plan that some establishments have used (Attachment 5).

If the held product tests positive for *L. monocytogenes*, the sampled product lot is considered adulterated and must be withheld from commerce. The establishment must destroy the held product, or rework the held product using a process that is destructive of *L. monocytogenes*. The establishment must document the results of the testing and the disposition of the product.

### **I. General Cleaning and Sanitation Procedures**

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

1. Remove waste material. Dry clean equipment, conveyor belts, tables, floors to remove meat particles and other solid debris. Some equipment such as slicers and dicers need to be disassembled so that parts can be cleaned thoroughly. Equipment may need to be cleaned and sanitized again after re-assembly.
2. Wash and rinse floor.
3. Pre-rinse equipment (rinse in same direction as product flow). Pre-rinse with warm or cold water – less than 140°F (hot water may coagulate proteins or “set soils”).
4. Clean and scrub equipment. Always use at least the minimum contact time for the detergent/foam. Written instructions should be provided on the location of possible niches and the cleaning method to use. CAUTION: Live steam for cleaning is not acceptable at this step since it may bake organic matter on the equipment.
5. Rinse equipment (rinse in same direction as product flow).
6. Visually inspect equipment to identify minute pieces of meat and biological residues (repeat steps 3 and 4 if not clean visually or by testing such as with ATP bioluminescence).
7. Sanitize floor and then equipment to avoid contaminating equipment with aerosols from floor cleaning. Care should be taken in using high pressure hoses in cleaning the floor so that water won't splash on the already cleaned equipment. Use hot water, at least 180°F, for about 10 seconds to sanitize equipment. Sanitizers (e.g., chlorine, quaternary ammonia, etc.) may be more effective than steam for *L. monocytogenes* control. If steam heating equipment in an oven or tarp, the target internal temperature is 160° F and hold for 20-30 min. Portable high-pressure, low volume cleaning equipment (131°F (55°C) with 20-85 kg/cm<sup>2</sup> pressure and 6- 16 liters/minute) can also be used.
8. Remove excess moisture. This can be done most safely and efficiently by air drying. Reduced relative humidity can speed the process. Avoid any possible cross-contamination from aerosol or splash if a method other than air drying (e.g., using a squeegee or towel) is used. If cross-contamination is suspected, repeat steps 4 – 7.

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

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

1. Visual inspection of the equipment and environment. Visual inspection is the minimum means of determining the effectiveness of the sanitation SOPs. It can only detect observable contamination.
  - a. Before the start of operation, visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria,.
  - b. Record the results of the visual inspection.
  - c. If any residue is noted, corrective action should be taken and recorded.
  - d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
  - e. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, after post-processing cleanup.
  
2. Visual inspection and use of ATP bioluminescence testing. Visual verification combined with ATP testing can determine both observable contamination and contamination from bacteria and meat/poultry residues that may not be visually detectable. The combined methods are more effective in determining the effectiveness of the sanitation SOP.
  - a. The ATP test indicates the presence of both bacteria and meat or poultry residues and can be used to verify that no meat or poultry residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation. The ATP test is a rapid test and results are available immediately.
  - b. Record the results of the ATP test and visual inspection.
  - c. If any residue is noted or observed visually or the ATP test indicates an insanitary condition, corrective action should be taken and recorded.
  - d. The monitoring record should be designed to show any trends of insanitary conditions. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
  
3. Visual inspection and total plate counts (TPC). Visual verification combined with TPC can determine both observable contamination and the level of bacterial contamination. Since TPC results are available in about 24 hours, and cannot be obtained at the time of inspection, its value lies in the measurement of the level of contamination. The level of contamination may assist the establishment in determining the source of contamination and the effectiveness of the sanitation SOP.
  - a. Visually verify that no meat or product residue is on the equipment, esp. those food contact surfaces and areas that may serve as niches for bacteria, before the start of operation.
  - b. Use swabs or RODAC plates for sampling food contact surfaces, non-food contact surfaces (e.g., push-button on/off switches for the conveyor belt), and the processing environment.
  - c. Record the results of the visual inspection.
  - d. If any residue is noted, corrective action should be taken and recorded.

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- e. Record the TPC when analysis is complete.
- f. The monitoring record should be designed to show any trends of insanitary conditions as determined by visual inspection or TPC. For example, if corrective action had to be taken on the first two days of operation for more than a week, this indicates a possible problem with cleaning and would have to be investigated to determine the source of the problem (e.g., improperly trained crew on those days, types of products processed).
- g. Visually verify that no meat or product residue is on the equipment, especially those food contact surfaces and areas that may serve as niches for bacteria, again after post-processing cleanup.

### **III. Traffic Control**

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

1. Establish traffic patterns to eliminate movement of personnel, meat containers, meat, ingredients, pallets and refuse containers between raw and finished product areas.
2. Control traffic into and within the RTE areas
  - a. If possible, use air locks between raw and RTE areas.
  - b. Clean, dry floors are preferable to foot baths at the point of entry because effective concentrations of disinfectant are difficult to maintain and may become a source of contamination.
  - c. If foot baths are used:
    - i) Wear rubber or other non-porous boots.
    - ii) Maintain them properly,
    - iii) Solutions should contain stronger concentrations of sanitizer than normally used on equipment
      - (1) For example, 200 ppm iodophor, 400-800 ppm quaternary ammonia compound).
      - (2) CAUTION: Chlorine is not recommended as it is too quickly inactivated esp. if cleated boots are used. The accumulation of biological material adhering to the cleats inactivate (or reduce) the bioavailability of chlorine and make it less effective. Monitor and maintain its strength if used.
    - iv) Use a minimum depth of 2 inches.
  - d. Use foam disinfectant spray on floor for people or rolling stock entering the room.
3. Employees should not work in both raw and RTE areas, if possible. If they must work in both areas, they must change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear.
  - a. Use different color smocks or helmets for raw and RTE areas so the workers and garments in the raw and RTE areas are readily distinguishable.
  - b. Remove outer garments (e.g., smocks) when leaving RTE areas.
4. Do not allow employees who clean utensils and equipment for raw materials to clean RTE utensils and equipment, if possible. If not possible, there should be a time separation when utensils for raw processing/handling are cleaned after RTE. The tools to clean utensils and equipment for raw materials must be different than those used to clean RTE utensils and equipment. In either case, the intent is to prevent cross contamination of finished product.
5. Do not permit maintenance employees in RTE areas during operations if possible, primarily because they may cause direct product contamination or adulteration if they touch or lay their “dirty” equipment hands onto food contact surfaces. If not possible:
  - a. Consider the need to cease operations until a full cleaning and sanitizing is done, or,

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- 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 to prevent cross contamination of finished product.
- 7. Pallets can serve as a source of cross-contamination – pallets for raw materials should not be used in RTE areas or used for finished product.
- 8. Drains from the “dirty” or “raw” side should not be connected to those on the “clean” or “cooked” side.
- 9. There are instances when small establishments cannot separate the raw and cooked areas, or separate employees handling raw and cooked products by operating time. In this case, the establishment should plan to process cooked products first, then do a complete clean-up (thorough cleaning and sanitizing) of the processing area, processing and maintenance equipment, and personnel, and then do the raw products. The establishment’s Sanitation SOP and their GMP or prerequisite program should address employee hygiene and traffic control during operation to prevent cross contamination and insanitary conditions.
- 10. Eliminate standing water which can facilitate the spread of *L. monocytogenes* into other areas of the plant. Sanitizer boluses can be used to sanitize standing water on a continuing basis.

### **IV. Employee Hygiene**

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

- 1. Employee responsibilities and actions should include:
  - a. Use a 20 second hand wash, allowing the soap suds to be in contact with the hands for this period of time, after using restroom facilities.
  - b. Wash hands before entering the work area, when leaving work area, and before handling product.
  - c. If gloves are worn:
    - i. Gloves that handle RTE product must be disposable.
    - ii. Dispose immediately and replace if anything other than product and food contact surface is touched.
    - iii. Dispose of gloves when leaving the processing line.
  - d. Remove outer clothing when leaving RTE areas.
  - e. Do not wear RTE clothing inside restrooms or cafeterias.
  - f. Do not store soiled garments in lockers.
  - g. Do not eat in the locker room or store food in lockers because food may attract insects and vermin.
  - h. Do not store operator hand tools in personal lockers. This equipment must remain in the RTE area at all times.
- 2. Management responsibilities should include:
  - a. Providing hand washing facilities at proper locations.
  - b. Ensuring the employee receives proper hygiene instruction before starting – use of hand soaps and sanitizers, no-touch dispensing systems, and boot and doorway sanitizing systems.
  - c. Developing a system for monitoring employee hygiene practices.
  - d. Developing a system for tracking the training, testing, and certification.



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e. Retraining employees before placing back into production if they are absent from the job or have failed to follow acceptable hygiene practices. This will help ensure that the employees are following current, acceptable hygiene habits.

### **V. Sanitizers**

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

The concentration and application processes for all sanitizers approved for use in meat and poultry establishments. 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:

- a. Product Description
- b. To Use – Instructions on how to use the product
- c. Properties
- d. Safety Information

### **VI. Sources and Control of *Listeria monocytogenes* Contamination**

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

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

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:

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- 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

1. Validate that the cleaning and sanitizing procedures are effective.
2. Maintain equipment and repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.
3. Implement a microbial sampling program to monitor and detect sources of *L. monocytogenes* in the environment. Environmental testing is more effective than product testing alone to monitor and detect *Listeria* in the environment. For positive test results, conduct intensified cleaning and other necessary corrective actions. Follow up with intensified and targeted testing of implicated sites.
4. Design a sampling scheme to locate a niche before *L. monocytogenes* becomes established.
  - a. Determine the physical area to sample. Use prior experience with processing conditions and observation of cleaning and sanitizing procedures and equipment to determine the most likely source of contamination. For example, the use of high water pressure during cleaning may embed *L. monocytogenes* into parts of the equipment that are hard to clean effectively. The cleaning and sanitizing procedures also should be monitored to assure that the established procedures are being followed. All surfaces of processing equipment should be sampled but with a bias toward those areas identified as possibly problematic.
  - b. Take 10 samples per line, with a maximum of 50 samples. The samples should include both food contact and non-food contact surfaces.
  - c. Review at least the last month of results to determine trends or to revise sampling scheme.
  - d. When a problem area is detected, take corrective action on the affected processing line as opposed to adjacent lines in the area. Target the area corresponding to the line associated with the findings for intensified cleaning. Contamination is usually line specific unless a vector in the system is present (e.g., an employee contaminates multiple sites; a common surface prior to splitting the lines is contaminated).

### Equipment Design

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

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

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3. Select equipment designed to minimize sites on the exterior or interior where *L. monocytogenes* can grow.
4. Select equipment designed to enhance cleaning.
5. All areas and parts should be accessible for manual cleaning and inspection or be readily disassembled.
6. Closed conveyor designs are more difficult to clean. Equipment on the processing line should be as easy to clean as possible.
7. Avoid hollow conveyor rollers and hollow framing. If hollow material is used, have a continuous weld seal instead of caulk.
8. Select food contact surfaces that are inert, smooth and non-porous.
9. Equipment should be self-draining or self-emptying.
10. 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.
11. Maintain equipment and machinery by adopting regular maintenance schedules.
  - a. Damaged, pitted, corroded, and cracked equipment should be repaired or replaced.
    - i. Repair parts or machinery in a manner to prevent food deposits that are not easily removed with normal cleaning.
    - ii. Use separate tools for RTE equipment only. Sanitize them before and after each use.
  - b. If compressed air is used, maintain and replace in-line filters regularly.
  - c. Use lubricants that contain listericidal additives such as sodium benzoate. *L. monocytogenes* can grow in lubricants that are contaminated with food particles.
  - e. Use the appropriate cleaners and sanitizers on surfaces or equipment.
12. Control the Environment During Construction If possible, suspend operations during construction. Otherwise:
  - a. Dust from construction can be difficult to detect and control. Therefore, increased monitoring of product, food-contact surfaces, and the environment is recommended during and after these disruptive events.
  - b. Establish negative air pressure in the construction area in order to ensure that air does not flow from the construction area into the plant.
  - c. Temporary partitions can be established to protect the undisturbed areas of the plant from construction dust and debris.
  - d. Cover any construction debris when moving out of the construction area.
  - e. Do not move debris through RTE processing areas or areas that directly connect to RTE processing areas, if possible.
  - f. Schedule construction during non-processing hours.
  - g. Conduct intensified cleaning and monitoring of food contact and environmental surfaces.
13. Control the Environment After Construction
  - a. Schedule removal of all construction equipment, barriers, and final debris after production hours.
  - b. Perform a thorough clean-up and increased sanitation sampling at pre-operation inspection.
  - c. Continue intensified cleaning and monitoring of food contact and environmental surfaces until 3 consecutive negative tests on the food contact surfaces for 3 consecutive days.

# **Control of *Listeria monocytogenes*, Alternatives 1, 2, 3**

## **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.

### **1. Food Contact Surface and Environmental Testing**

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

Generally, no more than 5 samples may be composited because when samples are composited, it becomes more difficult to trace the source of contamination. In addition, it is recommended that like or similar surfaces should be composited (e.g., food contact surfaces with other food contact surfaces, etc.). The individual locations for the composite sample should be noted to assist in determining the site of contamination to facilitate follow-up testing in case a positive is obtained. Environmental samples other than food contact surface samples should be sampled by the establishment. This will also assist the establishment in locating potential sources of contamination. The establishment is encouraged to hold all products being tested until the test results are received. This will prevent exposure of the consumer to a potential food hazard. Retaining the product being tested also will eliminate the cost of a recall to the establishment.

a. Alternative 1 – Use of a post-lethality treatment and an antimicrobial agent or process that limits growth of *L. monocytogenes*.

- i. Conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least twice a year. This low frequency of testing is recommended because the post-lethality treatment and the antimicrobial agent and process are expected to reduce and inhibit the growth of *L. monocytogenes* in the product.
- ii. Sample at least 1 square foot area for each surface, if possible.
- iii. Record the test results.
- iv. If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like or organisms:
  - (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
  - (2) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot that came in direct contact with a food contact surface would not summarily be considered adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing *L. monocytogenes*, and documented in the establishment's HACCP plan.
  - (3) Record the corrective actions taken.

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- (4) Retest the food contact surface.
  - (5) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms.
  - (6) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode.
- b. Alternative 2 - Use of a post-lethality treatment or an antimicrobial agent or process that limits growth of *L. monocytogenes*.
- i. If a post-lethality treatment is used, conduct tests of food contact surfaces for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms at least quarterly. This recommended frequency is 2 times that for Alternative 1 because in this case, the product only receives one of the interventions.
    - (1) Sample at least 1 square foot area for each surface, if possible.
    - (2) Record the test results.
    - (3) If test results are positive for *L. monocytogenes*, *Listeria* spp. or *Listeria*-like organisms:
      - (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
      - (b) If the FCS test is positive for *L. monocytogenes*, the product that came in direct contact with a food contact surface would not summarily be considered adulterated, because the post-lethality treatment should have been validated and thus shown to be effective in eliminating or reducing *L. monocytogenes*, and documented in the establishment's HACCP plan.
    - (c) Record the corrective actions taken.
    - (d) Retest the food contact surface.
    - (e) Repeat corrective action and testing until samples are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
    - (f) Initiate intensified environmental sampling after 2 consecutive positives, because this shows that the contamination was not eliminated by the corrective actions, and that there might be some other serious problems. FSIS will likely be looking at the support documentation following the first positive to see what the establishment did to justify that the product was not adulterated, particularly if there is evidence of harborage. Establishments should be on the preventive and reactive mode
- c. Alternative 3 – Use of sanitation control measures and testing to prevent contamination of product with *L. monocytogenes*. (Sampling is required in this case)
- i. For establishments that produce non-deli or non-hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted once a month for large, small or very small volume establishments.
  - ii. For establishments producing deli and hotdog products, tests for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms should be conducted at least four times per month per line for large volume establishments, two times per month per line for small volume establishments, and once per month per line for very small (or low) volume establishments. FSIS regards production volume as a more important risk factor than establishment's size and intends to use volume as one of the primary triggers for when considering its verification activity. For now, regarding deli meat and hotdog operations, FSIS is considering the break point between high volume and low volume to be approximately 1.3 million pounds yearly, as derived from the RTE survey.
  - iii. Sample at least 1 square foot area for each surface, if possible.

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- iv. Record the test results.
- v. If the first test result of a food contact surface is positive for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms, take corrective actions (as specified in the HACCP plan, Sanitation SOP or prerequisite program) and record.
  
- vi. If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
- vii. Each time a FCS tests positive, take corrective action, including intensified cleaning and sanitizing, and retest FCS area.
- viii. For establishments producing hotdog or deli meat products, if the second test result of a food contact surface is positive for *L. monocytogenes*, *Listeria* spp., *Listeria*-like organisms:
  - (1) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include intensified cleaning and sanitizing.
  - (2) If the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
  - (3) Record the corrective actions taken.
  - (4) Hold the product (see hold-and-test scenario below and in Attachment 6).
  - (5) Test product for *L. monocytogenes* at a rate that provides a level of statistical confidence that the product is not adulterated.
  - (6) Conduct follow-up test of the food contact surface each day until the test result is negative for *Listeria* spp., *Listeria*-like organisms.
  - (7) At the same time, continue to hold each day's production lot until the test results for the food contact surfaces are negative.
  - (8) If the test results for the product are positive for *L. monocytogenes*,
    - (a) Destroy the product, or
    - (b) Re-work the product with a process that is destructive to *L. monocytogenes*.
  
- ix. For establishments producing products other than hotdogs or deli meats, if the third consecutive test of food contact surfaces is positive for *Listeria* spp., or *Listeria*-like organism (sampling is required in this case):
  - (a) Take corrective action (as specified in the HACCP plan, Sanitation SOP or prerequisite program), which should include an intensified cleaning and sanitizing.
  - (b) In addition, if the FCS test is positive for *L. monocytogenes*, the product in the sampled lot would be considered adulterated because of the high probability of transfer of the pathogen to the product.
  - (c) Record the corrective actions taken.
  - (d) Hold the product.
  - (e) Test product for *L. monocytogenes*.
  - (f) Retest the food contact surface.
  - (g) Repeat corrective action and testing until food contact surface test results are negative for *L. monocytogenes*, *Listeria* spp., or *Listeria*-like organisms.
  - (h) If the test results for the product are positive for *L. monocytogenes*,
    - (i) Destroy the product, or
    - (ii) Re-work the product with a process that is destructive of *L. monocytogenes*.

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

- a. Review the cleaning and sanitizing procedures, including the types of cleaning agents.

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- b. Review traffic control patterns, equipment layout and adherence to employee hygiene procedures.
- c. Locate niches
  - i. Repeated, non-consecutive positives usually indicate the presence of a niche or harborage site for *L. monocytogenes*
  - ii. Increase testing of the positive site including individual pieces of equipment to locate the source of the contamination
- d. Thoroughly clean and sanitize the individual parts.
  - i. Intense scrubbing is necessary to breakup or dislodge a biofilm.
  - ii. A change of cleaning or sanitizing solutions may be indicated.
  - iii. Fogging of the equipment or room with a sanitizer such as quaternary ammonium compounds could be used if problems persist.
- e. Reassemble and test again during operation until the FCS test negative on consecutive tests.

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

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

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

	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