Voluntary Guidelines of

Sanitation Practices

Standard Operating Procedures

and Good Retail Practices

To Minimize Contamination and

Growth of Listeria monocytogenes

Within Food Establishments

Developed by the 2004 - 2006

Conference for Food Protection

Listeria monocytogenes Intervention Committee
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Introduction

Listeria monocytogenes (Lm) is a bacterium that can cause listeriosis, a serious disease that is primarily transmitted through foods. It is a ubiquitous microorganism that can be introduced into foods at multiple points in the food chain. Despite the wide occurrence of Lm in homes (people, pets and the environment), in foods, in food manufacturing facilities, and in food establishments, the incidence of listeriosis in the U.S. is low (less than 1,000 cases per year), but the mortality rate is estimated to be 20 % or higher. Extensive controls in the manufacturing of ready-to-eat foods have been responsible, in part, for reducing contamination of foods and a decreasing incidence of listeriosis.

Food establishments are very different from processing plants. They are open to the public, with customers, salesmen, employees and deliveries coming into the food establishment throughout the day. These situations increase the opportunity for Lm to be introduced. Therefore, it is very important that food establishment operators utilize active managerial control to implement appropriate procedures that minimize the potential for Lm contamination of ready-to-eat foods within their facilities.

Vigilant active managerial control is a key part in reducing the risk of listeriosis. Active managerial control means the purposeful incorporation of specific actions or procedures by industry management into the operation of their business to attain control over foodborne illness risk factors. It embodies a preventive rather than reactive approach to food safety through a continuous system of monitoring and verification. Every food establishment needs to have active managerial control of risk factors associated with foodborne illness. This may be achieved through training programs, manager oversight, and standard operating procedures. For example, some establishments incorporate control measures into individual recipes, production schedules, or employee job descriptions.

The FDA/FSIS L. monocytogenes Risk Assessment categorized the relative risk of ready-to-eat foods with respect to foodborne listeriosis. Ready-to-eat foods were placed into categories ranging from very high to very low risk. Food establishment operators can use these categories to identify specific foods, and related areas and equipment within their facilities that should be the focus for Listeria control measures.

The L. monocytogenes Risk Assessment identified very high and high risk foods to include: deli meats, unheated frankfurters, soft unripened cheeses, high fat and other dairy products, pasteurized fluid milk, pâté, meat spreads, unpasteurized fluid milk, and smoked seafood. It is important to note that the risk assessment did not address all ready-to-eat foods, and any food that supports the growth of Lm at refrigerated temperatures may also have the potential to cause listeriosis.
Risk factors may be managed without the use of formal record keeping; however, some food establishments may want to develop written records to ensure that monitoring is being performed using the correct method and at the proper frequency, and corrective actions are taken immediately. To minimize the risk of listeriosis, food establishment operators should keep refrigerated foods as cold as possible and limit their storage time; take steps to prevent contamination during in-store handling and storage, and target sanitation procedures to those areas most likely to be sources of $Lm$. Specific information on controlling $Lm$ in food establishments, with emphasis on these areas, is provided in this document.

**Targeted Sanitation Procedures**

*Listeria monocytogenes* ($Lm$) is found almost everywhere and can be present in most environments, including the soil, plants, humans, equipment, animals, foods, drains, and supplies. The categories listed below identify areas that could likely harbor $Lm$ within a retail food establishment. The items listed in the “areas of concern” category would generally have a higher probability of $Lm$ contamination than the items listed in the “additional areas that could require special attention” category. The items listed below are not exclusive and every operator should do an evaluation to identify specific areas and priorities within their own operation.

**Areas of Concern**

**Food Contact Areas:**
- Slicers
- Cutting boards
- Knives, knife racks, tubs, bowls, platters and utensils
- Food containers and trays in display cases and refrigerators
- Food contact surfaces inside display cases

**Non-Food Contact Surfaces:**
- Floors, drains, in preparation areas
- The interior of display cases and walk in coolers, specifically condensate, drip pans, drains and door tracks
- Cleaning tools for food contact surfaces, such as brushes and cleaning cloths
- Cleaning tools such as mops and buckets
- Wet floors, standing water

**Additional Areas That Could Require Special Attention**
- Door handles and handles of equipment
- Pallets, pallet jacks
- Push carts, especially the wheels
- Exterior of equipment or unused equipment
• Maintenance tools
• Non-disposable gloves, such as cleaning or safety gloves
• Walls and ceiling
• Hollow table and/or equipment legs/supports
• Seams and seals around cooler, freezer and refrigerator doors
• Trash containers
• Air filters, blowers, vents and fans
• Motor housings on food processing equipment
• Unsealed joints in food preparation areas, such as riveted information tags or plates on equipment
• Scales
• Food wrapping machines
• Hand contact surfaces, such as on-off switches, knobs, handles, phones, and intercoms.
• Hoses and nozzles
• Ice machines and the drain areas under and behind ice machines

Maintenance Concerns
• Defective walls and ceilings, overhead pipes
• Worn or cracked rubber seals around doors
• Cracked hoses
• Defective and unused equipment
• Bringing in used equipment from another location to replace broken equipment

Cleaning and Sanitizing Practices
The primary focus should be on sources most likely to cause contamination in high-risk food preparation areas. Refer to the list above, identified in the food contact and non-food contact sections.

All equipment should be easily cleanable and free of defects. Equipment should comply with the specifications listed in the FDA and CFP Food Establishment Plan Review Guide (http://www.cfsan.fda.gov/~dms/prev-toc.html). Remove any defective or unused equipment from food preparation areas.

Sanitation programs to specifically address Lm consists of three actions:
1. Effective removal of soil
2. An effective rinse step
3. Proper application of a sanitizing agent, which includes contact time, concentration and temperature.

Cleaning effectiveness depends upon the formulation and how the product is used and various other issues specific to the cleaning being attempted, such as type of soil, water hardness, tools used, and even the training on the proper procedure and the execution of the procedure by the person doing the cleaning.
A food establishment should implement written procedures for proper cleaning and sanitizing food contact and non-food contact surfaces. These procedures should include the frequency of cleaning, chemicals to use, instruction on how to perform the task, and the steps to verify it is being done correctly. A visual examination should be done of all food contact surfaces before the start of operations to ensure appropriate compliance with cleaning procedures and to take corrective action if necessary.

Written procedures for food establishments should include the cleaning and sanitizing of maintenance tools. Maintenance tools and ladders can easily get contaminated and can transfer *Lm* from one area to another if not cleaned and sanitized appropriately. Store maintenance tools and ladders away from food, food contact equipment, utensils, and food packaging material.

The cleaning and sanitizing procedures should also include floor drains in food preparation areas. Remove the drain cover and basket; remove all debris and discard into the trash container. Use a drain brush to scrub and remove organic material from the drain hole. Use quaternary ammonium compounds to sanitize the floor and drain area. Consider using bactericidal drain rings where ready-to-eat food is prepared and stored. Enzymatic cleaners can also be effective in removing organic material, prior to sanitation.

Only a dry cleanup should be done during food production. Splash from a wet cleanup can easily contaminate a cleaned surface. Splash can aerosolize and spread contamination throughout the entire area. Avoid mid-shift wet cleanup because it can produce aerosols and add water in the food preparation area.

Use only low pressure or foaming hoses rather than high-pressure sprays. Do not use low-pressure hoses for cleaning during food preparation or when there is any exposed food, equipment, utensils or food packaging. Low-pressure foaming guns and sanitizer rinse guns may be used only after removal or protection of all foods, previously cleaned equipment, and single service articles. Remove or protect all food from contamination before cleaning display cases or coolers. Keep the area where food-packaging and wrapping material is stored clean.

Clean as you go; remove food spills quickly. Bacteria like cool damp areas, so limiting standing water helps control *Lm* and most other bacteria. Bacteria from wet areas can easily be transferred to employee shoes, carts or other equipment if not wiped up quickly.

**Sanitizers**

All cleaners and sanitizers used in a food establishment must have at least the following information: product description, instructions on how to use the product, properties, yield or effective concentration, and safety information.
Sanitizing agents shall be used in accordance with EPA-approved manufacturer’s label use instructions. Effective sanitization can be achieved only when preceded by thorough cleaning and rinsing steps.

Cleaning Frequencies
A master-cleaning schedule should be developed for each facility to include all food and non-food contact surfaces. Follow equipment manufacturer’s instructions to assure complete disassembly and thorough cleaning of all equipment parts. Cleaning and sanitizing frequencies are listed in the FDA Food Code.

Additional Important Information
Minimize splash from hoses into floor drains. Plugged drains must be repaired immediately. Do not place equipment over floor drains. This practice would make it difficult to clean the floor drain and could result in equipment contamination during cleaning or drain backups.

Avoid pooling of water on low spots of floor in food prep areas and walk-in coolers. Also, avoid collection of water beneath service and display cases from condensate or water trapped under cases following case or floor cleaning.

Avoid water accumulation in condensate pans in service cases or coolers, which may potentially fall on open product.

Never clean display cases or coolers until all food is removed or protected from contamination.

Damaged, pitted, corroded or cracked equipment cannot be used and must be repaired or replaced. Do not repair equipment on site without protecting food and food contact surfaces. Avoid keeping unused equipment in food preparation areas.

Avoid floor cracks and other floor surfaces in disrepair that can harbor bacteria.

Never use cleaning tools used in raw food production for cleaning in ready-to-eat food preparation areas. Consider color-coding these items.

Direct hand contact with previously cleaned surfaces and food products after touching unclean surfaces is prohibited.

Prevent poor employee practices and inadequate cleaning by providing appropriate employee training.
Time and Temperature Control

*Lm* is unlike most other foodborne pathogens due to its ability to grow under refrigeration temperatures. *Lm* can grow in temperatures ranging from 31° F to 113°F. The organism grows best between 70° F and 100° F and slows down considerably at lower temperature such as those used in refrigeration. Although the Food Code requires that refrigerated foods be held at 41°F or below, the colder the temperature of the food, the greater the impact on limiting growth of *Lm*. It is important to get foods cold quickly and to keep them cold. If low levels of *Lm* are accidentally present in a ready-to-eat food item that supports growth, over time the organism can multiply to higher numbers and pose a significant risk of illness. A system of controls should be in place to limit the cold storage time for foods that support growth of *Lm*.

Temperature Control for Receiving
Temperature checks should be made of refrigerated deliveries. Frozen food should be solidly frozen and refrigerated food should be 41° F or below, unless a higher temperature is permitted by law. Report any high temperature problems to management immediately.

Consider using temperature-monitoring devices or time-temperature indicators (TTI) to ensure proper temperature control during shipment and storage.

Minimize the time that delivered food remains un-refrigerated. Potentially hazardous foods (time/temperature control for safety food) should be placed into cold storage immediately. The goal is to ensure that food products remain at temperatures that minimize growth of pathogens such as *Lm*.

Refrigeration and Freezer Units
All refrigeration units should have adequate capacity and sufficient air circulation to maintain product temperatures of 41° F or below. Freezers should be capable of keeping foods frozen solid.

Cold holding units for storage and display must be equipped with at least one permanently affixed accurate thermometer that is located to allow for easy viewing by food employees. The temperature of the warmest part of the refrigeration unit should be monitored. (See the FDA Food Code Section 4-204.112) Larger food establishments might consider using temperature recording devices and refrigeration alarm systems.

Cold holding units should not be loaded beyond the designated display load line, nor should vents be blocked to prevent proper air-flow in the cold holding units. Do not alter any shelving without verifying that proper air-flow and temperatures are not adversely affected.
Keep all refrigerated units and freezer doors closed whenever possible. Keeping the doors open may result in higher temperatures that could increase the potential for growth of *Lm*.

Improper sanitation/maintenance, accent lighting, warm air currents within the store and loading the case with warm product may affect the ability to maintain proper product temperatures within refrigerated cases.

**Time/Temperature Controls**

During cold storage, refrigerated units must be set low enough to keep foods that require time temperature control for safety (TCS) at temperatures of 41° F or below. The FDA/FSIS Risk Assessment on *Lm* in RTE foods demonstrated that this would have the biggest impact on preventing listeriosis.

Maintain a product rotation system based on the manufacturer’s date code or recommended shelf life, using the product with the shortest remaining shelf life first.

FDA guidelines recommend that certain ready to eat potentially hazardous foods (time/temperature control for safety), be date marked with a storage time of 7 days or less once opened or prepared in a food establishment and is stored at 41° F or below for more than 24 hours. (See the FDA Food Code Section 3-501.17) **Check with your state or local regulatory authority for specific requirements on Date Marking.**

Minimize the time refrigerated foods are kept at room temperature. For temperature control during preparation, work with only small batches, and limit the time that potentially hazardous foods (time/temperature control for safety) are held at room temperature in order to minimize growth of pathogens such as *Lm*.

FDA guidelines allow for a working supply of refrigerated potentially hazardous foods (time/temperature control for safety) that are displayed or held for service for immediate consumption to be safely kept out of temperature control for a limited time. The food must be marked with the time it was removed from temperature control and cooked and served, served, or discarded within six (6) hours. The food must have an initial temperature of 41° F or less when removed from temperature control and may not exceed 70° F. Written procedures must be maintained in the food establishment. (See the FDA Food Code Section 3-501.19) **Check with your state or local regulatory authority for specific requirements for the use of Time as a Public Health Control.**

Every food establishment needs to have active managerial control of risk factors. Active managerial temperature control can be applied by incorporating a plan to monitor temperatures along every step in the process. Follow FDA Food Code guidelines for proper cold holding, thawing, cooking, hot holding and cooling.
requirements. Control measures must include taking corrective action immediately when food exceeds the required temperature.

**Contamination**

Since *Lm* is present in many environments, it is extremely difficult to eliminate it completely in food establishments. Employees and incoming raw materials or products may easily reintroduce *Lm* into the food establishment. Unclean equipment and poor sanitation can result in the transfer of *Lm* onto ready-to-eat foods. The widespread nature of this organism mandates a systematic approach for control.

**Preventing Cross Contamination of Ready-To-Eat Foods by Raw Foods**

Ensuring complete separation of raw and ready-to-eat foods throughout all areas of receiving, storage, preparation, display, and service is ideal for preventing contamination.

If space is limited where raw and ready-to-eat foods are kept in the same area, separation can be achieved by using sufficient physical space, physical dividers, different production times for raw and ready-to-eat food items with a complete cleaning and sanitizing in between, or storing raw foods below ready-to-eat foods.

Color-coding of cutting boards, handles on knives, tongs and utensils can be a useful visual reminder for keeping food contact surfaces that touch raw foods separate from those that touch ready-to-eat foods.

**Preventing Contamination of Ready-To-Eat Foods From Other Sources**

Food and packaging material must be protected from contamination during storage and display. Store food and food packaging material in a clean, dry location protected from overhead contamination. These items must be stored at least six inches above the floor on shelves, racks, pallets, or other means to avoid moisture absorption and to facilitate cleaning and pest control.

Food or food packaging material should not be stored below dripping or leaking condensate.

Pallets, boxes, shipping containers or other items from outside the food establishment should not be brought directly into ready-to-eat food preparation areas, since they may be a source of *Lm* contamination.

Foot traffic into food preparation areas should also be controlled, since shoes might be a source of *Lm* contamination. Do not allow maintenance personnel, sales people, customers, visitors, or other unauthorized individuals into areas where ready-to-eat food is being prepared unless they have followed proper preventative procedures.
Maintenance personnel’s clothing, tools and equipment such as ladders can also be a source of contamination. So their access into food preparation areas must be limited. Food and food packaging materials must be removed or otherwise protected during any necessary maintenance activities. Food processing equipment that may have been contaminated during any maintenance activities must be cleaned and sanitized prior to use. Whenever possible, defective equipment should not be repaired in a food preparation area.

Garnishes may also be a source of contamination. To reduce this risk, fresh garnishes should be thoroughly washed if they come in contact with ready-to-eat foods and replaced regularly. Plastic garnishes should be cleaned and sanitized between uses.

Minimize adding to or topping off ready-to-eat foods while on display. If this is not possible, a system should be in place to ensure a complete break in the cycle of commingling ready-to-eat food products. The timeframe should be seven (7) days or less from the time the first ready-to-eat food was prepared and placed on display. The temperature of the commingled ready-to-eat product must be kept at 41°F or below.

As noted previously, wet cleaning and sanitizing should only take place after all exposed food and packaging products have been removed from the area or covered to protect them from splash contamination.

When it is necessary to temporarily retain product determined to be unsaleable for any reason, it should be segregated in a designated area (morgue) separate from saleable food items. Unsaleable products may include food items that are being returned to the distributor, food items that are out of code, or food items that are damaged or spoiled.

**Employee Practices to Prevent Lm Contamination**

*Lm* can enter the food establishment on employee’s clothing, including shoes, and contaminate food through poor food safety practices. A very important factor in limiting the risk of *Lm* contamination is ensuring employees are trained and knowledgeable about the sources of contamination and practices that can minimize or prevent problems. Employees should be aware of the severity of listeriosis and the damaging impacts it could potential have on the establishment and its customers.

A written employee health and personal hygiene policy should be established. Refer to the FDA Food Code (2-2 to 2-4) for specific requirements. Employees must be trained on proper hand washing, glove usage and other practices to prevent risks related to *Lm*.

An adequate number of hand washing sinks, including a supply of soap and paper towels, must be available and conveniently accessible to all employees in
food preparation areas and restrooms. If used, nailbrushes should be cleaned and sanitized regularly.

Employees should avoid direct bare hand contact with any RTE foods. Single-service gloves or cleaned and sanitized utensils, such as tongs, spoons or ladles should be used whenever possible.

Gloves should be changed and discarded and hands washed every time the employee changes tasks or the gloves become soiled or contaminated. Gloves are never a substitute for proper hand washing.

Because employees clothing might get contaminated with *Lm*, consideration should be given to having employees wear aprons or smocks in ready-to-eat areas. Prior to leaving food preparation areas, such as leaving for breaks, eating meals or visiting toilet facilities, employees should remove aprons and smocks.

Traffic flow of employees into and out of ready-to-eat food preparation areas should be limited where possible to prevent the introduction or spread of *Lm*. When movement in and out of the ready-to-eat food area is necessary, appropriate precautions must be taken, e.g., change of outer clothing and immediate hand washing.

**Employee Training**

Knowledgeable food employees are vital to a successful food operation. All food handlers need to understand risk factors associated with receiving, storing, preparing, holding, displaying and handling food in their food establishment. Food safety training should be a part of every food establishments’ active managerial control program. Training and supervision will provide employees with the knowledge and skills necessary to follow policies and procedures designed to control critical risk factors.

It is important for food establishment operators to design and implement a food safety training program appropriate for their operation. This *Lm* guidance document can be used to assist in covering important intervention strategies.

Training should be a continual process to ensure compliance with company policies and the most current food safety practices. The training should cover at least basic information on Lm interventions, which include employee health and hygiene, proper cleaning and sanitizing, frequency of cleaning, protection against contamination, and temperature control.

Verifying the Effectiveness of Sanitation Programs

Cleaning and sanitizing are very effective means for controlling Lm in a food establishment. If surfaces or equipment become contaminated with Lm, they can transfer the organism to ready-to-eat food products. Lm can also be found throughout the environment in nooks and crannies, called niches, where it is more difficult to clean.

Every food establishment must have a cleaning and sanitation program and should have a method for verifying its effectiveness. There are different ways to verify the effectiveness of sanitation programs and often a combination of approaches can be used. When determining which method to use, consideration should be given to factors such as:

- How difficult the area is to clean
- Whether possible Lm harborage sites are present
- Whether there have been previous problems with sanitation

The person-in-charge should be responsible for ensuring that employees are properly trained for the tasks assigned to them and that they fully understand how to perform the sanitation procedures. This includes mixing and testing cleaning and sanitation solutions for proper strength, cleaning and sanitizing certain equipment according to a prescribed schedule, and checking to be sure equipment and surfaces are cleaned as needed throughout the day.

Different methods can be used to verify the effectiveness of sanitation programs, for example:

- Observation and monitoring
- Rapid sanitation tests
- Microbiological testing

These methods vary by cost and level of technical expertise needed to use them. The following is a brief description of these three methods.
Observation and Monitoring
Visual inspections, observations, tracking chemical use, monitoring records and reviewing cleaning charts are simple, inexpensive and effective methods to verify compliance with cleaning procedures. Store management, internal food safety auditors, chemical suppliers, or third party audits can be used to conduct the visual observations.

Rapid Sanitation Tests
Rapid tests will give food establishments immediate results. To be of most benefit, these tests need to be done on a regular basis over time, so a food establishment should be willing to make a commitment to using this method. The results of these tests can be used for tracking trends and monitoring compliance with the sanitation program.

ATP bioluminescence and glucose tests are examples of rapid test kits. These are usually simple kits, which include a swab that is rubbed on a surface and a hand-held measuring device. These kits measure chemical components such as ATP or glucose that reflect the amount of organic matter food debris, sugars, microorganisms, etc., on a surface and provide a general indication of cleanliness.

Microbiological Testing
Before undertaking microbial testing, a food establishment should evaluate several important factors such as:

- What will be sampled
- For what organisms will the samples be examined
- When and where samples will be collected
- Where the samples will be analyzed and what criteria suggest a potential problem

A food establishment operator also needs to have a plan to address specifically what action will be taken to remedy the situation when results indicate a potential concern.

Total plate counts (TPC) and aerobic plate counts (APC) are more expensive than rapid testing and require using an internal or contract laboratory. TPC and APC can be used to assess the general level of bacteria on cleaned and sanitized surfaces. It is important to note that results from generic tests such as TPC or APC are not an indicator of the presence or absence of pathogens, including Lm. They can however provide useful information on the effectiveness of sanitation programs.

Testing the environment for Listeria species is more specific and can be useful if Listeria is suspected or known to be a problem. Listeria testing may be used as part of a foodborne illness investigation or as follow-up to a recall. It should be noted that Listeria species, and even Lm, can sometimes be found at retail.
because *Listeria* is a common environmental contaminant. When detected, the goal is to remove the organism by rigorous cleaning and sanitation.

**Sampling Protocol**
Before microbiological sampling of the environment and food contact surfaces is undertaken, a food establishment should have a written protocol in place. One of the most important factors to consider in a microbial testing protocol for *Listeria* is how a food establishment will handle a positive result. The time delay between sample collection and receiving the test result may mean that the source of the pathogen, and any potentially contaminated product, are already gone.

Additional information regarding verification of sanitation can be obtained from local regulatory authorities, sanitation vendors, private laboratories, or consultants who specialize in food safety and sanitation.

**Product Specifications and Recalls**

Food establishments should develop product specifications with their suppliers that include, where appropriate, the following:

- Environmental testing
- Ingredient testing
- Finished product testing
- Use of ingredients known to inhibit *Lm* growth

Suppliers should have a system to hold products that are being tested. Guidance for holding tested products can be found at [http://haccpalliance.org/alliance/HoldingTestedProdSept1905.pdf](http://haccpalliance.org/alliance/HoldingTestedProdSept1905.pdf).

In addition, supplier auditing should be considered to verify that the controls that have been specified are being followed. The audits can be done using in-house personnel or third party auditing firms.

In the event that a product a food establishment makes or distributes was contaminated by *Lm*, the food establishment should have a recall plan in place. This plan needs to address both of the following scenarios:

- Product received from a supplier
- Product produced by the food establishment

The plan should:

- Describe how to identify the specific product(s) involved
- Identify how the distribution of the product is determined
- Specify how customers are to be notified
- Contain a draft letter/press release
The letter should contain language about \( Lm \) that is acceptable to the regulatory agencies. Sample letters are available at [http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html](http://www.fda.gov/ora/compliance_ref/recalls/recallpg.html)

When conducting a recall:

- Clearly identify the product(s). Include pictures of the packaging and coding if available.
- Segregate recalled product from previous or subsequent “safe” food. Refer to the FDA Food Code section 6-404.11 ([http://www.cfsan.fda.gov/~dms/fc01-6.html#6-4](http://www.cfsan.fda.gov/~dms/fc01-6.html#6-4))
- Give specific directions to customers on how to handle the recalled product: for example, destroy, return, or hold and segregate for pick-up.

For further information about recalls of FDA regulated foods see [http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm](http://www.fda.gov/ora/compliance_ref/recalls/ggp_recall.htm).

Additionally, Subpart C of Part 7 of FDA regulations (21 CFR 7.40-59) provides general guidance for the voluntary recall of products, including those recalls initiated by a firm on its own and at FDA’s request.
