Sanitation Practices Standard Operating Procedures and Good Retail Practices to Minimize Contamination and Growth of *Listeria monocytogenes* within Food Establishments

Second Edition

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Introduction

Listeria monocytogenes is a bacterium that can cause listeriosis, a serious disease that is primarily transmitted through foods and that can be introduced into foods at multiple points in the food chain. Despite the wide occurrence of *L. monocytogenes* in homes, in foods, in food manufacturing facilities and in food establishments, the incidence of listeriosis in the U.S. is low with an estimated 1,591 foodborne disease cases per year and 255 deaths (Scallan et al., 2011) and details on recent *L. monocytogenes* multistate outbreaks can be found on CDCs website. 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 as defined by the FDA 2013 Food Code are very different from food processing plants. Food establishments are defined by the Food Code to be retail and foodservice establishments like grocery stores and restaurants. This guidance document is written to be relevant for all food establishments. They are open to the public, with customers, employees and others (e.g., contractors, delivery personnel) coming into the food establishment throughout the day. These situations increase the opportunity for *L. monocytogenes* to be introduced. Therefore, it is very important that food establishment operators utilize active managerial control (AMC) to implement appropriate procedures that minimize the potential for *L. monocytogenes* contamination of ready-to-eat foods within their food establishment.

Vigilant AMC is a key part in reducing the risk of listeriosis. AMC means the purposeful incorporation of specific actions or procedures by establishment management into the operation of their business to attain control over foodborne illness risk factors, as defined in the 2013 Food Code Annex 4, on pg. 549. It embodies a preventive rather than reactive approach to food safety through a continuous system of risk assessment, monitoring, and verification. Every food establishment needs to have AMC 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/Food Safety and Inspection Service (FSIS) 2003 *L. monocytogenes* Risk Assessment categorized the relative risk of ready-to-eat foods with respect to foodborne listeriosis. Ready-to-eat (RTE) foods were placed into categories ranging from very high to very low risk. The risk assessment identified very high and high risk foods to include: deli meats, unheated frankfurters, soft un-ripened cheeses, high fat and other dairy products, pasteurized fluid milk, pâté, meat spreads, unpasteurized fluid milk and smoked seafood. Food establishment operators could use these categories to identify specific foods and related areas and equipment within their establishments that should be the focus for *Listeria* control measures. 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 *L. monocytogenes* may have the potential to cause listeriosis.

The USDA FSIS/FDA Center for Food Safety and Applied Nutrition (CFSAN) Interagency Retail *Listeria monocytogenes* Risk Assessment Workgroup published a more recent risk assessment focused on *L. monocytogenes* in retail delicatessens in 2013. The purpose of the risk assessment was to provide a quantitative, scientific assessment of the risk of listeriosis posed by consumption of RTE foods prepared and sold in delicatessens inside of retail food stores and to mathematically model how that risk might be impacted by changes in practice.

There were five key findings from the 2013 risk assessment regarding the control of *Listeria:* (i) Practices that prevent bacterial growth dramatically reduced the predicted risk of listeriosis. (ii) Cross contamination by *L. monocytogenes* in the retail environment dramatically increased the predicted risk of listeriosis. (iii) Increasing *L. monocytogenes* concentration in incoming product increased the predicted risk of listeriosis, whether or not the contaminated RTE product itself supported growth. (iv) Sanitation practices that eliminate *L. monocytogenes* from food-contact surfaces resulted in a reduction in the predicted risk of illness. (v) Control of *L. monocytogenes* cross contamination at the slicer reduced the predicted risk of listeriosis.

Risk factors may be managed in a variety of ways; 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 that corrective actions are taken immediately. To minimize the risk of listeriosis, food establishment operators should know their suppliers and only buy foods from approved sources; 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 harbor *L. monocytogenes*. Specific information on controlling *L. monocytogenes* in food establishments, with emphasis on these areas, is provided in this document.

Targeted Sanitation Procedures

L. monocytogenes can be found almost everywhere and may be present in food establishments. Sanitation is an important means of controlling *L. monocytogenes*.

When developing a sanitation program, specific areas and equipment should be targeted. Scientific studies have shown specific areas and equipment can provide niches and harbor *Listeria* or are more vulnerable to *Listeria* contamination. The items listed below are not exclusive and every operator should identify specific risk areas and priorities within their own operation.

Food Contact surfaces

- 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, walls, coving and drains in preparation areas
- The interior of display cases and walk in coolers, specifically condensate, drip pans, drains, door tracks, light housings and bottom decks over fans and condensers
- Cleaning tools for food contact surfaces, such as brushes and cleaning cloths
- Cleaning tools such as mops, buckets and squeegees
- Three compartment sink
- Wet floors, standing water
- Prep sinks
- Floor wall juncture below and adjacent to sink drains
- Storage containers, including milk crates

Other items

Additionally, other items should be considered when developing a targeted sanitation program for *Listeria*. These may include:

- 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
- Ceilings
- Hollow table and/or equipment legs and 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
- Drain back-ups, toilet back-ups and roof leaks

The following should be properly installed, maintained and in good repair:

- Floors, coving and walls
- Gaskets and rubber seals in equipment and around doors

- Condensation units and drain lines
- Hoses
- Drains

Storing defective and unused equipment in food preparation areas and bringing in used equipment from another location to replace broken equipment, all raise potential *Listeria* concerns due to the potential for harborage and cross-contamination.

Cleaning and Sanitizing

Practices

The primary focus of cleaning and sanitizing should be on sources most likely to cause contamination in high-risk food preparation areas, as identified in the food contact and non-food contact sections above.

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.

Cleaning effectiveness depends upon the cleaning compound formulation and use conditions as well as and various other issues. Those issues are specific to the type of cleaning being attempted, the type of soil, water hardness, tools used, the training and 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, instructions 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 actions if necessary.

Cleaners

All cleaners used in a food establishment should have a product description, instructions on how to use the product, an effective concentration and safety information. Cleaners should be used according to a Sanitation Standard Operating Procedure (SSOP) specific to a location or piece of equipment being cleaned.

Cleaning Frequencies

A cleaning schedule should be developed for each establishment 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. Recommended cleaning and sanitizing frequencies are listed in the FDA Food Code.

Consider cleaning as you go and remove food spills quickly. Bacteria like cool damp areas; so limiting standing water helps control *L. monocytogenes* 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 sanitizers used in a food establishment should have a product description, instructions on how to use the product, an effective concentration and safety information. Sanitizing agents must be used in accordance with EPA-registered manufacturers label use instructions. Appropriate test kits should be available and in use. Effective sanitization can be achieved only when preceded by thorough cleaning and rinsing steps. The cleaning and sanitizing procedures should also include floor drains in food preparation areas (e.g., remove the drain cover and basket; remove all debris and discard into the trash container, use an appropriate procedure to remove organic material from the drain hole). Enzymatic cleaners may also be effective in removing organic material, prior to sanitation. Use an EPA registered product to sanitize the floor and drain area. Consider using bactericidal drain rings in drains located where ready-to-eat food is prepared and stored.

Additional Miscellaneous Cleaning Information

Minimize splash from hoses into floor drains. Plugged drains should be repaired immediately. Do not place equipment over floor drains, as this practice would make it difficult to clean the floor drain and could result in equipment contamination during cleaning or drain backups. Consider using 'best practices' when cleaning drains (e.g., controlling splash, use a drain brush with bristles smaller than the diameter of the drain line, clean/sanitize the drain brush itself).

Only a dry cleanup (i.e., clean up without the use of water) 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 materials are stored clean.

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

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

Damaged, pitted, corroded or cracked equipment cannot be used and should 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.

Maintenance and other service providers can be a source of cross contamination so written procedures should define the areas within the food establishment where they are permitted during food preparation. Written procedures for food establishments should include the cleaning and sanitizing of maintenance tools. Maintenance tools and equipment (e.g., ladders) can become contaminated and can transfer *L. monocytogenes* from one area to another if not cleaned and sanitized appropriately. Store maintenance tools and equipment away from food, food contact equipment, utensils and food packaging materials. Repairs that are performed on food contact surfaces and equipment should be cleaned and sanitized after repair and before being reinstated/reinstalled for use.

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

Cleaning tools used in raw food production should never be used for cleaning in ready-to-eat food preparation areas. Consider color-coding these items to distinguish between raw and ready-to-eat and using separate color coded tools for cleaning of toilet rooms.

Take care to insure that hands or gloved hands do not contact clean surfaces and food products after touching unclean surfaces.

Prevent poor employee hygiene practices and inadequate cleaning by providing appropriate employee training. The training should include a direct observation of the employee's ability to follow the written procedure.

Time and Temperature Control

L. monocytogenes is unlike most other foodborne pathogens due to its ability to grow under refrigeration temperatures. *Listeria* 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 temperatures such as those used in refrigeration. The Food Code requires that refrigerated foods be held at 41°F or below, but the colder the temperature of the food, the greater the impact on limiting growth of *Listeria*. It is important to get foods cold quickly and to keep them cold. If low levels of *L. monocytogenes* are accidentally present in a ready-to-eat food item that supports growth, over time the organism can multiply to higher numbers and increase the risk of illness. A system of controls should be in place to limit the cold storage time for foods that support growth of *Listeria*.

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. Appropriate action should be taken in response to any high food temperature problems detected.

Calibrated temperature-monitoring devices should be used to ensure proper temperature control during shipment and storage.

Time/temperature control for safety (TCS) foods (formerly called potentially hazardous foods or PHF foods) 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 *L. monocytogenes*.

Refrigeration and Freezer Units – Holding, Storage and Display

All refrigeration units used to store TCS foods 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 should 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(A)). Food establishments might consider using temperature recording devices and refrigeration alarm systems to improve compliance. Cold holding units should not be loaded beyond the designated display load line, nor should vents be blocked to prevent proper airflow. Do not alter any shelving without verifying that proper airflow 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 *Listeria*.

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

Time/Temperature Controls – Product Handling

During cooling or cold storage, refrigerated units should be set low enough to keep TCS foods at temperatures of 41°F or below. The 2003 FDA/FSIS Risk Assessment on *L. monocytogenes* 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.

The FDA Food Code recommends that ready-to-eat TCS foods prepared and held in a food establishment for more than 24 hours shall be clearly date marked. That date marking should indicate the date or day by which the food shall be consumed, sold, or

discarded when held at a temperature of 41°F or less for a maximum of 7 days (FDA Food Code Section 3-501.17). See the Food Code for which foods are exempt from date marking. 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 TCS foods are held at room temperature in order to minimize growth of pathogens such as *L. monocytogenes*.

FDA guidelines allow for a working supply of refrigerated TCS foods that are displayed or held for service for immediate consumption to be safely kept out of temperature control for a limited time; this is referred to as using "Time as a Public Health Control." The food must be marked with the time it was removed from temperature control and cooked, served, or discarded (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.

Minimize adding to or topping off TCS ready-to-eat foods that are stored in bulk containers for display. When a topping off procedure is conducted, a system should be in place to ensure a complete break in the cycle of commingling ready-to-eat food products occurs. The timeframe should be 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 should be kept at 41°F or below. For more details see the date marking provision of the Food Code (3-501.17 Ready-to-Eat Time/Temperature Control for Safe Food, Date Marking).

Every food establishment needs to have AMC 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 recommendations. Control measures should include taking corrective actions immediately when food exceeds the required temperature.

Consumer labeling should be provided with the pack date (at the time of purchase) and information to store at temperatures below 41°F. Some retailers are providing information regarding the usable shelf life of products including 3 days for meats and 4 days for cheeses.

Retailers are in a position to proactively share food safety information with their customers because they are a credible resource and are frequently in communication with consumers. There are many resources on the topic of maintaining proper temperatures in home refrigerators and how to reduce the risk of *Listeria* contamination and these can be found in Appendix 1 of this document.

Controls Other Than Time and Temperature

Although time and temperature are the primary controls for minimizing or preventing the growth of *L. monocytogenes*, other factors such as pH and water activity can limit or prevent *Listeria* growth. It is well established that *L. monocytogenes* does not grow when the pH of the food is less than or equal to 4.4 or if the water activity of the food is less than or equal to 0.92. Foods may naturally have a pH or water activity that prevents growth of *L. monocytogenes* or may be intentionally processed to achieve these characteristics; for example, acidifying deli-type salads by the addition of vinegar or citric acid to bring the pH to less than or equal to 4.4. *Listeria* growth inhibitors can be added to food to prevent or limit *L. monocytogenes growth*; for example, some deli-meat manufacturers add inhibitors to their products. Likewise, antimicrobial substances such as sorbic acid are commonly used to prevent the growth of *L. monocytogenes* in foods such as cheeses.

Minimizing or preventing the growth of *L. monocytogenes* via pH, water activity, or the use of growth inhibitors requires knowledge of the various chemical and physical interactions that can take place in different types of food. FDA provides detailed information on how to determine if a food does not support pathogen growth based on pH and/or water activity, as indicated in reference that follows at the end of this paragraph. Some foods may fall into a category whereby a specific product assessment (PA) must be made to determine if the food can support growth. Refer to the FDA Food Code (1-2 Definitions, Time/Temperature Control for Safety Food and Annex 2, Time/Temperature Control for Safety Food) for details.

New technologies are constantly being tested and developed to further help in the effort to control *L. monocytogenes*. Among these is newly designed equipment such as cold holding cases, advanced packaging systems that incorporate antimicrobial agents and processing techniques and additives that inhibit the growth of *Listeria*.

Preventing Cross-Contamination

Since *Listeria* 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 *Listeria* into the food establishment. Unclean equipment and poor sanitation can result in the transfer of *Listeria* onto ready-to-eat foods and food contact surfaces. The widespread nature of this organism means that a system-wide approach for control may be needed.

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. Containers that held raw ingredients should not be re-used for storing other RTE ingredients without prior cleaning and sanitizing.

If space is limited where raw and ready-to-eat foods are kept in the same area, separation can be achieved by using 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 should 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 should be stored at least six inches above the floor on shelves, racks, pallets, or other means to reduce potential contamination, facilitate cleaning and aid in pest control.

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

Care should be taken when bringing items such as pallets, boxes, milk crates, shipping containers, shopping carts, etc. into ready-to-eat food preparation areas, since they may be a source of *Listeria* contamination. These items should be handled to minimize cross-contamination of food contact surfaces.

Foot traffic into food preparation areas should also be controlled, since shoes might be a source of *Listeria* contamination. Do not allow maintenance personnel, salespeople, 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. Their access into food preparation areas should be limited. Food and food packaging materials should be removed or otherwise protected during any necessary maintenance activities. Food processing equipment that may have been contaminated during any maintenance activities should 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. Fresh garnishes should be thoroughly washed if they contact ready-to-eat foods and replaced regularly. Plastic garnishes should be cleaned and sanitized between uses.

When it is necessary to temporarily retain product determined to be unsalable for any reason, it should be segregated in a designated area, labeled appropriately and separated from saleable food items. Unsalable products may include food items that are being returned to the distributor, food items that are out of date, or food items that are damaged or spoiled.

Remodeling

Food and food preparation areas should be protected against contamination from construction during remodels, extensive repairs and installing or removing equipment. Special attention should be made to prevent possible *Listeria* harborage sites that may get exposed or introduced during construction.

Make sure all food contact surfaces and equipment are covered and protected against contamination. Because *Listeria* may spread via the air, either perform repairs during off hours or protect food prep areas against contamination by installing a dust and vapor proof plastic barrier. Following construction and before starting any food preparation, clean and sanitize all food contact surfaces along with cleaning floors, walls, drains, sides of equipment and cabinets where harborage sites might have been exposed.

Employee Practices and Training

Employee Practices

A very important factor in limiting the risk of *L. monocytogenes* 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 potentially 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 Employee Health, 2-3 Personal Cleanliness, 2-4 Hygienic Practices) for specific requirements. Employees should be trained on proper hand washing, glove usage and other practices to prevent risks related to *L. monocytogenes*.

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 damaged, soiled or contaminated. Gloves are never a substitute for proper hand washing.

Because employees clothing might become contaminated with *Listeria*, consideration should be given to having employees wear clean aprons or smocks (disposable is recommended) in ready-to-eat food areas. Prior to leaving food preparation areas, such as leaving for breaks, eating meals or visiting toilet facilities, employees should remove aprons and smocks. *Listeria* can enter the food establishment on employee's clothing, including shoes and then contaminate food or food contact surfaces through poor food safety practices.

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 *Listeria*. When movement in and out of the ready-to-eat food area is necessary, appropriate precautions should be taken, e.g., change of outer clothing and immediate hand washing.

Employee Training

Knowledgeable food employees are vital to food safety. All food handlers need to understand risk factors associated with receiving, storing, preparing, holding, displaying and handling food as it relates to their assigned duties. Food safety training should be a part of every food establishments' AMC 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 *L. monocytogenes* guidance document can be used to assist in covering important intervention strategies.

Other training materials are also available and listed below. The list below is not exhaustive and does not imply endorsement by CFP.

- SafeMark
- ServSafe
- FDA's Managing Food Safety: A Guide For The Voluntary Use of HACCP Principles for Operators of Food Service and Retail Food Establishments
- FDA Oral Culture Learner Project – Educational Videos for Retail Food Employees
- Association of Food and Drug Officials Retail Meat and Poultry Processing Guidelines
- Penn State Universities Control of Listeria monocytogenes in Retail Establishments

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

Verifying the Effectiveness of Sanitation Programs

Every food establishment should 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.

It is important to understand the difference between validation and verification. In addition, monitoring is another step in assuring effective food safety programs. Each of these terms – validation, verification and monitoring – have different meanings.

Validation

Validation is the assurance or proof that the elements of the food safety plan, including standard operating procedures (SOPs), are effective and capable of controlling identified hazards. Validation steps may include, but are not limited to, the application of regulations, policies, guidance documents, scientifically proven processes, technical information, expert advice and recognized best practices. Retail food establishments will most likely use only those procedures, steps or practices that are already validated when developing SOPs or other food safety plans. That validation might occur at the corporate level in the case of a chain, or by chemical suppliers, universities or trade associations in the case of independently operated facilities. Therefore, it is unlikely a given retail food establishment will need to validate its food safety practices itself. However, if an operator decides to request a variance (FDA Food Code Section 8-103.10) and a HACCP Plan is required (FDA Food Code Section 8-201.14) the operator may be required to submit validation information.

Verification

Verification is the ongoing process of applying the observations, methods, procedures, tests and other evaluations to determine if monitoring tasks as described below have been performed correctly. Verification can be accomplished using onsite verification, record verification, or both.

- Onsite Verification – Examples include observations to ensure tasks are completed as described in a written program or checking the use of chemicals to verify proper concentrations and applications.
- Record Verification – When records are required or kept in accordance with a company's food safety plan, then a review of those records for completeness should be made to ensure records have been filled out correctly. Examples include internal audit reports, temperature recording devices, sanitation checklists or corrective action reports.

Different methods can be used to verify the effectiveness of sanitation programs. Sanitation programs should be verified using 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, regulatory inspections or third party auditors can be used to conduct the verification.

Monitoring

Monitoring is an ongoing process of checking a specific limit or practice (temperature, cleaning, etc.) to ensure the standard is met and that results are properly recorded as

per the SOP or food safety plan. Monitoring is the act of:

- Conducting a planned sequence of observations or measurements
- Assessing if the step is under control and
- Recording the results of the check when required.

When monitoring a task, the steps outlined in the written program should be followed as written and all regulatory requirements must be met. Observing monitoring procedures and reviewing the findings are part of the verification process.

Supplemental verification methods

Additional verification methods are available to supplement observation and monitoring. These include: rapid sanitation tests and microbiological testing.

These two methods vary by cost and level of technical expertise needed to use them, and therefore may not be suitable depending upon the size and type of the facility. A customized approach based on the specific risks or technical expertise available in an operation is recommended. The following is a brief description of these two methods.

Rapid Sanitation Tests

To be of most benefit, these tests need to be done on a regular basis. 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 establishing or monitoring the sanitation program.

Adenosine triphosphate (ATP) bioluminescence and glucose tests are examples of rapid test kits. These kits usually 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. They do not measure bacterial counts or provide information on types of organisms that may be present.

Microbiological Testing

Before undertaking microbial testing, a food establishment should evaluate several important factors. Most important is to have a clear understanding of regulatory requirements around testing. For example, would testing require a “test and hold” situation as would occur in a food manufacturing facility? Other important factors should be considered such as:

- What will be sampled?
- What organisms will be considered for sample evaluation?
- When and where will the samples be collected?
- Where will the samples be analyzed?

- What criteria suggest a potential problem?

A food establishment operator also needs to have a plan to specifically address what action will be taken to remedy the situation when results indicate a potential concern. There are many variables to be considered when designing a microbiological sampling program. If an establishment is interested in considering a microbial sampling program, it is recommended it seek specific guidance and expertise regarding microbiological sampling and its use to verify sanitation.

Additional resources to assist with this process can be found in Appendix 1 of this document.

Supplier Specifications

The following recommendations are meant to help food establishments identify and approve potential suppliers. It is understood that not all items listed will be found to be critical for all food establishments. It is also understood that some suppliers will treat specific information as proprietary and confidential. Nonetheless, the supplier should provide some evidence that the requested programs are in place.

1. Only buy from an approved source. All food suppliers, including producers, manufacturers and distributors, should provide proof that they have a proactive food safety and food security program in place. While the FDA Food Code does not define ‘approved source’, it does define ‘approved’ to mean acceptable to the regulatory authority based on a determination of conformity with principles, practices and generally recognized standards that protect public health.

2. Develop a relationship with all suppliers and understand their processes and cold chain distribution.

3. All suppliers should be audited at least annually by a federal, state or local regulatory authority or a third party. You may ask your supplier if they are certified against a Global Food Safety Initiative (GFSI) or other recognized scheme.

4. Does the supplier's food safety plan include internationally recognized HACCP and sanitation standards? How is the plan validated and verified? Is an environmental monitoring and product-monitoring program in place? Do these programs include test-and-hold provisions?

5. Food suppliers’ buildings, facilities, grounds and equipment should be constructed and maintained in a manner consistent with regulatory requirements to prevent the contamination of food or food packaging materials.

6. Letters of Guarantee should be obtained from every supplier for each product supplied to insure that all food safety requirements are being met. Ask your supplier about their sanitation practices, cold chain management, or performance against

international and regulatory practices.

7. Additional information should be obtained from the supplier regarding ingredients, preservatives and microbial growth inhibitors that impact listeriosis risk in select foods. It is important for the establishment operator to understand the benefits and limitations to the use of these compounds.

8. The suppliers' facility should have a documented inspection process that occurs after sanitation that monitors and tracks cleaning effectiveness.

9. The supplier should have written cleaning procedures for the equipment and infrastructure within the establishment with the defined frequency for routine and deep cleaning based on risk.

10. The supplier should map different areas in the facility using a risk-based approach.

11. The supplier should review the sanitary design of any incoming equipment. Special care should be taken when using second–hand or refurbished equipment.

12. The supplier should have a risk management plan in place to address contractor activity including any planned construction projects.

Recalls

As this document is focused on procedures and practices used to minimize contamination and growth of *L. monocytogenes* within food establishments, a detailed discussion of food recalls for *L. monocytogenes* is out of scope. Properly managed recalls are an important part of controlling the risk of listeriosis; however, a number of good resources are available for food establishments including guidance from FDA, USDA-FSIS and the AFDO Food Recall Manual developed by the University of Florida.

Appendix 1. Resources for expert guidance regarding *L. monocytogenes*. The list below is not exhaustive and does not imply endorsement by CFP.

Entity type	Examples
Federal agency	Centers for Disease Control and Prevention (CDC), cdc.gov Environmental Protection Agency (EPA), epa.gov Food and Drug Administration (FDA), fda.gov United States Department of Agriculture, Food Safety Inspection Service (USDA/FSIS), fsis.usda.gov
State and local governments	See dslo.afdo.org for a directory
Trade, professional and non-governmental organizations and associations	Association of Food and Drug Officials (AFDO), afdo.org American Society for Microbiology (ASM), asm.org Fight Bac!, fightbac.org Food Marketing Institute (FMI), fmi.org International Association for Food Protection (IAFP), foodprotection.org International Commission on the Microbiological Specifications of Foods (ICMSF), icmsf.org National Environmental Health Association (NEHA), neha.org National Restaurant Association (NRA), restaurant.org
	National Registry of Food Safety Professionals (NRFSP), www.nrfsp.com
Academic institutions	Many universities and local or county extension programs can provide *L. monocytogenes* food safety expertise

Commercial entities	A variety of commercial entities can also provide specific recommendations regarding *L. monocytogenes*. Commercial testing labs, cleaning and sanitation chemical and service providers and a variety of private consultants can all provide assistance.