Control of *Listeria monocytogenes* in Ready-To-Eat Foods: Guidance for Industry

Draft Guidance

This guidance is being distributed for comment purposes only.

Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that FDA considers your comment on this draft guidance before we begin work on the final version of the guidance, submit either electronic or written comments on the draft guidance within 180 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number FDA–2007–D–0494 listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact the Center for Food Safety and Applied Nutrition (CFSAN) at 240-402-1700.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition
January 2017

Table of Contents

A. Collecting Samples from Surfaces (Including Both Food-Contact Surfaces and Non-Food-Contact Surfaces)
B. Collecting Rinse Samples
C. Collecting Liquid Samples (Including Floor Drain Effluents)
D. Compositing Samples Collected from Sponges or Swabs
E. Preparing Samples Collected from Liquids
F. Sample Analysis

Control of *Listeria monocytogenes* in Ready-to-Eat Foods: Guidance for Industry[1]

I. Introduction

This guidance is intended for those persons ("you") who are subject to our regulation, in 21 CFR part 117 (part 117), entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" and who manufacture, process, pack, or hold ready-to-eat (RTE) foods.[2] This guidance is intended for you regardless of whether you are only subject to the current good manufacturing practice requirements for human food of part 117 (CGMP requirements), the requirements for hazard analysis and risk-based preventive controls for human food in part 117 (PCHF), or both the CGMP requirements and the PCHF requirements. See section II.A of this guidance for additional information about the CGMP and PCHF requirements. This guidance is intended to help you comply with the CGMP and PCHF requirements of part 117 with respect to measures that can significantly minimize or prevent the contamination of RTE food with *L. monocytogenes* whenever a RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to *L. monocytogenes*) that would significantly minimize *L. monocytogenes*.

This guidance is not directed to processors of RTE foods that receive a listericidal control measure applied to the food in the final package, or applied to the food just prior to packaging in a system that adequately shields the product and food contact surfaces of the packaging from contamination from the food processing environment.

This guidance also is not intended for food establishments that are not subject to part 117, such as farms.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidance describes the Agency's current thinking on a topic and should

[1] This guidance has been prepared by the Office of Food Safety at the U.S. Food and Drug Administration.

[2] Ready-to-eat food (RTE food) means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards. (21 CFR 117.3)

be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

A. Regulatory Framework

Subparts A, B, and F of part 117 include CGMP requirements for manufacturing, processing, packing and holding human food. These CGMP requirements address topics such as personnel, buildings and facilities, equipment and utensils, production and process controls, and warehousing and distribution. With few exceptions (such as for farms and for establishments solely engaged in the holding and/or transportation of one or more raw agricultural commodities (RACs)), the CGMP requirements in part 117 apply to all persons who manufacture, process, pack, or hold human food.[3] See Table 1 for a list of the CGMP requirements that we discuss in this guidance.

Table 1.—CGMP Requirements Discussed in this Guidance

Section	Description
117.10	Personnel
117.20	Plant and grounds
117.35	Sanitary operations
117.37	Sanitary facilities and controls
117.40	Equipment and utensils
117.80	Processes and controls
117.93	Warehousing and distribution

Subparts A, C, D, E, F, and G of part 117 include requirements for hazard analysis and risk-based preventive controls, for preventive control management components (i.e., monitoring, corrective actions and corrections, and verification), and for associated records. In this document, we refer to these requirements as the "PCHF requirements." With some exceptions, the PCHF requirements apply to any food establishment that is required to register as a food facility under 21 CFR part 1, subpart H. Exceptions include "qualified facilities" (e.g., facilities that are a very small business as defined in 21 CFR 117.3) and activities that are subject to our Hazard Analysis and Critical Control Point (HACCP) requirements for seafood in 21 CFR part 123 or juice in part 120 at facilities required to comply with those regulations. Some facilities (i.e., those solely engaged in the storage of packaged food that is not exposed to the environment) are exempt from subpart C, but subject to modified requirements in subpart D of part 117 if they store packaged foods that require time/temperature control for safety. See 21 CFR 117.5 for a complete list of exemptions from the requirements of subpart C.

Although section VIII.B.3 of this guidance provides general recommendations for controls on suppliers, we are providing a separate, comprehensive guidance on the specific PCHF requirements for a supply-chain program (part 117, subpart G). That separate guidance will provide recommendations for all facilities that are subject to the PCHF requirements, not just to those facilities that manufacture, process, pack, or hold RTE foods.

[3] Although not specified in part 117, we do not apply the CGMP requirements to restaurants and retail food establishments.

See Table 2 for a list of the PCHF requirements that we discuss in this guidance.

Table 2.—PCHF Requirements Discussed in this Guidance

Section	Description
117.126	Food safety plan
117.130	Hazard analysis
117.135	Preventive controls
117.139	Recall plan
117.140	Preventive control management components
117.145	Monitoring
117.150	Corrective actions and corrections
117.155	Verification
117.160	Validation
117.165	Verification of implementation and effectiveness
117.170	Reanalysis
117.190	Implementation records required for this subpart

Section 21 CFR 117.3 defines several terms that apply to the CGMP and PCHF requirements. See the Glossary in section XIX of this guidance for the definition of applicable terms used in this guidance. The Glossary also includes definitions for some additional terms, not defined in 21 CFR 117.3, that we define for the purposes of this guidance. See section XX of this guidance for a table of abbreviations commonly used in this guidance.

B. Characteristics of *L. monocytogenes*

L. monocytogenes is an environmental pathogen that can contaminate foods and cause a mild, non-invasive illness (called listerial gastroenteritis) or a severe, invasive illness (called listeriosis). Listeriosis is characterized by a relatively high mortality rate compared to illnesses caused by most other foodborne pathogens (~20% compared to <1 % for *Salmonella* or *E. coli* O157) (Ref. 1 through Ref. 3). Persons who have the greatest risk of experiencing listeriosis due to consumption of foods contaminated with *L. monocytogenes* are pregnant women and their fetuses, the elderly, and persons with weakened immune systems (Ref. 4 through Ref. 6 and Ref. 7). Foods that have caused outbreaks are typically contaminated from the environment during manufacturing/processing or packing (see Ref. 8 through Ref. 11 for some examples).

Although temperatures below freezing prevent the growth of *L. monocytogenes* (Ref. 12 through Ref. 14), *L. monocytogenes* can multiply slowly at refrigeration temperatures. As a result, refrigeration is less effective as a control measure for *L. monocytogenes* than for other foodborne pathogens (such as *Salmonella*) (Ref. 12 through Ref. 16).

Listeriosis is largely associated with RTE foods (Ref. 6 and Ref. 7). It is well established that foods that pose the greatest risk of foodborne listeriosis are those RTE foods that have intrinsic characteristics[4] (such as pH and water activity) that support the growth of *L. monocytogenes*, whereas the RTE foods that pose the least risk of foodborne listeriosis are foods that have intrinsic characteristics that prevent the growth of *L. monocytogenes* (Ref. 6 and Ref. 7).

[4] Intrinsic characteristics include chemical and physical factors that are normally within the structure of the food.

Therefore, formulating RTE food to have intrinsic characteristics that do not support the growth of *L. monocytogenes* has the potential to reduce the risk of foodborne listeriosis.

It is well established (Ref. 12, Ref. 15, and Ref. 17 through Ref. 20) that *L. monocytogenes* does not grow when:

- The pH of the food is less than or equal to 4.4;
- The water activity of the food is less than or equal to 0.92; and
- The food is formulated to contain a combination of factors scientifically demonstrated to be effective in preventing growth (the "hurdles" concept).

Foods can naturally have characteristics that prevent the growth of *L. monocytogenes*, or they can be deliberately processed to achieve or attain such characteristics. For example, deli-type salads (such as potato salad) can be processed to achieve a pH that is less than or equal to 4.4 by the addition of an acidic substance (such as vinegar).

Some antimicrobial substances are added to food during production. For example, sorbic acid is sometimes added to prevent the growth of *L. monocytogenes* in foods such as cheeses, and a combination of sorbic acid and benzoic acid is commonly added to prevent the growth of *L. monocytogenes* in foods such as deli-type salads (Ref. 21 through Ref. 23). Other antimicrobial substances can occur naturally in a food or be produced in a fermented food by the microbial fermentation.

It is possible to effectively prevent the growth of *L. monocytogenes* in products such as deli salads (Ref. 7) through an interactive effect between intrinsic characteristics, processing temperature, and formulation (such as the presence of antimicrobial substances and other preservatives), even if such factors are not individually effective in preventing the growth of *L. monocytogenes* (Ref. 15 and Ref. 20).

Whether a particular formulation (such as an antimicrobial substance, or a combination of intrinsic characteristics and antimicrobial substances) is effective in preventing the growth of *L. monocytogenes* in a particular food can be demonstrated through scientific studies. A formulation is generally considered to be effective in preventing the growth of *L. monocytogenes* if replicate growth studies having samples pulled at various time periods throughout product shelf life show less than a one log increase in the number of *L. monocytogenes*. For an example of how such studies are conducted, see Ref. 24 and Ref. 25.

Examples of RTE foods that support the growth of *L. monocytogenes* and that have been found to be contaminated with *L. monocytogenes* are unpasteurized and pasteurized milk, high fat dairy products, soft unripened cheese (Cottage Cheese, Cream Cheese, Ricotta), cooked ready-to-eat crustaceans (shrimp, crab), smoked seafood, fresh soft cheese (Queso Fresco), semi-soft cheese (Blue, Brick, Monterey), soft-ripened cheese (Brie, Camembert, Feta), deli-type salads, sandwiches, fresh-cut fruits and vegetables, and raw molluscan shellfish (Ref. 7, Ref. 26, and Ref. 27). An example of an RTE food that does not support the growth of *L. monocytogenes*, but has been found to be contaminated with *L. monocytogenes*, is ice cream (Ref. 28 and Ref. 6).

C. *L. monocytogenes* in the Food Processing Environment

L. monocytogenes is widespread in the environment. It is found in soil, water, sewage, and decaying vegetation (silage) (Ref. 29 through Ref. 32). It can be readily isolated from humans, domestic animals, raw agricultural commodities, and food packing and processing environments (particularly cool damp areas) (Ref. 8 through Ref. 11 and Ref. 29 through Ref. 37). *L. monocytogenes* has been shown to persist in equipment and the processing environment in harborage sites (Ref. 16 and Ref. 38).

L. monocytogenes can survive longer under adverse environmental conditions than can many other vegetative bacteria that present a food safety concern. In addition to being able to survive and grow at refrigeration temperatures, *L. monocytogenes* tolerates high salt concentrations (such as in non-chlorinated brine chiller solutions) and survives frozen storage for extended periods (Ref. 39 and Ref. 40). It survives acid conditions and is more resistant to heat than many other non-spore forming foodborne pathogens, although it can be killed by heating procedures such as those used to pasteurize milk[5] (Ref. 17, Ref. 41, and Ref. 42).

The application of CGMPs and PCHF requirements to the production of RTE foods can significantly minimize or prevent contamination of an RTE food with *L. monocytogenes* (e.g., through controls on raw materials or other ingredients, listericidal control measures to consistently destroy viable cells of *L. monocytogenes*, listeristatic formulations to prevent viable cells of *L. monocytogenes* from growing, segregation of foods that have been cooked from those that have not, sanitation controls, sanitary equipment design, and physical barriers (separation) to avoid cross contamination). Several scientific publications provide detailed recommendations for the control of *L. monocytogenes* in the food processing environment (see, e.g., Ref. 16 and Ref. 43 through Ref. 48). Many of the recommendations in this guidance are adapted from these published recommendations.

In Appendix 1 of this guidance, we list potential sources of *L. monocytogenes* in the food processing environment. In Appendix 2 of this guidance, we provide examples of scenarios that could lead to contamination of RTE foods with *L. monocytogenes*.

III. How to Apply This Guidance to Your Operations Based on the Regulatory Framework That Applies to Your Food Establishment

In this guidance we identify those CGMP requirements that are most relevant to specific recommendations, even though additional PCHF requirements may also apply to certain facilities. For example, the CGMP requirement in 21 CFR 117.80(c)(4) specifies that measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling water activity that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated. Therefore, within this guidance, we note the applicability of 21 CFR 117.80(a)(4) to our recommendations for how to validate the adequacy of listeristatic and listericidal process controls (see sections IX and X). However, additional

[5] Because normal pasteurization will effectively eliminate *L. monocytogenes*, it is generally assumed that contamination of products such as pasteurized fluid milk is the result of post-pasteurization contamination (see Section V of Ref. 7, p. 170).

PCHF requirements (in 21 CFR 117.160) for validation of listeristatic and listericidal process controls apply to those facilities that are subject to PCHF requirements.

Some PCHF requirements are expressly directed to *L. monocytogenes* and to RTE foods. For example, the definition of "environmental pathogen" identifies *L. monocytogenes* as an environmental pathogen (21 CFR 117.3), and the hazard evaluation required by 21 CFR 117.130 must include an evaluation of environmental pathogens whenever an RTE food is exposed to the environment prior to packaging and the packaged food does not receive a treatment or otherwise include a control measure (such as a formulation lethal to the pathogen) that would significantly minimize the pathogen (21 CFR 117.130(c)(1)(ii)).

Because some persons who are subject to the CGMP requirements in subpart B are exempt from the PCHF requirements in subparts C and G, this guidance:

- Is written as a set of recommendations even though in some cases part 117 includes an explicit requirement. For example, with few exceptions, the PCHF requirements specify that you must validate that the preventive controls identified and implemented in accordance with 21 CFR 117.135 are adequate to control the hazard as appropriate to the nature of the preventive control and its role in the facility's food safety system (21 CFR 117.160(a)). If you are a facility subject to the PCHF requirements of part 117, you must comply with 21 CFR 117.160(a) even though this guidance "recommends" validation of process controls such as listeristatic and listericidal control measures.
- Uses general terms such as "control" and "control measure" even though in some cases the control or control measure is a preventive control.

You can access part 117 on the Internet from the Federal Digital System of the U.S. Government Printing Office. For your convenience, when we refer you to a single section of part 117, we repeat the text of the section in this guidance. However, when we refer you to more than one section, we do not repeat the text of the section in this guidance, because it is impractical to do so.

In general, the recommendations in this guidance complement, but do not supersede, recommendations that we have issued in other guidance documents. For example, if you process seafood for use as sushi, we continue to recommend that you follow the guidance implementing our HACCP regulations for fish and fishery products (Ref. 49). In some cases, specific recommendations in other guidance documents could provide more targeted recommendations on how to establish and implement a particular control measure for the type of products you process. For example, our guidance entitled "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards of Fresh-cut Fruits and Vegetables" (Ref. 50) includes specific recommendations for the design, construction and maintenance of facilities and equipment. Targeted information relevant to a fresh-cut processing plant and equipment is available in that guidance.

IV. Controls on Personnel

The actions of personnel can transfer *L. monocytogenes* from the processing environment to RTE food (Ref. 16, Ref. 43, and Ref. 46). In this section of this guidance, we provide recommendations to minimize the potential for RTE food to become contaminated with *L. monocytogenes* through the actions of personnel.

A. Hands, Gloves and Footwear

We recommend that all persons who will enter an area where RTE foods are processed or exposed to the environment thoroughly wash their hands before doing so.

We recommend that personnel use suitable utensils (such as spatulas or tongs), or wear gloves, when touching exposed RTE foods, food-contact surfaces (FCSs), and packaging materials, and not touch exposed RTE foods, FCSs, and packaging with bare hands. We recognize that contact between hands and food or packaging could be necessary under a wide variety of circumstances and that gloves could present a risk of introducing foreign material or interfere with an individual's ability to do a particular task. You should assess the job requirements and the risks of contamination potentially resulting in foodborne illness in making a decision that personnel may contact food with bare hands.

We recommend that gloves and footwear worn by personnel who handle RTE foods, or who work in areas where RTE foods are processed or exposed, be made of impermeable material, be in good repair and be easily cleanable or disposable. Personnel should not use cleated footwear unless it is necessary for their safety, because cleated footwear can collect particles of dirt or other waste from inside and outside the plant. When areas in your plant have been designated as RTE areas, we recommend that gloves and footwear worn by personnel who handle RTE foods or who work in areas where RTE foods are processed or exposed to the environment be used only in the RTE area and that gloves and footwear used in a non-RTE area of the plant not be used in the RTE area.

When gloves are used, we recommend that:

- Personnel wash their hands before putting the gloves on;
- Multi-use gloves be washed and sanitized before use and after the employee touches any non-food-contact surface (non-FCS) (such as clothing, doorknobs, equipment control panels, and tools);
- Single use gloves be discarded and replaced after an individual touches any non-FCS; and
- Gloves worn outside areas where RTE foods are processed or exposed (e.g., restrooms) be discarded before returning to the RTE area.

B. Foamers, Footbaths, and Dry Powdered Sanitizers

We recommend that you establish procedures to minimize the potential for personnel to transfer *L. monocytogenes* from non-RTE areas of the plant to the RTE area. To do so, we recommend that you consider whether the use of foamers or footbaths containing liquid sanitizers, or dry powdered sanitizers, is appropriate and useful when personnel enter areas where RTE foods are processed or exposed. A foamer delivers an automatic spray of foam disinfectant on the floor where personnel (and portable equipment (such as carts and forklifts) that personnel transport through the plant) enter the RTE area. A footbath is usually a low flat container, or a water tight recess in the floor, that has a non-slip surface and is filled with a suitable sanitizer.

Foamers or footbaths (which are wet) generally are more appropriate in a wet processing environment. A dry powdered sanitizer generally is more appropriate in a dry processing environment to keep the environment dry; in dry processing environments, the absence of water

prevents the growth of *L. monocytogenes*. When using foamers, footbaths, or a dry powdered sanitizer, we recommend you ensure that personnel cannot avoid walking through them and cannot jump over them when entering the RTE area.

You should appropriately maintain foamers to ensure they are properly spraying the correct amount of disinfectant over the intended area. If you use non-automatic footbaths, we recommend checking them at regular intervals, such as hourly, to ensure they are filled with sanitizer and the sanitizer is diluted to the proper concentration.

C. Clothing

We recommend that you establish and implement conditions and practices to prevent employee clothing from contributing to the contamination of food with *L. monocytogenes.* Depending on the type of operation, such conditions and practices include:

- Personnel do not wear street clothes in areas where RTE foods are processed or exposed unless the street clothes are adequately covered above the knees (e.g., with a clean smock);
- Smocks for personnel in areas where RTE foods are processed or exposed are worn only in the designated RTE area and an adjacent vestibule (i.e., the area where the smock would be put on);
- Personnel change into a clean uniform or smock before entering areas where RTE foods are processed or exposed;
- Smocks and uniforms are laundered or disposed of daily;
- Smocks or uniforms that will be used in areas where RTE foods are processed or exposed are distinguished from those that will be used in other areas (particularly areas where raw foods are processed or exposed) using a mechanism such as color coding; and
- Smocks or uniforms are distinguished according to the task that the personnel perform (e.g., production or maintenance). For example, if you restrict the access of maintenance personnel to areas of the plant where finished product is exposed, distinguishing smocks or uniforms by color coding helps to identify the personnel with such restricted access.

D. Controls on Personnel Associated with Specific Areas in the Plant

As noted in section V.A.1, we recommend that you provide separate locker areas, break areas, and cafeteria areas for personnel who handle RTE foods and personnel who handle raw foods, when practical. When doing so is not practical, we recommend that:

- Your environmental monitoring program (see section XIII of this guidance) include monitoring of the travel paths and service areas to show when extra cleaning or a procedural modification is needed;
- You establish a “captive shoe” policy in which footwear for the RTE area is only worn in that area; and

- You place more emphasis on other controls discussed in this section to minimize the potential for contamination of RTE foods by personnel who handle raw foods, such as:
  - Distinguishing smocks or uniforms used in the RTE areas from those used in the "raw area";
  - Providing an entry room to the RTE area to put on, and to store, smocks and footwear designated for that area; and
  - Establishing a chemical barrier (e.g., footbaths or foamers) to the RTE area.

E. Personnel Who Perform Sanitation, Maintenance, and Similar Functions

We recommend that sanitation and maintenance personnel who work in areas where RTE foods are processed or exposed follow the same hygiene requirements as production personnel in those areas. When practical, we recommend that you provide dedicated tools for the RTE area separate from tools in other parts of the plant. (See Ref. 16). If separate tools are not practical, we recommend that tools be cleaned and sanitized prior to entering the RTE area.

We recommend that you ensure that personnel who handle trash, offal, floor sweepings, drains, production waste, or scrap product do not handle RTE food, and do not touch RTE food-contact surfaces or food packaging material, unless they first change their smocks or uniforms, wash and sanitize hands, wear clean gloves, and don and sanitize footwear.

F. Relevant Sections of Part 117

Sections of part 117 that are relevant to the recommendations in this guidance regarding personnel hygiene include 21 CFR 117.4, 117.10(a), 117.10(b)(1), 117.10(b)(3), 117.10(b)(5), and 117.10(b)(9)

V. Design, Construction, and Operation of Your Plant

The processing environment can be a primary source of *L. monocytogenes* (Ref. 16, Ref. 32, and Ref. 43 through Ref. 48). In this section of this guidance, we provide recommendations on the design and construction of your plant to reduce the potential for contamination of an RTE food from the processing environment. The CGMPs in subpart B require that structures be suitable in size, construction, and design to facilitate maintenance and sanitary operations for food production purposes (21 CFR 117.20(b)).

A. Design and Construction of the Plant

1. General

During new construction or renovation, we recommend that you design and construct the plant to reduce the potential for contamination of RTE foods via air, aerosols, or traffic of personnel or equipment. To do so, we recommend that you separate areas where RTE foods are processed, exposed or stored from areas where raw foods are processed, exposed or stored, and from

equipment washing areas, microbiological laboratories, maintenance areas, waste areas, offices, lockers and toilet facilities. In addition, it is prudent practice to locate microbiological laboratories as far away as practical from the processing area, preferably in another building, because routine microbiological testing usually involves enrichment procedures that enable microorganisms to multiply before conducting analytical tests to detect them. Even if your analytical method tests for an indicator organism rather than a pathogen, if samples you test contain the pathogen *L. monocytogenes* your enrichment procedures have the potential to produce increased numbers of *L. monocytogenes*.

New construction and renovations could cause significant disruption of air patterns, walls, ceilings, and floors thereby leading to enhanced potential for cross contamination of FCSs, non-FCSs, products, ingredients or packaging. Actions you take can depend on the type of construction activity and the potential for contamination. Certain activities such as installing small pieces of equipment, painting or caulking windows and doors, or replacing parts on equipment are less likely to result in the introduction of *L. monocytogenes* than activities that are more extensive. When construction activities are more extensive, such as removing/replacing walls, floors or ceilings or installing major equipment or new processing lines, extra measures to ensure control of *Listeria* are needed. These measures include erecting temporary barriers to isolate the construction from the rest of the facility, revising traffic patterns, enhancing cleaning and sanitizing, and enhancing environmental monitoring.

We recommend that you design and construct the plant so that walls, ceilings, windows, doors, floors, drains, and overhead fixtures (e.g., pipes, air vents, and lights) in areas where RTE foods are processed or exposed resist deterioration by product or cleaning chemicals, and prevent condensate buildup and harborage of microorganisms. We also recommend that you design and construct the roof so that it drains freely and does not leak. We recommend that you not place windows that can be opened in areas where RTE foods are processed or exposed. To prevent harborage of microorganisms, we also recommend not using construction materials made of porous or absorbent materials, such as wood or foam, in areas where RTE foods are processed or exposed and in other wet processing areas in the plant. If your plant already contains such porous or absorbent materials, see section XIII of this guidance for recommendations on environmental monitoring until such materials can be replaced; following those recommendations can help prevent *L. monocytogenes* from becoming established in those materials and becoming a source of contamination in areas where RTE foods are processed or exposed.

When practical, we recommend that you provide separate locker areas, break areas, and cafeteria areas for personnel who handle RTE foods and personnel who handle foods that are not RTE.

2. Air and air flow

We recommend that you design the air flow in your plant to maintain positive air pressure on the RTE side of the operation relative to the “raw” side (i.e., maintain higher air pressures in RTE areas and lower air pressures in areas where unprocessed (“raw”) foods are handled). We recommend that you consider the room temperature and the impact of airflow on controlling condensation in the plant. We also recommend that you consult individuals with appropriate engineering skills to determine how to achieve proper air balance and the desired air exchange rate, including determining the number, size, and location of intake and exhaust fans.

Appendix 3 of this guidance provides some schematic diagrams relevant to air flow and room pressure differences. Figure 1 of Appendix 3 relates to air flow, and shows that the recommended air flow should have negative pressure in the raw processing area rather than in the RTE processing area. In Figures 2 and 3 of Appendix 3, we provide examples of plant design, including schematic recommendations related to air flow, product flow, and the use of partitions in the design of the plant. In Figure 2 of Appendix 3, the example of a plant design has a partition between the raw processing area and the RTE processing area. In Figure 3 of Appendix 3, the example of a plant design does not have this partition between the raw processing area and the RTE processing area; instead, the plant design in Figure 3 of Appendix 3 relies on positive air pressure in the RTE processing area.

We recommend that the location of the air intake not be adjacent to the location of the air exhaust or other sources of airborne contamination such as waste disposal areas. This can help prevent contamination of intake air. Preventing contamination of intake air is particularly important when major construction or remodeling occurs in an existing plant. Using air-tight barriers, limiting access between construction and food production areas, and providing proper air flow can prevent introduction of contamination into the plant environment.

There have been isolated reports of contamination associated with air (e.g., air from compressed air lines has been implicated in contamination traced to a niche (i.e., growth in a filter) near the point of use (Ref. 44). We recommend that you consider filtering the air in rooms where RTE foods are processed or exposed to reduce the potential for contamination of RTE foods with microorganisms (including *L. monocytogenes*). If you filter the air, we recommend that the final filter have an efficiency of at least 90-95 percent at 1 micron as rated in American Society of Heating Refrigerating and Air-Conditioning Engineers (ASHRAE) standard 52.2-2012.[6] Depending on your product, your process and the design and construction of your plant, it may be appropriate to use High Efficiency Particulate Air (HEPA) filters that have an efficiency of 99.97-99.99 percent at 0.3 micron for removing bacteria, yeasts and molds.

3. Water systems

You should take steps to prevent the accumulation of standing water in or around drains, because standing water in your plant can be conducive to contamination with *L. monocytogenes*. Examples of such steps include:

- Designing and constructing the plant in a way that will make drains function adequately;
- Designing and constructing the plant in a way that will make drains adequately accessible for cleaning;
- Not installing trench drains in areas where RTE foods are processed or exposed and, where practical, replacing existing trench drains with enclosed plumbing to a floor drain. Where replacement of existing trench drains is not practical, we recommend that you keep them clean and consider whether equipping them for automatic flushing would be of benefit, taking care to ensure that automatic flushing does not create aerosols that could contaminate product;

[6] American Society of Heating Refrigerating and Air-Conditioning Engineers. *Standard 52.2-2012 -- Method of Testing General Ventilation Air-Cleaning Devices for Removal Efficiency by Particle Size*.: ASHRAE. Available for purchase at http://www.webstore.ansi.org/.

- Designing and constructing drains so that the drains do not flow from areas where raw foods are processed or exposed to areas where RTE foods are processed or exposed. In an older plant with existing piping that has some flow from raw areas to RTE areas, you should establish systems that ensure adequate control of *L. monocytogenes* in the environment if you do not re-pipe the plant;
- Designing and constructing drains so that restroom drains are not connected to drains serving areas where RTE foods are processed or exposed;
- Designing and constructing the slope of floors to drains so that floors drain freely and water does not accumulate; and
- Not locating sewer lines above areas where RTE foods, FCSs, or food packaging materials are processed or exposed. If this is not practical, we recommend that you take steps to protect RTE foods and packaging materials from potential leakage, e.g., by shielding the sewer lines to prevent or convey leakage.

Part 117 requires that your plant be designed and constructed in such a manner that drip or condensate from fixtures, ducts and pipes does not contaminate food, FCSs, or food packaging material (21 CFR 117.20(b)(4)). Measures that can help prevent the formation of condensate include exhausting vapors from cooking operations, using dehumidifiers, and providing adequate ventilation. Exhausting room air during sanitation also helps to manage humidity. Other factors to consider are the room temperature, relative humidity of the air supply, positive air pressure, and the air exchange rate.

B. General Operation of the Plant

We recommend that you control traffic flow patterns for personnel, food products, food packaging materials, and equipment to minimize the potential for transfer of *L. monocytogenes* between areas where raw foods are processed or exposed and areas where RTE foods are processed or exposed.

We recommend that you develop and implement a management program for pallets in areas where RTE foods are processed or exposed to ensure the pallets are inspected, clean, and in overall good condition such that they do not serve as a source of contamination with *L. monocytogenes*. Both plastic and wooden pallets may be a source of *Listeria* contamination; in general, plastic pallets are better suited than wooden pallets for wet areas. Some manufacturers will only allow plastic pallets in production areas, confining wooden pallets to dry areas, such as warehouses. We recommend you consider whether such an approach would be beneficial for your facility. We also recommend that you designate one set of equipment (such as carts, forklifts, mobile racks, and pallets) to areas where raw foods are processed or exposed and designate a separate set of such equipment to areas where RTE foods are processed or exposed. Where this is not practical, we recommend that you clean and sanitize wheels of transport equipment (e.g., carts, forklifts, and mobile racks) before they enter an area where RTE foods are processed or exposed.

With respect to totes and other containers, we recommend that you:

- Select containers that can be cleaned easily and are fit for their purpose;
- Dedicate containers by area (e.g., use one set of containers in areas where RTE foods are processed or exposed and a different set of containers in areas where raw foods are

processed or exposed) and clearly distinguish these containers from each other (e.g., by color coding). Where this is not practical, they should be cleaned and sanitized prior to entering the RTE area; and

- Dedicate containers by function (e.g., product, rework or waste) and clearly distinguish these containers from each other (e.g., by color coding or labeling).

We recommend that you discard or treat continuous use brines and recycled process water used in direct contact with RTE foods with sufficient frequency to control *L. monocytogenes* (Ref. 16). We recommend that you use measures such as chlorination, ozonation, heat treatment, or other effective treatment to treat such brines and water. We recommend that you consider the results of environmental monitoring for *L. monocytogenes* (see section XIII of this guidance) when determining the frequency of treatment.

To prevent aerosols from contacting RTE food, FCSs, and food packaging materials, personnel should not use high-pressure water hoses during production in areas where RTE foods are exposed or after equipment has been cleaned and sanitized.

We recommend that you implement procedures to ensure that compressed gases or air used directly in or on RTE food, or on RTE food-contact surfaces, not become a source of *L. monocytogenes*. Examples of such procedures are drying and filtration. We recommend that dehydration be done at the source of gas or air supply and that filtration be done at the point of use, using a filter that can retain particles larger than 0.3 micron. You should take appropriate steps to maintain the filters.

We recommend that you maintain and inspect the water supply and any treatment systems to ensure that they do not become a source of microbial contamination. We also recommend that you produce, handle, and store ice and ice utensils in a manner that protects ice from microbial contamination. You should avoid storing ice scoops and ice shovels in direct contact with floors and other non-FCSs.

C. Relevant Sections of Part 117

Sections of part 117 that are relevant to the recommendations in this guidance regarding design and construction of the plant include 21 CFR 117.20(b), 117.35(a), 117.37, and 117.40(a).

Sections of part 117 that are relevant to the recommendations in this guidance regarding operation of the plant include 21 CFR 117.35, 117.37(a), 117.37(e), 117.40, 117.80(a), 117.80(b)(1), and 117.80(c)(16).

VI. Design, Construction, and Maintenance of Equipment

The processing environment can be a primary source of *L. monocytogenes* (Ref. 16, Ref. 32, and Ref. 43 through Ref. 48). In this section of this guidance, we provide recommendations on the design, construction and maintenance of equipment to reduce the potential for contamination of an RTE food from equipment.

A. Design and Construction of Equipment

Part 117 requires that equipment and utensils be designed and of such material and workmanship as to be adequately cleanable (21 CFR 117.40(a)(1)). We recommend that the equipment you purchase and use to process RTE foods be designed and constructed to minimize sites where microbial harborage and multiplication can occur. If you will modify existing equipment used to process RTE foods, we recommend that you or the manufacturer of the equipment review the design of the modifications to ensure that the modified equipment is designed and constructed to minimize sites where microbial harborage and multiplication can occur. When equipment is modified in-place or new equipment is installed in the establishment, there is an increased risk of contamination of FCSs and food with *L. monocytogenes.* See section V.A.1 for recommendations on controlling *Listeria* during construction.

We recommend that RTE FCSs be smooth, non-absorbent, sealed, and sloped, where feasible, in order to drain freely, and that junctures in RTE FCSs be covered. Piping used to convey RTE foods should not have dead ends or cross-connections between conveyance of raw and RTE foods. The sanitary standards inventoried by 3-A Sanitary Standards, Inc.[7] can be useful when designing and constructing equipment containing FCSs.

We recommend that you design and construct equipment such as catwalk framework, table legs, conveyor rollers, and racks so that they cannot collect water that could harbor *L. monocytogenes* (e.g., they should not be hollow or foam filled). You should either modify or replace existing equipment not designed this way, or establish and use some other method to reduce the risk of *L. monocytogenes* contamination from such equipment, including a schedule for periodic cleaning and sanitizing combined with an environmental monitoring program.

We recommend that you not position catwalks and stairs with open grating over exposed RTE food or FCSs so as to help prevent contamination of RTE foods with *L. monocytogenes* that could be harbored on catwalks, stairs, or bottoms of individuals' shoes. If this is not practical, you should use ladders and stairs designed to prevent debris from shoes or other personal items from falling onto the processing line (e.g., plating covering the underside of the stairs, or side plates along the stairs). Plate coverings should be on a cleaning schedule.

We recommend that you not install stationary equipment used to process RTE foods over floor drains. Doing so will help prevent contamination of the equipment (and RTE foods) with *L. monocytogenes* that could be harbored in floor drains. If this is not practical, you should use some other method to prevent contamination from *L. monocytogenes* that could be present in the drain and monitor the drain for the presence of *L. monocytogenes* (see section XIII of this guidance for additional information on environmental monitoring).

We recommend that you sufficiently elevate FCSs (including conveyors) above the floor. Doing so will reduce the risk of contamination of RTE foods and FCSs from floor splash/overspray. If this is not practical, you should use some other method to prevent contamination from *L. monocytogenes* that could be present on the floor (e.g., cover RTE food contact surfaces) and monitor the floor for the presence of *L. monocytogenes*. Although we are recommending that

[7] 3-A Sanitary Standards, Inc. is a non-profit association, representing equipment manufacturers, processors, regulatory sanitarians and other public health professionals, that has established an inventory of Sanitary Standards and Accepted Practices for dairy and food processing equipment and systems.

conveyors be elevated, we also recommend that you avoid overhead conveyors whenever practical. If overhead conveyors cannot be avoided, they should be designed to be easily accessible for cleaning; note that part 117 requires that they be constructed in such a manner that drip or condensate from them does not contaminate food, FCSs, or food-packaging materials (21 CFR 117.20(b)(4)).

We recommend that you use wheeled devices that are designed to reduce the risk of contamination of RTE foods and FCSs from wheel spray (e.g., guards over the wheels, fully enclosed/encased bearings, lowest shelf on the wheeled rack is located above splash height).

We recommend that condensate from refrigeration evaporation coils be directed to a sanitary drain through a hose or, alternatively, collected in a pan that drains through a hose or suitable pipe to a sanitary drain. An air gap or other back flow mechanism should be in the drain line to prevent back flow from the sewer system to the drip pan. We recommend that you regularly inspect the pan and drain to ensure that the hose or pipe does not become clogged. You should have a cleaning schedule for hoses and drip pans.

We recommend that you keep hoses and hose nozzles off the floor or other unclean surfaces when not in use. During use, you should ensure that nozzles do not come in contact with the floor or other unclean surfaces. Doing so will help prevent hose nozzles (and, subsequently, individual's hands or water coming through the nozzle) from becoming contaminated with *L. monocytogenes* that could be present on the floor or other unclean surfaces.

If you use raw product to cool RTE product in a heat exchanger, we recommend that heat exchangers have higher pressure on the RTE side than on the raw side.

B. Maintenance of Equipment

We recommend that you establish and use a preventive maintenance program that is designed to minimize breakdowns and prevent contamination that could occur during repair of equipment. See section IV.C for recommendations for a written preventive maintenance program

We recommend that you examine and change filters used on intake air and for compressed air systems either at a frequency based on the manufacturer's specification or more frequently based on pressure differential or the results of environmental monitoring.

As noted in section IV.E, we recommend that tools intended for maintenance of equipment used in areas where RTE foods are processed or exposed be dedicated to those areas. (See Ref. 16). Where this is not practical, you should ensure that tools are adequately washed before use in the RTE area and consider sanitizing the tools in addition to washing them.

Equipment and FCSs used in areas where RTE foods are processed or exposed, including equipment that could be contaminated as a result of maintenance on utilities (e.g., air or water systems) or plant remodeling, should be cleaned and sanitized after maintenance and prior to use in production consistent with the requirements of 21 CFR 117.35(d).

C. Records

We recommend that your written program for equipment maintenance include defined schedules for examination and maintenance of equipment such as valves, gaskets, O-rings, pumps, screens, filters, and heat exchanger plates.

D. Relevant Sections of Part 117

Sections of part 117 that are relevant to the recommendations in this guidance regarding design and construction of equipment include 21 CFR 117.20(b)(4), 117.37(b)(3), 117.40(a), 117.40(b), 117.40(c), and 117.40(d).

Sections of part 117 that are relevant to the recommendations in this guidance regarding maintenance of equipment include 21 CFR 117.35(d), 117.35(f), 117.40(a), 117.40(g), and 117.80(c)(1).

VII. Sanitation

The processing environment can be a primary source of *L. monocytogenes* (Ref. 16, Ref. 32, and Ref. 43 through Ref. 48). In this section of this guidance, we provide recommendations on sanitation in your plant to reduce the potential for contamination of an RTE food from the processing environment.

A. General Sanitation Program

To minimize the potential for contamination of RTE food and FCSs with *L. monocytogenes*, we recommend that you establish and use a sanitation program that includes written sanitation procedures and a sanitation schedule for areas where RTE foods or FCSs are processed or exposed.

We recommend that you wash equipment in a way that does not result in an increased risk of product contamination. In general, you should not wash equipment during times that RTE foods or packaging are exposed in the area because of the potential formation of aerosols that could contaminate foods or packaging. You should consider the potential for transfer of *L. monocytogenes* during washing procedures, e.g., when equipment used for RTE foods is cleaned in the same area as equipment used for raw materials.

1. Written Sanitation Procedures

We recommend that you design the written sanitation procedures to ensure that the RTE area, and equipment in the RTE area, are cleaned and sanitized in a manner that reduces the risk of contamination of RTE food-contact and non-FCSs with *L. monocytogenes.* In general, we recommend that a written sanitation procedure address:

- The condition and cleanliness of FCSs, including equipment, utensils, gloves, and outer garments; and
- The prevention of cross-contamination:
  - From insanitary objects to food;
  - From insanitary objects to food packaging material and other FCSs (including equipment, utensils, gloves, and outer garments);
  - From raw food to food that is cooked (or otherwise RTE);
  - After any listericidal control measure; and
  - As a result of traffic flow patterns for personnel and for equipment.

We recommend that you make your written sanitation procedures readily available to personnel who are responsible for cleaning, train personnel on the sanitation procedures, and monitor adherence to the sanitation procedures.

We recommend that written sanitation procedures for cleaning equipment and floors identify:

- Equipment or area to be cleaned;
- Disassembly of equipment, if applicable;
- Frequency of cleaning;
- Type and concentration of cleaning compounds and sanitizers;
- Type of cleaning tools to be used (e.g., brushes, scrapers, scrubbing pads, mops);
- Color coding of tools (e.g., red for those related to raw materials or other ingredients and blue for those related to RTE areas);
- Time/temperature of cleaning solutions; and
- Flow rate (velocity) or pressure of cleaning solution, if applicable.

In practice, equipment, floors, and drains should be cleaned together, with cleaning actions carefully sequenced to reduce the risk of contamination. Cleaning operations are followed by a sanitizing procedure. We recommend that your written sanitation procedures include the following steps:

1. Dry Clean – Using appropriate tools (such as brushes, scrapers), remove heavy soils or debris from equipment, then floors;
2. Pre-Rinse – Working from the top of the equipment down, rinse and scrub equipment to remove visible soils. Using appropriate tools, remove any additional debris from the floors and drains, and then rinse the floor;
3. Soap and Scour – Apply foam cleaner to ensure adequate coverage by first foaming walls (if applicable), floors, and then the equipment from the bottom of the equipment to the top. Clean drains using appropriate tools. Scour equipment to remove any residues, and avoid the drying of the foam cleaner;
4. Post-Rinse – Remove the foam cleaner by flood rinsing the walls (if applicable), floors and equipment in the same order that the foam cleaner was applied;
5. Prepare for Inspection – Remove any possible overhead condensation or standing water and prepare the equipment for inspection;
6. Pre-Op Inspection – Visually inspect the equipment for cleaning effectiveness and correct any deficiencies;
7. Sanitize and Assemble – Sanitize the equipment, floors, and (if applicable) walls and prepare the equipment for operation, using ATP bioluminescence or other appropriate testing as a sanitation check.

2. Frequency of cleaning/sanitizing

You should clean and sanitize with sufficient frequency to ensure control of *L. monocytogenes* and to minimize conditions that promote the survival or multiplication of *L. monocytogenes* in the environment. To determine the cleaning frequency, you should review the sanitary design of the room and equipment, the microbiological profile during a production run, the history of *Listeria* spp. in the room and on the line, and the degree of product exposure to the line and the environment. See Appendix 4 for examples of schedules for routine cleaning and sanitation. You should modify the schedules in Appendix 4 based on the condition of your plant, sanitary design, production schedule and product characteristics. You should keep rooms as dry as possible because moisture fosters the growth and transfer of *L. monocytogenes* (Ref. 43).

3. Recommendations for cleaning and sanitizing

For clean in place (CIP) systems, we recommend that you monitor the concentration of cleaning solutions and sanitizers and verify flow rate, duration of the cleaning cycle and temperature. For clean out of place (COP) systems, we recommend that you monitor the concentration and temperature of cleaning solutions and sanitizers.

Procedures for wet cleaning and sanitizing of equipment should ensure that equipment other than that being cleaned is not compromised during cleaning. You should verify that cleaned equipment is not compromised by the cleaning of adjacent equipment. We recommend that you:

- Not perform wet cleaning of equipment (e.g., down lines, storage and spiral coolers, and spiral freezers) in a room where RTE food or packaging is exposed, even if you cover the RTE food or packaging (e.g., with plastic or paper). If wet cleaning does occur, you should remove all exposed RTE food or packaging from a room before beginning any wet cleaning of equipment, floors, and other areas; and
- Remove all exposed RTE food from a cooler or freezer prior to cleaning the cooler or freezer, refrigeration condenser units or condensate drip pans and hoses.

If circumstances require you to clean and sanitize a production line in a room where another production line is operating, you should follow the recommendations described below to minimize the potential for contamination from *L. monocytogenes* due to overspray, condensation, drainage, the environment, or traffic patterns:

- Overspray – When using hoses, you should avoid contaminating equipment with water or chemical overspray while cleaning the adjacent line. The proximity of equipment and lines influences the risk of overspray; in general, the risk of contamination from overspray increases when using low pressure within 20 feet and when using high pressure within 30 feet. One mechanism to reduce the potential for contamination from overspray is to erect clean curtains or temporary walls.
- Condensation – You should sufficiently exhaust condensate from steam, fog, or mist generated from cleaning and sanitizing activities to prevent the formation of condensation over equipment that is operating.
- Drainage – You should conduct cleaning activities in a way that does not create drain backups in shared floor drains. Cleaning chemicals should not drain to equipment that is operating.

- Environment – You should conduct cleaning activities in a way that does not adversely affect room temperature, relative humidity, or air pressure balance.
- Traffic Patterns – You should take steps to reduce the potential that changes in traffic patterns during the cleaning process could contaminate product.

When using CIP systems, we recommend that you dedicate separate CIP systems for cleaning equipment used to process RTE food and for cleaning equipment used to process raw food. If you are unable to designate separate CIP systems and, thus, use a common CIP system, we recommend that you maintain the temperature of an alkaline cleaning solution at or above 71 degrees C (160 degrees F).

When using COP systems (e.g., wash tanks), we recommend that you dedicate separate COP systems for cleaning equipment used to process RTE food and for cleaning equipment used to process raw food. A separate COP system for RTE equipment should be in or near the RTE area where practical. Where this is not practical, you should establish other procedures (e.g., sequence of washing procedures, wash temperatures) to ensure that using a common COP system does not contribute to cross contamination with *L. monocytogenes*.

When assembling cleaned and sanitized equipment (e.g., pump impellers, pipes), you should not place the equipment directly on the floor or other unclean surfaces, but should place them on cleaned and sanitized surfaces. We recommend that you take steps to prevent water from the floor or unclean equipment from splashing onto clean equipment.

4. Equipment and utensils used for cleaning/sanitizing

We recommend that all wipes be disposable and discarded after each use on RTE food-contact surfaces and that scouring pads be discarded frequently. When scouring pads are not in use during the day, we recommend they be kept dry or placed in a sanitizer solution.

We recommend that you maintain and clean (and sanitize where appropriate) equipment that is used for cleaning (e.g., brushes, mops, floor scrubbers, sinks, tubs, and vacuum cleaners) so that it does not become a source of contamination. You should not use cleaning tools that are used for floors or drains (see section VII.B of this guidance, below) on FCSs. We recommend that you dedicate cleaning equipment either to areas where RTE foods are processed or exposed, or to areas where raw foods are processed or exposed, using a mechanism (such as color coding) that easily distinguishes the equipment dedicated to the two areas.

B. Cleaning Drains

We recommend that you clean and sanitize floor drains in a manner that prevents contamination of other surfaces in the room. Examples of how to do so include:

- Avoiding cleaning floor drains during times when RTE foods are processed or exposed or when unused packaging is present;
- Avoiding use of high-pressure hoses to clear or clean a drain, because use of such hoses could create aerosols that could spread contamination throughout the room;
- Using brushes that are at least ¼ inch (0.64 cm) smaller than the diameter of a drain opening to prevent splattering during cleaning of floor drains;

- Using a splashguard to prevent splashing during cleaning; and
- Dedicating tools that you use for cleaning drains to that purpose and taking steps to make tools used for cleaning drains easily distinguishable from utensils used for other purposes (e.g., by color-coding).

If a drain backs up and water flows into an area where RTE foods are being processed or exposed, we recommend that you take steps to avoid splashing any equipment and follow the sequence of steps described below to clear the drain and clean the area around it:

- Stop any production;
- Remove any uncovered RTE foods from the affected area;
- Clear the drain;
- Clean the affected area with an effective cleaner, then rinse and sanitize; and
- Remove excess water from the floor.

We recommend that personnel who clean a drain change clothes and gloves, and wash and sanitize hands before subsequently touching an FCS.

If you use bactericidal drain rings, we recommend that you monitor them and replace them when appropriate.

C. Sanitizers

Sanitizers containing quaternary ammonium compounds (QACs), peroxyacetic acid, iodine, or chlorine have been used to control *L. monocytogenes* in various situations (Ref. 43). All sanitizers have advantages and disadvantages. Some establishments use QACs for many applications, because QACs have been found to be effective against *L. monocytogenes* and leave a residual germicidal effect on surfaces (Ref. 43 and Ref. 51). We note that peroxyacetic acid sanitizers have been shown to be effective against biofilms containing *L. monocytogenes* (Ref. 43). Rotating sanitizers has been reported to provide for greater long term effectiveness and prevention of *L. monocytogenes* becoming established in niches in the environment and in forming biofilms (Ref. 43 and Ref. 52). However, the most important considerations for selecting a sanitizer include: regulatory approval for the intended purpose, efficacy against the target organism, and efficacy under conditions of use (concentration, temperature, pH, and water hardness). When using a sanitizer, you should take steps to ensure the sanitizer comes into contact with the surface to be sanitized, including crevices and niches.

Sanitizers are subject to registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which is administered by the U.S. Environmental Protection Agency. You should use sanitizing solutions in accordance with the conditions of use authorized under FIFRA, which should be on the product label. You should direct questions regarding the use of the sanitizer to control *L. monocytogenes* to the supplier of the sanitizer, who could have specific recommendations regarding factors (such as concentration, temperature, pH, and water hardness) that could influence the effectiveness of the sanitizer.

You can use hot water or steam to sanitize racks and equipment that are difficult to clean (Ref. 43). Using hot water or steam also can enhance sanitation efforts when addressing harborage sites for *L. monocytogenes* (Ref. 44).

D. Sanitation Monitoring

We recommend that you:

- Establish and implement written procedures, including the frequency with which they are to be performed, for monitoring sanitation conditions and practices;
- Monitor sanitation conditions and practices during processing with sufficient frequency to ensure the cleanliness of FCSs and prevent cross-contamination; and
- Correct, in a timely manner, any monitored sanitation conditions and practices that are not implemented in accordance with your written sanitation procedures.

E. Sanitation Records

We recommend that you establish and maintain sanitation records that document:

- Your written sanitation procedures;
- Your written procedures for monitoring sanitation conditions and practices;
- Your sanitation monitoring; and
- Corrections of monitored sanitation conditions and practices that are not implemented in accordance with your written sanitation procedures.

F. Relevant Sections of Part 117

Sections of part 117 that are relevant to the recommendations in this guidance regarding a general sanitation program include 21 CFR 117.35(a), 117.35(d)(1), 117.135(d)(3),117.80(c)(1), 117.80(c)(7), and 117.135(d)(3).

Sections of part 117 that are relevant to the recommendations in this guidance regarding cleaning drains include 21 CFR 117.10(b)(1), 117.10(b)(3), 117.35(a), and 117.37(b)(3).

Sections of part 117 that are relevant to the recommendations in this guidance regarding sanitizing procedures and solutions include 21 CFR 117.35(a), 117.35(b), 117.35(d), 117.35(d)(1), and 117.35(d)(2).

Sections of part 117 that are relevant to the recommendations in this guidance regarding sanitation monitoring include 21 CFR 117.35(a) and 21 CFR 117.145.

Sections of part 117 that are relevant to the recommendations in this guidance regarding sanitation records include 21 CFR 117.145(c) and 117.190.

VIII. Controls on Raw Materials and Other Ingredients

As discussed in section II.B of this guidance, *L. monocytogenes* has been detected in raw foods (such as raw seafood, raw produce, and unpasteurized milk) and in processed RTE foods (such as fresh-cut produce and soft cheeses), both of which can be used as ingredients in the manufacture of RTE foods.

In this section of this guidance, we recommend that you identify raw materials and other ingredients that are likely sources of *L. monocytogenes* and establish, implement, and monitor controls to reduce the potential that such an ingredient or other raw material will contaminate a finished RTE food with *L. monocytogenes*.

A. Raw Materials and Other Ingredients That are Potential Sources of *L. monocytogenes*

We recommend that you assess which raw materials and other ingredients (such as raw or minimally processed foods) are more likely to be contaminated with *L. monocytogenes* than others and focus control efforts on these ingredients. Based on this assessment, you should establish a list of raw materials and other ingredients for which it is reasonably foreseeable that the ingredients could be contaminated with *L. monocytogenes*. Depending on how an ingredient that you purchase is processed, it could be more or less likely to be contaminated with *L. monocytogenes*.

Raw materials and other ingredients processed with an adequate listericidal control measure that has been validated are not likely to contain *L. monocytogenes*. Examples of adequate listericidal control measures include:

- Aseptically processed and packaged;
- Retorted (e.g., canned);
- Ethylene oxide treated or irradiated in the package;
- Pasteurized (or equivalent treatment) in the package;
- Other approved lethal technologies (in the package)

We recommend that you verify that your supplier has validated the process and has programs to ensure that the process is being appropriately implemented and that recontamination is prevented on an ongoing basis. (See section VIII.B.3.)

Many raw materials and other ingredients that are not processed with a listericidal control measure can be a potential source of contamination. Factors that impact the potential for an ingredient to be a source of contamination include:

- The nature of an ingredient, including intrinsic factors such as pH and water activity;
- The manufacturing process for the ingredient;
- Supplier approval programs, programs that follow the practices described in this guidance for control of *L. monocytogenes*, and verification programs.

In the absence of adequate information about the risk presented by a particular ingredient, we recommend that you assume that the ingredient could be contaminated with *L. monocytogenes*.

B. Controlling *L. monocytogenes* in Raw Materials and Other Ingredients When Contamination With *L. monocytogenes* Is Reasonably Foreseeable

1. General

We recommend that you establish measures to prevent cross-contamination of finished RTE food by raw materials and other ingredients.

In the absence of adequate information about the risk presented by a particular ingredient, we recommend that you handle raw foods, and any other food raw materials and other ingredients that could be contaminated with *L. monocytogenes*, as if they are contaminated with *L. monocytogenes*.

2. Use of a listericidal control measure

We recommend that, where practical, you treat raw materials and other ingredients for which it is reasonably foreseeable that they will be contaminated with *L. monocytogenes* with a listericidal control measure during the manufacturing process, e.g., before a specific raw material or other ingredient is used in manufacture, or at an in-process stage of manufacture when the raw material or other ingredient is part of a mixture of ingredients.

3. Controls on suppliers

If you do not use a listericidal control measure, we recommend that you establish and implement supply-chain controls designed to reduce the potential that the ingredient or other raw material received from a supplier is contaminated with *L. monocytogenes*.[8] We recommend controls established in collaboration with your suppliers, rather than testing individual lots of raw materials or other ingredients, because limitations on product sampling make product testing a tool that primarily adds value in verifying the adequacy of control measures over time.

We recommend that you establish relationships with suppliers, develop procedures for selecting, evaluating and approving suppliers, and conduct periodic onsite audits to ensure that your suppliers have proper procedures and food safety programs in place and have a serious commitment to food safety. Examples of how to do so include:

[8] As noted in section II.A of this guidance, subpart G of part 117 establishes PCHF requirements for a supply-chain program. If you are a manufacturer/processor that is subject to subpart G of part 117, and you determine through your hazard analysis that *L. monocytogenes* in a raw material or other ingredient is a hazard that requires a preventive control and will neither control the hazard yourself nor distribute it to another manufacturer/processor who will control the hazard, part 117 requires that you establish and implement a risk-based supply-chain program for that raw material or other ingredient (21 CFR 117.405). As also noted in section II.A, we are providing a separate, comprehensive guidance on the specific PCHF requirements for a supply-chain program.

- Developing a written supplier approval program based in part on control measures the supplier has implemented for *L. monocytogenes*, using this guidance and relevant regulations as a basis for assessing the control measures to ensure that raw materials and other ingredients are not adulterated under section 402 of the FD&C Act. As part of this program, we recommend that you verify any applicable supplier environmental monitoring program, including results.
- Auditing the supplier's plant to assess whether the supplier's raw materials and other ingredients are produced under conditions that are consistent with this guidance.
- Obtaining the raw material or other ingredient under a supplier's Certificate of Conformance (COC) (guarantee). If you do so, we recommend that:
    - Any COC that you rely on include the period of guarantee, product safety specifications, and a statement that the supplier's raw materials and other ingredients are produced under conditions that are consistent with this guidance and in compliance with part 117 and
    - You obtain that COC and conduct an onsite audit of the supplier on at least an annual basis.
- Obtaining the ingredient under a supplier's Certificate of Analysis (COA) (keeping in mind the limitations associated with testing, discussed in section VIII.B.5 of this guidance) indicating that the raw material or other ingredient meets the written product safety specifications. We recommend that any COA that you rely on include the sampling plan and the analytical results of testing to detect *Listeria* spp. or *L. monocytogenes*, including the analytical method used and limits of the analytical method. See section XVII for our recommendations regarding analytical methods to detect *Listeria* spp. or *L. monocytogenes*.

4. Testing when receiving raw materials and other ingredients under a COC or COA

If your controls on raw materials or other ingredients include a COC for *L. monocytogenes*, we recommend that you periodically test raw materials and other ingredients received under the COC to verify the efficacy of the supplier's control programs. The frequency of your periodic testing should be sufficient to maintain confidence that the supplier's control programs are effective and could be reduced if the results of your audits and verification tests demonstrate compliance with your specifications and the supplier's COC.

If your controls on raw materials and other ingredients include a supplier's COA that includes test results for *L. monocytogenes*, we recommend that you verify the results of the supplier's COA on multiple lots of raw materials and other ingredients you receive until you have enough experience with that supplier to be confident in the results provided on the COA. After you have established confidence in your supplier, we recommend that you continue to test raw materials and other ingredients that you receive under a COA on a periodic basis (e.g., weekly, monthly, or quarterly, based on risk) to verify the efficacy of the supplier's control programs for *L. monocytogenes*.

We recommend that you establish and follow written procedures for any sampling and testing of raw materials and other ingredients, including your sampling plan and procedures for collecting samples, preparing samples for analysis, and your analytical methods for testing samples for L.

monocytogenes. See section XVII of this guidance for our recommendations for such procedures.

5. Testing as the only control on raw materials or other ingredients

We emphasize that testing a single lot of a food product for *L. monocytogenes* is of limited value in establishing the acceptability of that lot and cannot substitute for appropriate controls on its manufacture/processing. The primary value of product testing is as part of a history of test results that is used to verify the adequacy of control measures over time. We also emphasize that testing an incoming ingredient does not provide the same level of assurance as developing a supplier approval program based, in part, on the control measures the supplier has implemented for *L. monocytogenes* and your periodic verification that the supplier is implementing appropriate controls for *L. monocytogenes.*

However, if you choose to test an incoming ingredient for the presence of *Listeria* spp. or *L. monocytogenes* rather than establishing controls on your supplier (such as some or all of the controls recommended in section VIII.B.3 of this guidance), we recommend that you test incoming raw materials and other ingredients on a periodic basis (e.g., weekly, monthly, or quarterly) commensurate with your supplier's demonstrated ability to minimize the presence of *L. monocytogenes* based on your prior test results on raw materials and other ingredients provided by your supplier (keeping in mind the limitations associated with testing). Such testing should be more frequent if your final product is not formulated to prevent the growth of *L. monocytogenes*.

You should have a process in place to segregate and hold all raw materials or other ingredients that are tested prior to use and products that will be affected by test results.

C. Records

We recommend that you establish and maintain the following records regarding your raw materials and other ingredients:

- Your list of raw materials and other ingredients for which contamination with *L. monocytogenes* is reasonably foreseeable;
- Any written supplier program that you develop;
- Documentation of the results of any audit of a supplier;
- Any Certificate of Analysis or Certificate of Conformance (i.e., supplier's guarantee) that you rely on to control *L. monocytogenes* in raw materials or other ingredients;
- Your written procedures for sampling and testing raw materials and other ingredients, including your sampling plan and procedures for collecting samples, preparing samples for analysis, and your analytical methods for testing samples for *L. monocytogenes*;
- The results of any tests to detect *L. monocytogenes* in a raw material or other ingredient.

D. Relevant Sections of part 117

Sections of part 117 that are relevant to the recommendations in this guidance regarding control of raw materials and other ingredients include 21 CFR 117.80(a), 117.80(b)(2), 117.80(c)(4), and subpart G.

IX. Process Control Based on Formulating an RTE Food to Have Intrinsic Characteristics That Prevent the Growth of *L. monocytogenes*

As discussed in section II.B of this guidance, it is well established that the foods that pose the lowest risk of foodborne listeriosis have intrinsic (physical or chemical) characteristics that do not support the growth of *L. monocytogenes*. Formulating your food product to have one or more such intrinsic characteristics can enhance the safety of your product.

In this section of this guidance, we recommend that, as part of the process of developing an RTE food, you consider whether it is practical to use one or more of the following listeristatic formulations as a process control for *L. monocytogenes*:

- pH less than or equal to 4.4;
- Water activity less than or equal to 0.92;
- Formulated to contain one or more inhibitory substances that, alone or in combination, prevent the growth of *L. monocytogenes*, including formulation through processes such as fermentation or culturing.

As discussed more fully in sections IX.A and IX.B of this guidance, we also recommend that you demonstrate that any listeristatic formulation you use is effective and verify your formulation control on an ongoing basis.

A. Initial Demonstration That a Listeristatic Formulation is Effective (Validation)

Available approaches for demonstrating that your formulation consistently prevents growth of *L. monocytogenes* include (Ref. 53):

- Historically established formulation controls (e.g., pH less than or equal to 4.4 or water activity less than or equal to 0.92);
- Reference to scientific or technical information (e.g., published, peer-reviewed scientific studies that demonstrate the effectiveness of an antimicrobial ingredient to prevent the growth of *L. monocytogenes* in products that you manufacture, such as deli salads);
- Previous validation studies (published or internal to your establishment) (e.g., if you determine that an available validation study for one formulation of a deli salad applies at least in part to a second formulation);
- Mathematical modelling (e.g., using models related to inhibition of growth of *L. monocytogenes* to provide information useful in designing challenge studies);
- Scientifically valid experimental data (e.g., data from challenge studies that you conduct to determine inhibition of *L. monocytogenes* growth in a specific food).

These approaches are commonly used alone or in combination. For example, some formulation controls rely on a single parameter (such as pH alone or water activity alone), whereas other

formulation controls rely on a combination of parameters (such as an antimicrobial ingredient in combination with pH).

1. pH less than or equal to 4.4 or water activity less than or equal to 0.92

You may rely on data and information available in the scientific literature (e.g., Ref. 12, Ref. 15, Ref. 16, and Ref. 18 through Ref. 20) as an adequate demonstration that a listeristatic formulation that uses a pH less than or equal to 4.4, or water activity less than 0.92, is effective.

2. Listeristatic formulation that combines one or more antimicrobial substances and/or one or more other intrinsic factors

We recommend that you demonstrate, through scientific studies that include information from the scientific literature, modelling, and, where needed, challenge studies, that a listeristatic formulation that combines one or more antimicrobial substances and/or one or more other intrinsic factors will consistently prevent the growth of *L. monocytogenes*. A listeristatic formulation is generally considered to be effective if growth studies that include samples at various points during product shelf life show an increase of less than 1 log cycle over two or more time intervals in the number of *L. monocytogenes* during replicate trials with the food of interest (Ref. 25). For an example of how such studies are conducted, see Ref. 24 and Ref. 25. Such studies should be conducted by a microbiologist or other food safety expert (e.g., process authority) knowledgeable in food microbiology and pathogen control (Ref. 25). This information should provide the parameters (and the associated minimum or maximum values) that you would monitor to ensure consistent control of *L. monocytogenes*. We recommend that you use values for operating parameters that incorporate a margin of safety; this could prove useful in evaluating process deviations.

B. Ongoing Activities Relevant to a Process Control Based on a Listeristatic Formulation

1. Monitoring

If your formulation control depends upon pH or water activity alone, you should either monitor pH or water activity of each batch or monitor that all ingredients in the formulation have been added in the appropriate proportions to achieve the desired pH or water activity.

For other listeristatic formulations, you should monitor applicable process control parameters. Examples of how to do so include monitoring the amount of antimicrobial ingredient added, and/or the pH and any other parameter that is part of the hurdles that control *L. monocytogenes*, and monitoring that all ingredients in the formulation have been added in the appropriate proportions.

2. Verification

For any listeristatic formulation you use, we recommend that you establish and implement measures to verify process control on an ongoing basis. In general, these measures should

ensure that any formulation or process is consistently applied and the applicable control is consistently achieved. Examples of such measures include:

- Calibrating equipment used to measure pH or water activity in accordance with recommendations of manufacturers or other authoritative sources, or having someone other than those responsible for batch operations periodically observe the determination of pH or water activity measurement to verify the test is conducted correctly, when your listeristatic formulation is pH or water activity;
- Having someone other than those responsible for batch operations occasionally observe the addition of particular antimicrobial ingredients in specific amounts to verify batch control, when your listeristatic formulation involves a combination of one or more antimicrobial ingredients and/or one or more other intrinsic factors;
- Periodically testing a batch of your food product for pH or water activity, if your listeristatic control relies on adding ingredients in the formulation in the appropriate proportions; or
- Reviewing records of measurements to ensure the records are accurate and meet the minimum or maximum values for the process control parameters.

3. Corrective Actions or Corrections

If you have determined the pH, water activity or addition of antimicrobial ingredients of a batch is not correct during production, you can take appropriate actions to adjust the parameter to the appropriate value. If you have determined the pH, water activity or addition of antimicrobial ingredients of a batch is not correct after packaging, you should evaluate the food for safety and not release the food into commerce unless determined to be safe (e.g., by a Preventive Controls Qualified Individual (PCQI) if you are a facility subject to subpart C). You should determine what caused the problem and take steps to prevent it from reoccurring.

C. Records

We recommend that you establish and maintain records of:

- Process control parameters applicable to the listeristatic formulation, such as pH, water activity, and concentration of antimicrobial ingredient;
- Equipment calibration;
- Your validation of listeristatic process controls;
- Your monitoring and/or verification of listeristatic process control parameters (such as pH, water activity, and amount of antimicrobial ingredient added) as appropriate;
- Your review of listeristatic process control records; and
- Any corrective actions or corrections taken.

D. Relevant Sections of Part 117

Sections of part 117 that are relevant to the recommendations in this guidance regarding the use of listeristatic formulations include 21 CFR 117.80(c)(4), 117.135(c)(1), 117.145, 117.150, 117.155, 117.160, 117.165, and 117.190.

X. Listericidal Process Control

In this section of this guidance, we recommend that, as part of the process of developing an RTE food, you consider whether it is practical to include a listericidal process control in your manufacturing process. As discussed more fully in sections X.A and X.B of this guidance, we also recommend that you demonstrate that any listericidal control measure you use is effective and verify your listericidal process control on an ongoing basis. See Ref. 16.

As discussed in section II.C of this guidance, *L. monocytogenes* has been shown to persist in equipment and the processing environment in harborage sites, and can lead to recontamination of your RTE food after you apply a listericidal process control. In Appendix 1 of this guidance, we list potential sources of *L. monocytogenes* in the food processing environment. In Appendix 2 of this guidance, we provide examples of scenarios that could lead to contamination of RTE foods with *L. monocytogenes*. We recommend that you consider the information in Appendices 1 and 2 to prevent recontamination of your RTE food product after you apply a listericidal process control.

A. Initial Demonstration That a Listericidal Process Control is Effective (Validation)

We recommend that you demonstrate, through scientific studies that include information from the scientific literature, modelling, and where needed challenge studies, that a listericidal process control that you establish and use consistently destroys viable cells of *L. monocytogenes* and consistently leads to a food product that does not contain detectable *L. monocytogenes* using a method that has a sensitivity of detection of at least 0.04 CFU of *L. monocytogenes* per gram of food (<1 CFU/25 g). Determining the extent of the process necessary to achieve that goal depends, in part, upon determining the likely levels of *L. monocytogenes* prior to application of the listericidal process control.

In the absence of scientific studies, a listericidal process control that provides a reduction of the number of viable cells of *L. monocytogenes* of five orders of magnitude (five logarithms or 99.999%) could achieve that goal, particularly if the food is unlikely to be contaminated with more than 100 CFU/g. If it is reasonably foreseeable that ingredients you use could be contaminated with more than 100 CFU/g, then reducing the number of viable cells of *L. monocytogenes* by six orders of magnitude (six logarithms or 99.9999%) could be necessary to achieve that goal. Other log reductions, if appropriately validated, may adequately reduce the risk from *L. monocytogenes* to an extent sufficient to prevent illness.

Available approaches (used alone or in combination) for demonstrating that your process consistently destroys viable cells of *L. monocytogenes* include:

- Historically established process controls (e.g., milk pasteurization parameters consistent with the definition of “pasteurized” or “ultra-pasteurized” in 21 CFR 131.3);
- Reference to applicable scientific or technical information (e.g., a published, peer-reviewed scientific study that determines the thermal death time for *L. monocytogenes* in corn kernels when manufacturing corn kernels that are blanched and frozen);
- Previous validation studies (published or internal to your establishment) (e.g., determining that an available validation study for one formulation of a vegetarian “burger” applies at least in part to a second formulation);

- Mathematical modelling (e.g., using thermal death time models in laboratory media to inform decisions about appropriate times and temperatures for confirmation studies in a specific food); and
- Scientifically valid experimental data (e.g., data from challenge studies that you conduct to determine lethality of *L. monocytogenes* in a specific food).

In looking for listericidal process controls, we recommend that you consult a food safety expert (such as a microbiologist or process authority) knowledgeable in food microbiology and pathogen control and consider measures, alone or in combination, such as thermal treatment, irradiation (provided that irradiation has been approved as a direct food additive and listed in 21 CFR part 179), hydrostatic pressure processing, or product formulations that are listericidal. The information from validation studies should provide the parameters (and associated minimum or maximum values) that you would monitor to ensure consistent control of *L. monocytogenes.*

B. Ongoing Activities Relevant to a Listericidal Process Control

1. Monitoring

We recommend that you monitor parameters such as time, temperature, water activity, pH, and concentration of a listericidal ingredient with sufficient frequency to ensure that control is achieved. When practical, we recommend continuous monitoring and recording of such parameters.

2. Verification

For any listericidal process you use, we recommend that you establish and implement measures to verify process control on an ongoing basis. In general, these measures should ensure that any formulation or process is consistently applied and the applicable control is consistently achieved. Examples of such measures include:

- Calibrating process monitoring and verification equipment;
- Checking recorder charts, bed depths, pump or conveyor belt speeds, particle size (for heat penetration), and other parameters as appropriate during production to ensure they are functioning properly;
- Establishing a standard operating procedure in which an individual is responsible for periodically observing the addition of particular antimicrobial ingredients in specific amounts, if your listericidal formulation involves a combination of one or more antimicrobial ingredients;
- Verifying that all ingredients in the formulation have been added in the appropriate proportions, if you have established a process control parameter (such as pH or water activity); and
- Reviewing records of measurements to ensure the records are accurate and meet the minimum or maximum values for the process control parameters.

3. Corrective Actions or Corrections

If you have determined during processing that a process control parameter has not been met, you may be able to correct that during operations. For example, if temperature is found to be lower than the process control temperature, you may be able to increase the time to achieve an equivalent lethality. If you are subject to subpart C, we recommend that your PCQI be involved in making this correction. If you have determined after packaging that the process parameter was not met, you should evaluate the food for safety and not release the food into commerce unless determined to be safe (e.g., by your PCQI if you are a facility subject to subpart C). You should determine what caused the problem and take steps to prevent it from reoccurring. If the product evaluation indicates a safety concern and the product has been released into commerce, you should recall the product.

C. Records

We recommend that you establish and maintain records of:

- All process control parameters for the listericidal process;
- Equipment calibration;
- Your validation of listericidal process controls;
- Your monitoring of listericidal process control parameters (such as temperature, pH, water activity, and amount of antimicrobial ingredient added)
- Your review of listeristatic process control records; and
- Any corrective actions or corrections taken.

D. Relevant Sections of part 117

Sections of part 117 that are relevant to the recommendations in this guidance regarding the use of listericidal control measures include 21 CFR 117.80(c)(4), 117.135(c)(1), 117.145, 117.150, 117.155, 117.160, 117.165, and 117.190.

XI. Storage Practices and Time/Temperature Controls

As discussed in section II.B of this guidance, *L. monocytogenes* can multiply slowly at refrigeration temperatures. Even though *L. monocytogenes* can multiply slowly at refrigeration temperatures, refrigeration is a key control measure (Ref. 16).

In this section of this guidance, we recommend that you establish and implement procedures to minimize the potential for an increase in numbers of any *L. monocytogenes* that could be present. An example of such a procedure is minimizing the amount of time that ingredients and other raw materials, in-process materials, and finished foods are stored under conditions that allow growth of *L. monocytogenes*. In particular, we recommend that you establish and follow procedures to use such materials on a first-in, first-out basis or to use those with the shortest "use by" date first.

We recommend that you establish and implement time/temperature controls designed to ensure that foods are not held (e.g., before, during, or after production, or during transport) at a

combination of time and temperature that would allow a significant increase in the number of *L. monocytogenes.*

We also recommend that you establish and implement measures to verify time/temperature control on an ongoing basis. In general, these measures should ensure that the time/temperature controls are consistently applied and consistently achieved.

In the absence of specific data or other information about appropriate time/temperature controls for your particular operations, we recommend that RTE foods be stored at 4°C (~40°F) or below; higher temperatures may be appropriate when consistent with the Pasteurized Milk Ordinance (Ref. 54) or Food Code (Ref. 55).

Many foods are stored in a frozen state – e.g., to extend shelf life before retail sale or as a product available to consumers in the frozen state. *L. monocytogenes* does not grow at temperatures below freezing (Ref. 12 and Ref. 13). Therefore, freezing is a particularly effective temperature control measure to prevent growth during storage. Freezing will not eliminate *L. monocytogenes* from foods and cannot be relied upon as a control measure for the elimination or reduction of *Listeria monocytogenes*.

Sections of part 117 relevant to the recommendations in this guidance regarding storage practices and time/temperature controls include 21 CFR 117.40(e), 117.80(b)(5) and(6), 117.80(c)(2), 117.80(c)(3), 117.80(c)(4), 117.93, 117.130(c)(2)(vii), 117.145, and 117.206.

XII. Transportation

Contamination of an RTE food with *L. monocytogenes* can occur during transportation, and viable cells of *L. monocytogenes* can grow in an RTE food if the temperature is not controlled during transportation. In this section of this guidance, we provide recommendations for controls on transportation.

We recommend that you inspect transportation vehicles (trailers and tankers) for structural integrity, cleanliness, and overall suitability when unloading ingredients and prior to loading finished products.

We recommend that you transport foods that need temperature control using time/temperature controls that minimize the growth of *L. monocytogenes* (see section XI of this guidance). We also recommend that you use transportation vehicles that are equipped to maintain the temperature of applicable food (including incoming ingredients and outgoing RTE food products), where applicable, by controlling the temperature of the environment within the transportation vehicles used for such food. You should ensure food products are at the target temperature before loading the product into refrigerated trucks, which are designed to maintain a temperature but not to cool a product to the target temperature. Refrigerated vehicles should be pre-cooled with the pre-loading temperature documented prior to loading product.

We recommend that you either dedicate any tankers or repeat use bulk containers used to transport ingredients or finished food products to those specific uses or that you establish and implement procedures to prevent contamination from previously transported products. You should verify that the tanker or container has been adequately cleaned and sanitized prior to use (e.g., via wash tag from tanker wash facilities with validated washing procedures).

We also recommend that you refer to part 1, subpart O (Sanitary Transportation of Human and Animal Food) for requirements for shippers, loaders, carriers by motor vehicle and rail vehicle, and receivers engaged in the transportation of food to use sanitary transportation practices to ensure the safety of the food they transport. For example, see § 1.906 for requirements applicable to vehicles and transportation equipment and § 1.908 for requirements applicable to transportation operations.

Sections of part 117 that are relevant to the recommendations in this guidance regarding transportation include 21 CFR 117.93 and 117.130(c)(2)(iv).

XIII. Environmental Monitoring to Verify Control of *Listeria* spp. or *L. monocytogenes*

A. Goal of an Environmental Monitoring Program

Because of its pervasiveness in the environment, *L. monocytogenes* can be introduced into the environment of your plant. The goal of an environmental monitoring program is to:

- Verify the effectiveness of your control programs for *L. monocytogenes*;
- Find *L. monocytogenes* and harborage sites if present in your plant; and
- Ensure that corrective actions have eliminated *L. monocytogenes* and harborage sites when found in your plant.

A well-designed program for monitoring the environment of your plant includes:

- Collecting environmental samples[9] (i.e., collecting samples from FCSs and non-FCSs in your plant);
- Testing the collected environmental samples to identify potential sources of contamination; and
- Taking appropriate corrective actions if test results indicate the presence of *Listeria* spp. or *L. monocytogenes* in an environmental sample.

A well-designed environmental monitoring program promotes knowledge and awareness of the environmental conditions that could result in product contamination and is a more effective program than product testing alone.[10]

[9] See the glossary in section XIX.B. For the purpose of this guidance we define "environmental sample" as sample that is collected from a surface or area of the plant for the purpose of testing the surface or area for the presence of microorganisms, usually environmental pathogens.

[10] Note that part 117 requires, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system, environmental monitoring for *L. monocytogenes* or for an appropriate indicator organism (e.g., *Listeria* spp.), if contamination of an RTE food with *L. monocytogenes* is a hazard requiring a preventive control (21 CFR 117.165(a)(3)).

B. Strategies for Environmental Monitoring

We recommend that your environmental monitoring procedures use a risk-based approach in which you establish strategies for environmental monitoring (e.g., environmental sampling, sampling sites and frequency, test procedures, and corrective actions) based on both the characteristics of your RTE food products and the processing methods used to produce those products. In general, the greater the risk that an RTE food could become contaminated with *L. monocytogenes* and support growth of the organism, the greater the frequency of environmental sampling and testing, and the more stringent the corrective actions if you detect *Listeria* spp.

Table 3 lists a series of questions that you can address through a Yes/No answer. Table 3 then specifies how your answer would affect the risk that your RTE food product could become contaminated with *L. monocytogenes* – i.e., present a lower or higher risk. We recommend that you consider these questions in evaluating the risk that your RTE food product could become contaminated with *L. monocytogenes* and establishing strategies for environmental monitoring commensurate with that risk.

Table 3.--Questions to Ask in Establishing Strategies For Environmental Monitoring

Question	Lower Risk	Higher Risk
Does the food receive a listericidal treatment to adequately reduce *L. monocytogenes*?	Yes	No
Is the food formulated to prevent the growth of *L. monocytogenes* or be lethal to *L. monocytogenes* (e.g., through intrinsic characteristics such as pH or water activity)?	Yes	No
How much handling does the food receive subsequent to a pathogen reduction step and prior to packaging?	Minimal	Extensive
Does the food receive a listericidal control measure in the package?	Yes	No
What is the shelf life of the product during refrigerated storage?	Short	Long
Does the packaged RTE food support the growth of *L. monocytogenes* under normal storage conditions?	No	Yes

C. Sampling Areas

We recommend that you characterize areas in your plant according to the potential for product contamination for the purpose of collecting and testing environmental samples for the presence of *Listeria* spp. One way to do this is to characterize your plant in terms of a zone system. See Table 4 for an example of how to characterize your plant with four zones.

Table 4.--Example of a Food Plant with Four Zones

Zones	Description	Examples
Zone 1	Food-Contact Surfaces	Utensils, table surfaces, slicers, pipe interiors, tank interiors, filler bowls, packaging and conveyors, hoppers.

Zones	Description	Examples
Zone 2	Non-food-contact surfaces in close proximity to food and food contact surfaces.	Equipment housing or framework, and some walls, floors or drains in the immediate vicinity of FCSs carts
Zone 3	More remote non-food-contact surfaces that are in or near the processing areas and could lead to contamination of zones 1 and 2	Forklifts, hand trucks and carts that move within the plant and some walls, floors or drains not in the immediate vicinity of FCSs
Zone 4	Non-food-contact surfaces, remote areas outside of the processing area, from which environmental pathogens can be introduced into the processing environment	Locker rooms, cafeterias, and hallways outside the production area or outside areas where raw materials or finished foods are stored or transported

If you do not establish and use a zone-based system, we recommend that you otherwise characterize areas where you will collect environmental samples according to potential for contamination, and that you distinguish between FCSs and non-FCSs.

D. Written Procedures for Environmental Monitoring

We recommend that you have written environmental monitoring procedures.

Your written procedures should:

- Be scientifically valid;
- Specify whether you are testing for *Listeria* spp. or *L. monocytogenes*;
- Identify the locations from which samples will be collected and the number of sites to be tested during routine environmental monitoring. The number and location of sampling sites should be adequate to determine whether *Listeria* control measures are effective;
- Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples should be adequate to determine whether *Listeria* control measures are effective;
- Identify the test(s) conducted, including the analytical method(s) used to test for *Listeria* spp. or *L. monocytogenes*;
- Identify the laboratory you are using for conducting the testing; and
- Include corrective action procedures you will use when *Listeria* spp. or *L. monocytogenes* is found.

We discuss each of these recommendations for your written procedures in sections XIII.D.1 through XIII.D.7.

1. Scientifically valid

Procedures and methods for environmental sampling and the analytical testing of samples should be consistent with those described in an authoritative reference such as those by FDA's Bacteriological Analytical Manual (BAM), International Commission on Microbiological Specifications for Foods (ICMSF), American Public Health Association (APHA), and others (Ref. 56 through Ref. 60). For examples of procedures we consider to be scientifically valid, see Appendix 5 of this guidance for our recommended method to collect environmental samples, and see Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples (Ref. 60) for our recommended analytical methods for testing environmental samples. Additionally, BAM chapter 10 lists rapid screening methods for the detection of *Listeria* from environmental samples (Ref. 59).

2. Test organism

Your written environmental monitoring procedures should identify whether you are testing for *Listeria* spp. or *L. monocytogenes.* We recommend that you test for *Listeria* spp. because doing so will detect both *L. monocytogenes* as well as species of *Listeria* that are more common than *L. monocytogenes* and allow you to correct situations that could potentially lead to contamination with *L. monocytogenes*.

A positive test result for the presence of *Listeria* spp. on an FCS or non-FCS indicates the potential for contamination of an FCS or non-FCS with *L. monocytogenes* and suggests that conditions are suitable for survival and/or growth of *L*. *monocytogenes*. A positive test result for the presence of *Listeria* spp. on an FCS or a non-FCS does not establish the presence of *L. monocytogenes* on an FCS or non-FCS.

3. Sample locations and number of sites to be tested

Your written environmental monitoring procedures should specify an appropriate number of selected sampling sites. You should select these sites based on the potential for the site to be contaminated with *L. monocytogenes*. Sometimes an establishment will generate an extensive list of potential sampling sites and randomly select some number of sites from those listed sites at any specific sampling time. We recommend that such a program be designed to test all sites on the list within a defined period of time, e.g., one month. We recommend that an establishment test both FCS and non-FCS sites at each sampling time.

We recommend that you determine the appropriate number of FCS and non-FCS sampling sites based on the size of the plant, plant features, product flow, characteristics of the RTE food, the processing methods used to produce the food, and previous sampling results (if any). The number of samples generally is higher in zones 1 and 2 because of the greater risk of food contamination if the organism is present in these zones. For examples of FCSs and non-FCSs to sample, see the sites that we identify as potential sources of contamination with *L. monocytogenes* in Appendix 1. We recommend that even the smallest processors collect samples from at least 5 sites of FCS and 5 sites of non-FCS on each production line for RTE foods. We recommend that larger processors determine the appropriate number of sampling sites based on the size of the plant.

Generally we recommend that you do not composite samples taken from FCS sites because this can increase the time required to identify the source of contamination should a sample result be positive for *Listeria* spp.

As discussed in section II.C, *L. monocytogenes* is widespread in the environment, has been isolated from food packing and processing environments, and has been shown to persist in equipment and the processing environment in harborage sites. As a result, you should expect to detect the presence of *Listeria* spp. or *L. monocytogenes* on an occasional basis in environmental samples collected from your plant. As discussed in section XIII.A, the goals of an environmental monitoring program include finding *L. monocytogenes* and harborage sites if present in your plant and ensuring that corrective actions have eliminated *L. monocytogenes* and harborage sites when found in your plant. If you consistently see negative test results in environmental samples collected from your plant, we recommend that you revise your environmental monitoring procedures to add, substitute, or both add and substitute other surfaces in your plant for sample collection and testing to ensure you are not missing a source of contamination.

4. Timing and frequency for collecting environmental samples

Your written environmental monitoring procedures should specify the time(s) at which environmental samples will be collected. The most important time to collect environmental samples is at a time that is several hours into production (e.g., 3 to 4 hours) or preferably just prior to cleanup, because this allows time for *L. monocytogenes* (if present) to work its way out of harborage sites and contaminate the environment, the processing line (including FCS sites), and, potentially, RTE product. Note that if you take samples too close to the time when surfaces have been sanitized, the sanitizer may not be adequately neutralized and could interfere with the analytical test.

Your written environmental monitoring procedures should specify the frequency of sample collection. Frequency of routine sampling should be based on risk. We recommend the lowest frequency (e.g., monthly) of routine sample collection be for those RTE foods that do not support growth of *L. monocytogenes.* We recommend that the highest frequency (e.g., weekly) of routine sample collection be for those RTE foods that support growth of *L. monocytogenes*. Frequency of sampling should be increased when *Listeria* spp. positive samples are found in the plant (see section on Corrective Actions).

An example of how to specify the frequency of sample collection in a written environmental monitoring plan for FCSs in an establishment producing an RTE food that supports growth of *L. monocytogenes* is as follows:

- Collect environmental samples from specific FCSs on the production lines at least once every week when the plant is in operation; and
- Test each FCS in the plant at least once each month.

An example of how to specify the frequency of sample collection in a written environmental monitoring plan for non-FCSs in an establishment producing an RTE food that supports growth of *L. monocytogenes* is as follows:

- Collect environmental samples from representative sets of non-FCSs at least once weekly for zone 2 sites, every two weeks for zone 3 sites, and monthly for zone 4 sites when the plant is in operation; and
- Test all non-FCS sites identified in the monitoring plan at least once each quarter.

5. Test(s) conducted (including analytical method(s))

We recommend that you use the procedures described in Appendix 5 for preparing environmental samples for analysis. We recommend that you follow the FDA procedure in "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples" (Ref. 60) to test the samples you prepared for analysis. We recommend that you either test the individual environmental samples that you collect, or test a composite that you make from multiple environmental samples taken from a given area. However, you should not composite more than 5 environmental samples, because methods have not been validated to show that this does not reduce the sensitivity of detecting the presence of the organism. Consistent with our recommendations in section XIII.D.4, when compositing samples taken during production you should take samples at least 3 to 4 hours into production.

Importantly, we do ***NOT*** recommend compositing environmental samples when the purpose of your sampling is to locate the source of contamination (e.g., if you are conducting follow-up sampling after finding a positive test result for *Listeria* spp.).

6. Laboratory that conducts the testing

You may analyze samples in your own, in-house laboratory or send the samples to an outside commercial laboratory for testing. We recommend that you identify in your written environmental monitoring procedures the laboratory that will analyze your samples. We recommend that you take steps to ensure the laboratory you use is knowledgeable of the most current scientifically valid methods applicable to environmental samples. One way to do so is to determine whether the laboratory is accredited (e.g., to a laboratory testing standard such as ISO 17025). Because multiple, scientifically-valid analytical methods could be available for a particular application, the analytical methods used could differ among laboratories.

7. Corrective action procedures

We recommend that your written environmental monitoring procedures include corrective action procedures that describe the steps to be taken and assign responsibility for taking those steps, to:

- Ensure that the cause of the contamination is identified and corrected; and
- Minimize the potential for foods to be contaminated with *L. monocytogenes* from any source (e.g., equipment, people, and the processing or packing environment).

We recommend that your corrective action procedures be risk-based from the perspectives of:

- The environmental monitoring strategy for the food;
- Whether the environmental contamination is on an FCS or a non-FCS;

- Whether testing environmental samples results in an isolated positive result or multiple positive results; and
- The proximity of a contaminated non-FCS to FCSs.

The types of corrective actions are highly varied (e.g., conducting intensified cleaning and sanitizing, conducting intensified sampling and testing, conducting a root cause analysis, and implementing "hold and test" procedures). Which corrective actions you take depends upon your specific situation. For specific recommendations for corrective actions if you detect *Listeria* spp. or *L. monocytogenes* in environmental samples collected during routine or follow-up sampling and testing, see sections XIII.E through XIII.G of this guidance and Appendix 6. We have not identified all manners in which foods or FCS can be contaminated, and it is not possible to provide a comprehensive set of corrective actions that apply in all situations. The actions you take should be based on the risk that contamination could result in contaminated food and consumer illness.

8. Periodic verification of the written environmental monitoring procedures

We recommend that you periodically verify your written environmental monitoring procedures by increased and intensive environmental sampling of the plant to assess whether the sampling sites are appropriate.

E. Corrective Actions if You Detect *Listeria* spp. on a Non-Food-Contact Surface

If you detect *Listeria* spp. on a non-FCS, as discussed in section XIII.D.7 of this guidance we recommend that you follow risk-based corrective action procedures that describe the steps to be taken, and assign responsibility for taking those steps, to ensure that the cause of the contamination is identified and corrected, and to minimize the potential for FCSs, RTE food, ingredients or packaging to become contaminated. In this section, we focus on corrective actions for positives in zone 2, which are in close proximity to food and food contact surfaces. You should also take corrective actions to eliminate *Listeria* spp. in zones 3 and 4 so as to prevent contamination moving to zones 1 or 2. Corrective actions in zones 3 and 4 may be less rigorous than those for zone 2.

As noted in section XIII.D.7, the types of corrective actions are highly varied and depend upon your specific situation. However, some of these corrective actions broadly apply to most situations. For example, when a follow-up sample taken from a non-FCS is positive for *Listeria* spp. and the applicable food is a food that supports the growth of *L. monocytogenes*, we recommend that intensified cleaning and sanitizing activities include disassembly of affected (or potentially affected) equipment[11] (if practical), along with sampling and testing, to determine the source of *Listeria* spp.

[11] In some cases the equipment that is disassembled is (or is part of) the non-FCS that tested positive (e.g., support structures for a conveyor). In other cases, the equipment that is disassembled is (or is part of) a FCS that is in close proximity to the non-FCS that tested positive (e.g., the food conveyor).

Immediately below, we describe examples of what your corrective action procedures for positive sample results on a non-FCS in zone 2 could include.

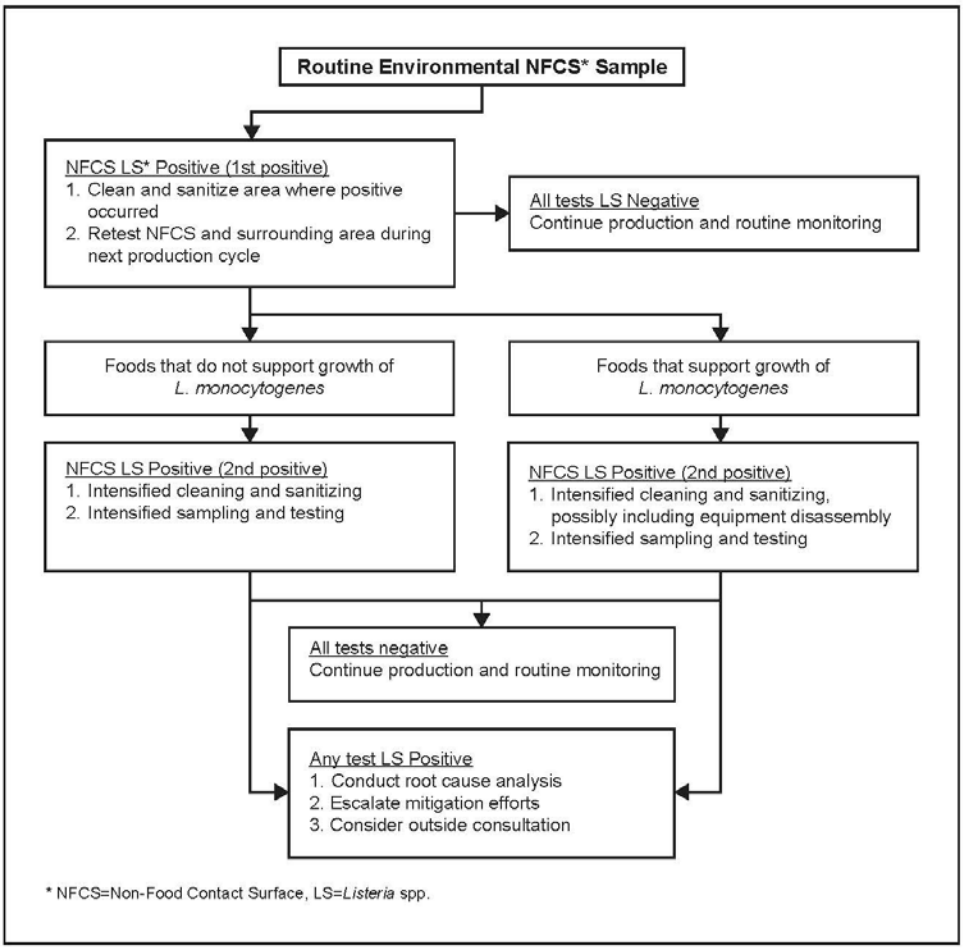
- If the positive test result is from a composite sample, conduct additional testing to identify the specific non-FCS that is contaminated with *Listeria* spp. or, alternatively, take action as if each non-FCS site represented by the composite is positive.
- When you receive notification of a positive result of a routine sample for a non-FCS site, pay particular attention to cleaning and sanitizing that site at the end of production and retest the non-FCS and surrounding area (i.e., conduct intensified sampling and testing[12]) at least 3 hours into the next production run.
- If the follow-up samples are negative for *Listeria* spp., assume the contamination has been eliminated and resume routine environmental monitoring during subsequent production.
- If any of the follow-up samples show the presence of *Listeria* spp. (i.e., if you obtain a second positive result), conduct intensified cleaning and sanitizing[13], with intensified sampling and testing to identify the source of the contamination.
    - For foods that support the growth of *L. monocytogenes,* based on the likelihood that the non-FCS could serve as a source of contamination for an FCS and/or food, these intensified cleaning and sanitizing activities could include, for example, disassembly of affected (or potentially affected) equipment if practical to determine the source of *Listeria* spp. Sample and test areas of the equipment exposed by disassembly prior to cleaning and sanitizing the equipment.
    - For foods that do not support the growth of *L. monocytogenes,* disassembly of affected (or potentially affected) equipment is less common unless sampling and testing conducted after a second positive result results in a third positive.
- If your intensified sampling and testing results are all negative, return to routine environmental monitoring.
- If your intensified sampling and testing results are not all negative, conduct a root cause analysis, escalate mitigation efforts to identify and eliminate the *Listeria* spp. source, and consider consultation with a *Listeria* control expert. Take risk-based actions to determine how the site became contaminated, including activities involved in a comprehensive investigation as discussed in section XIII.F. These actions vary depending on the risk that an FCS or food could become contaminated from the positive non-FCS site and the risk that a contaminated food would present to the consumer (e.g., based on whether the potentially contaminated food supports growth of *L. monocytogenes*). Repairing or replacing broken equipment and plant construction may be needed to remedy problems.

[12] Intensified sampling and testing involves collecting and testing follow-up samples to a positive test site. The follow-up samples should include the positive site and at least 3 surrounding sites, which could include both FCSs and non-FCSs in close proximity to the positive site.

[13] Intensified cleaning and sanitizing includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continuing findings of positives. Intensified cleaning and sanitizing can include increasing the frequency of cleaning and sanitizing for certain pieces of equipment, breaking down the equipment into its parts for further cleaning, and steam treating equipment.

See Figure 1 for a flow diagram that is a visual representation of the example corrective actions described above. (While these focus on zone 2, similar corrective actions can be applied in other zones.) See Table 6 in section XIII.G for an alternative presentation, in table format, of the flow diagram in Figure 1. Table 6 summarizes the recommended corrective actions when you detect Listeria spp. in an environmental sample taken from non-FCSs and FCSs. For each type of surface (i.e., non-FCS and FCS), Table 6 also compares the corrective actions for growth foods to the corrective actions for non-growth foods.

Figure 1.--Example of Non-FCS* testing and follow up activities for Zone 2.



The example in Figure 1 addresses testing and follow-up actions for specific positive findings of *Listeria* spp. in Zone 2 during one sampling period. Detecting *Listeria* spp. at several Zone 2 sampling locations during the same sampling period could indicate that your routine sanitation procedures are inadequate, and could indicate that the *Listeria* spp. has become established in one or more harborages in Zone 2. In such situations, the risk associated with cross-contamination from a contaminated Zone 2 site to Zone 1 or food increases as the number of contaminated Zone 2 sites increases. When several Zone 2 site positives are detected during one sampling period, we recommend that you review your written sanitation procedures to identify and implement more effective routine sanitation procedures and escalate your corrective actions until the situation is resolved.

In general, there is minimal value in determining whether *Listeria* spp. detected on a non-FCS is *L. monocytogenes*, because you should eliminate the *Listeria* spp. regardless of whether it is *L. monocytogenes*. If you find *Listeria* spp. on a non-FCS or in the same general area on multiple occasions, we recommend that you conduct a root cause analysis to determine why this area continues to be a source of positive results and take actions to eliminate the contamination, such as by determining the efficacy of your sanitation procedures and modifying them as necessary. (See Analysis of Data for Trends in Section XV.)

We also recommend that you establish and maintain a record of all corrective actions taken.

Sections of part 117 that are relevant to the recommendations in this guidance regarding corrective actions if you detect *Listeria* spp. or *L. monocytogenes* on a non-FCS include 21 CFR 117.35, 117.80(a), and 117.150.

F. Corrective Actions If You Detect *Listeria* spp. on a Food-Contact Surface

If you detect *Listeria* spp. on an FCS, as discussed in section XIII.D.7 of this guidance we recommend that you follow risk-based corrective action procedures that describe the steps to be taken, and assign responsibility for taking those steps, to ensure that the cause of the contamination is identified and corrected, and to minimize the potential for release of RTE food that is contaminated with *L. monocytogenes*. In this section XIII.F, we describe corrective action procedures that differ based on whether a food supports growth of the pathogen or not. However, we recommend that for a food that does not support growth and that is specifically intended for establishments such as hospitals and nursing homes (where the food would be consumed by populations at high risk for listeriosis), you take corrective actions in a similar manner as for foods that support growth.

1. Recommended corrective actions regarding your plant and your processing

If you detect *Listeria* spp. on an FCS, we recommend that you conduct a comprehensive investigation (i.e., an expanded root cause analysis) and take corrective actions immediately based on your written environmental monitoring procedures.

Immediately below, we provide an example of a comprehensive investigation.

- Examine the equipment that yielded the positive finding and the area surrounding the positive site in all directions for potential sources of *Listeria* spp. or *L. monocytogenes* as

described in Appendix 1 of this guidance (Categories C, D and E). Pay particular attention to possible niches that allow harborage of *L. monocytogenes*;

- Review your HACCP or Food Safety Plan, if any, and its implementation to determine if there are any design or execution flaws and modifying your plan as necessary;
- Conduct intensified sampling and testing of sites that represent a potential source of *L. monocytogenes* identified in the earlier examination, collecting samples several times during production to identify the source of contamination (the number of samples collected during production depends on the product and the production process);
- Test upstream from the positive FCS in the production area to help identify a source of contamination;
- Check maintenance records for modifications or repairs to major equipment;
- Interview and observe sanitation, maintenance, and production personnel to determine whether appropriate procedures are being followed;
- Review production, maintenance, and sanitation procedures to determine whether to modify the procedures to prevent contamination and then make those modifications identified by the review;
- Review the scenarios that we provide in Appendix 2 of this guidance as an aid to identifying causes of contamination;
- Review traffic patterns, equipment layout, and adherence to personnel hygiene procedures; and
- Take appropriate actions based on findings of the above activities.

As noted in section XIII.D.7, the types of corrective actions are highly varied and depend upon your specific situation. However, some of these corrective actions broadly apply to most situations. For example, when a follow-up sample taken from an FCS is positive for *Listeria* spp., we recommend that intensified cleaning and sanitizing activities include disassembly of affected equipment (if practical), along with sampling and testing, to determine the source of *Listeria* spp. For the purpose of this guidance we assume that a “lot” of food is one day’s production on a processing line, with cleaning and sanitizing between production lots.

Immediately below, we describe examples of what your corrective action procedures for positive sample results on an FCS could include.

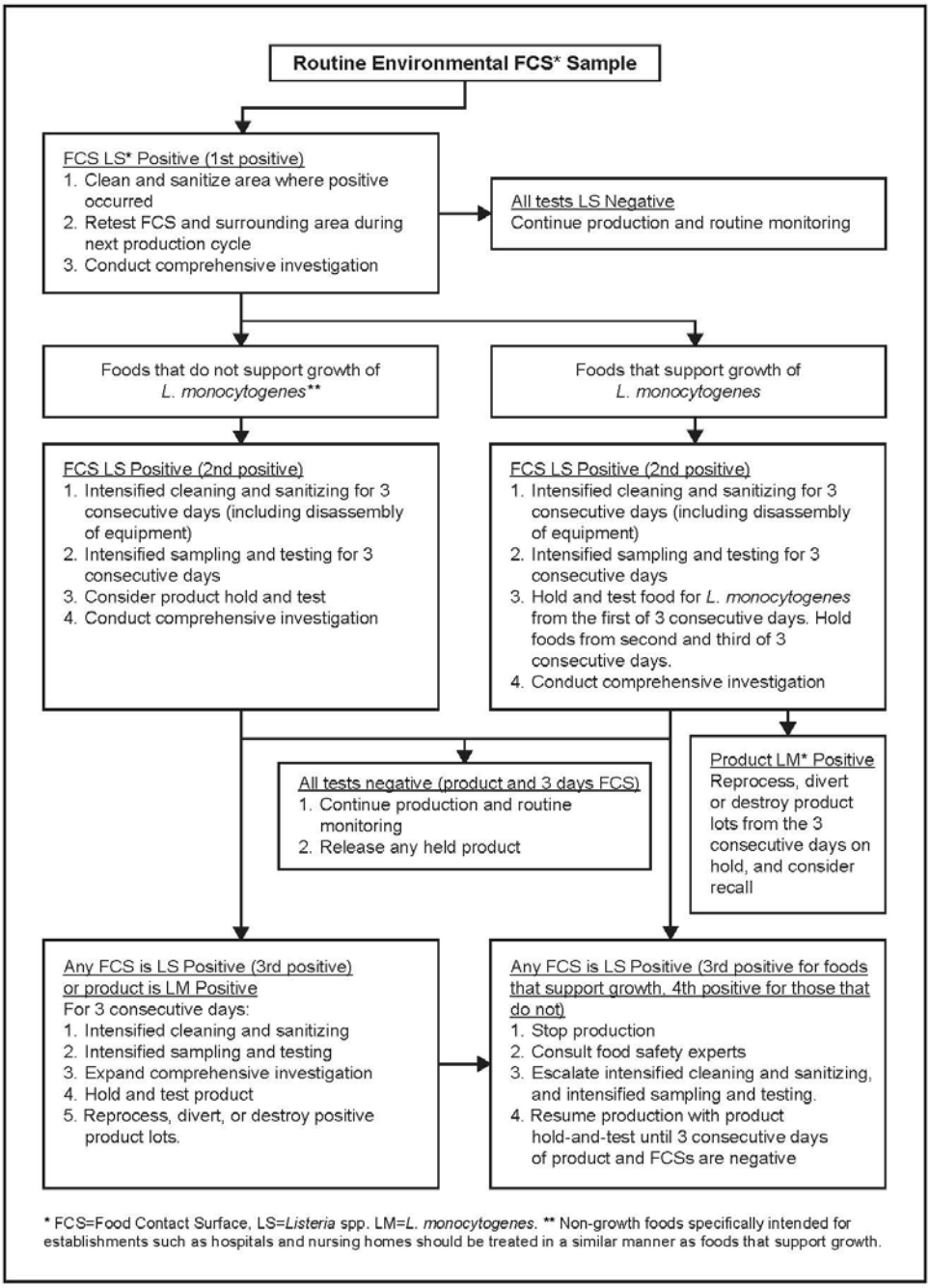
- Although we do not recommend composite sampling for FCS sites, if you initially tested a composite sample, conduct additional testing to identify the specific FCS that is contaminated with *Listeria* spp. or, alternatively, take action as if each FCS site represented by the composite is positive.
- When you receive notification of a positive result of a routine sample for an FCS site, pay particular attention to cleaning and sanitizing that site at the end of production and retest the FCS and surrounding area (i.e., conduct intensified sampling and testing) at least 3 hours into the next production run.

- If the follow-up samples from intensified sampling and testing are negative for *Listeria* spp., assume the contamination has been eliminated and resume routine environmental monitoring during subsequent production.
- If any follow-up sample from intensified sampling and testing is positive for *Listeria* spp. (second FCS positive), take enhanced corrective actions such as:
    - Conduct intensified cleaning and sanitizing, including disassembly of equipment if practical to determine the source of *Listeria* spp. Sample and test areas of the equipment exposed by disassembly prior to cleaning and sanitizing the equipment.
    - Conduct intensified sampling and testing.
    - Follow "Hold and Test" procedures as appropriate:
        - When food supports growth of *L. monocytogenes*, hold the production lot associated with that production day and test the food for presence of *L. monocytogenes* using a statistically-based sampling protocol and methods that provide a level of confidence in the results which the firm deems appropriate based on risk (e.g., a 95% confidence of detecting *L. monocytogenes* in the sample if present). (See section XIII.F.3 for our recommendations regarding "Hold and Test" procedures for RTE food.)
        - When the food does not support growth of *L. monocytogenes*, consider whether to "hold and test" the production lot associated with that production day. (The decision should be based on the likelihood of product contamination and the risk that contaminated product presents to the consumer.)
- Conduct a comprehensive investigation to determine and mitigate *Listeria* sources, and modify procedures where appropriate.
- On the next two production days, continue your enhanced corrective actions:
    - Conduct intensified cleaning and sanitizing, including disassembly of equipment. Sample and test areas of the equipment exposed by disassembly prior to cleaning and sanitizing the equipment.
    - Conduct intensified sampling and testing.
    - Hold product from these two production days. (Disposition of these lots will depend on results of the environmental testing for FCS sites taken during production and on results of the previous day's product being tested.)
- If results from the product lot that was tested (taken after the second FCS positive for food that supports growth and possibly for food that does not support growth) are negative for *L. monocytogenes* and the retest of the FCS is negative for three sequential days, release that product lot.
- Resume routine production, release additional product on hold, and return to routine environmental monitoring after all results for FCS samples taken during 3 sequential production days yield negative results for *Listeria* spp.
- If the food tests positive for *L. monocytogenes*, reprocess, divert to non-food use, send for use in food to be consumed by animals where appropriate, or destroy that product lot and the additional product lots on hold, and consider whether there is product in commerce that should be recalled.

- If a follow-up sample from intensified sampling and testing continues to detect *Listeria* spp. (third positive) on an FCS site, assume that you have a harborage site.
    - For foods that support growth of *L. monocytogenes,* stop production and consult food safety experts familiar with troubleshooting *L. monocytogenes* contamination problems in plants to conduct a comprehensive investigation and make recommendations for appropriate actions to take based upon that investigation. After these corrective actions have been taken and production begins, hold and test product and conduct intensified sampling and testing until you have three consecutive dates of negative results for FCSs and product.
    - For foods that do not support growth of *L. monocytogenes*, after the third FCS positive, take the same corrective actions as you would take for a food that supports growth after a second FCS positive, including the same hold and test procedure for foods that support growth.

See Figure 2 for a flow diagram that is a visual representation of the example corrective actions described immediately above. See Table 6 in section XIII.G for an alternative presentation, in table format, of the flow diagram in Figure 2. Table 6 summarizes the recommended corrective actions when you detect *Listeria* spp. in an environmental sample taken from non-FCSs and FCSs. For each type of surface (i.e., non-FCS and FCS), Table 6 also compares the corrective actions for growth foods to the corrective actions for non-growth foods.

Figure 2.--Example of FCS* testing and follow-up activities.



The example in Figure 2 addresses testing and follow-up actions for specific positive finding of *Listeria* spp. on an FCS during one sampling period. Detecting *Listeria* spp. at several FCS sampling locations during the same sampling period could indicate that your routine sanitation procedures are inadequate, and could indicate that the *Listeria* spp. has become established in one or more harborages sites that are FCS or in Zone 2 nearby FCS. In such situations, the risk associated with cross-contamination from contaminated FCS sites to food increases as the number of contaminated FCS sites increases. When several FCS site positives are detected during one sampling period, we recommend that you immediately review your written sanitation procedures to identify and implement more effective routine sanitation procedures, escalate your corrective actions, and conduct a root cause analysis to identify and eliminate the *Listeria* spp. source.

If you find *Listeria* spp. on FCS sites in the same general area on multiple occasions, we recommend that you conduct a root cause analysis to determine why this area continues to be a source of positive results and take actions to eliminate the contamination, such as by determining the efficacy of your sanitation procedures and modifying them as necessary. (See Analysis of Data for Trends in Section XV.)

2. Determining whether *Listeria* spp. is *L. monocytogenes*

If an FCS tests positive for the presence of *Listeria* spp., we recommend that your corrective action procedures specify when to determine whether the *Listeria* spp. is *L. monocytogenes*. In general, the greater the risk of foodborne illness presented by the RTE food being produced on an FCS that has tested positive for *Listeria* spp., the greater the importance of determining whether any *Listeria* spp. you detect on an FCS is *L. monocytogenes*.

3. "Hold and Test" procedures for RTE food

FSIS has issued guidelines to help establishments that produce certain RTE meat or poultry products to comply with FSIS' requirements (established in 9 CFR part 430) for the control of *L. monocytogenes* in those RTE meat and poultry products (Ref. 61) (the FSIS Guidelines). The FSIS guidelines include procedures to hold and test RTE foods for *L. monocytogenes*, The FSIS guidelines describe ICMSF's scientifically-based sampling plans that can be used to provide statistical confidence for results of product testing (Ref. 61). The following description is based on the discussion of the ICMSF sampling plans in the FSIS guidelines.

ICMSF categorizes microbial hazards according to risk:

1) Moderate
2) Serious
3) Severe

ICMSF ranks *L. monocytogenes* as either a serious hazard in foods for the general population or a severe hazard in foods for restricted populations (high risk groups e.g., hospital and nursing home patients) (Ref. 62). ICMSF does not identify any circumstances in which *L. monocytogenes* would be ranked as a moderate hazard.

ICMSF describes 15 different cases of sampling plans (Ref. 62), with sampling plan stringency based on degree of risk and the effect on risk of the conditions of use. Cases 10, 11, and 12 would apply to the serious category of microbial hazards and cases 13, 14, or 15 would apply to the severe category of microbial hazards. ICMSF considers cases 13, 14, and 15 to apply to

foods intended specifically for highly susceptible individuals (e.g., patients in hospitals and nursing homes) because a large proportion of the individuals would be potentially susceptible to foodborne illness; thus, increasing the stringency of the sampling plans is appropriate.

For cases 10 or 13, conditions of use reduce risk (e.g., the numbers of *L. monocytogenes* will decrease). For cases 11 and 14, conditions cause no change in the hazard (e.g., *L. monocytogenes* cannot grow), and for cases 12 and 15, conditions could increase the risk (e.g., foods in which *L. monocytogenes* can grow are subjected to conditions that allow growth). Sampling plans for the cases are given in Table 5, where n is the number of samples and c=0 means that none of the "n" samples can be positive for *L. monocytogenes*. The table also provides the sampling plan performance, assuming a log-normal distribution with a standard deviation of 0.8; lots having the calculated mean concentrations or greater will be rejected with at least 95% confidence. Each of these plans achieves assurance that *L. monocytogenes* is present at <1 CFU in the sample size.

We recommend analyzing a 25 g sample. If the risk of the population is unknown, we recommend that you use cases 13-15.

Table 5.--Sampling plans for ICMSF cases 10 – 15

Conditions Reduce Concern[14]	Conditions cause no change[15] in concern	Conditions increase concern[16]
Case 10 n[17]=5, c[18]=0 Mean Concentration 1 cfu/32g	Case 11 n=10, c=0 Mean Concentration 1 cfu/83g	Case 12 n=20, c=0 Mean Concentration 1 cfu/185g
Case 13 n=15, c=0 Mean Concentration 1 cfu/135g	Case 14 n=30, c=0 Mean Concentration 1 cfu/278g	Case 15 n=60, c=0 Mean Concentration 1 cfu/526g

When RTE products are sampled (hold and test), the number of samples (randomly selected) would be as specified for these cases based on the risk of the product and the intended consumers.

The number of samples recommended should be collected in one day and all affected products should be held during the testing period. Testing can be for *Listeria* spp. or *L. monocytogenes*. If you obtain any positive results from this follow-up testing (using the ICMSF approach), you should conduct more significant investigations of the cause of the contamination and rigorous corrective actions.

[14] Conditions prior to consumption will result in a decrease of the number of *L. monocytogenes* (e.g., product will be heated prior to consumption, thereby killing *L. monocytogenes*).
[15] Conditions prior to consumption are not likely to change the number of *L. monocytogenes* (i.e., the organism will neither die off nor multiply).
[16] Conditions prior to consumption could result in an increase in the number of *L. monocytogenes* (i.e., the food will be held under conditions in which *L. monocytogenes* can multiply).
[17] n is the number of samples to be tested.
[18] c is the number of samples that can be positive.

G. Summary of Recommended Corrective Actions When You Detect *Listeria* spp. in an Environmental Sample

See Figure 1 in section XIII.E and Figure 2 in section XIII.F.1 for flow diagrams of examples applying the recommendations and example corrective action procedures discussed regarding your plant and your processing, including recommendations and example corrective action procedures for testing non-FCSs and FCSs, respectively, and for follow up actions based on the test results. Table 6 summarizes the recommended corrective actions when you detect *Listeria* spp. in an environmental sample taken from non-FCSs and FCSs. For each type of surface (i.e., non-FCS and FCS), Table 6 also compares the corrective actions for growth foods to the corrective actions for non-growth foods.

Table 6.--Corrective Actions when *Listeria* species is found in an environmental sample

	Non-FCS Food supports growth	**Non-FCS Food does not support growth**	**FCS Food supports growth**	**FCS Food does not support growth***
Routine sampling positive #1	• Clean and sanitize area of positive • Retest during next production cycle	• Clean and sanitize area of positive • Retest during next production cycle	• Clean and sanitize area of positive • Retest during next production cycle • Conduct comprehensive investigation	• Clean and sanitize area of positive • Retest during next production cycle • Conduct comprehensive investigation
Follow up sampling positive #2	• Intensified cleaning and sanitizing (possibly including disassembly of equipment) • Intensified sampling and testing	• Intensified cleaning and sanitizing • Intensified sampling and testing	• Intensified cleaning and sanitizing (including disassembly of equipment) • Intensified sampling and testing • Hold and test product • Reprocess, divert or destroy product on hold if there is positive product • Comprehensive investigation	• Intensified cleaning and sanitizing (including disassembly of equipment) • Intensified sampling and testing • Consider hold and test • Comprehensive investigation

	Non-FCS Food supports growth	**Non-FCS Food does not support growth**	**FCS Food supports growth**	**FCS Food does not support growth***
Follow up sampling positive #3	Root cause analysis	Root cause analysis	• Stop production and consult experts for comprehensive investigation • Intensified cleaning and sanitizing (escalated, e.g., steam equipment) • Intensified sampling and testing • Resume production with product hold and test until 3 consecutive days of product and FCSs are negative	• Intensified cleaning and sanitizing (including disassembly of equipment) • Intensified sampling and testing • Hold and test product • Expand comprehensive investigation • Hold and test product • Reprocess, divert or destroy positive product lots
Follow up sampling positive #4				Stop production and consult experts for comprehensive investigation

* We recommend that corrective actions for non-growth foods specifically intended for establishments such as hospitals and nursing homes be similar to those for foods that support growth.

H. Corrective Actions If You Detect *Listeria monocytogenes* on a Food-Contact Surface

1. Recommendations regarding your plant and your procedures

If you detect *L. monocytogenes* on an FCS, we recommend that you follow a risk-based corrective action procedure that describes the steps to be taken, and assigns responsibility for taking those steps, to ensure that the cause of the contamination is identified and corrected. We specifically recommend that your corrective actions regarding your plant and your procedures include the recommendations in section XIII.F.1 of this guidance. The goal is to find the source of contamination and eliminate it.

2. Recommendations regarding an RTE food

If you detect *L. monocytogenes* on an FCS, you should either reprocess with a validated listericidal control measure, divert to a use in which the food will not be consumed by humans or animals, send for use in food to be consumed by animals where appropriate, or destroy that lot of RTE food, and consider whether there is product in commerce that should be recalled.

I. Records

We recommend that you establish and maintain records of:

- Your written procedures for environmental monitoring, including procedures for collecting samples, procedures for preparing environmental samples for analysis, your analytical methods for testing environmental samples for *Listeria* spp. or *L. monocytogenes*, and your corrective action procedures;
- Any corrective actions that you take after detecting contamination (with *Listeria* spp. or *L. monocytogenes*) on an FCS or non-FCS; and
- The results of any tests to detect *Listeria* spp. or *L. monocytogenes* on an FCS or non-FCS.

J. Relevant Sections of part 117

Sections of part 117 that are relevant to the recommendations in this guidance regarding environmental monitoring in your plant include 21 CFR 117.80(a)(5), 117.150, 117.155, and 117.165

XIV. Sampling and Testing of RTE Foods

A. Periodic Sampling and Testing of RTE Foods to Verify Adequacy of Your Controls

Periodic sampling and testing of RTE foods that you produce can provide a historical reference of performance for your production plant and verify the adequacy of your control of *L. monocytogenes* over time. We recommend that you test food products for *L. monocytogenes* rather than for *Listeria* spp. because of the risk to public health from *L. monocytogenes* in food. If you choose to test food for *Listeria* spp. and find it to be positive, we recommend you determine whether the *Listeria* spp. is *L. monocytogenes* or treat the food as if it were contaminated with *L. monocytogenes*. We recommend that you hold all product that is represented by the food you test, e.g., food lots produced from cleanup to cleanup.

We recommend that you establish and implement a written procedure for the periodic collection of samples of your RTE food product, and for testing those samples for the presence of *L. monocytogenes*. We recommend that your written procedure include the frequency of sampling (e.g., monthly, quarterly) and the sampling plan. The frequency of sampling and the sampling plan will depend on many things, such as customer requirements, the risk of foodborne illness if the finished product is contaminated with *L. monocytogenes*, and the frequency of detection of *Listeria* spp. in environmental samples.

For recommendations on corrective actions to take if you find *L. monocytogenes* in samples of an RTE food, see section XIV.B of this guidance.

B. Corrective Actions If You Detect *L. monocytogenes* in an RTE Food

If you detect *L. monocytogenes* in an RTE food, we recommend that:

- You reprocess with a validated listericidal control measure, divert to a use in which the food will not be consumed by humans or animals, send for use in food to be consumed by animals where appropriate, or destroy the lot(s) of RTE food in which *L. monocytogenes* has been detected. You should consider lots produced between two cleaning and sanitizing cycles to be implicated by the product positive;
- You determine whether other lot(s) of food are potentially contaminated with *L. monocytogenes* and segregate and hold those lots of food. We recommend that you also review environmental monitoring results to determine if other lots could be contaminated. We recommend that you subject potentially contaminated lots to "hold and test" procedures (see our recommendations for "hold and test" procedures in section XIII.F.3 of this guidance). You should reprocess with a validated listericidal control measure, divert, or destroy any lot of RTE food in which *L. monocytogenes* is detected;
- Your corrective actions regarding your plant and your procedures include intensified sampling and testing of FCSs and non-FCSs, followed by the corrective actions we discuss in sections XIII.E and XIII.F of this guidance, until you find the source of contamination and eliminate it; and
- You determine whether food in commerce would be subject to a recall.

C. Records

We recommend that you establish and maintain records of:

- Your written procedures for sampling and testing RTE food, including your sampling plan and procedures for collecting samples, procedures for preparing samples for analysis, your analytical methods for testing samples for *L. monocytogenes*, and your corrective action procedures;
- Any corrective actions that you take after detecting contamination with *L. monocytogenes* in an RTE food; and
- The results of any tests to detect *L. monocytogenes* in an RTE food.

D. Relevant Sections of Part 117

Sections of part 117 that are relevant to the recommendations in this guidance regarding sampling and testing of RTE food include 21 CFR 117.80(a)(5) and (6), 117.150, 117.155, and 117.165.

XV. Analysis of Data for Trends

A. Trends in Data Collected from Environmental Monitoring

As discussed in section XIII.A, a well-designed environmental monitoring program promotes knowledge and awareness of the environmental conditions that could result in product contamination. The goal of an environmental monitoring program is to:

- Verify the effectiveness of your control programs for *L. monocytogenes*;
- Find *L. monocytogenes* and harborage sites if present in your plant; and

- Ensure that corrective actions have eliminated *L. monocytogenes* and harborage sites when found in your plant.

To make the best use of the verification data that you collect through your environmental monitoring program, we recommend that you analyze the data you collect through your environmental monitoring program over time for trends that can help you to continuously improve sanitation conditions in your plant by reducing the percentage of overall positive environmental samples in your plant. This trend analysis could provide evidence that *L. monocytogenes* in your plant is not being controlled (e.g., if a resident strain has become established in a niche environment) so that you can take steps to control it. Examples of trends that could indicate that *L. monocytogenes* in your plant is not being controlled are:

- Increases in positive environmental samples in particular sites or areas;
- Finding *Listeria* in the same area on multiple but non-consecutive sampling occasions (e.g., positive one week and negative the next, appearing to be isolated positives); and
- An increase in the percentage of overall positive environmental samples in the plant.

Even if you have taken appropriate corrective actions for individual positive sites from a particular area, the continued finding of positive environmental samples in that area over time could indicate a continuing problem such as an unidentified harborage site. We recommend you conduct a more complete investigation to determine if further actions are warranted if your analysis of data for trends indicates a continuing problem in a particular area.

If your trend analysis shows an increased incidence of *Listeria* species in the plant, we recommend that you conduct an investigation of the reasons and take appropriate corrective actions to reduce the incidence.

B. Trends in Data Collected from Product Testing

As discussed in section XIV, periodic sampling and testing of RTE foods that you produce can provide a historical reference of performance for your production plant and verify the adequacy of your control of *L. monocytogenes* over time. To make the best use of the verification data that you collect through your product testing program, we recommend that you analyze the data you collect through your product testing program over time for trends that can help you to continuously improve the performance of your production plant. As with the analysis of data collected from your environmental monitoring program, this trend analysis could provide evidence that *L. monocytogenes* in your plant is not being controlled so that you can take steps to control it. If your trend analysis shows an increased incidence of positive sample findings in product, we recommend that you conduct an investigation of the reasons and take appropriate corrective actions to reduce the incidence.

C. Records

We recommend that you establish and maintain a record of any trend analysis that you conduct.

XVI. Training

Part 117 requires that all individuals engaged in manufacturing, processing, packing or holding food, (including temporary or seasonal personnel, or the supervisors of such individuals) receive training in the principles of food hygiene and food safety, including the importance of personal health and personal hygiene as appropriate to the food, the facility, and the individual's assigned duties (21 CFR 117.4(b)(2)).

We recommend that you provide training in health and hygienic practices specific to control of *L. monocytogenes* for all personnel and contractors who enter production and storage areas (e.g., individuals who conduct production, maintenance, quality assurance, quality control, or warehousing operations). The training should emphasize each individual's role in control of *L. monocytogenes*¸ why that role is important, and management's expectations for adherence to the program. We also recommend that the training be conducted before the individual performs job activities, with refresher training on at least an annual basis.

We recommend that personnel who supervise or are otherwise responsible for the activities listed below successfully complete training in the application of the principles of the practices recommended in this guidance to the control of *L. monocytogenes* in RTE food.

- Establishing effective listericidal and listeristatic controls and ensuring that such controls consistently operate as intended;
- Collecting and testing environmental samples and samples of RTE food products;
- Determining and taking corrective actions; and
- Establishing and using written sanitation procedures and conducting associated monitoring.

Sections of part 117 that are relevant to the recommendations in this guidance regarding training include 21 CFR 117.4.

XVII. Procedures to Collect Samples, Prepare Samples for Analysis, and Test Samples for *Listeria* spp. or *L. monocytogenes*

We recommend that you use the following procedures to collect samples, prepare samples for analysis, and test the prepared samples for the presence of *Listeria* spp. or *L. monocytogenes*:

- Use the procedures described in Appendix 5 for preparing environmental samples for analysis.
- Use FDA's "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples" (Ref. 60) for testing environmental samples.
- Use the procedures described in FDA's Bacteriological Analytical Manual Online (BAM), Chapter 10 – "*Listeria monocytogenes*," "Detection and Enumeration of *Listeria monocytogenes* in Foods" (Ref. 56) for preparing food samples and testing them for the presence of *L. monocytogenes*.

You can conduct the tests yourself or use an outside commercial testing laboratory to conduct the tests. See our recommendations in section XIII.D.6 regarding the use of an outside commercial testing laboratory for testing.

If you or an outside commercial testing laboratory use an analytical method other than those we recommend in this section, we recommend that the method be a written, scientifically valid method that is at least equivalent to the recommended method in accuracy, precision, and sensitivity for detecting *Listeria* spp. and *L. monocytogenes*.

XVIII. Records

For your convenience, in this section of this guidance we list the records that we have recommended throughout this guidance.

- Your written program for equipment maintenance;
- The following sanitation records:
  - Your written procedures for monitoring sanitation conditions and practices;
  - Your sanitation monitoring; and
  - Corrections of monitored sanitation conditions and practices that are not implemented in accordance with your written sanitation procedures
- The following records regarding your raw materials and other ingredients:
  - Your list of ingredients and other raw materials for which contamination with *L. monocytogenes* is reasonably foreseeable;
  - Any written supplier program that you develop;
  - Documentation of the results of any audit of a supplier;
  - Any Certificate of Analysis or Certificate of Conformance (i.e., supplier's guarantee) that you rely on to control *L. monocytogenes* in raw materials or other ingredients;
  - Your written procedures for sampling and testing raw materials and other ingredients, including your sampling plan and procedures for collecting samples, preparing samples for analysis, and your analytical methods for testing samples for *L. monocytogenes*; and
  - The results of any tests to detect *L. monocytogenes* in a raw material or other ingredient.
- The following records applicable to a listeristatic process control:
  - Process control parameters applicable to the listeristatic formulation, such as pH, water activity, and concentration of antimicrobial ingredient;
  - Equipment calibration;
  - Your validation of listeristatic process controls;
  - Your monitoring of listeristatic process control parameters (such as pH, water activity, and amount of antimicrobial ingredient added);
  - Your review of listeristatic process control records; and
  - Any corrective actions or corrections taken.

- The following records applicable to a listericidal process control;
  - All process control parameters for the listericidal process;
  - Equipment calibration;
  - Your validation of listericidal process controls;
  - Your monitoring of listericidal process control parameters (such as temperature, pH, water activity, and amount of antimicrobial ingredient added)
  - Your review of listericidal process control records; and
  - Any corrective actions or corrections taken.
- The following records applicable to an environmental monitoring program:
  - Your written procedures for environmental monitoring, including procedures for collecting samples, procedures for preparing environmental samples for analysis, your analytical methods for testing environmental samples for *Listeria* spp. or *L. monocytogenes*, and your corrective action procedures;
  - Any corrective actions that you take after detecting contamination (with Listeria spp. or L. monocytogenes) on an FCS or non-FCS; and
  - The results of any tests to detect *Listeria* spp. or *L. monocytogenes* on an FCS or non-FCS.
- The following records applicable to sampling and testing RTE food:
  - Your written procedures for sampling and testing RTE food, including your sampling plan and procedures for collecting samples, procedures for preparing samples for analysis, your analytical methods for testing samples for *L. monocytogenes*, and your corrective action procedures;
  - Any corrective actions that you take after detecting contamination with *L. monocytogenes* in an RTE food; and
  - The results of any tests to detect *L. monocytogenes*.

We recommend that you review and update, as needed, your written procedures at least once a year.

XIX. Glossary

A. Terms Defined in 21 CFR part 117

Acid foods or **Acidified foods:** Foods that have an equilibrium pH of 4.6 or below.

Adequate: That which is needed to accomplish the intended purpose in keeping with good public health practice.

Allergen cross-contact: The unintentional incorporation of a food allergen into a food.

Correction: An action to identify and correct a problem that occurred during the production of food, without other actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Critical control point (CCP): A point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level.

Environmental pathogen: A pathogen capable of surviving and persisting with the manufacturing processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic spore forming bacteria.

Facility: A domestic facility or foreign facility that is required to register under section 415 of the Federal Food, Drug, and Cosmetic Act, in accordance with the requirements of 21 CFR part 1, subpart H.

Food: Includes (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article and includes raw materials and ingredients.

Food allergen: A major food allergen as defined in section 201(qq) of the Federal Food, Drug, and Cosmetic Act (e.g., any of the following: (1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans. (2) A food ingredient that contains protein derived from a food specified in paragraph (1), except any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.)

Food-contact surfaces (FCS): Those surfaces that contact human food and those surfaces from which drainage, or other transfer, onto the food or onto surfaces that contact the food ordinarily occurs during the normal course of operation. “Food contact surfaces” includes utensils and food-contact surfaces of equipment.

Hazard: Any biological, chemical (including radiological), or physical agent that has the potential to cause illness or injury.

Hazard requiring a preventive control: A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would, based on the outcome of a hazard analysis (which includes the severity of the illness or injury if the hazard were to occur and the probability that the hazard will occur in the absence of preventive controls) establish one or more preventive controls to significantly minimize or prevent the hazard in a food and components to manage those controls (such as monitoring, corrections or corrective actions, verification and records) as appropriate to the food, the facility and the nature of the preventive control and its role in the facility’s food safety system.

Known or reasonably foreseeable hazard: A potential biological, chemical (including radiological), or physical hazard that is known to be, or has the potential to be, associated with the facility or the food.

Lot: the food produced during a period of time and identified by an establishment’s specific code.

Microorganisms: Yeast, molds, bacteria, viruses, protozoa, and microscopic parasites and includes species that are pathogens. The term "undesirable microorganisms" includes those microorganisms that are pathogens, that subject food to decomposition, that indicate that food is contaminated with filth, or that otherwise may cause food to be adulterated.

Monitor: To conduct a planned sequence of observations or measurements to assess whether a process, point, or procedure is under control and to produce an accurate record for use in verification.

Pathogen: A microorganism of public health significance.

Pest: Any objectionable animals or insects including birds, rodents, flies, and larvae.

Plant: the building or structure or parts thereof, used for or in connection with the manufacturing, processing, packing, or holding of human food.

Preventive controls: Those risk-based, reasonably appropriate procedures, practices, and processes that a person knowledgeable about the safe manufacturing, processing, packing, or holding of food would employ to significantly minimize or prevent the hazards identified under the hazard analysis that are consistent with the current scientific understanding of safe food manufacturing, processing, packaging, or holding at the time of the analysis.

Preventive controls qualified individual (PCQI): A qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or is otherwise qualified through job experience to develop and apply a food safety system.

Qualified individual: A person who has the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. A qualified individual may be, but is not required to be, an employee of the establishment.

RTE (Ready-to-eat) food: Any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.

Sanitize: To adequately treat cleaned surfaces by a process that is effective in destroying vegetative cells of pathogens, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

Significantly minimize: To eliminate or reduce to an acceptable level, including to eliminate.

Validation: Obtaining and evaluating scientific and technical evidence that a control measure, combination of control measures, or the food safety plan as a whole, when properly implemented, is capable of effectively controlling the identified hazards.

Verification: The application of methods, procedures, tests and other evaluations, in addition to monitoring, to determine whether a control measure or combination of control measures is or has been operating as intended and to establish the validity of the food safety plan.

B. Terms Defined for the Purpose of This Guidance

Adequately reduce: capable of reducing the presence of *L. monocytogenes* to an extent sufficient to prevent illness.

Certificate of Analysis: a document, provided for a food prior to or upon receipt of the food, that documents certain characteristics and attributes of the food.

Certificate of Conformance: a supplier's guarantee stating that raw materials and ingredients conform to a product safety specification.

Clean in place (CIP): The removal of soil from product contact surfaces in their process position by circulating, spraying, or flowing chemical solutions and water rinses onto and over the surfaces to be cleaned.

Clean out of place (COP): A system (*e.g*., cleaning tanks) used to clean equipment parts, piping, etc. after disassembly.

Control point (CP): Any step at which biological, physical, or chemical factors can be controlled.

Cleaning: The removal of soil, food residue, dirt, grease or other objectionable matter.

Control, Control measure: See Preventive controls

Corrective action: An action to identify and correct a problem that occurred during the production of food, including actions associated with a corrective action procedure (such as actions to reduce the likelihood that the problem will recur, evaluate all affected food for safety, and prevent affected food from entering commerce).

Environmental sample: A sample that is collected from a surface or area of the plant for the purpose of testing the surface or area for the presence of microorganisms, usually environmental pathogens.

Food safety plan: A set of written documents that is based upon food safety principles and incorporates hazard analysis, preventive controls, and delineates monitoring, corrective action, and verification procedures to be followed, including a recall plan.

Food Safety System: The result of the implementation of a food safety plan.

HACCP, Hazard Analysis and Critical Control Point: A system which identifies, evaluates, and controls hazards that are significant for food safety.

Hazard analysis: The process of collecting and evaluating information on hazards and conditions leading to their presence to decide which should be addressed through a preventive control.

High efficiency particulate air (HEPA) filter: an air filter that has an efficiency of 99.97 percent to 99.99 percent when tested using the dioctylphthalate (DOP) test with a particle size of 0.3 microns. Such filters can remove all yeast, mold, bacteria and other particles that are larger than 0.3 microns.

Hold and test procedures: procedures establishing the criteria for releasing product after receiving the results of tests conducted to determine the presence of a pathogen on an FCS.

Lethality treatment: a process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogens on or in a product to make the product safe for human consumption.

***Listeria* species (*Listeria* spp.):** microorganisms within the genus *Listeria*, including the species *L. monocytogenes*.

Listericidal control: a control that will consistently destroy viable cells of *L. monocytogenes* and consistently lead to a finished food that contains less than 0.04 colony forming units (CFU) of *L. monocytogenes* per gram (g) of food.

Listeristatic formulation: pH less than or equal to 4.4; water activity less than or equal to 0.92; and formulations (including those established in whole or in part through processes such as fermentation or culturing) containing a combination of factors scientifically demonstrated to be effective in preventing growth.

Non-food-contact surface (non-FCS) any surface that, under normal operating procedures, does not contact food or the food-contact surfaces of equipment. Examples of non-FCSs include, depending on the circumstances, equipment, vents, fixtures, drains, walls, floors, and employee clothing, shoes, and accessories.

Operating limits: Criteria that could be more stringent than minimum or maximum values for process parameters and are established for reasons other than food safety.

Prerequisite programs: Procedures, including CGMPs, that provide the basic environmental and operating conditions necessary to support the Food Safety Plan.

Severity: The seriousness of the effects of a hazard.

We, us, and our: the U.S. Food and Drug Administration.

You: A person who is subject to part or all of part 117 and who manufactures, processes, packs, or holds RTE food.

Zone means a designation about a surface or area reflecting how near that surface or area is to a ready-to-eat food and the risk the surface or area poses to ready-to-eat food if the surface or area is contaminated with *L. monocytogenes*.

XX. Table of Abbreviations

Abbreviation	What It Means

Abbreviation	What It Means
2003 Risk Assessment	Quantitative Assessment of the Relative Risk to Public Health from Foodborne Listeria monocytogenes Among Selected Categories of Ready-to-Eat Foods
ASHRAE	American Society of Heating Refrigerating and Air-Conditioning Engineers
a_w	Water activity
CCP	Critical control point
CDC	Centers for Disease Control and Prevention
CIP	Clean in place
CFR	Code of Federal Regulations
CGMP	Current good manufacturing practice
COA	Certificate of Analysis
COC	Certificate of Conformance
Codex	Codex Alimentarius Commission
COP	Clean out of place
CP	Control point
D/E broth	Dey-Engley broth
EPA	U.S. Environmental Protection Agency
EPIA	Egg Products Inspection Act
FCS	Food-contact surface
FDA	U.S. Food and Drug Administration
FD&C Act	Federal Food, Drug, and Cosmetic Act
FMIA	Federal Meat Inspection Act
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture

Abbreviation	What It Means
FSIS Guidelines	FSIS' "Compliance Guideline: Controlling Listeria monocytogenes in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products"
HACCP	Hazard Analysis and Critical Control Point
ICMSF	International Commission on Microbiological Specifications for Foods
LM	*Listeria monocytogenes*
LS	*Listeria* spp.
NFCS, non-FCS	Non-food-contact surface
PCHF	Hazard Analysis and Risk- Based Preventive Controls for Human Food
PCQI	Preventive controls qualified individual
RTE food	Ready-to-eat food
Subpart B	21 CFR part 117, subpart B--Current Good Manufacturing Practice
Subpart C	21 CFR part 117, subpart C--Hazard Analysis and Risk-Based Preventive Controls
Subpart G	21 CFR part 117, subpart G--Supply-Chain Program
USDA	U.S. Department of Agriculture

XXI. References

Ref. 1 Crerar S, Dalton C, Longbottom H, Kraa E. 1996. Foodborne disease: current trends and future surveillance needs in Australia. The Medical journal of Australia 165(11-12):672-675.

Ref. 2. de Valk H, Jacquet C, Goulet V, Vaillant V, Perra A, Simon F, Desenclos JC, Martin P. *Listeria* Surveillance Feasibility Study P. 2005. Surveillance of listeria infections in Europe. Euro surveillance: bulletin Europeen sur les maladies transmissibles = European communicable disease bulletin 10(10):251-255.

Ref. 3. Scallan E, Hoekstra R, Angulo F, Tauxe R, Widdowson M, Roy S, Jones J, Griffin P. 2011. Foodborne illness acquired in the United States--major pathogens. Emerging Infectious Diseases 17(1):7-15

Ref. 4. Goulet V, Hebert M, Hedberg C, Laurent E, Vaillant V, De Valk H, Desenclos JC. 2012. Incidence of listeriosis and related mortality among groups at risk of acquiring listeriosis. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 54(5):652-660.

Ref. 5. Pouillot R, Hoelzer K, Jackson K, Henao O, Silk B. 2012. Relative risk of listeriosis in Foodborne Diseases Active Surveillance Network (FoodNet) sites according to age, pregnancy, and ethnicity. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America 54 Supplement 5:S405-410.

Ref. 6. Pouillot R, Hoelzer K, Chen Y, Dennis S. 2015. *Listeria monocytogenes* dose response revisited--incorporating adjustments for variability in strain virulence and host susceptibility. Risk Analysis 35(1):90-108.

Ref. 7. U.S. Food and Drug Administration (FDA) and U.S. Food Safety and Inspection Service (FSIS). 2003. Quantitative Assessment of the Relative Risk to Public Health from Foodborne *Listeria monocytogenes* Among Selected Categories of Ready-to-Eat Foods. (http://www.fda.gov/Food/ScienceResearch/ResearchAreas/RiskAssessmentSafetyAssessment/ucm183966.htm)

Ref. 8. Lyytikaninen O, Autio T, Maijala R. et al. 2000. An outbreak of *Listeria monocytogenes* serotype 3a infection from butter in Finland Journal of Infectious Diseases 181: 1838-1841.

Ref. 9. FDA. 2012. Information on the recalled Jensen Farms whole cantaloupes. (http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm272372.htm).

Ref. 10. FDA. 2013. FDA investigates a multi-state outbreak of *Listeria monocytogenes* linked to certain Crave Brothers farmstead classics cheeses. (http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm359588.htm), 2013

Ref. 11. FDA. 2014. Notice of Opportunity for Hearing (NOOH) - Roos Foods Inc, 3/11/14. (Letter dated March 11, 2014, from Margaret A. Hamburg of FDA to Ana Roos of Roos Foods, Inc.). (http://www.fda.gov/regulatoryinformation/foi/electronicreadingroom/ucm388921.htm)

Ref. 12. International Commission on Microbiological Specifications for Foods (ICMSF). 1996. Chapter 8. *Listeria monocytogenes***.** In *Microorganisms in Foods 5 - Characteristics of Microbial Pathogens*. pp. 141-182. Blackie Academic & Professional, London.

Ref. 13. Lou Y, Yousef AE. 1999. Characteristics of *Listeria monocytogenes* important to food processors. In *Listeria, Listeriosis, and Food Safety*, eds. ET Ryser and EH Marth. pp. 131-224. New York: Marcel Dekker, Inc. Ref. 14. El-Kest SE, Marth, EH. 1992. Freezing of *Listeria monocytogenes* and other microorganisms: a review. Journal of Food Protection. 55: 639-648.

Ref. 15. Institute of Food Technologists. 2001. Evaluation and Definition of Potentially Hazardous Foods. IFT/FDA Contract No. 223-98-2333. (http://www.fda.gov/food/foodscienceresearch/safepracticesforfoodprocesses/ucm094141.htm)

Ref. 16. Codex Alimentarius Commission. 2007. Guidelines on the application of the General Principles of Food Hygiene to the control of *Listeria monocytogenes* in foods. CAC/GL 61-2007.

Ref. 17. Sorrells KM, Enigl DC, Hatfield JR. 1989. Effect of pH, acidulant, time, and temperature on the growth and survival of *Listeria monocytogenes*. Journal of Food Protection 52 (8): 571-573.

Ref. 18. Petran RL, Zottola EA. 1989. A Study of factors affecting growth and recovery of *Listeria monocytogenes* Scott A. Journal of Food Science 54 (2): 458-460.

Ref. 19. Tienungoon S, Ratkowsky DA, McMeekin TA, Ross T. 2000. Growth limits of *Listeria monocytogenes* as a function of temperature, pH, NaCl, and lactic acid. Applied and Environmental Microbiology 66 (11): 4979-4987.

Ref. 20. Leistner L. 1995. Principles and applications of hurdle technology. In *New Methods of Food Preservation*, ed GW Gould. pp. 1-21. London: Blackie Academic & Professional.

Ref. 21. Liewen MB. Marth, EH. 1985. Growth and inhibition of microorganisms in the presence of sorbic acid: a review. Journal of Food Protection 48:364-375.

Ref. 22. Vermeulen A, Smigic N, Rajkovic A, Gysemans K, Bernaerts K, Geeraerd A, Van Impe J, Debevere J, Devlieghere F. 2007. Performance of a growth–no growth model for *Listeria monocytogenes* developed for mayonnaise-based salads: influence of strain variability, food matrix, inoculation level, and presence of sorbic and benzoic acid. Journal of Food Protection 70: 2118-2126.

Ref. 23. Tassou CC, Samaras FJ, Arkoudelos JS, Mallidis CG. 2009. Survival of acid-adapted or non-adapted *Salmonella* Enteritidis, *Listeria monocytogenes* and *Escherichia coli* O157:H7, in traditional Greek salads, International Journal of Food Science & Technology 44: 279–287.

Ref. 24. Scott VN, Swanson KMJ, Freier TA, Pruett WP, Sveum WH, Hall PA, Smoot LA, Brown DG. 2005. Guidelines for conducting *Listeria monocytogenes* challenge testing of foods. Food Protection Trends 25 (11): 818-825.

Ref. 25. National Advisory Committee on Microbiological Criteria for Foods. 2010. Parameters for determining inoculated pack/challenge study protocols. Journal of Food Protection 73 (1): 140-202.

Ref. 26. Gombas DE, Chen Y, Clavero RS, Scott VN. 2003. Survey of *Listeria monocytogenes* in ready-to-eat foods. Journal of Food Protection 66: 559-569.

Ref. 27. J. Kozak, T. Balmer, R. Byrne, K. Fisher. 1996. Prevalence of *Listeria monocytogenes* in foods: incidence in dairy products. Food Control 7: 215-221.

Ref. 28. CDC. 2015. Multistate Outbreak of Listeriosis Linked to Blue Bell Creameries Products (Final Update). (http://www.cdc.gov/listeria/outbreaks/ice-cream-03-15/)

Ref. 29. Weller D, Shiwakoti S, Bergholz P, Grohn Y, Wiedmann M, Strawn LK. 2016. Validation of a previously developed geospatial model that predicts *Listeria monocytogenes* prevalence for New York State produce fields. Applied and Environmental Microbiology 82(3), 797-807.

Ref. 30. Weller D, Wiedmann M, Strawn LK. 2015. Spatial and temporal factors associated with an increased prevalence of *Listeria monocytogenes* in spinach fields in New York State. Applied and Environmental Microbiology 81 (17), 6059-6069.

Ref. 31. Weller D, Wiedmann M, Strawn LK. 2015. Irrigation Is significantly associated with an increased prevalence of *Listeria monocytogenes* in produce production environments in New York State. Journal of Food Protection 78 (6), 1132-1141.

Ref. 32. National Advisory Committee on Microbiological Criteria for Foods. 1991. *Listeria monocytogenes*. Recommendations by the National Advisory Committee on Microbiological Criteria for Foods. International Journal of Food Microbiology 14 (3-4): 185-246.

Ref. 33. Nightingale KK, Schukken YH, Nightingale CR, Fortes ED, Ho AJ, Her Z, Grohn YT, McDonough PL, Wiedmann M. 2004. Ecology and transmission of *Listeria monocytogenes* infecting ruminants and in the farm environment. Applied and Environmental Microbiology 70: 4458–4467.

Ref. 34. Nightingale KK, Windham K , Wiedmann M. 2005. Evolution and molecular phylogeny of *Listeria monocytogenes* isolated from human and animal listeriosis cases and foods. Journal of Bacteriology 187: 5537–5551.

Ref. 35. Crépet A, Albert I, Dervin C, Carlin F. 2007. Estimation of microbial contamination of food from prevalence and concentration data: application to *Listeria monocytogenes* in fresh vegetables. Applied and Environmental Microbiology 73: 250-258.

Ref. 36. Fenlon DR, Wilson J, Donachie W. 1996. The incidence and level of *Listeria monocytogenes* contamination of food sources at primary production and initial processing. Journal of Applied Bacteriology 81 (6): 641-650.

Ref. 37. Fenlon DR. 1999. *Listeria monocytogenes* in the natural environment. Eds. ET Ryser and EH Marth. pp. 21-37. New York: Marcel Dekker, Inc. .

Ref. 38. Carpentier B, Cerf O. 2011. Persistence of *Listeria monocytogenes* in food industry equipment and premises. International Journal of Food Microbiology 145: 1-8.

Ref. 39. Miller, AJ, Call, JE, Eblen BS. 1997. Growth, injury, and survival potential of *Yersinia enterocolitica*, *Listeria monocytogenes*, and *Staphylococcus aureus* in brine chiller conditions. Journal of Food Protection, 60: 1334-1340.

Ref. 40. Golden DA, Beuchat LR, Brackett, RE. 1988. Inactivation and injury of *Listeria monocytogenes* as affected by heating and freezing. Food Microbiology 5:17-23.

Ref. 41. Conner, DE, Scott, VN, Bernard, DT. 1990. Growth, inhibition, and survival of *Listeria monocytogenes* as affected by acidic conditions. Journal of Food Protection 53: 652-655.

Ref. 42. Doyle ME, Mazzotta AS, Wang T, Wiseman DW, Scott VN. 2001. Heat resistance of *Listeria monocytogenes*. Journal of Food Protection 64 (3): 410-429.

Ref. 43. Tompkin RB, Scott VN, Bernard DT, Sveum WH, Gombas KS. 1999. Guidelines to prevent post-processing contamination from *Listeria monocytogenes*. Dairy, Food and Environmental Sanitation 19 (8): 551-562.

Ref. 44. Tompkin RB. 2002. Control of *Listeria monocytogenes* in the food-processing environment. Journal of Food Protection 65 (4): 709-725.

Ref. 45. Moretro T, Lansgrund S. 2004. *Listeria monocytogenes*: Biofilm formation and persistence in food processing environments. Biofilms 1: 107-121.

Ref. 46. Gall K, Scott VN, Collette R, Jahncke M, Hicks D, Wiedmann M. 2004. Implementing targeted good manufacturing practices and sanitation procedures to minimize *Listeria* contamination of smoked seafood products. Food Protection Trends 24 (5): 302-315.

Ref. 47. Kornacki JL. 2005. Controlling *Listeria* in the food processing environment. Food Technology 59 (11): 36-42.

Ref. 48. Scott VN, Wiedmann M, Collette R, Jahncke ML, Gall K. 2005. Guidelines for *Listeria* testing of environmental, raw product and finished product samples in smoked seafood processing facilities. Food Protection Trends 25 (1): 23-24.

Ref. 49. FDA. 2011. Fish and Fisheries Products Hazards and Controls Guidance, 4th ed. (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Seafood/ucm2018426.htm)

Ref. 50. FDA. 1998. Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. (http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/ucm064574.htm)

Ref. 51. Fatemi P. Frank JF. 1999. Inactivation of *Listeria monocytogenes/Pseudomonas* biofilms by peracid sanitizers. Journal of Food Protection 62(7):761-5.

Ref. 52. FSIS. 2014. Best practices guidance for controlling *Listeria monocytogenes* in retail delicatessens. (http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index#Listeria)

Ref. 53. Codex Alimentarius Commission 2008. Guidelines for the Validation of Food Safety Control Measures, CAC/GL 69-2008. (www.codexalimentarius.org/input/download/standards/11022/CXG_069e.pdf)

Ref. 54.FDA. 2015. Grade “A” Pasteurized Milk Ordinance. (http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/Milk/ucm2007966.htm)

Ref. 55. FDA. 2013. Food Code. (http://www.fda.gov/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/ucm374275.htm)

Ref. 56. Hitchins AD (ret.), Jinneman K, Chen, Y. 2003. U.S. Food and Drug Administration, Bacteriological Analytical Manual, Ch. 10, Detection and enumeration of *Listeria monocytogenes* in foods. (http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm071400.htm)

Ref. 57. Ryser E, Donnelly C. 2013. *Listeria*. In *Compendium of Methods for the Microbiological Examination of Foods*, eds. Stephanie Doores, Yvonne Salfinger, Mary Lou Tortorello. Washington, DC: American Public Health Association. (http://ajph.aphapublications.org/doi/pdf/10.2105/MBEF.0222.040)

Ref. 58. ICMSF. 2002. Chapter 11. Sampling to assess control of the environment. In *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*. pp. 199-224. Kluwer Academic/ Plenum Publishers, NY.

Ref. 59. ICMSF. 2011. Chapter 4. Verification of environmental control. In *Microorganisms in Foods 8: Use of Data from Assessing Process Control and Product Acceptance*. pp 41- 45. Springer. NY.

Ref. 60.FDA. 2015. Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples. (http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm)

Ref. 61. FSIS. 2014. Compliance Guideline: Controlling *Listeria monocytogenes* in Post-Lethality Exposed Ready-To-Eat Meat and Poultry Products, (http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index#Listeria)

Ref. 62. ICMSF. 2002. Chapter 8. Selection of cases and attributes plans. In *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*. pp. 145-165. Kluwer Academic/Plenum publishers.

Ref. 63. FDA. 2015. Microbiological Methods & Bacteriological Analytical Manual (BAM). (http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm)

Appendix 1. Potential Sources of *L. monocytogenes*

Category	Description of Category	Potential Sources of *L. monocytogenes**

A	Ingredients	• Raw foods, such as:
		  o Raw meat, poultry, and seafood
		  o Raw milk
		  o Raw produce

B	Processing materials	• Compressed air • Ice • Brine solutions used in chilling refrigerated RTE foods
C	Contact surfaces for RTE foods	• Fibrous and porous-type conveyor belts • Filling and packaging equipment • Belts, peelers, and collators • Containers, bins, tubs and baskets • Slicers, dicers, shredders and blenders • Utensils • Gloves
D	Surfaces that generally do not contact RTE foods	• In-floor weighing equipment • Cracked hoses • Hollow rollers for conveyances • Equipment framework • Wet, rusting, or hollow framework • Open bearings within equipment • Poorly maintained compressed air filters • Condensate drip pans • Motor housings • Maintenance tools (e.g., wrenches and screw drivers) • Forklifts, hand trucks, trolleys, and racks • On/off switches • Vacuum cleaners and floor scrubbers • Trash cans and other such ancillary items • Tools for cleaning equipment (e.g., brushes and scouring pads) • Spiral freezers/blast freezers • Ice makers • Aprons
E	Plant environment	• Floors, especially cracks and crevices • Walls • Drains • Ceilings, overhead structures, and catwalks • Wash areas (e.g., sinks), condensate, and standing water • Wet insulation in walls or around pipes and cooling units • Rubber seals around doors, especially in coolers • Metal joints, especially welds and bolts • Contents of vacuum cleaners

* Adapted from Ref. 43.

Appendix 2. Examples of Scenarios That Could Lead to Contamination of RTE Foods With *L. monocytogenes*

The examples below of scenarios that could lead to contamination of RTE foods with *L. monocytogenes* are adapted from Ref. 43 and Ref. 47.

- A packaging line is moved or modified significantly.
- Used equipment is brought from storage or another plant and installed into the process flow.
- An equipment breakdown occurs.
- Construction or major modifications are made to an area where RTE foods are processed or exposed (e.g., replacing refrigeration units or floors, replacing or building walls, modifications to sewer lines).
- A new employee, unfamiliar with the operation and *L. monocytogenes* controls, has been hired to work in, or to clean equipment in, the area where RTE foods are processed or exposed.
- Personnel who handle RTE foods touch surfaces or equipment likely to be contaminated (e.g., floor, trash cans) and do not change gloves or follow other required procedures before handling the food.
- Periods of heavy production make it difficult to clean the floors of holding coolers as scheduled.
- A drain backs up.
- Product is caught or hung-up on equipment. (Stagnant product in a system can be a major site of microbial growth during production.)
- Raw or under-processed foods are placed in an area designated for cooked foods.
- Frequent product changes on a packaging line cause you to change packaging film, labels, forming pockets or molds, line speeds, etc.
- Personnel are used interchangeably for packaging raw and cooked foods.
- Increased production causes you to perform wet cleaning of lines that have been taken down from production in the same room as lines that are running product.
- Heat exchangers have become compromised (e.g., with pinholes).
- Equipment parts, tubs, screens, etc. are cleaned on the floor.
- Waste bins in the RTE area are not properly maintained, cleaned and sanitized.
- Personnel handling RTE foods come into contact with these items and then contaminate the foods and/or food contact surfaces.
- Re-circulating pumps and lines are not cleaned and sanitized.
- Indiscriminate use of high-pressure hoses in cleaning.
- Inappropriate use of footbaths in dry processing areas.

- Water is sprayed on wheels on transport cars when in-process product is stored near the wheels.

Appendix 3. Schematics Relevant to Recommended Plant Design

Figure 1.--Air Flow

Figure 2.-- Separation of Raw and RTE Areas by Partitions

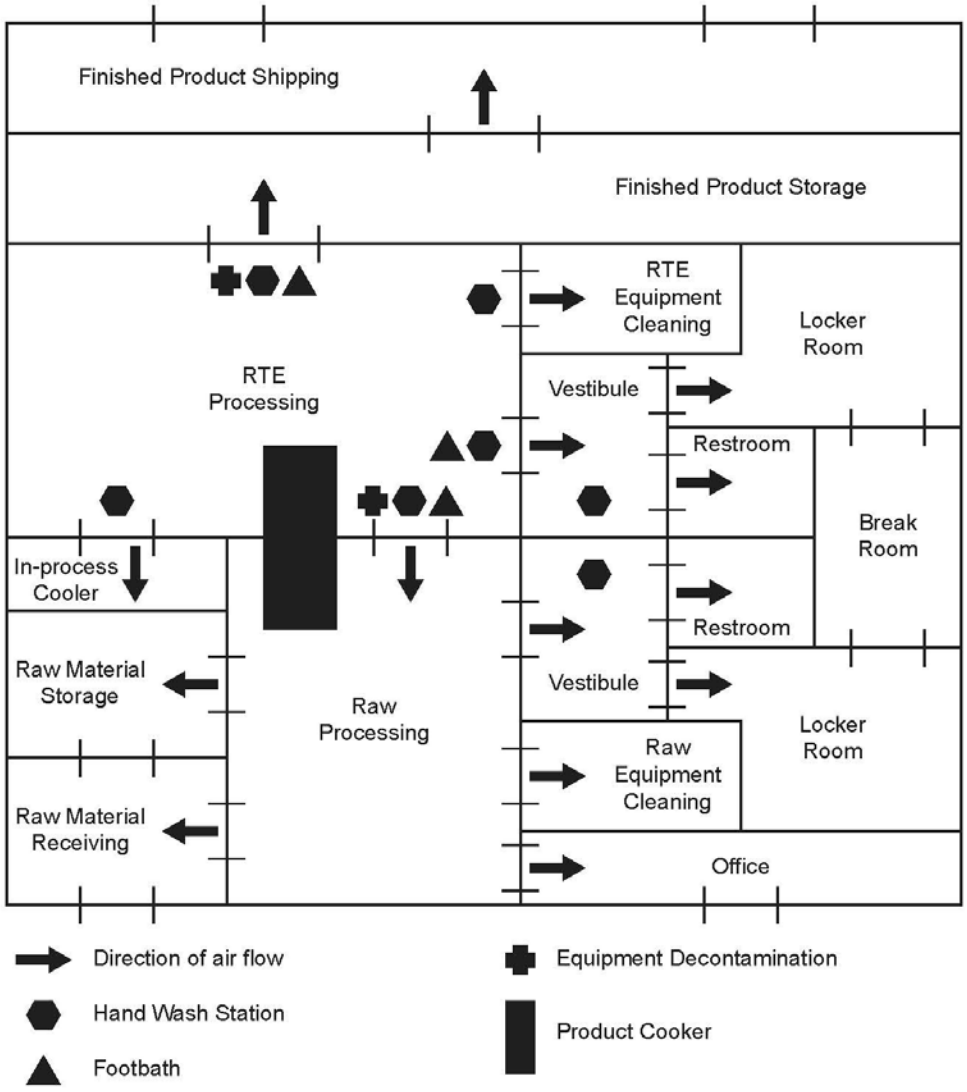
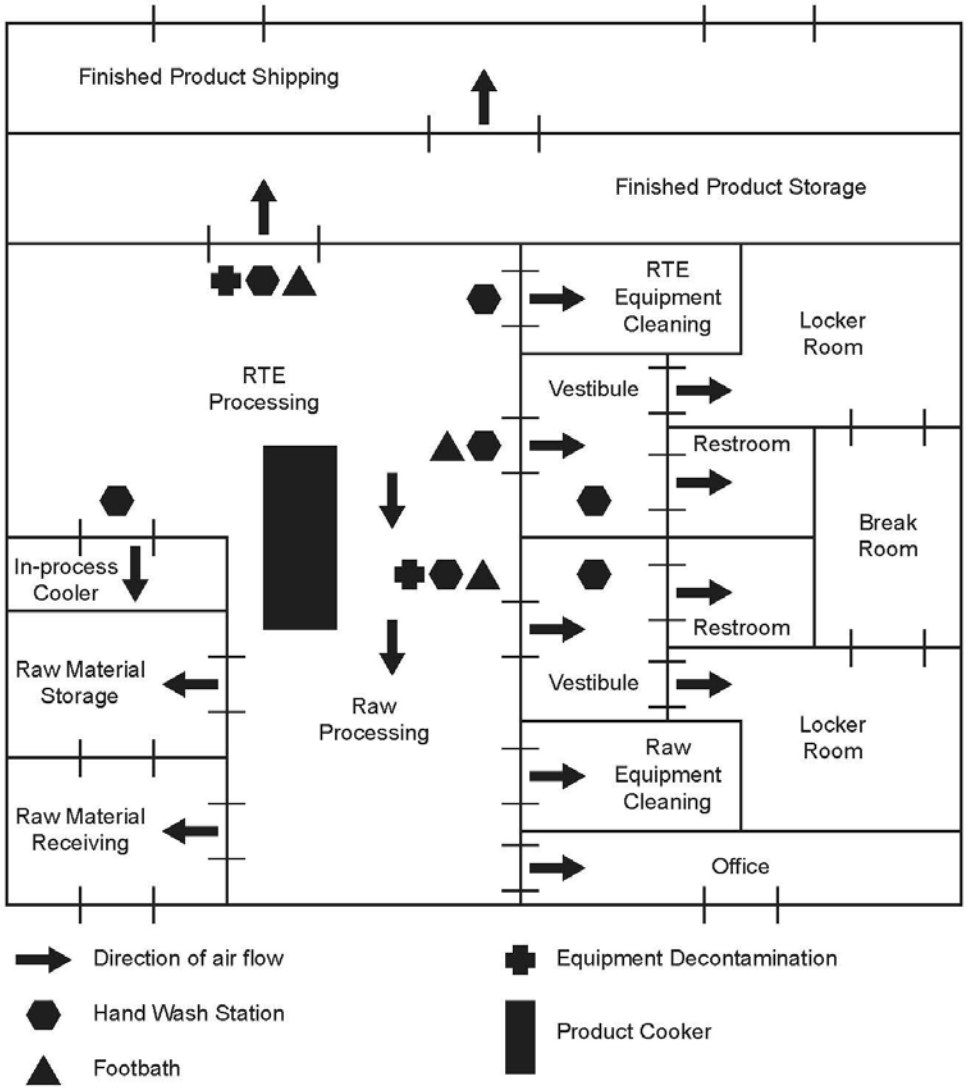


Figure 3.-- Separation of Raw and RTE Areas by Air Flow



Appendix 4. Recommended Schedules for Routine Cleaning and Sanitizing

A. Food-Contact Surfaces

In general, we recommend that you clean and sanitize FCSs at least once every 24 hours, with sanitizing or sanitary wipe-downs as needed. However, you may establish the cleaning/sanitizing schedule for any particular surface based on the characteristics of your products and processes. If you clean and sanitize less frequently than every 24 hours, you should validate the frequency of your cleaning and sanitizing by microbial testing and not allow the reduced frequency of cleaning and sanitizing to impact the microbiological condition of the production equipment.

If the results of environmental monitoring or product testing indicate a problem, you should consider increasing the frequency of cleaning and sanitizing as part of an overall corrective action procedure.

B. Non-Food-Contact Surfaces

The recommendations in the following table are adapted from Ref. 43.

If the results of environmental monitoring or product testing indicate a problem, you should consider increasing the frequency of cleaning and sanitizing as part of an overall corrective action procedure.

Surface, Area, or Equipment	Frequency of Cleaning and Sanitizing [a]
Drains and floors	Daily
Waste containers	Daily
Cleaning tools (e.g., mops, brushes)	Daily
Surfaces that have a greater potential to become a source of *L. monocytogenes* contamination (e.g., surfaces likely to be touched by personnel who touch product or FCSs during operations, or areas where there could be a build-up of moisture or product residue)	Daily
Condensate drip pans	Weekly/Monthly
Motor housings, external surfaces of enclosed processing systems	Weekly
Overhead piping, ceilings and walls[b]	Weekly/Monthly
Coolers	Weekly/Monthly
Freezers (e.g., spiral, blast, tunnel) containing exposed RTE foods[c]	Semi-annually
HVAC	Weekly/Monthly
Interiors of Ice Makers	Semi-annually

[a] Production environments vary, along with the soil characteristics of the product being produced. It may be appropriate to increase or decrease cleaning frequencies depending on the specific circumstances of the product area.

[b] We recommend that that you clean and sanitize some walls and ceilings (e.g., those in close proximity to a production line) at the same time as the production equipment (e.g., daily).

[c] If the manufacturer of the equipment recommends cleaning on a more frequent basis, we recommend that you increase this frequency to match the recommendations of the manufacturer.

Appendix 5. Recommended Procedures for Collecting Environmental Samples

We recommend that you use FDA's "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples" (version 1, Oct 2015) (Ref. 60). We describe additional recommendations related to environmental sampling in the remainder of this appendix. Because we periodically add and update microbiological methods on our Web site "Microbiological Methods & Bacteriological Analytical Manual (BAM)" (Ref. 63), we recommend that you periodically check that Web site for any updates to the procedure described in this appendix.

Laboratory analysis of samples should only be conducted by persons with appropriate microbiological training or experience*. Listeria monocytogenes* infection can cause serious illness and death, including fetal death. We recommend that pregnant women and persons who are immunocompromised because of illness, medication, or advanced age avoid working with this organism. Contaminated equipment and media should be sterilized before disposal or reuse.

A. Collecting Samples from Surfaces (Including Both Food-Contact Surfaces and Non-Food-Contact Surfaces)

The two most common methods to collect samples are "surface sponging" and "swabbing." In general, we recommend that you sample most surfaces using surface sponging, except for small or hard-to-access surfaces where swabbing works better. Another method used for sampling difficult to clean areas is liquid rinse samples.

The sample size depends on the methodology being used; to the extent practical this should be from as large an area as possible (e.g., 1 ft by 1 ft), except where sampling small nooks and crannies that can serve as harborage sites. Use swabbing or a rinse method to sample areas such as head screws, small water collection points, screw holes, threaded surfaces or interior corners of equipment.

We recommend that you wear sterile gloves. For wet surfaces, wipe and absorb moisture and wet product and residue with the sponge. For dry surfaces, wipe the sample site area with a sponge or swab moistened with D/E broth. Use a systematic technique that swabs in multiple directions. Add more buffer if necessary.

We recommend that you package properly identified samples with ice packs and ship them under refrigerated conditions within 24 hours after sampling. We recommend that the maximum time frame between sampling and receipt at an external or internal pathogen testing laboratory be 48 hours. You should not freeze samples.

B. Collecting Rinse Samples

To collect samples using a rinse technique, add small pieces from equipment (such as screws, nuts or gaskets) directly to the bag containing D/E broth and hand massage the bag for sufficient time to remove soil and residues (approximately 1 min.). Then aseptically remove the items from the bag and subject the broth to analysis.

In some situations involving small cracks and crevices, try using a plastic bulb transfer pipette and tubes containing 10 mL sterile D/E broth. Pull the D/E broth into the pipette bulb and transfer the D/E broth to the crack or crevice, then pull it back into the bulb. Repeat this several times to thoroughly rinse the crack or crevice. Then aseptically transfer the D/E broth to a sterile container for further analysis.

C. Collecting Liquid Samples (Including Floor Drain Effluents)

We recommend that you use a sterile beaker or similar container to collect 110 $\pm$ 5 ml of liquids, where possible, such as drainage effluents, standing water, melt water from thawed processing ice, and vacuum or drip pan condensate. We recommend that you immediately transfer the collected sample into a sterile screw-capped bottle and then chill and store the bottle at 5 degrees C (41 degrees F), including during transport to the testing laboratory.

D. Compositing Samples Collected from Sponges or Swabs

A common technique is to combine analytical portions from several samples and analyze the mixture of the portions (which is referred to as a "composite"). A recommended composite scheme can be used to composite up to 5 sponges or swabs. Individual samples are subject to primary enrichment as described in Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples (version 1, Oct 2015). During the transfer from the primary enrichment to the secondary enrichment, 0.1 ± 0.02 ml of each primary enrichment is transferred into an appropriate amount of secondary enrichment broth (i.e., the volume required for one sample times the number of samples) (e.g., for five sponges it would be 0.1 ml from each primary enrichment into 5 x 10 mL of secondary enrichment broth). The reserve portion of the primary enrichment can be stored at refrigeration temperature for up to 48 h, and used to analyze for *Listeria* species in each individual samples if the composite is determined to be presumptive positive.

E. Preparing Samples Collected from Liquids

For larger samples (e.g., 100 mL or greater), we recommend that you filter 100 ml of the collected liquid through one or more sterile 0.45 micron pore-diameter filters as soon as possible after sample collection. If particulate content is high (e.g., judging from the sample turbidity), we recommend that you pass the liquid through a sterile glass pre-filter before the 0.45 micron filter. Rinse the retentate on the filter plus any pre-filter with 5-10 ml of D/E broth to remove any residual inhibitory substances. If necessary, excise the filters from the funnel devices, using sterile scalpels. Put each filter and the pre-filter, if any, in a sterile bag (if you will use a Stomacher) or in a sterile container (such as a blender jar, if you use a blender). Add 225 mL of UVM broth, and follow procedures in "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples" (version 1, Oct 2015) beginning with incubation of the primary enrichment.

For small volumes of liquid samples, we recommend that you add the liquid sample to 225 mL of UVM broth, and follow procedures in "Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples" (version 1, Oct 2015) beginning with incubation of the primary enrichment.

Note: If composites are made from the filters, cut filter and any pre-filter in half using sterile instruments. Use one half of each filter to form a composite and retain the other half at 5 degrees C (41 degrees F) as a reserve for analysis if the composite is positive for *Listeria* spp.

F. Sample Analysis

See “Testing Methodology for *Listeria* species or *L. monocytogenes* in Environmental Samples” (version 1, Oct 2015).