



MARYLAND Department of Health

Sanitation Verification for Listeria and FSMA Rules

The Code of Federal Regulations (CFR) 21 part 117 states in part 117.165 (a)(3) that a firm must verify “Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food (RTE) with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples.”

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.

Requirements of 117.165 (a)(3) of this section; procedures for environmental monitoring must:

- Be scientifically valid
- Identify the test microorganism(s)
- 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 must be adequate to determine whether preventive controls are effective
- Identify the timing and frequency for collecting and testing samples. The timing and frequency for collecting and testing samples must be adequate to determine whether preventive controls are effective
- Identify the test(s) conducted, including the analytical method(s) used
- Identify the laboratory conducting the testing
- Include the corrective action procedures required by § 117.150(a)(1)

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:

- Validate the effectiveness of the methods used for your control program for *L. monocytogenes*
- Verify that your control program is consistently implemented
- Find *L. monocytogenes* and harborage sites if present in your plant
- 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 (i.e., collecting samples from food-contact surfaces (FCS) and non-FCSs in your plant)
- Testing the collected environmental samples to identify potential sources of contamination
- Taking appropriate corrective actions if test results indicate the presence of *Listeria spp.* or *L. monocytogenes* in an environmental sample

Strategies of Environmental Monitoring

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.*

Divide areas of plant into Zones 1-4: Zone 1 FCS, Zone 2-4 non-FCS

- 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*. This practice will allow you to correct situations that could potentially lead to contamination with *L. monocytogenes*
- Minimum of five FCS and five non-FCS at each sampling time for even the smallest processors

- Swab Zones 1 and 2 at a minimum during each sampling; The draft *Listeria* guidance suggests Zone 1 swabbing for *Listeria* spp., but in certain circumstances swabbing for indicator organisms such as Enterobacteriaceae (EB) or total plate count (TPC) instead may also be appropriate
- Do not composite samples (multiple locations on one swab), especially in Zone 1
- Personnel conducting sampling must have training on correct swabbing procedures

Source: *Control of Listeria monocytogenes in Ready-To-Eat Foods: Guidance for Industry*
 U.S. Department of Health and Human Services, Food and Drug Administration, Center for Food Safety and Applied Nutrition
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Listeria Fact Sheet for Food Processing Environments

What is *Listeria monocytogenes*?

Listeria monocytogenes is a bacterium found in the natural environment such as in soil, on sidewalks and in streams. *Listeria* is small (0.5 um, compared to hair's ~75 um thickness) and therefore can't be seen by the naked eye. It is also odorless and therefore leaves no visible signs of existence. The only way to detect its presence is by microbiological testing. It can survive freezing and can grow beginning at refrigeration temperatures.

Why should we care?

Listeria monocytogenes causes human illness. For healthy people, illness may resemble mild, flu-like symptoms. However, susceptible individuals, such as those who are immunocompromised and the elderly, can suffer much more severe infections with complications including meningitis. Those who are pregnant are also considered susceptible and can suffer from miscarriages and stillbirths if they become infected with *Listeria*. Most importantly, people who get sick from *Listeria* have a 15-20 percent chance of death. Therefore, it is critical that we keep *Listeria* out of the food supply.

How does *Listeria* get into food?

Oftentimes, *Listeria* gets into the food supply at the facility or retail level. It has been shown to survive in food facilities for weeks, months, and years. For example, *Listeria* may be living in the drain of a food facility or in the walk-in cooler at a retail deli. It doesn't take long before the *Listeria* moves its way to a food contact surface, either via employees or another avenue such as on the spray from a high-pressure hose. Once it gets onto a food contact surface, *Listeria* can continue to re-contaminate any food that touches that surface, surviving and growing until the moment the food is consumed by a person.

What should I do to prevent *Listeria* food contamination?

Cooking kills *Listeria*. To prevent *Listeria* contaminating food that has already been cooked or won't be cooked at all, it's important to understand if your product is a *Listeria* risk. Ask questions such as:

- Do you prepare your food in an environment that's cool or wet?
- Is your food exposed to the outside environment before being packaged or served?
- Has your food been compromised in a *Listeria* outbreak previously?

If your review indicates your product may be at risk, you should set up an environmental monitoring program designed to detect the presence of *Listeria* in the environment. This often includes routinely collecting sponge samples in areas such as drains and floor cracks.

How do I get more information?

Listeria monocytogenes: <https://www.cdc.gov/listeria/index.html>

Listeria Control Guidance:

<https://www.fda.gov/downloads/food/guidanceregulation/guidancedocumentsregulatoryinformation/ucm535981.pdf>

Listeria Environmental Sampling: <https://nyfoodsafety.cals.cornell.edu/environmental-sampling/>

Where to collect sponge samples:

General sites:

- Wet, relatively undisturbed areas
- Areas that may trap organic material and are difficult to access (e.g., weld seams, metal cracks, brushes, rollers and along threads of bolts)
- Hollow rollers
- Hollow equipment legs
- Overlapped materials such as metal on metal or plastic bolted to stainless steel
- Partially open electrical conduits
- Electrical or hydraulic junction boxes and equipment that is bagged to protect from water exposure
- Drains
- Fatigue mats and no-slip runners
- Damaged bins/totes or pallets
- Cooling units
- Drip pans
- Condensate on walls or ceilings
- Difficult-to-access or difficult-to-clean pieces of equipment
- Motor or control housings
- Flume covers
- Bearings
- Pallet jacks
- Dump tank areas
- Areas with wax build-up
- Overhead doors
- Fork lifts
- Fork lift stops (floor sandwich juncture)
- Steps/ladders/stands
- Floor cracks/holes
- Squeegees
- Catch pans
- Loading docks
- Employee footwear