Sanitation Concerns in RTE Processing Environments

Objectives

Upon completion of this training, in plant inspection personnel (IPP) will be able to:

1. Identify why establishments producing ready-to-eat (RTE) products have a special responsibility for adequate sanitation in the RTE processing environment.

2. Describe effective methods of sanitation in RTE processing environments.

3. Identify potential sanitation issues in RTE processing environments.

Introduction

IPP must have a general knowledge about the processes that the industry uses to produce safe products. It is important for IPP to be aware of the sanitation principles essential to the production of safe RTE products. In this section we will focus on establishments' responsibilities for sanitation in the RTE environment. Our focus will not be so much on regulatory requirements or their verification as much as it will be on how and why certain sanitation principles are so important to the effectiveness of the overall food safety system in RTE production processes. Previous training modules have covered verification tasks for specific sanitation regulatory requirements, and a subsequent module will consider certain regulatory requirements (9 CFR 430) specific to the production of post-lethality exposed RTE products.

Establishments producing RTE products have a special responsibility for sanitation because of the high risk of foodborne illness due to post-lethality contamination of RTE product. Of particular concern is post-lethality contamination of RTE products with the pathogen *Listeria monocytogenes*. IPP must understand effective methods of sanitation in RTE processing environments, and be able to identify potential issues that may compromise the effectiveness of an establishment's sanitation in the post-lethality processing environment.

Before we go further, let's define some of these terms. ***RTE*** products have received a ***lethality*** treatment. An example of a lethality treatment would be a process that cooks the product sufficiently to achieve food safety. The lethality treatment must be designed to eliminate pathogens, because the product must be safe to eat by the consumer without additional preparation to achieve food safety.

Many RTE processes involve handling the product after it has been subjected to an initial lethality treatment (***post-lethality exposure***). When the product is directly exposed to the environment it can become cross-contaminated. ***Cross-contamination*** is the transfer of bacteria, possibly including pathogenic bacteria, to the exposed RTE

product after the lethality treatment. These bacteria can come from the environment, from the employees, or from the equipment. They can be transferred directly, such as when an exposed RTE product is placed on a table top that has bacteria on it. Often they are transferred indirectly, such as when a pallet placed on the floor in a raw area is subsequently used in the RTE area, or when an employee handles a pallet and then touches exposed product.

Some RTE products may be reheated by the consumer to enhance palatability, but a reheating process will not necessarily eliminate any pathogens that exist on or in the product. Because many RTE products are consumed right from the package or minimal reheating, any pathogens that are present will be consumed along with the product. Thus, there is an increased risk of these products causing foodborne illness, and establishments producing these products have an increased responsibility for sanitation of the RTE processing environment.

Listeria monocytogenes in the Establishment Environment

Establishments are responsible for producing product that is free from any pathogen. The pathogen *Listeria monocytogenes* (*Lm*), one species of Listeria bacteria, is of particular concern because it has potentially fatal consequences. *Lm* is a biological food safety hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through Sanitation SOPs or some other prerequisite program. RTE product is considered adulterated if it contains *Lm* or if it comes into direct contact with a food contact surface that is contaminated with *Lm*.

Lm is particularly pathogenic to high-risk populations, including pregnant women, newborns, elderly, and people with weakened immune systems. Because *Lm* is found in the intestines of healthy animals (including humans) and in the environment in which food-producing animals are raised and processed, for example, in soil, water, and vegetation, it can be continuously introduced into the processing environment. *Lm* can contaminate surfaces of equipment, floors, walls, drains, overhead structures, etc.

Lm is spread very easily by direct contact with a contaminated surface. *Lm* can survive and grow in cool, damp environments such as those found in processing areas, coolers, or floors. Incomplete removal of product debris can provide nutrients and a place of attachment which allows bacterial growth. *Lm* can form biofilms on solid surfaces such as stainless steel and rubber, and can survive adverse conditions on apparently smooth surfaces. Recall that biofilms protect the bacteria embedded in the biofilm from sanitizers.

Lm is more heat resistant than most foodborne bacterial pathogens and also can survive freezing and drying. *Lm* is very hardy. It can survive and grow in refrigerated, packaged, ready-to-eat products and resists high salt levels, nitrite, and acid. In addition, it can grow in vacuum packaged products. Thus, it is vitally important for an

establishment to maintain strict sanitary controls to prevent the organism from contaminating products.

Foodborne illnesses and deaths have been linked to some recalled products adulterated with *Lm*. It has generally been concluded that the adulteration occurred through cross-contamination from environmental sources after cooking.

Establishments must focus on preventing contamination of RTE products with *Lm*. *Lm* can be introduced by contaminated food contact surfaces, by employees, or by environmental reservoirs or niches. Cross-contamination occurs when post-lethality exposed RTE product directly contacts a surface that has been contaminated with *Lm*. In order to prevent cross-contamination, establishments need to ensure that sanitation is effectively maintained, with special attention being given to those areas where product is stored or handled after a lethality treatment has been applied to the product.

Sanitizers that have proven most effective against *Lm* are quaternary ammonia compounds, chlorine solutions, iodophors, and products containing peroxyacetic (peracetic) acid. Note that any sanitizer must be used at appropriate levels in order to be effective, and while not required, rotation of sanitizers helps avoid development of resistant bacteria.

Because this organism needs moisture to grow, keeping storage and production areas and equipment as dry as possible helps reduce the opportunity for *Listeria* to reproduce. For example, product contact equipment, and production area floors should be maintained free of standing water and kept as dry as possible.

Sanitation Programs to Prevent *Listeria monocytogenes (Lm)*

Pre-Operational Sanitation in the RTE Processing Environment

Sanitation is critical for ensuring that RTE products do not become cross-contaminated. Sanitation SOPs should be established to provide effective and consistent results. Effective sanitation is a complex process. A successful establishment must understand and apply the cleaning and sanitizing process and select the proper methodology and chemical agents for the particular environment and equipment being cleaned. Typically, effective preoperational sanitation can be distilled down to the following recommended steps:

a) Perform **dry cleaning of the equipment**, floors, conveyor belts, and tables to remove meat particles and other solid debris. Some equipment, such as slicers and dicers, may require disassembly so that parts can be adequately cleaned.
b) **Wash and rinse floor**.

c) **Pre-rinse equipment** (rinse in same direction as product flow). Pre-rinse with warm or cold water – less than 140°F (hot water may coagulate proteins or "set soils").

d) **Clean, foam, and scrub equipment.** Always use at least the minimum contact time for the detergent/foam. Instructions should be provided on identifying possible niches and use of appropriate cleaning methods. Live steam for cleaning is not acceptable at this step since it may bake organic matter on the equipment.

e) **Rinse equipment** (rinse in same direction as product flow).

f) **Visually inspect equipment** to identify minute pieces of meat and biological residues.

g) **Sanitize floor and then equipment** to avoid contaminating equipment with aerosols from floor cleaning. Care should be taken in using high pressure hoses in cleaning the floor so that water won't splash on the already cleaned equipment. Use hot water, at least 180°F, for about 10 seconds to sanitize equipment. Sanitizers (e.g., acidic quaternary ammonia) may be more effective than steam for *Lm* control.

h) **Rotate sanitizers periodically.** Alternating between alkaline-based and acid-based detergents helps to avoid "soapstone" and biofilms. This also helps change the pH to prevent adaptation of bacteria to a particular environment.

i) **Dry.** Removing excess moisture can be done most safely and efficiently by air drying. Reduced relative humidity can speed the process. Avoid any possible cross-contamination from aerosol or splash if a method other than air drying (e.g., using a squeegee or towel) is used.

Note that ***cleaning*** consists of removing the soil from the equipment and environment. The "soil" in this case is product residue, which provides nutrients for bacterial growth. On the other hand, ***sanitizing*** is the application of either heat or chemicals to substantially reduce the numbers of microorganisms to an acceptable level. In some situations, the acceptable level for a specific pathogen is zero. Sanitizing is done after cleaning, because a sanitizer can not work effectively unless the equipment is cleaned first. Chemical solutions commonly used are chlorine, iodophors, peroxyacetic acid, or quaternary ammonium compounds. To be effective, the sanitizer must be applied at the appropriate temperature and concentration for the proper length of time. Heat, usually in the form of sufficiently hot water, can also sometimes be used to sanitize equipment, but it is still necessary to clean the equipment first. Otherwise, the hot water may cause product residue to adhere to surfaces.

Operational Sanitation in the RTE Processing Environment

Cleaning and sanitizing are very important. Pathogens can be transferred to RTE products from equipment and employee hands that have not been adequately cleaned and sanitized. Lm can hide in poorly accessible areas of equipment, and it may take several hours of production before it has seeded onto direct product contact surfaces of

equipment sufficiently to become detectable on the product contact surface or the product itself.

Protecting exposed RTE product after the initial lethality step as it moves throughout the establishment is an important consideration in preventing post-lethality contamination. Products that are inadequately packaged or covered or contained in damaged packaging could become contaminated. Packaging or covering used to protect RTE products during processing and storage should be adequate for preventing the entry of contaminants.

Examples of potential post-lethality contamination sources include:

- Solutions to chill foods, brine solutions
- Slicers, dicers, saws
- Casing peelers
- Application of contaminated non-meat or non-poultry food ingredients to RTE product post-lethality
- Lugs, tubs, containers
- Hand tools
- Packaging materials and equipment
- Tables, conveyors, belts
- Door pulls and equipment controls (employee hand contact areas)
- Employee hygiene and handling practices, including storing gloves or utensils in undesignated areas and taking gloves, outer garments, or utensils into restrooms
- Inadequate pest control programs
- Standing water
- Product falling on the floor that is either not discarded or appropriately reconditioned
- Using pallets from raw product areas in the RTE processing environment
- Condensation in the RTE processing environment
- Using high pressure hoses near exposed RTE product and product contact surfaces

Sanitation Performance Standards and Environmental Reservoirs for *Lm*

Processing activities may expose the RTE product to an environment that may lead to the product's contamination. Products must be protected during processing. Not maintaining the facility in good repair could allow for the possibility of *Lm* contamination. Workers' shoes can carry contamination onto the floors of food preparation and storage

areas. Even trace amounts of refuse or wastes in rooms used as toilets or in rooms used for storing trash or housing equipment can become sources of food contamination. Moist conditions in storage areas promote microbial growth. Sources of environmental contamination may include splash from cleaning operations, drips from overhead ventilation units, or even air currents from an insanitary environment. Bacteria can be conveyed considerable distances on air currents through fine sprays or aerosols. This could originate, for example, from a water spray directed at a drain. Ice that has been in contact with insanitary surfaces or raw meat or poultry products may contain pathogens. If this ice contacts RTE products or food contact surfaces it could lead to contamination of the final product.

Personnel hygiene practices are essential to prevent RTE product cross-contamination. Pathogens could be present on the hands of workers handling the food. The hands are particularly important in transmitting foodborne pathogens. Workers with dirty hands or fingernails may contaminate the food being prepared. Any activity which may contaminate the hands must be followed by thorough hand washing. Examples of activities which may contaminate the hands include using toilet areas, picking up any item from the floor, handling boxes, and touching door handles or other hand-contact devices. The hands of employees can be contaminated by touching their nose or other body parts. Hand washing is a critical factor in reducing pathogens that can be transmitted from hands to RTE products. Many employees fail to wash their hands as often as necessary and even those who do may use flawed technique.

Examples of potential environmental sources of contamination include:

- Poorly maintained floors
- Drains
- Standing water, e.g., from clogged drains or in overhead drip pans
- Leaking ceilings or overhead pipes
- Refrigeration units
- Wet insulation
- Equipment motor housings
- Cleaning tools: mops, brushes, squeegees or other utensils
- Employee hands, gloves and aprons
- Overhead rails and trolleys
- Maintenance personnel and tools
- Pallets
- Forklifts
- Any recessed or hollow material: rollers, switch boxes, motor housing

- Rusted materials
- Cracked or pitted rubber hoses or seals
- Walls that are cracked or pitted, and inadequately sealed surfaces
- Vacuum or air pressure pumps, lines, and hoses
- Ice makers
- Air filters
- Condensation
- Hole in the wall
- Use of high pressure hoses

Considerations in Establishment Design

There are important considerations in the layout of the establishment and the location of post-lethality processing. Cross-contamination can be avoided by separating raw meat and poultry from RTE products. Cross-contamination may also occur when raw unprepared vegetables contact ready-to-eat foods.

Air flow is an important concern. Air will flow from areas of high pressure to lower pressure. Air flow can be influenced by the location and operation of refrigeration units and other types of ventilation equipment. Air flow from a raw product area into a RTE product area could possibly carry *Lm* and contaminate the RTE product or product-contact surfaces.

An effective establishment design will include sufficient **ventilation** to prevent the formation of condensation and control humidity.

Many different types of **establishment layouts** exist. It is the establishment's responsibility to control the processing procedures in its particular processing environment in order to ensure that only safe product is produced.

Examples of establishment design considerations include:

- Maintaining the temperature in RTE processing areas and packaging rooms at a level sufficient to slow the growth of Lm in those environments. Even though Lm can grow at typical refrigeration temperatures, 31-40 degrees F is not its optimal growth range. Therefore, maintaining processing and packaging rooms under refrigeration will at least slow the microbe's growth to some extent.
- Establishing traffic patterns to eliminate movement of personnel, meat containers, meat, ingredients, pallets, and refuse containers between raw and finished product areas. If possible, employees should not work in both raw and

RTE areas. If they must work in both areas, they must change outer and other soiled clothing, wash and sanitize hands, and clean and sanitize footwear.

- Creating adequate separation between RTE and raw processing areas.
- Establishing positive air pressure movement out of the RTE room into the raw processing areas.
- Installing equipment that can be adequately cleaned, inspected, and sanitized
- Installing overhead fixtures and cooling units to ensure they can be cleaned as frequently as necessary.
- Having ventilation adequate enough to control condensation.
- Plumbing drip pans so as to properly convey accumulated moisture into drains

Listeria monocytogenes and Construction Activities

Lm contamination has been linked with disruptions in the production process or environment. In particular, disruptive construction (e.g., breaking out walls or other activities that can generate dust) has been shown to have a clear association with *Lm* contamination of both product and the surrounding environment. *Lm* can survive in moist, enclosed areas of the environments, such as cracks in walls and floors, and in crevices around drains; often these areas are disturbed during construction.

Dust generated by construction and other disruptive activities can establish contamination on food contact and other environmental surfaces. For example, dust can travel throughout the establishment on air currents or be transferred by people or equipment traveling through the construction area into other areas of the establishment. Dust from construction can be difficult to detect and control. Therefore, increased monitoring of product, food contact surfaces, and the environment is recommended **during and after** these disruptive events.

Some examples of disruptive construction activities include:

- Removal of drains
- Removal of floor coatings
- Removal of a wall or ceiling that has absorbed moisture
- Movement through an RTE area of potentially contaminated materials
- Exposure of an area typically not accessible for cleaning

Establishments have the responsibility to control establishment activities during construction in order to ensure that only safe food is produced. An establishment might decide to suspend production operations during a construction project. If not possible, the establishment should consider the following guidelines:

- Schedule construction during non-processing hours, if possible.
- Dust from construction can be difficult to detect and control. Therefore, intensive cleaning and monitoring of product, food-contact surfaces, and the environment might be necessary during and after these disruptive events.
- Air pressure in the construction area should be negative relative to production areas in order to ensure that air does not flow from the construction area into production areas.
- Temporary partitions can be established to protect the undisturbed areas of the establishment from construction dust and debris.
- Construction debris might need to be covered when moving it out of the construction area.
- Avoid moving construction debris through RTE processing areas or areas that directly connect to RTE processing areas, if possible.
- Schedule removal of all construction equipment, barriers, and final debris after production hours, if possible.
- After construction, a thorough clean-up of the area should be performed. Increased sanitation sampling might be necessary. Intensified cleaning and monitoring of food contact and environmental surfaces is recommended until surfaces test negative for 3 consecutive days.

Note that the guidelines above are not regulatory requirements

How Establishments Can Assess the Effectiveness of Sanitation Programs

Establishments can verify the effectiveness of their sanitation program through monitoring the implementation of their pre-operational and operational procedures in their Sanitation SOP. The most basic level of daily verification occurs within the post-lethality environment by monitoring the effective implementation of cleaning and sanitizing of food contact surfaces (FCSs) and observing whether operational sanitation procedures are implemented to prevent cross-contamination (9 CFR 416.13(c)). Maintaining daily records to document the implementation and monitoring of the Sanitation SOP procedures targeted to the RTE environment is also a regulatory requirement to track the effectiveness of the sanitation program (9 CFR 416.16(a)). In addition, observation of employee hygiene practices within the RTE area is required to verify compliance with the Sanitation Performance Standard and prevent cross-contamination (9 CFR 416.5(c)). There are also requirements in the Listeria Rule (9 CFR 430) for sampling for *Lm* or an indicator organism to verify sanitation.

It is also important that establishments take steps to prevent future contamination events. This can include reevaluating and modifying the Sanitation SOP for specific pieces of equipment or areas of the establishment, increasing cleaning and sanitation

frequency, and repairing or replacing equipment or areas of the establishment that may represent harborage sites for *Lm*.

Establishment Testing Programs

The **design** of establishment testing programs will vary depending on the purpose, the microorganisms tested for, the sampling method used, and the analytical methods. Some establishments will design their program for the purpose of measuring the effectiveness of the cleaning procedures; other testing programs might be designed to verify that finished product is free of a *Lm*. Some establishments test for organic residues. Another establishment might test for spoilage organisms, for example, yeast and mold, coliforms, or non-pathogenic bacteria. Other establishments might test for indicators of potential pathogens, such as *Listeria* spp. (see below). There are a wide variety of sampling methods used and many more are being developed. Some examples are: swabs and sponges used with standard plating methods, prepared plates and other testing kits of various types, and air collection systems. The amount of time it takes test results to be available also varies from several minutes to several days, depending on the type of method used.

Testing for *Listeria* spp. versus *Listeria monocytogenes.* The term *Listeria* spp. (spp. = species) refers to all strains of *Listeria*. Because *Lm* may be present only in very low numbers, it can be difficult to detect with the available testing capabilities. Therefore, many establishments use a testing plan for *Listeria* spp. because it is easier and faster to find *Listeria* spp. since the method is testing for more than one species of *Listeria*. Positive test results for *Listeria* spp. should be viewed as an indication that *Lm* may be present and alert the establishment that there are generally undesirable conditions present in the facility. However, it should be kept in mind that from both a regulatory and public health standpoint, finding *Listeria* spp. would not have the same level of significance as finding *Lm*. Finding *Listeria* spp. indicates that a pathogen may be present, but is not conclusive evidence of a pathogen. Finding *Lm* is direct evidence of a pathogen and the product would be considered adulterated. FSIS would anticipate that the company would initiate actions that address any positive findings of *Listeria* spp*.* as a means to ensure that product does not become adulterated with *Lm.*

Environmental surface testing is most often performed in the areas where exposed product is handled, such as in the post-lethality processing and packaging areas, to discover where *Listeria* might be found. Examples are air handling units, walls, floors, and drains. Environmental testing results would be used to evaluate the effectiveness of sanitation programs and develop methods to improve them. Positive tests may indicate a problem with the sanitation program such that *Listeria* exists in the environment and may or may not have been transferred to product produced in that environment. Positive environmental tests should be followed up by corrective actions such as intensive cleaning and further testing.

While not required by regulation, an environmental testing program can be an important means of confirming that the establishment’s controls are effective in maintaining an

environment that will minimize the hazard of pathogens, including *Lm*. In addition to measuring the effectiveness of a sanitation program, a correctly designed environmental testing program may:

- Provide information about sources of environmental contaminants.
- Identify the extent of pathogen contamination of the environment.
- Provide information about faulty equipment design or operation.
- Identify probable post-lethality cross-contamination sites.

Good recordkeeping is important in environmental testing programs. The results of environmental sampling may not be available until after products are produced. Therefore, adequate and accurate records are essential because the environmental sampling program is of retrospective value only. For example, identification of the site sampled and the visible condition of the site is necessary to effectively utilize the sampling results.

Food contact surface testing includes any equipment or utensils that would come into direct contact with the exposed RTE product. Examples are slicers, peelers, tables, and knives. A positive *Listeria* spp. result on a food contact surface implies that any finished product that has touched that surface may have become contaminated. A positive *Lm* result on a food contact surface means that the product that has come in contact with the contaminated surface is adulterated. We will see in a subsequent module that food contact surface testing for *Lm* or an indicator organism is required in certain situations.

Product testing determines whether *Lm* is present on the product. RTE product is adulterated if it contains *Lm* and is evidence that *Lm* contamination may be a food safety hazard reasonably likely to occur in the post-lethality processing environment. Generally, product testing for *Lm* or an indicator organism is not required.

Other methods that may be used by some establishments to help verify the effectiveness of their Sanitation SOPs include the use of organoleptic inspection along with total plate counts or ATP bioluminescence measurements, as well as organoleptic inspection. It is important to note that these methods cannot be used to replace testing performed for *Lm* or an indicator organism to meet the requirements of the Listeria Rule (9 CFR 430).

Visual verification combined with Total Plate Counts (TPCs) can determine both observable contamination and the level of bacterial contamination. Since TPC results are available in about 24 hours, and cannot be obtained at the time of inspection, their value lies in the measurement of the level of contamination. The level of contamination on cleaned and sanitized equipment should be very low (e.g., less than 100 CFU/in^2). The level of contamination may assist the establishment in determining the source of Listeria contamination and the effectiveness of the Sanitation SOP. Establishments may

be able to use the results from TPC monitoring to indicate areas where Listeria spp. testing should be performed.
Adenosine triphosphate (ATP) bioluminescence swab testing on food contact surfaces can also be a measure of sanitary conditions. ATP is an organic molecule produced in and used by living cells as their main source of energy. Animal, plant, bacterial, yeast, and mold cells utilize ATP to drive various biological processes including muscle contraction, photosynthesis, and the creation of different proteins. ATP, then, is naturally present in food residues, bacteria, yeasts, and molds. The level of ATP measured through ATP bioluminescence analysis is one method to test for sanitation effectiveness. The more ATP that is present in a sample, the greater the degree of bioluminescence. A computerized luminometer determines the amount of bioluminescence and provides a digital readout for the user. The product manufacturer specifies “acceptable” and “unacceptable” levels. The ATP test can detect contamination that is not observable, is a rapid test, and results are available immediately prior to the start of operations. It is important to note that this test only provides an indicator of the cleanliness of a surface. A high reading could indicate the presence of organic residues, microbes (living or dead), or both. Therefore, the presence of a high level of ATP on a surface indicates that the surface was inadequately cleaned and has the potential to harbor bacteria and support their growth.

It is important for the establishment to verify that the cleaning and sanitizing procedures are effective. In addition, the recordkeeping should be used for data analysis and the establishment should evaluate the monitoring records for trends. 9 CFR 416.14 requires that each official establishment routinely evaluate the effectiveness of the Sanitation SOP and the procedures therein. Therefore, trend analysis, evaluation, and appropriate revision of Sanitation SOPs should be conducted, as necessary, to remain effective and current with respect to changes in facilities, operations, equipment, utensils, personnel, and equipment within the post-lethality environment.

Relationship Between Sanitation and HACCP in RTE Production Processes

For most RTE products, there probably is a CCP in the HACCP plan for the lethality step (e.g., thermal destruction of pathogens). Another CCP may need to be established to address the prevention of contamination of RTE products that are exposed to the environment after the initial lethality treatment. This will depend on the hazard analysis and the method the establishment decided to use for control of that hazard. In some cases, part of an Sanitation SOP may be transferred to the actual HACCP plan if those controls are determined to be critical to the production of a safe meat or poultry product, and there is no post-lethality treatment later in the process which will control the hazard. For example, an establishment might have a CCP for the concentration and application of sanitizers, or for environmental testing as a verification of the effectiveness of cleaning and sanitizing programs. In other cases, the establishment’s hazard analysis may reveal that post-lethality contamination is a hazard not reasonably likely to occur because it has sanitation measures incorporated into a prerequisite program or its

Sanitation SOP to control pathogens in the environment. You will learn more about the application of inspection methods for verifying regulatory requirements in later parts of this training.

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Workshop

1. Mark T for “true” and F for “false” for each of the following statements

a) ___ A locker room shared between RTE product handlers and raw product handlers could be a source of RTE product cross-contamination.

b) ___RTE product which occasionally contacts the wall in the cooler is at risk for contamination with *Listeria monocytogenes*.

c) ___RTE products must be cooked by the consumer before they are eaten.

d) ___Periodically rotating sanitizers will provide greater effectiveness against bacteria.

e) ___*Listeria monocytogenes* is especially harmful to pregnant women and infants.

f) ___ *Listeria monocytogenes* is fragile and cannot grow in refrigerated, packaged, RTE products.

g) ___ *Listeria monocytogenes* can grow in cool, damp environments such as coolers and floors.

h) ___Establishment construction has been linked to contamination with *Listeria monocytogenes*.

i) ___An environmental testing program can be a means of confirming that the establishment’s controls are effective in maintaining an establishment environment that will minimize the hazard of pathogens.

j) ___Environmental testing could include sampling in the post-lethality processing area to discover where *Lm* might be found.

k) ___An establishment finds *Lm* in finished product through product testing. FSIS would consider this to be evidence that *Lm* contamination may be a food safety hazard reasonably likely to occur in that establishment’s processes.

l) ___Establishments are responsible for ensuring that their Sanitation SOPs are effective in preventing contamination by *Lm* in the post-lethality processing environment.

2. Case Study. (Please note: this is a simplified training example only.) You are assigned to a large RTE establishment that produces a variety of sliced, cooked ham products. Raw meats are extruded into a plastic bag, placed in a metal form, and cooked in a water bath. After cooking and cooling, the meat is removed from the bags, sliced, and sealed in 8-oz plastic film packages.

a. From the standpoint of post-lethality contamination, why is the slicing area the most critical?

You observe the slicing process. The cooked meat is dumped out of the metal forms onto a stainless steel table by one person. A second worker opens the bags with a knife and removes the meat from the bags, pushing the unwrapped meat toward the other side of the table. In that area, a third worker places the meat into the slicer. The slicing equipment deposits the sliced meat into the packaging machine, where it is sealed into the film packages.

b. List the potential food contact surfaces in this scenario.

This establishment is updating the equipment in one of the coolers. You decide to observe. You see that there is no product in the cooler and that construction workers wearing frocks over their street clothes, are dismantling the fans, overhead refrigeration units, pipes, and drains. Other workers are replacing the material on the walls. There is debris from the construction scattered about. You observe a construction worker load some of the old materials and equipment onto a pallet and take it out through the only door. This door opens into the main hallway in this establishment, used by all departments. There is no covering over the old equipment on the pallet. The other departments are working as usual.

c. What concerns do you have about this situation? Please explain.

Attachment 1 – FSIS Sanitation Verification in RTE Environments

IPP will verify the SPS requirements, the effectiveness of the Sanitation SOPs, and implementation of the establishment's HACCP plan including any prerequisite programs that address RTE product sanitation. This may include review of the establishment's environmental and product testing programs.

The following is provided as a resource to IPP to verify the effectiveness of the sanitation program within the post-lethality environment. There are numerous potential harborage sites for *Listeria monocytogenes* to establish and multiply. These harborage sites are niches. When developing its sanitation program, the establishment should consider several factors in the formation of niches and the contamination of food contact surfaces (FCS) such as: (1) construction activities (2) traffic patterns between raw and ready-to-eat (RTE) (3) equipment design/disassembly (4) handling practices of uninspected product; exempt operation activities, dual jurisdiction (5) facility maintenance program. The following list provides potential harborage sites and example responses. However, it is not intended to be an all inclusive list.

Potential Harborage Sites	Example Establishment Responses
Overhead condensation	• Improve ventilation • Add insulation
High pressure hose use after FCSs are rinsed/sanitized, high pressure hose use embeds debris into crevices	• Use low pressure hoses • Use high pressure hoses before FCS are rinsed/sanitized
Cracked, pitted or inadequately sealed wall coverings	• Repair/seal
Uncaulked floor/wall junctures	• Seal
Floor drains	• Use of quat rings • Ideally the drain should not cross-connect with drains in the raw processing area
Standing water	• Eliminate • Use sanitizing boluses
Drip pans and condensate from refrigeration unit	• Use of iodine tablets
Hollow rollers on conveyors	• If hollow material is used, have a continuous weld seal instead of caulk
Maintenance tools	• Do not permit maintenance employees in post-lethality environment during operations if possible
Worn or cracked rubber seals around door	• Replace

Peelers, slicers, shredders, blenders, brine chill, casing removal system	• Adequate maintenance/sanitation
Boot dips are not maintained [effective concentrations (200 ppm iodophor, 400-800 ppm quaternary ammonia compound) of disinfectant are difficult to maintain and may become a source of contamination]	• Eliminate use or properly maintain
Damaged, pitted, corroded, and cracked equipment	• Repair or replace • FCS should be inert, smooth and non-porous
Compressed air filters are not maintained	• Replace filters regularly
Uncontrolled traffic pattern for movement of personnel and product between raw and post-lethality processing area	• Control traffic, vestibules, air locks, positive air pressure, foam sanitizing spray system at the RTE doorway • Change outer garments prior to entry to post-lethality environment
Post-lethality environment is not controlled during construction	• Increase monitoring of FCSs, product, and environment during and after a disruptive event • Establish negative air pressure in the construction area to ensure that air does not flow from the construction are into the plant • Establish temporarary partitions • Schedule construction during non-processing hours, if possible • Conduct intensified cleaning and monitoring of FCS and environmental surfaces
Same employees working within uninspected or exempt areas and inspected areas of the establishment and handling inspected and uninspected product	• Establish procedures to dedicate employees to separate areas and/or operational sanitation procedures to prevent cross contamination from uninspected area to inspected area
Inspected exposed, product in an uninspected area (retail exempt, custom, game animal, FDA designated) moves to the inspected official premises	• Establish procedure to eliminate cross contamination of inspected product from uninpected areas

Attachment 2 – Example of Intensified Sanitation Following a Positive Listeria Sample

The following are sanitation actions an establishment **might** take in response to a sample result positive for *Lm* or *Listeria* spp. Not all steps may be necessary to address contamination in every case, but the establishment's actions should probably be escalated to address consecutive positives.

If positives occur:

- Thoroughly clean and scrub sites where positives were found
- Identify all possible harborage sites and cross contamination pathways. Clean and sanitize harborage points and address cross contamination.
- Remove equipment parts and soak overnight.
- Increase the frequency of all less than daily sanitation procedures (e.g., walls and ceilings).
- Scrub surfaces where product residue accumulates. Pay special attention to gaps, cracks, rough welds, and crevices in equipment.

If positives continue to occur, consider:

- Disassembling equipment and soaking of parts in quaternary ammonia overnight.
- After cleaning and sanitizing of larger pieces of equipment, applying steam heat via an oven at 160 degrees F and holding for 20-30 minutes.
- Fogging the room with a sanitizer solution.
- Replacing rusty, pitted, peeling tools or parts of equipment with new, smooth-surfaced ones. These rusty, pitted tools and equipment parts serve as ideal harborage places for *Lm* to grow and multiply.

If positives still continue to occur, consider:

- Identifying harborage points in equipment, such as spiral freezers and slicers, and repairing or replacing.
- Thoroughly cleaning all areas of the establishment, including raw and non post-lethality exposed areas, to address possible harborage sites leading to contamination of RTE areas.
- Repairing or replacing leaky roofs, broken and cracked equipment, floors, overhead pipes, and cooling units, fans, doors, and windows. Suspend operations during repairs or replacement. It is recommended to test the environment for *Listeria spp*. after repairs are finished.
- Constructing new walls to separate raw and RTE areas. If drains or air handling units lead to raw areas or outside, consider rerouting.