ESTABLISHMENT RESPONSIBILITIES FOR READY-TO-EAT (RTE) SANITATION

Objectives

Upon completion of this training, Consumer Safety Inspectors will be able to determine whether there is reason to question the sanitation of the ready-to-eat product processing environment.

Introduction

As regulators, you must have a general knowledge about the processes that the industry uses to produce safe products. It is important that you are aware of some of the sanitation issues essential to the production of safe RTE products. In this section we will discuss some of the establishment's responsibilities for sanitation in the RTE environment. Establishments producing RTE products have a special responsibility for sanitation because of the high risk of foodborne illness due to post-lethality contamination. Therefore, the CSI must be able to determine whether there is reason to question the effectiveness of the establishment's procedures for controlling *Lm* or indicator organisms in the post-lethality processing environment.

Before we go further, let's define some of these terms. ***Ready-to-eat*** **(RTE)** products have received a ***lethality*** treatment. The lethality treatment, generally a cooking procedure, must be designed to eliminate pathogens, or harmful bacteria. This lethality treatment makes the product safe to eat by the consumer without additional preparation to achieve food safety, and we normally refer to these products as "ready-to-eat."

Many RTE processes involve handling the product after it has been subject 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 and possibly pathogens 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 which has bacteria on it. Often they are transferred indirectly, such as when a pallet placed on the floor in the raw area is subsequently used in the RTE area, or when an employee handles a pallet and then touches exposed product.

Many RTE products are taken right from the package and consumed as they are, with little or no heat treatment. If any pathogens are present, they will be consumed along with the product. Thus the risk of these products producing foodborne illness is increased. Because of this, establishments producing these

products have an increased responsibility for sanitation of the RTE processing environment.

RTE Processing Environment Sanitation

Sanitation is critical for ensuring that RTE products do not become cross-contaminated. Sanitation Standard Operating Procedures (SSOPs) 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. RTE sanitation may include the following steps.

a) Dry/waterless cleaning, removing large debris
b) Pre-rinsing equipment
c) Foaming and scrubbing
d) Rinsing
e) Visual inspection of equipment
f) Sanitizing
g) Drying

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.

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, 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 hot water, is also sometimes used to sanitize.

Rotating sanitizers is generally a good practice as it will provide greater effectiveness against bacteria. Some establishments rotate sanitizers by using one for a certain time period, and then switching to a different one. Another way to rotate sanitizers is to use them for different applications, for example, using one on equipment and a different one in boot dip stations. Alternating between alkaline-based detergents and acid-based detergents also helps to avoid "soapstone" or hard-water buildups. Alternating detergents helps change the pH regularly to prevent adaptation of bacteria to a particular environment. Therefore rotating sanitizers can help prevent formation of biofilms. A ***biofilm*** is a thin layer of microorganisms that essentially glue themselves together in order to adhere to the surface of equipment or other structures. Because of the nature of this film, the bacteria are difficult to remove and are protected from chemicals used to clean and sanitize surfaces.

Listeria monocytogenes

Establishments are responsible for producing product that is free from any pathogen. However, one strain of the *Listeria* species, the pathogen *Listeria monocytogenes* (*Lm*), is of particular concern because it has potentially fatal consequences. *Lm* is especially 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 the 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 process 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.

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.

***Listeria monocytogenes* in the Plant Environment**

Plants 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. 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 and newer products containing peracetic acid.

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.

***Listeria monocytogenes* and Construction**

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 plant 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. When construction is necessary, there are several solutions that establishments may employ. Establishments may establish negative air pressure in the construction area in order to ensure that air does not flow from the construction area into the plant. Temporary partitions can be established to protect the undisturbed areas of the plant from construction dust and debris. Intense cleaning is also a control method used by establishments following the disruptive construction.

Possible Post-Lethality Contamination Sources—Direct Food Contact

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.

Protecting exposed RTE product after the initial lethality step as it moves throughout the plant 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.

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 on 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 post-lethality contamination sources:

- Solutions to chill foods, brine solutions
- Slicers, dicers, saws
- Casing peelers
- 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

Potential Reservoirs in the Environment — Non Food Contact

Processing activities may expose the RTE product to an environment that may lead to the product's contamination. Products must be protected during processing. 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 air from an insanitary atmosphere. 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

unsanitized surfaces or raw meat or poultry products may contain pathogens. If this ice contacts RTE products or food contact surfaces it could contaminate the final product.

Examples of environmental reservoirs:

- Floors and drains
- Standing water, e.g., in overhead drip pans
- Ceilings and 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 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

Considerations in Plant Design

There are important considerations in the layout of the plant 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 another 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 plant design will include sufficient **ventilation** to prevent the formation of condensation and control humidity.

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

Examples of plant design considerations:

- Traffic between raw and RTE areas
- Physical proximity between RTE and raw products
- Air supply and flow between raw and RTE areas
- Humidity
- Overhead fixtures that harbor dirt or moisture
- Condensation
- Plumbing from drip pans

Sanitation Program to Control *Listeria Monocytogenes (Lm)*

An environmental testing program can be a means of confirming that the establishment's controls are effective in maintaining a plant 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.

The **design** of the testing program 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 certain pathogen, for example, *Listeria monocytogenes*. 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.

Listeria* spp. versus *Listeria monocytogenes. The term *Listeria* spp. (species) refers to all strains of *Listeria*. Because *Lm* is typically present only in very low numbers on RTE products, 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 testing is looking for more types of *Listeria*. Positive test results for *Listeria* spp. should be viewed as an indication that *Lm* may be present and alert the plant 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, findings of *Listeria* spp. would not have the same level of significance as findings of *Lm*. Findings of *Listeria* spp. indicate that a pathogen may be present, but are not conclusive evidence of a pathogen. Findings of *Lm* are evidence of a pathogen. 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.*

Types of In-plant Testing

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.

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.

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.

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.

Regulatory Requirements for Sanitation Standard Operating Procedures

The requirements for specific classes of product (9 CFR Part 430) requires the establishment to maintain sanitation in the post-lethality processing environment in accordance with the Sanitation SOP regulations. The **Sanitation SOP**

regulations (9 CFR Part 416) require each official establishment to develop, implement, and maintain written Sanitation SOPs that are sufficient to prevent the direct contamination or adulteration of product.
When the establishment includes sanitation procedures to control *Lm* in the post-lethality processing environment in its SSOP, the plant must evalutate the effectiveness of the measures in accordance with the regulation governing the **maintenance** of the Sanitation SOPs (9 CFR 416.14). This regulation requires the establishment to routinely evaluate both the overall effectiveness of the SSOPs and the specific procedures employed in preventing direct contamination or adulteration of products. The establishment is required to revise these procedures as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

The Sanitation SOP **corrective action** regulation (9 CFR 416.15) requires that the establishment take appropriate corrective action when either the establishment or FSIS determines that the establishment's Sanitation SOPs or the procedures specified therein, or the implementation or maintenance of the SSOPs, may have failed to prevent direct contamination or adulteration of products.

Establishments that produce RTE products are responsible for ensuring on an on-going basis that their Sanitation SOPs are effective in preventing contamination and adulteration in the post-lethality environments. Establishments producing RTE post-lethality exposed products must meet the requirements for one or more of the alternatives described in 9 CFR 430. The alternatives provide the establishment the flexibility of determining which alternative or alternatives they use to control *Listeria monocytogenes* or indicator organisms in the post-lethality processing environment. Two of the alternatives require establishments to perform food contact surface testing for *Lm* or for indicator organisms to verify the on-going effectiveness of their sanitation procedures in the post-lethality processing environment.

It is particularly important that establishments that produce RTE products such as hot dogs and deli meats conduct on-going evaluation of their control of *Lm* in the post-lethality processing environment. Performing environmental and product testing for *Lm* or an indicator organism is an effective way to accomplish this evaluation.

Relationship Between Sanitation and HACCP in RTE Product Processes

For most RTE products, there probably is a CCP in the HACCP plan for 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 plant decided to use for control of that hazard. In some cases, part of an SSOP 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 plant'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 SSOP to control pathogens in the environment. You will learn more about the application of HACCP in later parts of this training.

FSIS Verification

You will verify the effectiveness of the Sanitation SOPs, HACCP plan, and any prerequisite program that addresses RTE product sanitation. This may include review of the establishment's environmental and product testing programs.

References

- FSIS Directive 10240.4, Rev.1, 3/15/06, Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes (Lm)* Regulation and Introduction of Phase 2 of the *Lm* Risk-Based Verification Testing Program, including related attachments and compliance guidelines
  FSIS website http://www.fsis.usda.gov/OPPDE/RDAD/FSISDir10000.htm

- Controlling *Listeria monocytogenes* in Small and Very Small Meat and Poultry Plants, September 2001, The Pennsylvania State University.
  FSIS website http://www.fsis.usda.gov/OPPDE/Nis/Outreach/Listeria.htm

- FSIS *Listeria* Guidelines for Industry, May 1999,
  FSIS website http://www.fsis.usda.gov/OA/topics/lmguide.htm

- Food Code, U.S. Public Health Service, FDA, 2001,
  FDA website http://www.cfsan.fda.gov/~dms/fc01-toc.html

- Guidelines for Developing Good Manufacturing Practices (GMPs), Standard Operating Procedures (SOPs) and Environmental Sampling/Testing Recommendations (ESTRs) Ready-to-Eat (RTE) Products, In Cooperation With North American Meat Processors; Central States Meat Association; South East Meat Association; Southwest Meat Association; Food Marketing Institute; National Meat Association; and American Association of Meat Processors, April 1999.
  National Meat Association web site:
  http://www.nmaonline.org/files/guifinal.pdf

- Microbiological Testing, Bruce Floyd, Food Product Design: Focus On QA/QC – June 2001. http://www.foodproductdesign.com/archive/2001/0601qaqc.html

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) ___Plant 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 a plant 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 plant’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 plant, 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.