

***Listeria monocytogenes* Regulations**

Objectives

Upon completion of this training module, Inspection Program Personnel (IPP) will be able to:

1. Identify reasons *Listeria monocytogenes* (*Lm*) is a public health threat for ready-to eat (RTE) meat and poultry products.
2. Verify compliance with the regulations in 9 CFR 430 by following instructions in FSIS Directive 10,240.4, Rev. 3 *Verification Procedures for Consumer Safety Inspectors for the Listeria monocytogenes (Lm) Regulation and Lm Sampling Programs*

Listeria monocytogenes

Listeria monocytogenes (*Lm*) is a pathogen that is considered to be ubiquitous, which literally means to exist everywhere. In practical terms, this means *Lm* is widespread in the environment. It can be found in the soil, on plant materials, animal feedstuffs, and the intestinal tract of various mammals and birds. Some humans may be intestinal carriers of the organism. This microbe is so widespread in part because it is capable of surviving under a variety of environmental conditions. It is very tolerant of freezing, drying, salt, and heat. It is capable of reproducing (i.e., growing) at temperatures as low as 31.3°F or as high as 113°F. It can adapt to significant changes in pH values, having demonstrated the capacity to reproduce at a pH as low as 4.39 and as high as 9.4. It can also reproduce with a water activity (a_w) as low as 0.92.

In susceptible individuals, *Lm* can produce a disease called listeriosis. The Centers for Disease Control and Prevention has estimated that there are annually approximately 1,600 cases of foodborne listeriosis with 1,500 hospitalizations and 260 deaths in the United States. Most healthy adults are generally not susceptible to infection with *Lm*. Groups that are considered to be at high risk for infection are pregnant women and their unborn children, young children, the elderly, and persons whose immunity might be compromised by treatment with certain medications or because of certain diseases. The infective dose of *Lm* probably varies with the pathogenicity of different strains of the organism present and an individual's susceptibility, but is believed to be fewer than 1,000 organisms. With mild infections, an individual may have general flu-like symptoms, including nausea, vomiting, and diarrhea. However, more severe infections can lead to septicemia, meningitis, encephalitis, and death. Infections during pregnancy generally do not lead to death of the mother, but the unborn child typically will not survive through the second or third trimester, resulting in a miscarriage or stillbirth. Those that do make it to term often do not survive the

early neonatal period. If a child does survive the early neonatal period, he or she may have severe, ongoing medical and developmental problems.

Foodborne listeriosis has been linked to a wide variety of foods, including certain meat and poultry products. Here are some examples of outbreaks that have been tied to meat and poultry products:

- A multistate outbreak occurring between 1998 and 1999 caused 101 cases and 21 deaths. It was linked to the contamination of hotdogs and deli meats by *Lm*. Thirty million pounds of hotdogs and deli-meats were recalled.
- In 2000, RTE turkey deli meat contaminated with *Lm* caused 29 illnesses across 10 states. There were 4 deaths.
- In 2002, a multi-state outbreak caused 54 illnesses, 8 deaths, and 3 fetal deaths. The outbreak was associated with contaminated turkey deli meat. Over 27 million pounds of fresh and frozen RTE turkey and chicken products were recalled.
- In 2017 and 2018, fully cooked ham products were recalled. *Listeria* specimens from 4 people were collected. All four people were hospitalized. One death was reported.

The common link with these outbreaks was the contamination of product with *Lm* in the post-lethality environment prior to packaging. *Lm* can contaminate a food processing environment in a variety of ways. *Lm* may be present in slaughter animals and subsequently in raw meat and poultry products. Therefore, the organisms can be continuously introduced into the processing environment by incoming raw product. In addition, pallets, equipment, personnel, or other ingredients may serve as vehicles for bringing *Lm* into a processing environment or spreading the organism throughout processing areas and storage areas. Once it contaminates the processing environment, *Lm* can become established, growing in drains, on processing equipment, and on refrigeration units. The organism can also form durable biofilms on surfaces of facilities and equipment.

Inadequate sanitation practices may allow *Lm* to come into contact with product exposed to the post-lethality environment. The dust and movement of personnel and equipment associated with construction projects (e.g., repairs to air handling systems, removal of walls, or repairs to plumbing systems.) create opportune times for *Lm* to ultimately contaminate post-lethality exposed product. An establishment may need to consider whether additional sanitation practices and containment procedures are necessary when doing any construction projects in or around processing areas where post-lethality exposed products are handled and packaged.

As you can see, *Lm* is a significant foodborne pathogen with great potential to impact public health. Because of this, *Lm* is considered by FSIS to be a hazard which establishments producing post-lethality exposed ready-to-eat products

must control. FSIS has developed regulatory requirements specifically for controlling *Lm* in the production of post-lethality exposed RTE products. In addition, the agency has developed *Lm* sampling programs as part of its public health strategy for protecting consumers against this important pathogen. The next section of this module discusses how in plant inspection personnel (IPP) verify compliance with regulatory requirements for control of *Lm*.

***Listeria monocytogenes* Verification**

Introduction

On June 6, 2003, FSIS published an interim final rule requiring establishments producing post-lethality exposed RTE products to prevent product adulteration by *Lm*. *Lm* is a bacterial pathogen and environmental contaminant in the post-lethality processing environment. The regulation, 9 CFR 430.4(a), states that *Lm* is a hazard that an establishment producing an RTE product exposed to the post-lethality environment must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. It also states that RTE product is adulterated if it contains *Lm* or if it comes into direct contact with a food contact surface that is contaminated with *Lm*. 9 CFR 430.4(b) sets out three alternatives that establishments producing post-lethality exposed RTE product are to choose from in order to meet the requirements of 9 CFR 430.4(a). In-plant inspection personnel (IPP) are responsible for verifying that establishments are in compliance with 9 CFR 430.4(b). The appropriate HACCP, or SSOP, task will be used to perform and document the verification.

Definitions (9 CFR 430.1)

9 CFR 430.1 defines a ***ready-to-eat (RTE) product*** as a meat or poultry product that is in an edible form without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. As we have discussed, RTE products are not labeled with the Safe Handling Instructions required for NRTE products. While some RTE product labels may include some instruction on reheating the product, these products do not need to be cooked to a level necessary to ensure food safety. It is important to note that even if RTE products are sold frozen, they are still considered RTE.

Two particular RTE products defined in 9 CFR 430.1 are deli products and hotdog products. A ***deli product*** is an RTE meat or poultry product that is typically sliced, either in an official establishment or after distribution from an official establishment, and assembled in a sandwich for consumption. A ***hotdog product*** is an RTE meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181 (cheesefurters). It is important to note that a risk assessment performed jointly by FSIS and the FDA indicated that

on a per serving basis deli meats and hotdogs (not reheated) posed the greatest risk of illness and death from *Lm*.

RTE meat and poultry products have undergone some lethality treatment. A **lethality treatment** is a process that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments include cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms. As described in the NRTE/RTE module, FSIS regulations specify levels of pathogen reduction for particular RTE product types.

The following three terms are important with respect to understanding the distinction among different approaches for controlling or preventing *Lm* in an RTE product:

- An **antimicrobial agent** is a substance in or added to an RTE product that has the effect of suppressing or limiting growth of *Lm* in the product throughout the shelf life of the product. Common examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate. FSIS Directive 7120.1, *Safe and Suitable Ingredients Used in the Production of Meat, Poultry and Egg Products*, identifies more antimicrobial agents used in the production of meat and poultry products. Note that some antimicrobial agents may have the effect of reducing the level of *Lm* on a product and suppressing growth of *Lm* throughout the shelf life of the product.
- An **antimicrobial process** is an operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of *Lm* in the product throughout the shelf life of the product. Drying and fermenting are operations that may be applied to a product to make it RTE and subsequently suppress or limit the growth of *Lm*.
- A **post-lethality treatment** (PLT) is an additional lethality treatment that is applied or is effective after post-lethality exposure of the product. It is applied to the final product or sealed package of product in order to reduce or eliminate *Lm* should contamination occur during post-lethality exposure. Some examples of post-lethality treatments include steam pasteurization, hot water pasteurization, radiant heating, and high pressure processing. Some antimicrobial agents may also serve as post-lethality treatments.

The term **post-lethality processing environment** refers to the area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

A **post-lethality exposed product** is an RTE product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment. Remember that only post-lethality exposed RTE products are subject to 9 CFR 430.

Prerequisite program is an important term defined in 9 CFR 430.1 as a procedure or set of procedures designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered to be necessary condition for an effective HACCP system. For example, an establishment formulates a hotdog product to include an antimicrobial agent that will suppress the growth of *Lm* over the usual shelf life of the product. For this establishment, addition of this antimicrobial agent is carried out through a prerequisite program. Failure of the establishment to adequately design or implement this prerequisite program permits conditions whereby the product may become adulterated with *Lm*.

While not defined in 9 CFR 430.1, the term **indicator organism** is used in 9 CFR 430. Indicator organisms are bacteria used to determine objectionable microbial conditions of food, such as the presence of potential pathogens, as well as the sanitary conditions of food processing, production areas, or storage rooms. *Lm* belongs to the genus *Listeria* and the species is *monocytogenes*. The genus *Listeria* includes other nonpathogenic species (spp.) in addition to the pathogenic species *monocytogenes*. A positive test for *Listeria* spp. on a food contact surface would indicate the potential presence of *Lm*. However, the product is only considered adulterated if *Lm* is found on a food contact surface or product. If *Listeria* spp. is found, the product is not considered adulterated, however the establishment is expected to take corrective action, according to their control alternative, to address *Listeria* spp. positives so that the product does not become adulterated. If a test is negative for *Lm* or *Listeria* spp., this indicates *Lm* is not present. Note that tests for other indicator organisms, like aerobic plate counts (APC), total plate counts (TPC), and total coliforms are not appropriate indicators for *Lm*. Although such tests could provide a measure of general sanitation, they do not indicate the potential presence or absence of the pathogen of concern.

IPP Responsibilities for Verifying Compliance with 9 CFR part 430.4

You must be familiar with the establishment products and processes that must comply with 9 CFR 430.4 in order to verify compliance. If necessary, you can ask establishment management whether they produce any RTE product that is exposed to the environment after the initial lethality step.

Note: the establishment is **not** required to comply with 9 CFR 430.4 if the RTE products produced are **not exposed** to the environment after the lethality step.

Examples:

- Hotdogs exposed to the environment after peeling.
 - Establishment is required to comply with 9 CFR 430
 - Must choose one of 3 alternatives
- Cooked ham sliced and film wrapped in retail packages.
 - Establishment is required to comply with 9 CFR 430
 - Must choose one of the 3 alternatives
- Bologna cooked in an impermeable plastic casing. The casing is not removed prior to packing, and the product is not sliced at the official establishment.
 - Establishment is not required to comply with 9 CFR 430

Ready to Eat (RTE) vs Not Ready to Eat (NRTE)

The fully cooked not shelf stable HACCP processing category applies to establishments that further process products by using a lethality process, which includes a full cook step to achieve food safety. The term lethality is used to refer to the process step(s) that achieve food safety through the reduction or elimination of pathogenic microbes. The lethality process is expected to achieve at least a 7 log reduction for *Salmonella* in poultry products, a 6.5 log reduction for cooked beef, roast beef and corned beef, and at least a 5 log reduction in other products. Finished products produced in this category are not shelf stable (NSS), and must be kept frozen or refrigerated to maintain food safety. Products in this category are expected to meet the definition of ready-to-eat (RTE), which is defined in 9 CFR 430.1 as a meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. However, only certain RTE products are required by standards of identity to be fully cooked (e.g. hot dogs, fully cooked sausages, barbecued meats, and cooked beef and roast beef) or by a common or usual identity (e.g., pate) as fully cooked.

Some establishments may produce products that are fully-cooked (e.g., casserole, meat balls, and ham); however, the products may be considered NRTE by the establishment because they are not required to meet a fully cooked standard of identity, or common or usual identity, and the establishment chooses to label the product as NRTE (e.g., includes safe handling instructions). These products should be classified under the Heat Treated but Not Fully Cooked –Not Shelf Stable Category. The FSIS expectation is that products in the Fully-Cooked Not Shelf Stable processing category are RTE, therefore, categorizing the product in a Fully-Cooked Not Shelf Stable HACCP processing category would not be consistent with a NRTE product.

If establishments consider a fully cooked product as NRTE, then it is FSIS expectation that they have safe handling instructions, and a statement such as

“must be cooked” on the label. A prudent establishment would include validated cooking instructions on the label. In addition, the establishment would need to ensure that the following are consistent with a NRTE product:

- *Labeling.* Use of the terms “Baked” or “Broiled” in the label (e.g., “baked chicken”) would not be consistent with a NRTE product.
- *HACCP category.* The FSIS expectation is that products in the Fully-Cooked Not Shelf Stable processing category are RTE, therefore, categorizing the product in a Fully-Cooked Not Shelf Stable HACCP processing category would not be consistent with a NRTE product.
- *Intended use statement.* In order to be consistent with a NRTE product, the intended use statement should include how the product is expected to be cooked or otherwise treated for safety before consumption.

Note: Only RTE products that are post-lethality exposed are required to meet the 9 CFR 430.4 regulations.

If the establishment is producing post-lethality exposed RTE products, you should ask establishment management which alternative they have chosen for each of the post-lethality exposed RTE products. You should inform them that, as set out in 9 CFR 430.4(c)(7), verification results that demonstrate the effectiveness of the measures they employ are to be made available upon request.

You should verify that the establishment is meeting the requirements of the alternative that it has chosen by using the appropriate SSOP or HACCP tasks. If the establishment decides to produce different products using different alternatives, you should verify that they meet the requirements for **each** of the alternatives selected, for **each** of the post-lethality exposed RTE products.

As you become familiar with the three alternatives, keep in mind that all establishments are required to maintain sanitary conditions sufficient to prevent direct product contamination including *Lm*. Sanitation is the foundation for controlling *Lm* and without it no alternative will be successful in controlling the organism.

Note: See Attachment 1 and 2 for graphic summaries of the 3 alternatives and their requirements. The *Listeria* Compliance Guidelines have additional resources that help with determining whether a product is RTE or NRTE.

Alternative 1

9 CFR 430.4(b)(1) *Use of a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*.*

The thought process you should use when verifying regulatory requirements includes:

- Gathering information by asking questions;
- Assessing the information; and
- Determining regulatory compliance.

Gather information by asking questions

When verifying compliance with the requirements in Alternative 1, seek answers to the following questions:

1. Is the post-lethality treatment (PLT) (which may be an antimicrobial agent) incorporated in the HACCP plan?
2. Does the establishment have scientific supporting documentation for the effectiveness of its post-lethality treatment in accordance with 9 CFR 417.5(a)(2)?
3. Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?
4. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?
5. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?
6. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program, and can it scientifically support how the antimicrobial agent or process is being used?

Note: According to the *Listeria* Guidelines, the post lethality treatment should demonstrate at least 1-log decrease before the product is released into commerce and the antimicrobial agent or process should demonstrate no more than 2-logs of growth over the shelf life of the product.

Assess the information

To answer these questions you should:

- Review the HACCP plan,
- Review validation data (supporting documentation) for the post-lethality treatment,
- Review HACCP records,
- Review the Sanitation SOP and/or prerequisite programs associated with the use of the antimicrobial agent or process (as necessary), and
- Review Sanitation SOP and/or prerequisite program records (as necessary).

Alternative 1 Examples:

Example 1: You are verifying that the establishment is meeting the requirements of Part 430 and Alternative 1. You review the establishment's hazard analysis for sliced semi-dry sausage products such as Genoa salami, sandwich pepperoni, cervelat, thuringer, etc., and find that the fermentation, heating, drying, and packaging steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. The hazard analysis and HACCP plan identify lowered acidity (pH) through the use of bacterial starter cultures and lowered water activity due to drying as measures to limit the growth of *Lm* in the finished product throughout the shelf life of the product. A steam pasteurization process after the product has been vacuum packaged has been identified as the treatment to reduce or eliminate post-lethality *Lm* contamination. There are critical limits at the respective steps in the plan for pH, water activity, and time and temperature exposure for the steam pasteurization process. You request the supporting documentation for the critical limits. The establishment provides scientific literature and the results of challenge studies conducted by a processing authority that show that the pH and water activity (achieved in the product) allows no more than a 2-log increase of *Lm* during its refrigerated shelf life and that the surface steam pasteurization treatment is effective in achieving at least a 1-log decrease of *Lm* resulting from the post-lethality contamination. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(1).

Example 2: You are verifying that an establishment complies with 9 CFR 430.4(b)(1) in its deli products, which include sliced and unsliced roast beef, ham, turkey breast, and bologna. Because of concerns the establishment had with the flavor of some of its deli products, it decided to move away from incorporating the antimicrobial agents sodium lactate and sodium diacetate into the formulation for each of its deli products (i.e., prior to cooking). The establishment had previously supported that it met Alternative 2, Choice 2 through the incorporation of these antimicrobial agents to limit the growth of *Lm*

in its deli products. Now the establishment is applying a post-lethality surface treatment to its deli products. The surface treatment is a solution containing an Lm-specific bacteriophage (ListexT P100) and a combination of sodium lactate and sodium diacetate. For the deli products that are sold unsliced, this solution is sprayed directly on the surface of each deli product loaf just before the vacuum packaging step. For the sliced deli products, the solution is sprayed on each slice as part of the slicing and vacuum packaging steps. You review the establishment's hazard analyses and HACCP plans for its deli products. You note that the establishment has identified the bacteriophage application as its post-lethality treatment to reduce or eliminate Lm on the product and the application of sodium lactate and sodium diacetate as antimicrobial agents to limit or suppress the growth of Lm throughout the shelf life of the product. Both elements are incorporated into the establishment's deli meat HACCP plans as CCPs. You review supporting documentation for the location of these CCPs, critical limits, and monitoring and verification procedures. Supporting documents include published research studies supporting the effectiveness of the bacteriophage as a post-lethality treatment and of the antimicrobial agents as inhibitors of the growth of Lm in deli products throughout their shelf life, technical information from the manufacturer of the bacteriophage product on its use, establishment decision making documents, and the results of challenge studies performed at a university-based food research and development laboratory on each of the establishment's deli products. You discuss some questions about the establishment's Lm controls with your supervisor. Based upon your review, you and your supervisor conclude that the establishment is in compliance with 9 CFR 430.4(b)(1).

Determine compliance

After you have gathered and assessed all available information pertaining to Alternative 1, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, i.e., the answer to any of the questions was “no”, there is noncompliance. You document a noncompliance on an NR under the appropriate PHIS task as described in FSIS Directive 5000.1 Rev. 5 and reference 9 CFR 430.4(b)(1) and the appropriate section of 417 (for HACCP and prerequisite programs) or 416 (for Sanitation SOP). You should verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative. You will receive more information about making compliance determinations in a later section.

Noncompliance with Alternative 1

The following are examples of noncompliance with Alternative 1.

1. The establishment has a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan, but does not have the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(1) and 417.5(a)(1) & (2))
2. The establishment has the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program, but does not have a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan. (Cite 430.4(b)(1) and 417.5(a)(1) & (2))
3. The establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism, but does not have a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan OR the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(1) and 417.5(a)(1) & (2))
4. The establishment has included a post-lethality treatment to reduce or eliminate *Lm* in its HACCP plan, but has not validated the effectiveness of the treatment. (Cite 430.4(b)(1) and 417.4.)

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Alternative 2

9 CFR 430.4(b)(2) *Use of either a post-lethality treatment (which may be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product OR an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*.*

Under Alternative 2, an establishment may select either **Choice 1** or **Choice 2** as follows.

Alternative 2, Choice 1 - The establishment chooses to use a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates *Lm* on the product.

Alternative 2, Choice 2 - The establishment chooses to use an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

The thought process you should use when verifying regulatory requirements includes:

- Gathering information by asking questions;
- Assessing the information; and
- Determining regulatory compliance.

Gather information by asking questions

When verifying compliance with the requirements in Alternative 2, seek answers to the following questions. Alternative 2 is based on the same requirements as Alternative 1, **except** that the establishment can choose to **just** have a post-lethality treatment that meets Choice 1, **or** an antimicrobial agent or process that meets Choice 2.

Choice 1

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan?
2. Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4?
3. Is the establishment implementing the post-lethality treatment as described in the HACCP plan?

Choice 2

1. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?
2. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

Also, if the establishment chooses Choice 2, you should seek answers to these additional questions, regarding the establishment's sanitation procedures.

Does the establishment's testing for verifying the on-going effectiveness of their sanitation procedures:

1. Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism?

2. Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *Lm* or an indicator organism?
3. State the frequency with which testing will be done?
4. Identify the size and location of the sites that will be sampled? Note that establishments should identify all possible sites (see AskFSIS QA dated 2-17-12)
5. Include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained?

Assess the information

To answer these questions you should:

- Review the HACCP plan,
- Review validation data for the post-lethality treatment,
- Review HACCP records,
- Review the Sanitation SOP and/or prerequisite programs associated with the use of the antimicrobial agent or process (as necessary),
- Review the Sanitation SOP and/or prerequisite programs associated with the testing program for verification of effectiveness of sanitation procedures (as necessary), and
- Review Sanitation SOP and/or prerequisite program records (as necessary).

Alternative 2 Examples:

Example 1: An establishment's product line includes wet salads, like chicken salad and ham salad. It hermetically seals containers filled with these ready-to-eat salad products, the containers are batch loaded into cylinders, the cylinders enter a chamber, and the products undergo high pressure processing. You are reviewing the establishment's hazard analysis and HACCP plan for these products to verify compliance with the requirements for Alternative 2, Choice 1 as specified in 9 CFR 430. In its hazard analysis, the establishment concluded that *Lm* was a hazard reasonably likely to occur in the post-lethality processing steps. The establishment identified the high pressure processing as its post-lethality treatment and included it in its HACCP plan as a CCP. The critical limit is time at a specific pressure level. In reviewing supporting documents for the CCP, you discover there are other critical parameters associated with this type of treatment, including product temperature before high pressure processing and water fill level of the pressure chamber. You request additional documentation supporting that the establishment achieves these additional critical parameters. The establishment provides documents that show the product temperature is

consistently 40 degrees F or less at the packaging step and that the pressure chamber water level is monitored to ensure that the required level of pressure can consistently be achieved in the process. You conclude that the establishment is in compliance with 9 CFR 430.4(b)(2).

Example 2: You are verifying that the establishment is meeting the requirements of Part 430 and Alternative 2, Choice 2. You review the establishment's hazard analysis for fully cooked frozen breaded chicken products and find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. In addition to these CCPs, *Lm* was considered a potential hazard at the packaging step but was not likely to occur because the establishment has *Listeria* control measures in its SSOP to prevent *Lm* in the post-lethality processing environment. You decide to request the supporting documentation for the decision made in the hazard analysis that *Lm* is not likely to occur in the post-lethality environment. The establishment provides a scientific document that identifies the temperature that would inhibit *Lm* growth in the finished product throughout the shelf life of the product. The establishment also provides the procedures (verification activities) and the associated records it uses to demonstrate that products are frozen below the level that the scientific validation document establishes as preventing the growth of *Lm*. The records for the past several months show that the product is achieving the frozen temperature needed to suppress the growth of *Lm* and is labeled with the instructions "Keep Frozen." You review the establishment's SSOP and records and find that the establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. The establishment has identified the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria* spp., the size and location of the sample sites, and the testing frequency. It also provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(2).

Determine compliance

After you have gathered and assessed all available information pertaining to Alternative 2, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, i.e., the answer to any of the questions was "no", there is noncompliance. You should document the noncompliance on an NR under the appropriate PHIS task as described in FSIS Directive 5000.1 Rev. 5 and reference 9 CFR 430.4(b)(2) and, depending where the use of the antimicrobial agent or process is addressed, either the appropriate section of 417 (for HACCP and prerequisite programs) or the appropriate section of 416 (Sanitation SOP).

You should verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative. You will receive more information about making compliance determinations in a later section.

Noncompliance with Alternative 2

The following are examples of noncompliance with Alternative 2.

1. The establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism but does not have a post-lethality treatment to reduce or eliminate *Lm* incorporated into the HACCP plan OR the use of the antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite 430.4(b)(2), 417.2, and 417.5(a)(1) & (2))
2. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 only addresses the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism. (Cite 430.4(b)(2), 416, and 417.5(a)(1) & (2))
3. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the conditions under which or at what point hold-and-test procedures following a positive test of a food-contact surface for *Lm* or an indicator organism will be initiated. (Cite 430.4(b)(2), and 417.5(a)(1) & (2))
4. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the size of the site to be sampled. (Cite 430.4(b)(2), and 417.5(a)(1) & (2))
5. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not articulate its explanation as to why the testing frequency it selected is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained. (Cite 430.4(b)(2), and 417.5(a)(1) & (2))

You will document any noncompliance in accordance with our discussion of documentation and enforcement in a later section.

Alternative 3

9 CFR 430.4(b)(3) Use of sanitation measures only
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The thought process you should use when verifying regulatory requirements includes:

- Gathering information by asking questions;
- Assessing the information; and
- Determining regulatory compliance.

Gather information by asking questions

When verifying compliance with the requirements in Alternative 3, seek answers to the following questions.

Does the establishment that produces post-lethality exposed product and that selects this alternative have on-going verification testing procedures that are designed to:

1. Have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program?
2. Test food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism?
3. Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *Lm* or an indicator organism?
4. State the frequency with which testing will be done?
5. Identify the size and location of the sites that will be sampled? Note that establishments should identify all possible sites (see AskFSIS QA dated 2-17-12)
6. Include an explanation of why the testing frequency is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained?

Also, does an establishment producing a **deli product or a hot dog product**:

1. Verify that the implemented corrective actions (with respect to sanitation after an initial positive result on a food contact surface in the post-lethality processing environment) are effective by follow-up testing that includes targeted testing of the specific site on the food contact surface area and other sites as necessary to ensure effectiveness of the corrective actions?

2. Hold lots of product (that may have become contaminated by contact with the food contact surface when the establishment obtains a second positive test for *Lm*, or an indicator organism, during this follow-up testing) until the establishment corrects the problem as indicated by follow-up test (negative) results?
3. Sample and test the lots for *Lm* or an indicator organism, using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *Lm*, in order to be able to release into commerce the lots of product that may have been contaminated with *Lm*?
4. Document the results of the testing?
5. Rework the held product using a process that is destructive of *Lm*?

Assess the information

To answer these questions you should:

- Review the HACCP plan, Sanitation SOP, and/or prerequisite programs associated with the testing program for verification of effectiveness of sanitation procedures.
- Review HACCP records, SSOP records, or the records associated with the prerequisite program

Alternative 3 Examples:

Example 1: You are verifying that the establishment is meeting the requirements of Part 430 and Alternative 3. You review the establishment's hazard analysis for fully cooked breakfast type products such as bacon, sausage patties, sausage links, etc., packaged and sold refrigerated. You find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and have been incorporated into the HACCP plan. *Lm* was considered a potential hazard at the packaging step but the establishment concluded that it was a hazard not likely to occur because it has *Listeria* control measures in a prerequisite program to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is not likely to occur in the post-lethality environment. You review the establishment's prerequisite program and records and find that the establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria spp.* It also has identified the conditions under which it will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria spp.*, the size and location of the sample sites, and testing frequency. The establishment provided a thought process as to why the testing

frequency it selected is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(3).

Example 2: You are verifying that the establishment is meeting the requirements of Part 430 and Alternative 3. You review the establishment's hazard analysis for fully cooked deli and hot dog type products such as franks, sliced ham, sliced bologna, sliced roast beef, sliced turkey breast, etc., packaged and sold refrigerated. You find that the cooking and chilling steps have been identified as CCPs in the hazard analysis and are incorporated into the HACCP plan. *Lm* was considered a potential hazard at the packaging step but the establishment concluded that it was a hazard not likely to occur because it has *Listeria* control measures in its SSOP to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is not likely to occur in the post-lethality environment. You review the establishment's SSOP and records and find that the establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria spp.* The establishment has identified the conditions under which it will implement hold-and-test procedures following a positive test of a food-contact surface for *Listeria spp.*, the size and location of the sample sites, and the testing frequency. It also provided a thought process as to why the testing frequency it selected is sufficient to ensure that effective control of *Lm*, or an indicator organism, is maintained.

You find that the establishment verifies the effectiveness of the corrective actions it takes with respect to sanitation after an initial positive test on a food contact surface in the post-lethality processing environment through follow-up testing, including a targeted test of the specific site that is the most likely source of contamination by the organism, and other additional tests in the surrounding food contact surface area. When the establishment obtains a second positive test during this follow-up testing, it holds the lots of product that may have become contaminated by contact with the food contact surface until a test result indicates that the sanitation problem is corrected. The establishment only releases into commerce the lots of product that may have become contaminated with *Lm* from the food contact surface after it has sampled and tested the lots for *Lm* using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *Lm*. The establishment considers sampled product lots that test positive for *Lm* as adulterated and withholds them from entering commerce. The establishment destroys the held product, or reworks the held product using a process that is destructive of *Lm*. The establishment documents the test results and the disposition of the product. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(3).

Determine compliance

After you have gathered and assessed all available information pertaining to Alternative 3, you must determine regulatory compliance. If you find that the establishment has met all regulatory requirements, then there is no regulatory noncompliance. If you find that the establishment has not met all regulatory requirements, i.e., the answer to any of the questions was “no”, there is noncompliance. You should issue an NR under the appropriate PHIS task as described in FSIS Directive 5000.1, rev.4 and reference 9 CFR 430.4(b)(3) and, depending where the use of the sanitation measures are addressed, either the appropriate section of 417 (for HACCP and prerequisite programs) or the appropriate section of 416 (Sanitation SOP). You should verify that the establishment takes corrective and preventive action to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan to determine whether the decisions made in the hazard analysis regarding the use of the prerequisite program remain valid, and the establishment’s choice of another alternative. You will receive more information about making compliance determinations in a later section.

Noncompliance with Alternative 3

The following are examples of noncompliance with Alternative 3.

1. The establishment does not have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program. (Cite 430.4(b)(3), and 417.5(a)1&2.)
2. The written sanitation procedures the establishment is using to meet the requirements of this alternative only address the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism. (Cite 430.4(b)(3), and 417.5(a)(1) and (2).)
3. An establishment that produces deli and hot dog products does not conduct follow-up testing of target sites on the food contact surface area that is the most likely source of contamination after an initial positive test for *Lm*, or its indicator organisms, to verify the effectiveness of its sanitation corrective actions. (Cite 430.4(b)(3), and 417.5(a)(1) and (2).)
4. An establishment that produces deli and hot dog products does not hold-and-test lots of product for *Lm*, or an indicator organism, that may have become contaminated by contact with the food contact surface when it obtains a second positive test for *Lm*, or an indicator organism, during its follow-up testing. (Cite 430.4(b)(3), and 417.5(a)(1) and (2).)

Documentation and Enforcement

If noncompliance with the *Lm* regulations is found, IPP are to issue a Noncompliance Record (NR) under the appropriate HACCP, or SSOP, task as described in FSIS Directive 5000.1 rev.4 and reference 9 CFR 430.4(b)(1), (2), or (3) and the appropriate sections of 9 CFR 417 or 416, if applicable. CSIs are to verify that the establishment takes action to bring itself into compliance with 9 CFR Part 430. Such actions may include, but are not limited to, a reassessment of the HACCP plan and the establishment's choosing of another alternative or determining that the decisions it made in the hazard analysis regarding the use of a prerequisite program remain valid.

If an establishment is producing post-lethality exposed products and has failed to meet any of the requirements of 9 CFR 430, you should contact the District Office through supervisory channels. A NOIE may be issued if the establishment HACCP system and/or SSOP is inadequate due to failure to meet the 430 regulations.

ATTACHMENT 1: CONTROL REQUIREMENTS for *LISTERIA MONOCYTOGENES*

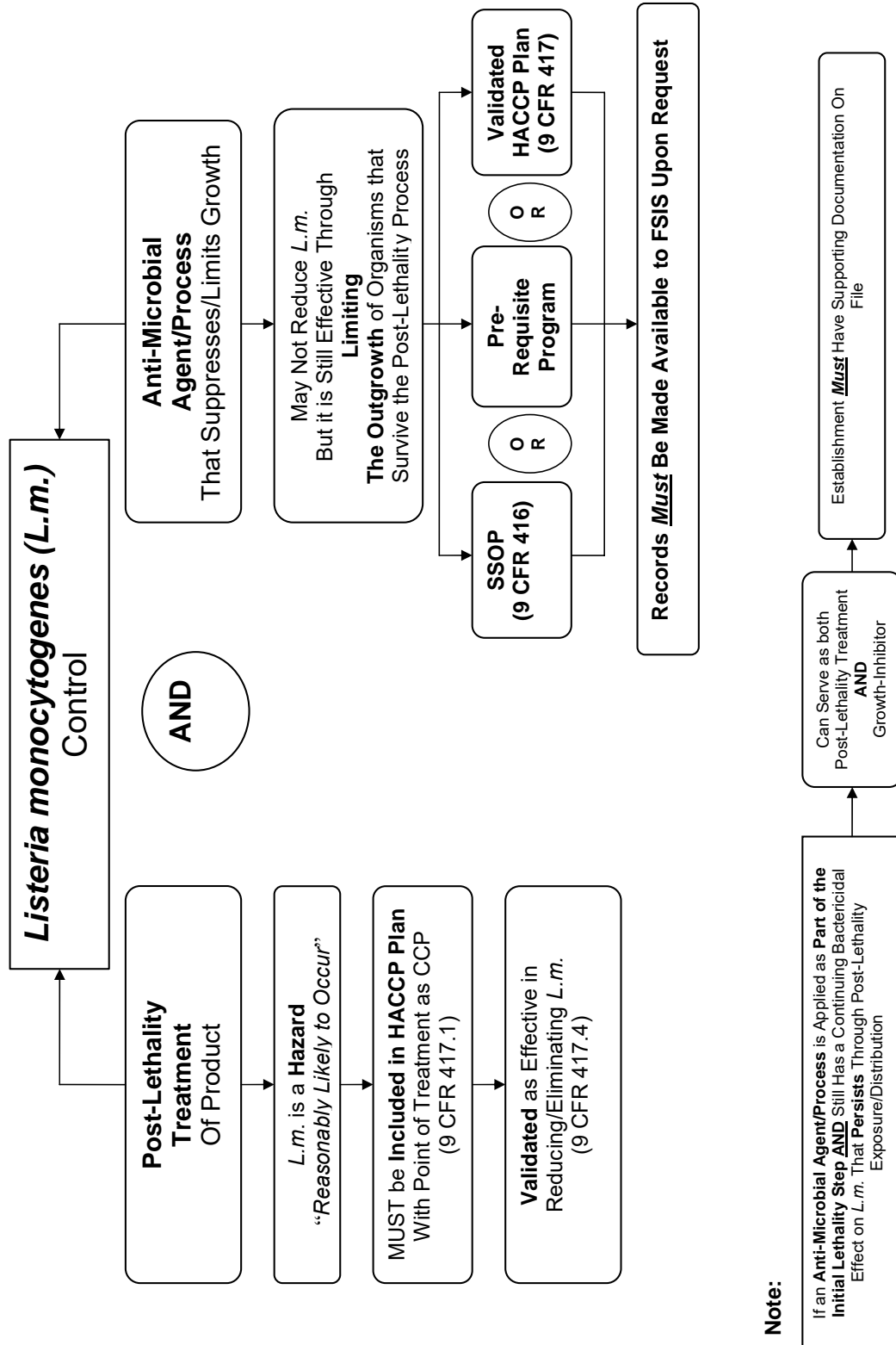
Requirements	→ Increasing Risk Levels and Frequency of FSIS Verification Testing →				
	ALTERNATIVE 1	ALTERNATIVE 2		ALTERNATIVE 3	
	Post-lethality Treatment <u>AND</u> Antimicrobial agent or Process	Post-lethality Treatment <u>OR</u> Antimicrobial agent or Process		Sanitation and Testing Program	
		Choice 1: Post-lethality Treatment	Choice 2: Antimicrobial Agent or Process	Non-deli, Non-hotdog	Deli or hot-dog product
Validate effectiveness of post-lethality treatment (PLT). Must be included as a CCP in the establishment's HACCP Plan and should show at least a 1-log reduction in <i>Lm</i> prior to distribution of the product into commerce	X	X			
Document effectiveness of antimicrobial agent or process: Must be included as part of the establishment's HACCP, Sanitation SOP, or Pre-requisite Program and should demonstrate no more than 2-logs growth of <i>Lm</i> over the estimated shelf life.	X		X		
Sanitation Program Requirements			X	X	X
Testing food contact surfaces (FCS) in the post-lethality processing environment for <i>Lm</i> or an indicator organism.			X	X	X
State testing frequency.			X	X	X
Identify size and location of sites to be sampled.			X	X	X
Explain why testing frequency is sufficient to control <i>Lm</i> or an indicator organism.			X	X	X
Identify conditions for Hold-and-Test, when FCS (+) for <i>Lm</i> or an indicator organism.			X	X	X
Additional Sanitation Program Requirements					
Follow-up testing to verify corrective actions are effective after 1 st FCS (+) for <i>Lm</i> or an indicator organism. Includes testing of targeted FCS as most likely source and additional testing of the surrounding area.					X
If follow-up testing yields 2 nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing.					X
Hold and test product lots using a sampling plan that provides statistical confidence that the lots are not contaminated with <i>Lm</i> or an indicator organism. Release, rework or condemn products based on results. Document results and product disposition.					X
Establishments in all three alternatives must maintain sanitation in accordance with 9 CFR 416.	X	X	X	X	X

ATTACHMENT 2: CHART OF RTE VS NRTE PRODUCTS

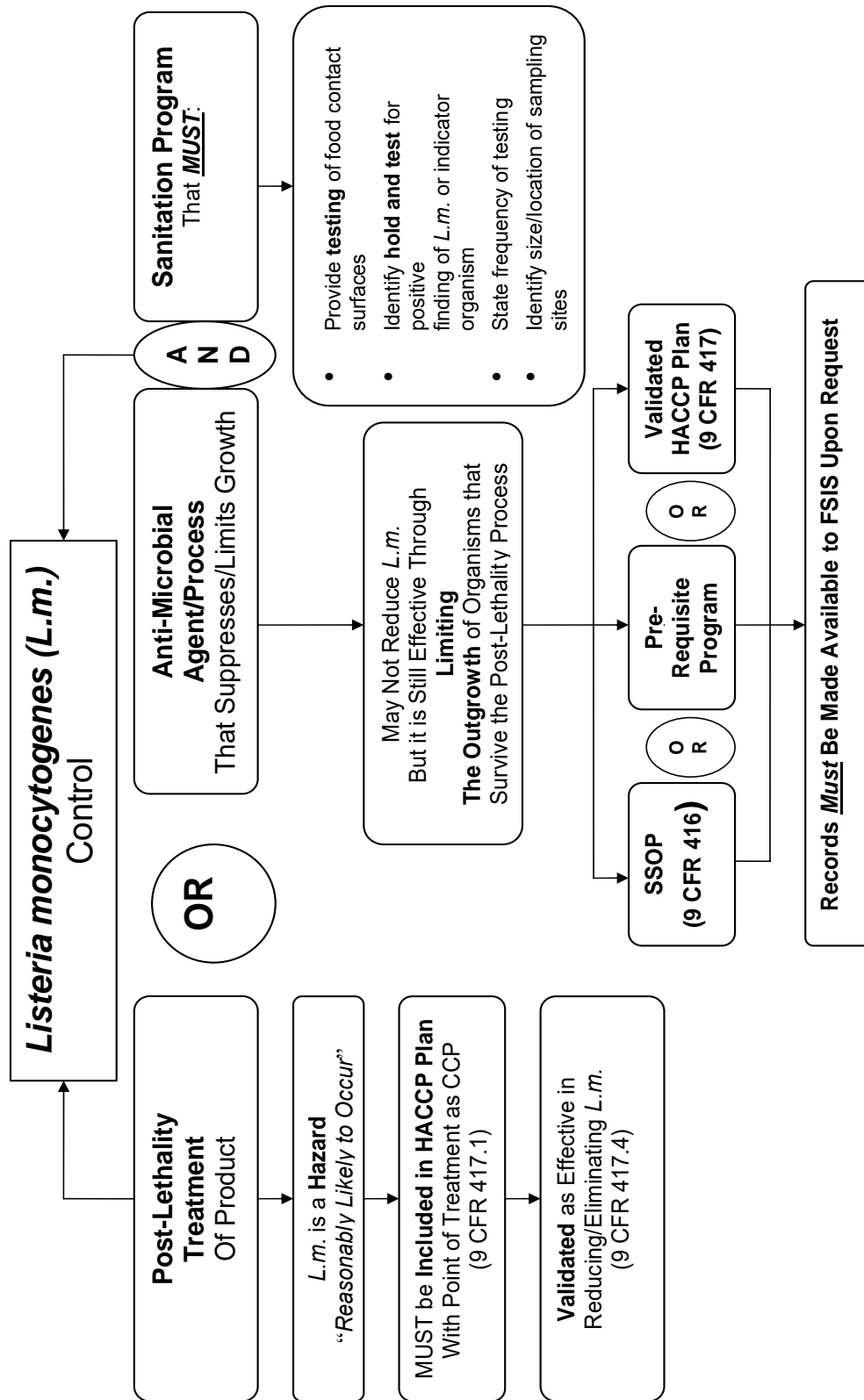
TYPE	CLASS	PROCESSING CATEGORY	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS OR HACCP PLAN MAY ADDRESS
<p>A meat/poultry product (in whole or in part) which has not received an adequate lethality treatment for <i>Salmonella</i> (i.e., raw or partially cooked product). May include cuts of meat and poultry, cured pork products, and NRTE sausage</p> <p style="text-align: center;">Or</p> <p>A meat/poultry product (in whole or in part) which has received an adequate lethality treatment for <i>Salmonella</i>, that is not defined by a standard of identity or common or usual name that consumer understand to refer to RTE product <u>and</u> does not meet the definition of RTE in 9 CFR 430.1. May include NRTE ham, casseroles, and other meat or poultry dishes</p>	Not-ready-to-eat	<ul style="list-style-type: none"> Raw Product Nonintact Raw Product Intact Not Heat Treated Shelf Stable Heat Treated –shelf stable Heat Treated but not Fully Cooked Not Shelf Stable Products with secondary inhibitors Not Shelf Stable 	Product must be labeled with statements such as keep refrigerated, keep frozen, or refrigerate leftovers, if not shelf stable. Use of Safe Handling Instruction (SHI) labeling required.	<ul style="list-style-type: none"> Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). <p>If it is not obvious that the product is raw and needs to be cooked:</p> <ul style="list-style-type: none"> Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel or by a burst stating such things as “needs to be fully cooked,” “see cooking instructions,” or “cook before eating.” Validation that: <ol style="list-style-type: none"> Cooking and preparation instructions on the product are sufficient to destroy pathogens. Instructions are realistic for the intended consumer.
A product containing a meat/poultry component that is RTE in combination with nonmeat/poultry components that needs to receive a lethality treatment by the intended user. The final product does not meet the definition of RTE in 9 CFR 430.1 because it contains raw components. May include meals, dinners, and frozen entrees.	Not-ready-to-eat	<ul style="list-style-type: none"> Heat Treated but not Fully Cooked Not Shelf Stable 	<p>Product must be labeled with statements such as keep refrigerated or frozen. Use of SHI labeling is recommended.</p> <p>Note: SHI are not required because the meat or poultry component is RTE. However, FSIS recommends SHI for these products because raw non meat ingredients are added.</p>	<ul style="list-style-type: none"> Validation that: <ol style="list-style-type: none"> The meat/poultry component received an adequate lethality treatment for pathogens. Cooking and preparation instructions on the product are sufficient to destroy pathogens. Instructions are realistic for the intended consumer. Features on labeling are conspicuous so that intended user is fully aware that product must be cooked for safety. This is best conveyed through the product name (e.g., “Cook and Serve”) but may also be conveyed by the use of an asterisk on the product name that is associated with a statement on the principle display panel, or by a burst stating such things as “needs to be fully cooked”, “see cooking instructions”, or “cook before eating.” If necessary, hazard analysis should address whether instructions on the label are needed related to cross-contamination (e.g., avoid contact of contents) and prevention of pathogenic growth (e.g., promptly refrigerate leftovers). <p>NOTE: Inspection program personnel are to collect samples as RTE if the establishment does not follow the guidance above.</p>

TYPE	CLASS	PROCESSING CATEGORY	REG REQUIRED SAFETY LABELING	WHAT THE HAZARD ANALYSIS OR HACCP PLAN MAY ADDRESS
A meat/poultry component that has received an adequate lethality treatment for <i>Salmonella</i> that may or may not be defined by a standard of identity or common or usual name that consumer understand to refer to RTE product and meets the definition of 9 CFR 430.1. RTE products that are post lethality exposed must meet the requirements of 9 CFR 430. May include hotdogs, deli meat, and RTE sausages.	Ready-to-eat	<ul style="list-style-type: none"> • Not Heat Treated Shelf Stable • Heat Treated Shelf Stable • Fully Cooked Not Shelf Stable • Products with secondary inhibitors Not Shelf Stable 	If the product is not shelf stable, labeling such as keep refrigerated or frozen is required. SHI are not required and should not be used because they could be misleading to consumers	<ul style="list-style-type: none"> • Validation that the meat or poultry component received an adequate lethality treatment for pathogens (e.g., a 5-log reduction of <i>Salmonella</i>). • The establishment meets the requirements of 9 CFR 430 if the product is post-lethality exposed. • Heating (not cooking) instructions may be included. • Statements on the principle display panel may indicate that the product is RTE and does not have to be cooked for safety (e.g., "fully cooked", "heat and serve").

Alternative 1



Alternative 2



Alternative 3

Listeria monocytogenes (L.m.) Control

Sanitation Program That MUST:

For RTE Products:

- Provide **testing** of food contact surfaces
- Identify **hold and test** for positive finding of *L.m.* or indicator organism
- State frequency of testing
- Identify size/location of sampling sites
- Support testing frequency

AND

For Hotdog & Deli-Type Products:

- Verify corrective actions after initial positive sample of food contact surface
- Test and hold in the case of a second positive
- Sample and test lots to release OR rework to destroy *L.m.*

Records Must Be Made Available to FSIS Upon Request

Workshop: *Listeria monocytogenes* Regulations

1. Establishments are required to comply with section 9 CFR 430.4 (Control of *Listeria monocytogenes*) if they produce:
 - a. Ready-to-eat products processed and sold in impermeable packaging.
 - b. Not ready-to-eat products with secondary inhibitors.
 - c. Ready-to eat products.
 - d. Ready-to-eat products exposed to the environment after the lethality step.
2. Fill in the blanks with one of the following:

Alternative 1

Alternative 2, Choice 1

Alternative 2, Choice 2

Alternative 3

- a. _____ Use of only a post-lethality treatment (which may be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product
- b. _____ Use of a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*
- c. _____ Sanitation measures only, in the HACCP plan, SSOP, or prerequisite program, including testing of food contact surfaces to verify the effectiveness of the sanitation procedures
- d. _____ Use of an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*, along with a sanitation program addressing the testing of food contact surfaces to verify the effectiveness of the sanitation procedures

3. An establishment MUST implement hold and test procedures when a positive result for an indicator organism is found on a food-contact surface during follow-up testing (second consecutive food contact surface positive) if the establishment is producing:
 - a. RTE products exposed to the environment after the lethality treatment using Alternative 1, 2, or 3.
 - b. Non-deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 3.
 - c. Deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 3.
 - d. Deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 2, Choice 2

4. An establishment MUST identify the conditions under which it will implement hold and test procedures after a positive result for an indicator organism is found on a food-contact surface if the establishment is producing:
 - a. Non-deli and hot dog type or deli or hot dog type RTE products exposed to the environment after the lethality treatment using either Alternative 2 (Choice 2) or Alternative 3.
 - b. Deli and hot dog type RTE products exposed to the environment after the lethality treatment using either Alternatives 1, 2, or 3.
 - c. Deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 1 or Alternative 2, Choice 1.
 - d. Non-deli and hot dog type RTE products exposed to the environment after the lethality treatment using Alternative 2, Choice 1

5. **Case Study.** (Please note: This is a simplified training example only.) You are assigned to an establishment that makes smoked turkey for slicing at delis. The establishment has chosen to produce this product under Alternative 2, Choice 2. In order to comply with Part 430.4(b)(2), the establishment's sanitation program must provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria monocytogenes*. The establishment includes sanitation measures to prevent *Listeria monocytogenes* in processing environment in the Sanitation SOP. The sanitation program targets the packaging room, where product is taken off of smokehouse racks, cut into halves, and vacuum packaged. The establishment conducts routine, random food contact surface testing as follows:

- It has identified 20 food contact surface sites, such as table tops, packaging equipment, and knife blades. These represent all possible sites.
- Each month 5 sites are randomly selected and tested for *Listeria* spp. The sites are tested twice weekly, at the end of production before cleaning. Testing frequency is based on past data. For 6 months testing was done weekly, and data showed that the process ensured control of *Lm*. Additionally, they are testing more frequently than recommended by FSIS in the *Compliance Guidelines to Control Listeria monocytogenes in Post-lethality Exposed Ready to Eat Meat and Poultry Products*.
- Sample size is 1 square foot for each surface.
- Sample sites are recorded, along with visual observation of each site. Test results are recorded on the same form.
- If a positive food contact surface sample result is detected, that site is given intensified cleaning and sanitizing during the next sanitation, and re-swabbed daily for 5 days.
- If the site is again positive for *Listeria* spp. during this 5-day period, the food contact surface is taken out of production and subjected to intensive cleaning and sanitizing, holding product, and retesting, as follows.
 - Equipment is completely disassembled.
 - The food contact surface and surrounding areas receive intensified cleaning and sanitizing, and the item is re-assembled and placed back into production.
 - Corrective actions are recorded.
 - Food contact surface swabs are then taken every two hours during production.
 - All product is placed on hold until results are received.
 - If all food contact surface swabs are negative, product is released.
 - If any swab tests positive for *Listeria* spp., product from that 2-hour time period and from each period on either side of the positive result is tested for *Listeria monocytogenes*.
 - Testing will be done following a statistically derived sampling plan.
 - Product that tests negative for *Lm* is released.
 - Product that tests positive for *Lm* is destroyed.
 - The process of intensified sanitation, holding product, and testing food contact surfaces is repeated daily until test results are negative for *Listeria* spp.

- a. At what point during production are the random food contact surface samples taken?

- b. Does this program identify conditions under which the establishment will implement hold-and-test procedures following a positive test of a food contact surface? If so, what are those conditions?

- c. Does this program identify the frequency with which testing will be done? If so, what is that frequency?

- d. Does this program identify the size and location of the sites that will be sampled? If so, what is the size and location?

- e. When are product samples for *Listeria monocytogenes* taken?

- f. Would you review records associated with this program? If so, when? Please explain your answer.

- g. Would you observe employees performing the sampling procedures? If so, when? Please explain your answer.

Regulations

9 CFR 430.1, Definitions.

Antimicrobial agent. A substance in or added to an RTE product that has the effect of reducing or eliminating a microorganism, including a pathogen such as *L. monocytogenes*, or that has the effect of suppressing or limiting growth of *L. monocytogenes* in the product throughout the shelf life of the product. Examples of antimicrobial agents added to RTE products are potassium lactate and sodium diacetate.

Antimicrobial process. An operation, such as freezing, applied to an RTE product that has the effect of suppressing or limiting the growth of a microorganism, such as *L. monocytogenes*, in the product throughout the shelf life of the product.

Deli product. A ready-to-eat meat or poultry product that typically is sliced, either in an official establishment or after distribution from an official establishment, and typically is assembled in a sandwich for consumption.

Hotdog product. A ready-to-eat meat or poultry frank, frankfurter, or wiener, such as a product defined in 9 CFR 319.180 and 319.181.

Lethality treatment. A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product to make the product safe for human consumption. Examples of lethality treatments are cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

Post-lethality exposed product. Ready-to-eat product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.

Post-lethality processing environment. The area of an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed to the environment in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Post-lethality treatment. A lethality treatment that is applied or is effective after post-lethality exposure. It is applied to the final product or sealed package of product in order to reduce or eliminate the level of pathogens resulting from contamination from post-lethality exposure.

Prerequisite program. A procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. It is called "prerequisite" because it is considered by scientific experts to be prerequisite to a HACCP plan.

Ready-to-eat (RTE) product. A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.

RTE product is not required to bear a safe-handling instruction (as required for non-RTE products by 9 CFR 317.2(l) and 381.125(b)) or other labeling that directs that the product must be cooked or otherwise treated for safety, and can include frozen meat and poultry products.

9 CFR 430.4, Control of *Listeria monocytogenes* in post-lethality exposed ready-to-eat products.

(a) *Listeria monocytogenes* can contaminate RTE products that are exposed to the environment after they have undergone a lethality treatment. *L. monocytogenes* is a hazard that an establishment producing post-lethality exposed RTE products must control through its HACCP plan or prevent in the processing environment through a Sanitation SOP or other prerequisite program. RTE product is adulterated if it contains *L. monocytogenes* or if it comes into direct contact with a food contact surface which is contaminated with *L. monocytogenes*.

(b) In order to maintain the sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with the requirements included in one of the three following alternatives:

(1) Alternative 1. Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit the growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of the post-lethality treatment incorporated in its HACCP plan in accordance with Sec. 417.4. The establishment must document, either in its HACCP plan or in its Sanitation SOP or other prerequisite program, that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(2) Alternative 2. Use of either a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product or an antimicrobial agent or process that suppresses or limits growth of *L. monocytogenes*. If an establishment chooses this alternative:

(i) The post-lethality treatment must be included in the establishment's HACCP plan. The antimicrobial agent or process used to suppress or limit growth of the pathogen must be included in either the establishment's HACCP plan or its Sanitation SOP or other prerequisite program.

(ii) The establishment must validate the effectiveness of a post-lethality treatment incorporated in its HACCP plan in accordance with Sec. 417.4. The establishment must document in its HACCP plan or in its Sanitation SOP or other prerequisite program that the antimicrobial agent or process, as used, is effective in suppressing or limiting growth of *L. monocytogenes*.

(iii) If an establishment chooses this alternative and chooses to use only an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(iv) An establishment that chooses this alternative and uses a post-lethality treatment of product will likely be subject to more frequent verification testing by FSIS than if it had chosen Alternative 1. An establishment that chooses this alternative and uses an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes* will likely be subject to more frequent FSIS verification testing than if it uses a post-lethality treatment.

(3) Alternative 3. Use of sanitation measures only.

(i) If an establishment chooses this alternative, its sanitation program must:

(A) Provide for testing of food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism;

(B) Identify the conditions under which the establishment will implement hold-and-test procedures following a positive test of a food-contact surface for *L. monocytogenes* or an indicator organism;

(C) State the frequency with which testing will be done;

(D) Identify the size and location of the sites that will be sampled; and

(E) Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of indicator organisms is maintained.

(ii) An establishment producing a deli product or a hotdog product, in addition to meeting the requirements of paragraph (b)(3)(i) of this section, must meet the following requirements:

(A) The establishment must verify that the corrective actions that it takes with respect to sanitation after an initial positive test for *L. monocytogenes* or an indicator organism on a food contact surface in the post-lethality processing environment are effective by conducting follow-up testing that includes a targeted test of the specific site on the food contact surface area that is the most likely source of contamination by the organism and such additional tests in the surrounding food contact surface area as are necessary to ensure the effectiveness of the corrective actions.

(B) During this follow-up testing, if the establishment obtains a second positive test for *L. monocytogenes* or an indicator organism, the establishment must hold lots of product that may have become contaminated by contact with the food contact surface until the establishment corrects the problem indicated by the test result.

(C) Further, in order to be able to release into commerce the lots of product that may have become contaminated with *L. monocytogenes*, the establishment must sample and test the lots for *L. monocytogenes* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *L. monocytogenes*. The establishment must document the results of this testing. Alternatively, the establishment may rework the held product using a process that is destructive of *L. monocytogenes* or the indicator organism.

(iii) An establishment that chooses Alternative 3 is likely to be subject to more frequent verification testing by FSIS than an establishment that has chosen Alternative 1 or 2. An establishment that chooses Alternative 3 and that produces deli meat or hotdog products is likely to be subject to more frequent verification testing than one that does not produce such products.

(c) For all three alternatives in paragraph (b):

(1) Establishments may use verification testing that includes tests for *L. monocytogenes* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

(2) Sanitation measures for controlling *L. monocytogenes* and procedures for antimicrobial agents or processes that suppress or limit the growth of the pathogen may be incorporated either in the establishment's HACCP plan or in its Sanitation SOP or other prerequisite program. When these control procedures are incorporated into the Sanitation SOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation that supports the decision in its hazard analysis that *L. monocytogenes* is not a hazard that is reasonably likely to occur.

(3) The establishment must maintain sanitation in the post-lethality processing environment in accordance with part 416.

(4) If *L. monocytogenes* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of measures for controlling *L. monocytogenes* included in its HACCP plan in accordance with Sec. 417.4.

(5) If *L. monocytogenes* control measures are included in the Sanitation SOP, the effectiveness of the measures must be evaluated in accordance with Sec. 416.14.

(6) If the measures for addressing *L. monocytogenes* are addressed in a prerequisite program other than the Sanitation SOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain under 9 CFR 417.5.

(7) The establishment must make the verification results that demonstrate the effectiveness of the measures it employs, whether under its HACCP plan or its Sanitation SOP or other prerequisite program, available upon request to FSIS inspection personnel.

(d) An establishment that produces post-lethality exposed RTE product shall provide FSIS, at least annually, or more often, as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each of the alternatives in paragraph (b) of this section.

(e) An establishment that controls *L. monocytogenes* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of the organism may declare this fact on the product label provided that the establishment has validated the claim.