



Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Inspection Methods Hybrid (IMH)

Class Workbook **Part 2 of 3**

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Only this provided printed workbook may be used during the test. Handwritten notes and highlights are allowed on the provided pages. No additional pages, sticky notes, paper clips, or anything else added to the workbook is allowed.

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18 SANITARY DRESSING

Objectives:

1. Define:
 - a. Process control procedures
 - b. Sanitary dressing procedures
 - c. Contamination of carcasses and parts
2. Describe the role of sanitary dressing and process control procedures as part of an establishment's food safety system.
3. Identify points in the slaughter process where contamination is most likely to occur.
4. Explain how to verify that slaughter operations are implementing appropriate sanitary dressing procedures to prevent contamination.
5. Explain how to verify that establishments are properly applying intervention treatments.
6. Describe how to use a system-based approach to determining compliance.

Inspection program personnel (IPP) who perform off-line slaughter verification duties are to use the PHIS Beef Sanitary Dressing task to verify compliance with the sanitation performance standards. They need to gather as much information as possible for a sound regulatory decision about the system. As IPP enter the kill floor, they observe the process, review plant records and results, FSIS records and results, NRs, pathogen testing results, generic *E. coli* testing results, online IPP feedback, weather conditions, etc. The thought process should use the systems-based approach to make compliance determinations.

Sanitary Dressing: Practice of handling carcasses by establishment employees and machinery, throughout the slaughter process, in a manner that produces a clean, safe, wholesome meat food product in a sanitary environment.

Process Control Procedure: A defined procedure or set of procedures designed by an establishment to provide control of operating conditions that are necessary to produce safe, wholesome food. The procedures establishments follow typically include observing or measuring system performance, analyzing the results to set control criteria, and acting when needed to ensure that the system continues to perform within the control criteria. The procedures would include planned measures taken by the establishment in response to any loss of process control. In addition, the procedures can be used as support for decisions made in the hazard analysis.

Contamination of Carcasses and Parts: Carcasses and parts are deemed contaminated, based on organoleptic inspection if they have been prepared, packed, or held under insanitary conditions. **Contamination can originate from two sources:**

- **Extraneous Substances:** Substances not related to the species being slaughtered like oils, rail dust, condensate, and unidentified foreign material.
- **Intrinsic Sources:** Substances related to the species being slaughtered, like digestive content, milk, ingesta, or bile. Establishments need to prevent the creation of insanitary conditions and prevent the contamination of carcasses and parts to meet regulatory requirements.

Effective sanitary dressing and process control procedures lay the foundation for the critical control points (CCPs) that prevent, eliminate, or reduce to an acceptable level food safety hazard that are deemed reasonably likely to occur in the slaughter process. It is the responsibility of the establishment to reduce *E. coli* O157:H7 to below detectable levels and reducing the amount of contamination that is present on a carcass helps the establishment accomplish that.

Note: Positive results can be attributed to ineffective sanitary dressing and process control procedures that lead to insanitary conditions during slaughter.

Establishments must operate and be maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure the product is not adulterated, as required by 9 CFR 416.1-416.5. Establishments that slaughter cattle must do so in a manner designed to prevent contamination from occurring at any step in the process. SPS plays a role, especially with regard to equipment, utensils, sanitary operations, employee hygiene. SPS is the most appropriate category for addressing incidental contamination.

Each establishment must design their own procedures. Effective sanitary dressing and process control procedures, coupled with effective decontamination and antimicrobial intervention treatments, are needed to prevent the creation of insanitary conditions.

Establishments that fail to control these procedures and treatments create the potential for carcass contamination in their food safety systems. Establishments may elect to maintain written sanitary dressing and process control procedures as part of their HACCP Plan, Sanitation SOP, Good Manufacturing Practices (GMP), or other prerequisite programs. If the sanitary dressing procedures are used to support decisions made in the hazard analysis in accordance with 9 CFR 417.5(a)(1), establishments must maintain records addressing the sanitary dressing and process control program. The records must demonstrate that the program is effective and thus decisions made in the hazard analysis can be supported on an on-going basis. Establishments have flexibility on how they demonstrate effective sanitary dressing and maintain records.

Verification of a food safety system requires that IPP evaluate production operations by looking at all aspects of those operations and assessing the interactions between them using a systems-based approach. IPP accomplish this through observation of the implementation of a variety of plans and procedures and through the review of documents associated with those plans and procedures. When the information gathered suggests that the establishment has lost process control, IPP are to determine if the establishment has taken measures to restore process control.

FSIS has identified the **points** in the slaughter process where carcasses are **most vulnerable to contamination**. This was determined through scientific literature review as well as best practice guidance created by industry. **The steps are** live receiving/holding, sticking, hide removal, wash cabinets, bunning, head removal, rodding the weasand, evisceration, carcass splitting, and head and cheek meat processing. When cattle arrive, there is an increased potential for contamination with enteric pathogens such as *E. coli* O157:H7 and *Salmonella* due to their presence on the hide and in feces. Stressors cause increase shedding of pathogens like *E. coli* O157:H7.

An **intervention** is a step in the process added for the **purpose of eliminating/reducing a hazard to an acceptable level**. How well the establishment performs its sanitary dressing procedures impacts whether the antimicrobial intervention treatments will be effective and accomplish their intended results. Intervention may be a sprayed solution of water and/or chemicals, a shower, some sort of drip application, steam vacuum device, a combination of all of these—the **multiple hurdle** approach. Each one of these interventions has a certain capability. Sanitary dressing directly impacts whether antimicrobial treatments will accomplish intended results. When incoming **contamination overwhelms** the antimicrobial properties of **the intervention** treatments, **reduction of *E. coli* O157:H7 may no longer meet the standard** of reduction to an undetectable level.

FSIS has questions about the establishment's ability to support the food safety system as the hazard analysis anticipates, unless the establishment has: documentation that supports that the food safety system at slaughter, including sanitary dressing procedures coupled with all intervention treatments, is effective under the actual conditions that apply in its operation; the establishment has reassessed its system in response to new or revised procedures or interventions that have been implemented and has determined that no changes were needed. If the establishment **determines it can prevent contamination through its SOP, GMP or other prerequisite program, it needs to include support in the hazard analysis**. Before you make a compliance (meets regulatory requirements) determination, base it on in-plant observations, your own test results, establishment results, FSIS results, and communication with other inspectors; on-line IPP and PHV/SPHV findings, historical information; NRs, MOIs, ongoing noncompliance related to zero tolerance, increased contamination based on environmental conditions, positive pathogen results, and feedback from on-line IPP indicating increased contamination.

Regulations to cite include 9 CFR 310.18(a) for carcass contamination, and 9 CFR 416.1 (remember: only cite this regulation in response to egregious and repetitive insanitary conditions, and only in consultation with your IIC and FLS). Include in the description of the noncompliance the appropriate SPS regulations to address the source(s) of the insanitary condition. **Noncompliance is not likely to be documented in response to one contamination** incident or one single point in the process. Review NRs to determine if a trend is developing. NRs can be associated as necessary in accordance with the instructions in FSIS Directive 5000.1.

19 SLAUGHTER FOOD SAFETY STANDARD

Objectives:

1. List the three contaminants covered by the food safety standard in livestock slaughter.
2. Identify the carcass parts that must be free of the three contaminants covered by the livestock food safety standards.
3. Identify the location where FSIS verifies the food safety standard for livestock carcasses.
4. Identify the contaminants covered by the food safety standard in poultry standard.
5. Identify the location where FSIS verifies the food safety standards for poultry carcasses.
6. Describe how to perform the livestock zero tolerance verification task.
7. Describe how to perform the poultry zero tolerance verification task.
8. List the actions IPP take when they find a zero tolerance failure during the performance of the poultry and livestock zero tolerance verification tasks.
9. Describe the enforcement actions when repetitive zero tolerance noncompliance is documented in PHIS.

The Food Safety and Inspection Service (FSIS) published in FR 97-067N notification that the Agency views its “**zero tolerance**” for visible fecal material as a food safety standard. In slaughter establishments, fecal contamination of carcasses is the primary avenue for contamination by pathogens, including Shiga toxin-producing *E. coli* (STECs), *Salmonella*, and *Campylobacter*.

Pathogens may reside in fecal material, both in the gastrointestinal tract and on the exterior surfaces of the animal or bird going to slaughter. Without proper handling and sanitary dressing procedures during slaughter, the edible portions of the carcass can become contaminated with bacteria capable of causing illness in humans. The organisms may spread directly from carcass to carcass or indirectly by hands, utensils, or equipment.

Enforcing Food Safety Standard for Livestock Postmortem

References: FSIS Directive 6420.2, Regulations 9 CFR 310.17(a), 9 CFR 310.18(a), and Part of 9 CFR 417.

The contaminants that are covered by the food safety standard in **livestock** slaughter are **feces, ingesta, milk**. Carcasses, and head meat, cheek meat and weasand meat must be free of these contaminants.

On-line IPP verify the removal of contamination while examining heads, viscera, carcasses, and carcass parts during post-mortem inspection. If on-line IPP observe contamination on heads, viscera, carcasses, and carcasses parts, IPP do not pass the carcass or part until all of the contamination is promptly removed in a satisfactory manner. When contamination is present the line is stopped unless the establishment provides a rail-out loop and the IIC has no concerns

about the rail-out procedures. On-line IPP will notify the IIC when they suspect the establishments slaughter or sanitary dressing procedures are not under control or rail-out procedures are inadequate. IPP verify that livestock slaughter establishments are complying with 9 CFR 310.17(a), and 9 CFR 310.18(a).

Off-line IPP are to perform the Livestock Zero Tolerance Verification task on carcasses and head, cheek, and weasand meat at a **minimum of one time per slaughter shift**.

When performing the Livestock Zero Tolerance Verification Task, inspection program personnel (IPP) are to **determine the number of carcasses** or carcass sides to be examined **based on the expected slaughter volume** for that shift (number of animals). For head, cheek, and weasand meat, IPP are to examine no less than the amount of product the establishment has listed in its HACCP plan for the monitoring procedure.

FSIS verify the food safety standards for livestock carcasses **at or after the postmortem rail inspection station and before the final wash**.

FSIS verify the food safety standard for **head meat, cheek meat, and weasand meat** in livestock slaughter operations **at the completion of the harvesting process, after all of the establishment controls and interventions**. This verification may occur at the time of packaging or when the product is placed in a container for storage.

For livestock (except swine) the HACCP plan must include as appropriate, **critical control points (CCPs) that are designed to control identified food safety hazards** (9 CFR 417.2(c)(2)). This is because fecal material is a vehicle for pathogens, and because virtually all slaughter establishments recognize that contamination of meat by pathogenic microorganisms from fecal material, ingesta, or milk is a food safety hazard that is reasonably likely to occur in the slaughter production process.

Note: 9 CFR 310.18(c) requires **swine slaughter establishments** to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens, and visible fecal material, ingesta, and milk contamination throughout the entire slaughter and dressing operation. Establishments **must incorporate these procedures into their HACCP plans, or sanitation SOPs, or other prerequisite programs**.

Enforcing the Food Safety Standard for Poultry Postmortem

References: FSIS Directives 6420.5 and 6500.1, FSIS Regulation 9 CFR 381.65(f), and part 417.

The contaminant that is covered by the food safety standard in **poultry** slaughter is **feces**. At poultry slaughter, the **fecal** contamination checks are performed at the **pre-chill testing station** or any location **after the final wash** and before the chilling tank in establishments operating under traditional inspection.

Off-line IPP are to conduct the Poultry Zero Tolerance task **at least two** fecal contamination checks for each evisceration **line for every shift**. The verification method involves randomly selecting ten carcasses and examining following the FSIS Directive 6420.5.

Note: Poultry major portions and parts are not subject to poultry zero tolerance verification but are subject to slaughter HACCP or SSOP verification.

Documenting Compliance with the Zero Tolerance Task

When IPP **do not observe** any fecal material, ingesta, or milk on livestock carcasses or on head, cheek, or weasand meat, or feces on poultry carcasses during the verification, they **select the mandatory regulation on the “Regulations” tab**. IPP mark the zero-tolerance task as **‘Inspection Completed’** at the bottom of the Inspection Results page.

Documenting Noncompliance with the Zero Tolerance Task

If IPP **find feces, ingesta, or milk on livestock** carcasses or head meat, cheek meat, or weasand meat while performing the livestock zero tolerance verification task, or find **feces on poultry** carcasses while performing the poultry zero tolerance verification task, IPP are to:

- **Verify regulatory requirements associated with 9 CFR 310.18(a) (livestock) or 9 CFR 381.65(f) (poultry);**
- **Notify the establishment** that a zero tolerance noncompliance with 9 CFR 310.18(a) or 9 CFR 381.65(f) exists;
- **Document the noncompliance** on an NR citing 9 CFR 310.18(a) or 9 CFR 381.65(f);
- **For poultry zero tolerance failures include a statement that the establishment is not preventing feces from entering the chiller.**

Additional Verification after Positive Zero Tolerance Findings (Livestock except Swine)

- When IPP determine zero tolerance noncompliance while performing the Zero Tolerance Verification task they are to perform a Slaughter HACCP Verification task to verify that the establishment performs corrective actions for the affected product in accordance with 9 CFR 417.3(a).

Additional Verification after Positive Zero Tolerance Findings (Poultry or Swine)

After notifying the establishment of the zero-tolerance noncompliance, off-line IPP are to:

- Schedule either a **directed Slaughter HACCP or Operational SSOP Review and Observation verification task** in PHIS;
- **Indicate “zero tolerance noncompliance” as the reason** for performing the directed task in PHIS; and
- **Verify** the establishment has performed all the required **corrective actions** in accordance with 9 CFR 417.3(a) if the controls are in the HACCP plan, 9 CFR 417.5(a)(1) if the controls are in the prerequisite programs, or 9 CFR 416.15(b) if the controls are in the SSOP's and is properly implementing its HACCP system.

Note: If IPP find zero tolerance failures on livestock carcasses past the final rail or on poultry carcasses, major portions, or parts at or beyond the pre-chill testing station **while performing inspection tasks other than the zero tolerance task (“stumble-on” occurrences)**, they are to document the noncompliance under the appropriate PHIS task (Slaughter HACCP or Operational SSOP Review and Observation verification task).

The System Approach in Enforcement

If IPP find **repeated zero tolerance noncompliances** and determine that these findings **are an ongoing trend of related noncompliances or systemic problems with the establishment's food safety system**, the current NR is to be associated with the most recent zero tolerance or related NR. When associating NRs, IPP are to follow the methodology set out in FSIS Directive 5000.1.

IPP are to associate two or more NRs when they indicate an ongoing trend of related noncompliances or systemic problems with the establishment's food safety system.

20 *SALMONELLA* & *CAMPYLOBACTER* TESTING

Objectives:

1. Understand why *Salmonella* and *Campylobacter* is a huge concern for FSIS and Industry in poultry slaughter and processing establishments.
2. List the types of products that are eligible for testing.
3. Recognize the sampling codes for the eligible products.
4. Know the frequency at which samples should be taken.
5. Explain how FSIS uses the moving window approach when assessing process control.
6. Explain how to obtain completed results using LIMS-Direct and PHIS
7. Understand the three process control categories.
8. Know what actions to take when an establishment is in Category 2 or 3.
9. Explain when and how to document a MOI regarding categorization.
10. Be able to verify ineligible raw product destined for ready-to-eat at an official establishment.

Performance Standards

The purpose of the microbiological performance standards for the reduction of *Salmonella* in raw products is to allow FSIS to verify whether establishments have effective process controls to address *Salmonella*.

FSIS originally selected *Salmonella* as the target organism because it is a commonly reported cause of foodborne illness and is present in all major species. *Salmonella* bacteria are the most frequently reported cause of foodborne illness.

Campylobacter species, specifically *C. jejuni* and *C. coli*, are most often isolated from the intestinal tract of poultry as well as in poultry products. *Campylobacter* bacteria are the second most frequently reported cause of foodborne illness, and *C. jejuni* is the most common strain causing illness.

Salmonella and *Campylobacter* contamination of raw poultry products occurs during slaughter operations, as well as during the live animal rearing process. Contamination can be minimized with the use of proper sanitary dressing procedures and by the application of antimicrobial interventions during slaughter and fabrication of the carcasses into parts and comminuted product. In addition, if raw poultry is improperly handled during food preparation, *Salmonella* and *Campylobacter* can cross-contaminate other foods or food contact surfaces.

FSIS Directive 10,250.1 *SALMONELLA* AND *CAMPYLOBACTER* VERIFICATION

Salmonella and *Campylobacter* verification sampling is conducted in establishments by FSIS inspection program personnel (IPP). IPP will collect samples using ongoing scheduled sampling (routine sampling), employing a moving window approach to assess process control for all *Salmonella* and *Campylobacter* performance standards.

Aseptic Sampling

FSIS inspectors collect verification samples using aseptic techniques. Aseptic techniques help prevent contamination of the sample and help protect the integrity of subsequent test results.

Follow these steps:

1. Choose a staging area for gathering and preparing your sampling supplies. Use a wheeled, stainless-steel cart and a small tote or caddy to transport your supplies and the sample to and from the sample collection location.
2. Prepare the supplies you need for the specific sampling project. For example, for sampling turkey carcasses, you would mix the sample solution with sponges prior to collecting the sample.
3. Label your sample containers before collecting the sample.
4. Wear a clean lab coat and hair net to avoid contamination. Follow your plant's garment requirements when you collect the samples.
5. Wash your hands and forearms and dry them with a paper towel. (If there is no sink at the sample collection location, wash your hands and forearms when you first enter the processing floor and head directly to the sampling location. Another option is to use a waterless hand sanitizer.)
6. After cleaning your hands and forearms, clean and sanitize your work surfaces. Use the same sanitizing solution the establishment uses, according to label directions. Allow the surface to air dry completely prior to placing any sampling utensils on it.
7. Ensure that your sample collection equipment is clean, sanitized, or sterile, as applicable to the sampling project. Clean totes frequently that are used to store and transport supplies.
8. Put on the gloves included in your sampling supplies. (See Gloving Technique below.) If the gloves tear or become contaminated at any time, discard them, and put on a new pair. Once you put on the gloves, touch nothing other than the sample equipment and sample.
9. Follow the sample collection protocol. Collect all samples in sterile containers that came with the sample supplies. Ensure that no items, surfaces, or clothing touch the sample or sampling site.
10. When you collect liquid samples in a jar with a lid, hold the lid in one hand while collecting the sample. If any product spills on the outside of the jar, cap the jar, and wipe it clean with a dry paper towel. Do not use any sanitizer solution to clean the jar.

Gloving Technique

1. Wash and sanitize your hands up to the mid-forearm. Dry your hands using disposable paper towels. If a sink is not available at the sample collection location, use a waterless sanitizer. Wash your hands prior to sanitizing the work surface as well.
2. The gloves will arrive in secondary packaging. After you sanitize your work surface, open the glove package on the sanitized surface.
3. Pinch the cuff end with two fingers to pull the gloves from the outer packaging, protecting the outer surface from contact with any un-sanitized surfaces.
4. Hold the glove open at the inside cuff area. Insert your hand into the glove, palm side up. Put on the first glove: grasp and pull the cuff with your ungloved hand. If your fingers become stuck, gently wiggle them while gently pulling the cuff. To protect from contamination, do not touch your gloved hand to any un-sanitized surface. If the glove tears or becomes contaminated, discard it, and put on a new pair. (If you need more gloves, send a request to the laboratory on the sampling form or in the instructions specific to the sampling project.)
5. Put on the second glove: use your gloved hand to slide your fingers under the cuff. Grasping the cuff with your gloved hand, insert the fingers of your non-gloved hand into the glove and pull the glove on.
6. Once you have donned both gloves, you may touch the outside of a glove with the other gloved hand to adjust the fit. To avoid contamination, be careful not to touch any un-sanitized surfaces with your gloved hands.
7. If at any time you think a glove may have become contaminated, discard it, and repeat the donning procedure with a new pair.

Poultry Carcasses:

1. Young chicken carcasses including broilers, fryers, roasters, and Cornish game hens, as described in 9 CFR 381.170(a) (HC_CH_CARCO1), and
2. Young turkey carcasses (HC_TU_CAR)

Collecting the Sample

How To Collect the Sample:

1. IPP are to randomly select a carcass from the post-chill area **after** all interventions have taken place.
2. IPP are to allow excess fluid to drain (for at least 1 minute) without contaminating any sterile sample items.
3. Place the carcass in the bag (neck first) and place the bag with the carcass on the flat **sanitized** surface.

4. Gently invert the sampling broth container three (3) times immediately prior to pouring the broth into the cavity of the carcass inside to the bag.
5. Once the broth has been added to the carcass, remove the excess air from the bag, close it and mix the broth through the carcass cavity and outside of the carcass for one minute.
6. Place the bag with the chicken on the sanitized flat surface with the top of the bag facing up.
7. Carefully open the plastic bag containing the bird without touching the inside of the bag or the inside corners.
8. Work the plastic bag down around the carcass and firmly grip one leg, without touching the inside of the plastic bag.
9. While holding the bag with one hand, carefully remove the bird from the bag with the other hand and place the bird back on the conveyor or table.
10. Remove the screwcap from the sterile sample container and aseptically pour 100 ml of rinsate into the sample container.
11. Close the sample container while trying not to touch the inside of the lid so that it does not contaminate the sampling broth. (Ensure that the lid is correctly threaded and tightened, but do not over-tighten.)
12. Place the sample container in the small resealable bag, expel excess air, and seal the bag.
13. Discard all remaining liquid from the carcass rinse bag into a drain (do not share remaining rinsate with establishment personnel).
14. Refrigerate the sample promptly after collection. IPP are to hold the rinsate in a refrigerator set at 40° F or lower and under FSIS control until the samples are shipped. IPP are not to freeze samples.

Raw Chicken Parts (HC_CPT_LBW 01):

Products eligible for sample collection under the chicken parts sampling project include raw chicken legs, breasts, and wings that would typically be available for consumer purchase. These products can be skin- on or skinless and can be bone-in or boneless. Eligible parts can be mechanically tenderized, vacuum tumbled, or injected or otherwise marinated or coated in solutions or dry spice mixtures, but cannot be breaded, stuffed, or wrapped in dough.

Cut-up chicken parts are eligible for sampling provided they are equal to or larger than 3/4 inch in size in at least one dimension and are of a type that would typically be available for consumer purchase.

1. For **legs**, whole legs (no backbone attached), drumsticks, thighs, thighs with backbone attached, and cut up or portioned leg meat (3/4 inch or larger in at least one dimension) are eligible for sampling;

2. For **breasts**, whole and half breasts (with or without ribs), boneless and skinless chicken breasts, tenderloins, and tenders, and cut up or portioned breast meat (3/4 inch or larger in at least one dimension) are eligible for sampling; and
3. For **wings**, whole wings (with or without the wing tip), mixed wing sections, drummettes, midsections (flats), wing tips, and boneless wings are eligible for sampling.

How to Collect the Sample:

IPP are to collect a rinsate from 4 lbs. \pm 10% (3 pounds, 10 ounces to 4 pounds, 6 ounces) of the specified raw chicken parts. Finished chicken parts are to be sampled prior to freezing.

1. Randomly select which available eligible chicken parts (legs, breasts, and wings) to sample.
2. Collect and place into the sampling bag approximately **4 lbs. \pm 10%** (3 pounds, 10 ounces to 4 pounds, 6 ounces) of randomly selected product. (Avoid transferring excess processing liquid when placing the chicken parts in the sampling bag).
3. Place the bag with the parts on the flat sanitized surface.
4. Gently invert the sampling broth container three (3) times immediately prior to adding the sampling broth to the chicken parts.
5. Open the container and pour the sampling broth onto the parts inside the bag.
6. Once the broth has been added to the bag, remove the excess air from the bag, close it and mix the broth throughout the parts for one minute.
7. Place the bag with the chicken parts on the **sanitized** flat surface with the top of the bag facing up;
8. Carefully open the plastic bag containing the parts without touching the inside of the bag or the inside corners.
9. Pour approximately 120 ml of the sampling broth into the specimen jar. **Do not allow the bag to touch the sterile specimen jar.**
10. Close the sample container while trying not to touch the inside of the lid so that it does not contaminate the sampling broth. (Ensure that the lid is correctly threaded and tightened, but do not over-tighten.)
11. Discard any remaining rinse fluid into a drain and return the parts to where you initially collected them unless the establishment requests otherwise.
12. Refrigerate the sample promptly after collection. IPP are to hold the rinsate in a refrigerator set at 40°F or lower and under FSIS control until the samples are shipped. IPP are not to freeze samples.

NRTE Ground And Other Comminuted Poultry Sampling Program (HC_CH_COM 01):

NRTE comminuted poultry is any non-breaded, non-battered, raw NRTE chicken or turkey product that has been processed to reduce the particle size, which may or may not contain added ingredients. NRTE comminuted poultry includes:

- Ground (ground product group category) – Ground chicken or turkey for any purpose (e.g., packed for consumer or for any type of further processing); or
- Mechanically Separated (Mechanically Separated product group) – mechanically separated chicken or turkey, as defined in 9 CFR 381.173; or
- Hand or mechanically deboned and further chopped, flaked, minced, or otherwise processed to reduce particle size. Chicken or turkey product, other than ground or mechanically separated falls under the “Other Comminuted” product group (sausage, patties, meatloaf, and other non-breaded and non-battered comminuted products).

NRTE comminuted chicken product may be derived from any age chicken, including young chickens (broilers, fryers, and roasters), fowl, capons, and roosters, as defined in 9 CFR 381.170(a)(1).

NRTE comminuted turkey product may be derived from any age turkey, including young turkeys, yearling turkeys, and old turkeys, as defined in 9 CFR 381.170(a)(2).

The following products are **not** eligible for sampling under this project:

1. Injected, needle- or blade-tenderized, or vacuum tumbled raw poultry parts or carcasses, because they are not considered to be NRTE comminuted poultry;
2. Mixed-species NRTE comminuted poultry products (for example, raw sausage containing both raw ground turkey and raw ground pork or containing both raw ground chicken and raw ground turkey);
3. Diced, chunked, or sectioned poultry that is not in small pieces or that is otherwise not comminuted. In general, this would refer to pieces 3/4 inch or greater in any dimension;
4. Hand- or mechanically deboned products that are not further chopped, flaked, minced, or otherwise processed to reduce particle size;
5. Whole muscle parts because they are not comminuted;
6. Poultry trimmings because they are not comminuted;
7. Comminuted poultry that is portioned (product from a larger package broken down into smaller packages but not cut-up or otherwise processed) only or repackaged only;
8. Any NRTE finished product containing comminuted poultry that has been cooked or heat-treated (for example, in the HACCP processing category “Heat-treated but not Fully Cooked – Not Shelf Stable”); and
9. Dumplings, wontons, potstickers, eggrolls, pelmeni, or other comminuted chicken or turkey products wrapped in dough or other similar covering (nor their source material when these are the final products in the establishment).

When an establishment **processes all its products into ready-to-eat (RTE) product or diverts all of its raw products (including NRTE comminuted poultry) to another federally inspected establishment for further processing into an RTE product**, FSIS will exclude the establishment from the *Salmonella* verification-testing program schedule.

If an establishment states that the intended use of its ground or comminuted product produced is RTE product, then IPP are to verify the intended use while performing the appropriate HACCP task. IPP are to verify, either by observing or by reviewing records, that the entire product is actually processed into RTE product. IPP should verify:

1. HACCP records matched with Bills of Lading
2. Letters of Guarantee
3. Contractual agreements between the producing establishment and receiving establishment

It is not sufficient for the IPP to accept only labels that state "for further processing."

It is not sufficient if the establishment only maintains a letter from the receiving establishment that says it only produces RTE product, without the receiving establishment gathering additional information to verify that all product is processed into RTE product in an official establishment.

* Note: If an establishment does not have procedures incorporated into its food safety movement of all products to another federally inspected establishment, at which the product is further processed into RTE products, the establishment is subject to sampling under the *Salmonella* and *Campylobacter* Verification Testing program.

How to Collect the Sample:

1. IPP are to randomly collect eligible raw comminuted poultry samples by product group.
2. IPP are to collect finished product in its final package whenever possible.
 - a. IPP are to collect the appropriate number of packages so that the sample equals **two pounds** or may collect a slack-filled package for larger products. IPP are to place the product collected in its final packaging in the larger, nonsterile bag provided with the sampling supplies.
3. For finished product not available in final packaging or when the package is too large, IPP are to collect the sample aseptically, as close to packaging as possible, after all antimicrobial interventions have been applied.
 - a. Collect sufficient product to fill the two provided Whirl-Pak® bags up to the fill-line indicated on each bag. When the bag is closed, product should meet the line indicated on the Whirl-Pak® bag.
 - b. Ensure that each Whirl-Pak® bag is properly closed. To do this, IPP are to carefully squeeze out the air remaining in the bag and tightly fold over the top at least four times as trapped air and loose closures may lead to leakage. When folding over the tops of each bag, IPP are to ensure that they do not touch the bag near its opening. Next, IPP are to fold over the side tabs to secure the folds in place and to not tie the ends. This process is to be repeated for the second bag.

- c. IPP are to place both Whirl-Pak® bags in the same secondary containment bag (zipper-lock type bag), expel excess air from the bag, and close the containment bag using the zipper lock closure.

NRTE Breaded Stuffed Chicken Products

Testing will begin May 2025. More information is upcoming.

Raw Comminuted Pork Products (HC_PK_COM01)

Raw Intact and Non-Intact Pork Cuts (HC_PK_CUT01)

The purpose of the *Salmonella* Verification Program for Raw Pork Products is to collect data that will aid in the develop of future policies designed to reduce the levels of *Salmonella* in raw pork products. Refer to FSIS Directive 10,510.1 for sampling instructions

| Table 1: Raw Pork Products Sampling Eligibility | | | |
|-------------------------------------------------|--------------|-------------------------|----------------|
| Raw Pork Products | Project Code | Establishment Volume | Task Frequency |
| Comminuted | HC_PK_COM01 | > 6,000 lbs./day | Up to 2/Month |
| Comminuted | HC_PK_COM01 | 1,001 – 6,000 lbs./day | Random |
| Intact and Non-Intact Cuts | HC_PK_CUT01 | > 50,000 lbs./day | 1/Month |
| Intact and Non-Intact Cuts | HC_PK_CUT01 | 1,001 - 50,000 lbs./day | Random |

Eligible establishments will receive sampling tasks based on the establishment's average daily volume (lbs. per day) and the number of days of production that are entered in the PHIS establishment profile across all the eligible product groups listed above.

FSIS DIRECTIVE 10,250.2 Performance Standards

The *Salmonella* and *Campylobacter* performance standards apply to the establishment's overall process control, not to individual products. Products are not tested to determine their disposition, but rather to measure the effectiveness of the slaughter and grinding process in limiting contamination. Establishments do not have to hold product or recall product based on results of the *Salmonella* and *Campylobacter* samples.

Salmonella and *Campylobacter* performance standard verification samples are taken as part of a 52-week moving window and the results are used to determine if an establishment is meeting the performance standard on a continuous basis. In conclusion, establishments fail to meet the standards when verification samples are found to exceed the maximum allowed percent positive during a 52-week analysis period (moving window).

The purpose of the *Salmonella* and *Campylobacter* verification-sampling program is to verify the establishment's process control for **all applicable products**. All eligible products produced at an establishment will be scheduled for sampling during the month under routine sampling.

| Product | Performance Standard | Maximum Acceptable Percent Positive | Minimum Number of Samples to Assess Process Control ** |
|--------------------|----------------------|-------------------------------------|--------------------------------------------------------|
| Broiler Carcasses | 5 of 51 | 9.8 % | 11 |
| Turkey Carcasses | 4 of 56 | 7.1 % | 14 |
| Comminuted Chicken | 13 of 52 | 25 % | 10 |
| Comminuted Turkey | 7 of 52 | 13.5 % | 10 |
| Chicken Parts | 8 of 52 | 15.4% | 10 |

Performance Categorization

Category 1 – Consistent Process Control: Establishments that have achieved 50 percent or less of the maximum allowable percent positive during the most recently completed 52-week moving window.

Category 2 – Variable Process Control: Establishments that meet the maximum allowable percent positive but have results greater than 50 percent of the maximum allowable percent positive during the most recently completed 52-week moving window.

Category 3 – Highly Variable Process Control: Establishments that have exceeded the maximum allowable percent positive during the most recently completed 52-week moving window.

IPP Responsibilities

For Category 2 – IPP and supervisors will receive an alert entitled, “Warning: Product Exceed One Half of Performance Standard”, through the PHIS dashboard. During the next weekly meeting, IPP will discuss with plant management that the results indicate variable control of *Salmonella*, as well as advise the establishment to make changes to avoid failing the performance standard, document the discussion in an MOI.

For Category 3 – IPP and supervisors will receive an alert entitled, “Failure to Meet a *Salmonella* Performance Standard”, through the PHIS dashboard. During the next weekly meeting, IPP will discuss with plant management the failure to meet the *Salmonella* performance standard and that FSIS will be collecting follow-up samples, document in an MOI. In addition, IPP are to determine if:

- Corrective actions have been identified and implemented as written, as per 9 CFR 417.3.
- Establishment has reassessed its HACCP system and modified its HACCP plan including supporting documentation (417.3(b) and 381.65(g)).

The follow-up samples will be assigned for raw poultry carcasses, chicken parts, and NRTE comminuted poultry products under the project codes below:

F_CH_CARC01 (for young chicken carcasses)

F_TU_CARC01 (for young turkey carcasses)

F_CPT_LBW01 (for raw chicken parts)

F_CH_COM01 (for NRTE comminuted chicken product)

F_TU_COM01 (for NRTE comminuted turkey product)

FSIS Directive 10,250.1 describes the sampling steps appropriate to the product class sampled. For NRTE comminuted poultry products and raw chicken parts, IPP are to follow instructions as stated in the “IPP Help” menu under FSIS Applications. Following is a brief narrative for the procedures described in FSIS Directive 10,250.1 that the IPP will be carrying out when collecting the samples.

IPP can review the status and results of the sampling through LIMS (Laboratory Information Management System) Direct. You can access the link for LIMS under the FSIS Applications short cut on your FSIS government computer.

Documenting the MOI

IPP are to ensure that the MOI documenting the weekly discussion with the establishment management follows the content and formatting guidance in Chapter IV of FSIS Directive 8010.2 Investigative Methodology.

1. It is written in the first-person point-of-view of the FSIS employee preparing the MOI.
2. Documents the date and location of the meeting.
3. Documents the name and official position of the FSIS employee conducting the meeting and of any other FSIS employee present.
4. Documents the name and official position of all establishment employees attending the meeting.
5. Summarize all information discussed during the meeting.
6. Includes a closing statement certifying that the MOI includes all the information discussed during the meeting.
7. Is promptly signed and dated by the preparer upon completion.

21 RAW BEEF SAMPLING

Objectives:

1. Identify the pathogen of concern for raw beef products.
2. Select from a list those raw beef products eligible for sampling.
3. State where to find FSIS raw beef product sampling instructions.
4. Explain the steps of raw beef product sampling.
5. Describe how to determine which raw beef product to sample.
6. State how sample results are received.
7. State when to mail samples to the FSIS laboratory.
8. List the actions associated with positive pathogen results.
9. List the requirements for transportation of raw beef product which has tested positive or presumptive positive for a pathogen.
10. Explain the IPP responsibilities for review of establishment sampling data.

In raw beef, the pathogen of concern is Shiga toxin-producing *Escherichia coli* (STEC). The most well-known STEC is ***Escherichia coli* (*E. coli*) O157:H7** is a foodborne pathogen, but it is not the only one; other STEC serogroups are pathogenic as well. STEC is a food safety hazard that **establishments need to consider** in their hazard analysis if they are slaughtering, receiving, grinding, or otherwise processing raw beef products. Establishments may list *E. coli* O157:H7, all 7 STEC adulterants, or STEC in their hazard analysis. FSIS considers all **raw non-intact beef and raw intact beef intended for use in raw non-intact product** that is contaminated with the following STEC serogroups to be adulterated under the Federal Meat Inspection Act (21 U.S.C. 601(m)(1)): *E. coli* (O157, O26, O45, O103, O111, O121, and O145).

FSIS verification sampling programs are designed to verify that an establishment's controls or food safety procedures adequately address STEC.

Definitions

Alternative - Alternative sampling and alternative lotting.

Recall - An establishment's voluntary removal of distributed meat or poultry products from commerce.

Sample - Represent a larger amount of product. Samples of raw products may be destructive, collecting actual product to send to the lab, or non-destructive, swabbing the products with a cloth to send to the lab.

Sampled lot - Amount of product represented by the sample.

The establishment determines their lotting procedures. Establishments must support how they identify adulterated product when they experience a positive sample result.

Samples are selected randomly from the type of product requested. Select day, shift, and time within the collection dates indicated in PHIS establishment Task List. Sample during all shifts that the establishment operates. Samples are collected **after all antimicrobial interventions** are applied to the production lot to be sampled, except for any microbiological testing intervention. Take samples prior to freezing, except when the freezing step is a CCP in the HACCP plan. Collect in their final packaged form, using aseptic technique. If the product is not in its final package, you must put the grab samples in the sterile roll top bags.

The **PHIS task name** will identify the **sampling project code**. **Determine eligible products, focusing on the establishment's process(es), and allow adequate time for the establishment to hold the sampled lot, but not enough time for them to alter their normal processes**—less than 1 days' notice (if it does not cause undue hardship to the plant), 1 days' notice is sufficient, but possibly 2 days' notice if necessary. If more than 2 days' notice is requested, contact your supervisor. IPP collect supplier information for each sample taken, at the time the sample is taken. The goal of **traceback** is two-fold: (1) to ensure all affected product is quickly accounted for and (2) to trace it back to the originating slaughter plant. The District Office (DO) will use the supplier information to identify the originating slaughter facility, if the sample result is confirmed positive. Information that needs to be collected for source materials from other establishments includes name of the beef components or information that clearly identifies the source material. **Document the source** material and foreign supplier information in a memorandum of interview (**MOI**) in PHIS and maintain the MOI in the official file. Provide a copy to establishment management. You also make a note of any information that the establishment is unable to provide in the MOI.

An accurate Establishment Profile is critical – FSIS uses the information in the PHIS establishment profile to generate specific sampling tasks.

The key policy related to raw beef sampling can be found in **FSIS Directive 10,010.1, Sampling Verification Activities for Shiga Toxin-Producing Escherichia coli in Raw Beef Products**. This directive has been revised with instructions for collecting and submitting samples of raw beef products. Below is an abbreviated version of sampling directions.

Sampling Project Codes

The routine sampling project codes for STEC testing of domestic raw beef at federal establishments are:

- **MT60_C** –Raw Beef Manufacturing Trimmings from cattle slaughtered onsite
- **MT64** –Components other than Trim
- **MT65_C** –Bench Trim, derived from cattle not slaughtered onsite
- **MT43** – Routine Testing of Raw Ground Beef in Federal establishments

The raw beef products collected under routine verification testing will be analyzed for ***E. coli* O157:H7, non-O157 STEC, and Salmonella**.

Selecting and collecting MT60_C / MT65_C samples

Raw beef manufacturing trimmings and bench trim samples are to be collected using the Cloth Sample Collection Method (fresh product) or the N60 excision method (frozen product) only when the establishment uses freezing as an intervention in their HACCP system.

A. Cloth Sample Collection Method

1. The Cloth sampling technique is used for routine verification sampling of eligible domestic raw beef products. With the cloth sampling method, **1 cloth is a sample unit**. Do not use the cloth to sample frozen beef products. If the establishment uses freezing as an intervention in their HACCP system, request sample supplies for N60 excision sampling of the frozen trim.
2. If the establishment packages product in combo bins, then IPP are to select one random combo bin from the specific production (e.g., day's production) available for sampling. Use 1 cloth to sample the entire surface of the combo bin. If the establishment packages product in boxes, totes, tubs, or containers other than combo bins, IPP are to use 1 cloth to sample up to 5 containers from the same lot of products. A total of 1 cloth is collected and shipped to the lab.
3. IPP are to wash and dry hands to the mid-forearm. Put on plastic long-sleeved gloves, followed by non-sterile short gloves over the top. Using an alcohol-based spray sanitizer (available from the FSIS Material Management Supply Center), IPP are to sanitize gloved hands and plastic sleeves simultaneously.
4. IPP are to grasp the cloth with both hands and apply downward pressure to **vigorously massage the surface area** of the product including the **spaces and crevices between meat pieces**, to ensure as much of the product surface area is sampled, while moving around the combo in a uniform manner.
5. After sampling, the cloth will be **damp** and have picked up moisture and **bits of meat** scraps when the collection is completed.
6. Fold the cloth and return it to the plastic sample bag. Add the entire contents of the liquid buffer to the bag. Carefully expel excess air from the sample bag, tightly fold over the top at least four times, and then fold over the side tabs to secure the folds in place.

B. N60 Excision Method

1. Sanitize the knife, steel, and hook. Wash and dry hands, open the sterile Whirl-Pak® bags and then put on the sterile gloves (don't forget to wear a mesh glove under the sterile glove).
2. If a specific production lot is composed of greater than 5 containers, randomly select 5 containers for sampling. If the specific production is composed of fewer than 5 containers, use the table below.

| Number of Sample Pieces to Collect Per Container | |
|---------------------------------------------------------|---------------------------------------------------------|
| <i># of containers in each specific production</i> | <i># of sample pieces to select from each container</i> |
| 5 | 12 pieces |
| 4 | 15 pieces |
| 3 | 20 pieces |
| 2 | 30 pieces |
| 1 | 60 pieces |

3. Aseptically collect the appropriate number of pieces of beef **trim from one production lot**. Cut off a slice of the surface that is approximately 3 inches long by 1 inch wide and 1/8 inch thick from each of the **60 pieces of meat**. The priority is to collect samples from pieces of product taken from the original **external surface** of the beef carcass (this is the outside surface of the carcass when it is first dehided). It is important to collect thin slices because the surface of the beef carcass can be contaminated through improper sanitary dressing procedures. Also, make sure that each sample slice contains some meat and only collect one slice from each piece of trim.
4. Place each slice in one of the sterile Whirl-Pak® bags. Continue this process until you have collected 30 pieces in one Whirl-Pak® bag. Next, repeat the same steps with the second Whirl-Pak® bag.
5. In the third sterile Whirl-Pak® bag, aseptically collect samples of trimmings from the same production lot by using a grab sample technique. Again, collect pieces with as much external surface as possible. Leave at least 2 inches of space at the top of the bag to prevent leakage. The total weight of the 3 bags of samples should be **approximately 2 pounds**.
6. Once sample collection is complete, carefully expel excess air from the sample bag, tightly fold over the top at least four times and then fold over the side tabs to secure the folds in place.

NOTE: Do not use the N60 method when collecting MT60_C beef manufacturing trim or MT65_C bench trim **unless the establishment implements freezing as an intervention** to reduce STEC. If freezing is used as an intervention, then the sample is to be collected by the N60 excision method.

Collecting Raw Ground Beef Products in final packaging (MT43)

1. You are to collect a 2 lb. sample of ground beef product from the current day's production in final packaged form whenever possible. You are to put the product in its final packaging in the larger, non-sterile bag provided.
2. Collect the number of packaged products so that the sample equals 2 lbs. This may be more than one package if the product is packaged in containers that weigh less than 2 lbs.

Collecting a Raw Ground Beef Aseptic Grab Sample (MT43 and MT64)

NOTE: Use this method to collect raw ground beef product samples if it is not available in its final packaging or the package is too large.

1. Wash and dry your hands.
2. Open the sterile roll top bags and put on sterile gloves.
3. Aseptically (avoiding contamination) collect grab samples of raw ground beef.
4. Collect a sufficient quantity of raw ground beef to fill each of the three Whirl-Pak® bags to the fill-line. Do not under-fill or overfill the bag. This should give you the 2 lbs.
5. Once sample collection is complete, carefully expel excess air from each Whirl-Pak® sample bag, tightly fold over the top at least four times and then fold over the side tabs to secure the folds in place.

Packing and Mailing the Sample

On the day of sample collection, you will enter sample collection data and additional product info in PHIS, click “submit to lab” to submit the Sample Analysis Request Form electronically to the laboratory, and then you will print and sign the form and include it with the sample in the sample shipment container. If the lab receives a sample with missing or incomplete paperwork, or if the sample is the wrong type of raw beef product, the lab **will** discard the sample. Also, if the lab receives an insufficient amount of product to perform the specified analyses, the sample is discarded. Be sure the identification on the sample and the paperwork match, otherwise the lab will discard sample. Raw beef product samples are mailed to the laboratory on the first available day the contract carrier picks up after collecting the sample. **Samples should be shipped when collected, do not wait for the establishment to complete their pre-shipment review for the product sampled.**

Results

Access Laboratory Information Management System (LIMS)-Direct to track your sample receipt and results. **LIMS-Direct** is a computer application that provides sample data electronically to FSIS program personnel.

Every FSIS verification sample that the laboratory confirms **positive for STEC** goes through three stages of analysis: **Potential Positive, Presumptive Positive, and Confirmed STEC Positive**. Any presumptive or confirmed positive product must be maintained under establishment control. Consider the possibility that the establishment may have moved the product off-site but did not transfer ownership of the product, and therefore the establishment did not yet complete the pre-shipment review. When an FSIS verification sample is confirmed STEC positive, **IPP are to issue and NR, unless the establishment also tested the same lot of products and found it positive** for STEC. If the establishment has a written program to divert all product that FSIS samples to cooking, the establishment must take corrective action per 9 CFR 417.3. If the establishment does not take corrective action, then issue an NR. Use a directed HACCP Verification task for the appropriate HACCP category, raw ground, or raw not-ground. Cite 9 CFR 417.4(a) (Verification regulation – because sampling is considered a verification of the overall effectiveness of the system) and 301.2. When writing NRs, associate where appropriate.

IPP are to review the establishment's **Sanitation SOPs** for the days of production associated with the positive STEC sample to see if there was a problem with the implementation of their

sanitation programs. IPP are to use the “risk based” approach. Verify sanitary dressing procedures, if the positive result is from beef manufacturing trimmings or other components produced at a slaughter establishment.

Raw beef products confirmed positive for STEC **may be moved off-site** for proper disposition, under appropriate controls. Product may be **transferred to another official establishment for further processing to destroy the pathogen.**

Establishments may opt to dispose of the product through rendering or disposal in a landfill. As part of the follow up HACCP Verification task, verify that the establishment maintained records identifying the official establishment, renderer, or landfill operation that received positive product. When the product is destined for a **landfill or rendering operation**, it moves **under company controls**. When the product is shipped **to another official establishment**, establishments may use their own company seals or move the product under USDA seals or FSIS Form 7350-1. Documentation from the official establishment, landfill operation, or renderer **must show** that the positive product was further processed to destroy E coli. O157:H7 or the specific product was destroyed. The establishment cannot complete the pre-shipment review until it receives documentation from the official establishment showing proper disposal.

If you are the IPP at the establishment that **receives** components **positive** for STEC, you have verification to perform. **Verify the HACCP plan includes adequate lethality** treatment to destroy the pathogen, and that the establishment has supporting documentation validating the effectiveness of the lethality treatment. When raw beef products are confirmed positive, FSIS will conduct verification activities at **supplier establishments**, particularly the **originating supplying slaughter establishment** that produced the source materials, trimmings, components, or primal cuts that were used to produce the positive product. The DO will contact the IIC at each of the supplying establishments, including the originating supplying slaughter establishments. **The IIC at the supplying establishment will ensure that a HACCP Verification task is performed to verify that the supplier met all the HACCP regulatory requirements.**

Each time that an FSIS, or other Federal or State sample of raw beef product tests positive for STEC, IPP will receive a directed sample task for **16 follow-up samples to sample product from the establishment that produced the positive raw beef product**. IPP will also receive a directed sample task for 16 follow-up samples when FSIS follow-up samples of beef trimmings or other raw beef patty components or ground beef test positive for STEC **or** when an originating slaughter establishment is the **sole supplier**, or a **repeat** supplier of the source materials implicated in positive sample result. For low volume establishments, 8 follow-up samples need to be collected. **DO NOT** wait for the establishment to complete the corrective actions. Collect follow-up samples from the same type of product that tested positive. If the establishment is not producing the product that tested positive, collect follow-up samples from Beef Manufacturing Trimmings or other components. Collect a maximum of 2 follow-up samples per shift per day from different lots (up to 4 samples per day for a 2-shift establishment). At a minimum collect 3 samples per week. **Do not** collect a follow-up sample and a routine verification sample from the same product lot.

FSIS continues to collect samples after a positive follow-up sample result until the FSIS laboratory finds no positive sample results. PHIS automatically assigns the requested follow-up sampling tasks. If an originating slaughter establishment was the **only supplier = 16 follow-up samples**, if multiple originating slaughter establishments supplied source materials for the positive product or they are a **repeat supplier = 16 follow-up samples**, when a supplier is not

the sole supplier or a repeat supplier, a **single follow-up** sample is collected from the supplier for **each** source material used in the positive raw beef product.

There is no regulatory requirement for establishments to have their own STEC sampling and testing program. Many establishments do sample raw beef products for a variety of reasons. You are to review the results of the establishment's testing programs related to its food safety systems on a weekly basis and document it on **Review of Establishment Data task**. The establishment **does not have to tell you when it gets a positive result, but it must always implement corrective actions, and IPP should verify them**. If the establishment uses cooking to eliminate STEC as a food safety concern, the establishment's HACCP plan must address the presence of STEC. CCP and critical limits must be designed to eliminate STEC.

22 SAMPLING REQUIREMENTS TO DEMONSTRATE PROCESS CONTROL IN SLAUGHTER OPERATIONS

Objectives:

1. Understand the purpose of generic *E. coli* testing in slaughter operations.
2. Learn the regulatory requirements for the testing of generic *E. coli*.
3. Identify who is responsible for selecting and analyzing livestock (other than swine) samples for generic *E. coli*.
4. Identify who is responsible for selecting and analyzing swine and poultry samples for microbiological analysis.
5. Explain the purpose of performance criteria and statistical process control.
6. Describe how to verify the regulatory requirements for generic *E. coli* testing when conducting the Generic *E. coli* verification task.
7. Describe how to verify the regulatory requirements for microbiological sampling and analysis of swine and poultry slaughter when conducting the appropriate PHIS inspection verification task.
8. Explain the appropriate enforcement actions to take when noncompliance is found while performing the generic *E. coli* verification task or the appropriate swine and poultry slaughter inspection verification task.

The purpose of generic *E. coli* testing is to verify the effectiveness of sanitation and process control in slaughter facilities.

1. Establishments that slaughter livestock (other than swine) or ratites are required to test.
2. Each establishment must develop written sampling procedures that identify the following:
 - location of sampling.
 - employee(s) designated to collect the sample.
 - how randomness is achieved.
 - measures to ensure sample integrity
3. Official Import establishments are not required to perform generic *E. coli* sampling and IPP are not to verify whether establishments meet generic *E. coli* requirements.

Fecal material is one of the principal vehicles of carrying pathogens. The best indicator of fecal contamination is *Escherichia coli*, Biotype I, also called generic *E. coli*.

- Generic *E. coli* is commonly found in the intestinal tract of food animals.
- Generic *E. coli* is not considered a pathogen.
- Generic *E. coli* is considered the best indicator organism for fecal contamination

FSIS has developed performance criteria for some species (not all of them), and specifies approved sampling techniques, such as for beef using excision sampling.

There are two sampling methods that are used: excision and sponging.

- **Excision** – This is the method described in the regulation; rarely used because it is a destructive method, only need to excise the surface, so it's not necessary to do a deep cut.
- **Sponging** – **The most commonly used** since it is a non-destructive method.

Performance criteria – These are numbers published in the regulations that represent the highest expected microbial loads on carcasses when the slaughter process is under control. The **performance criteria** give livestock slaughter establishments **guidance (not enforceable)** about the effectiveness of their slaughter sanitary dressing procedures in preventing fecal contamination. Test results that meet the criteria in the regulations provide evidence that the establishment is maintaining adequate process control for fecal contamination and sanitary dressing.

Establishment Procedures - The establishment is to collect samples from the type of livestock that it slaughters in the **greatest number**. Livestock samples are collected after they have been in the cooler for 12 hours or more. However, carcasses can be selected while on the rail or after the final wash and set aside in a convenient spot in the cooler for testing after 12 hours. For hot boning: Samples are taken after the final wash prior to boning. Samples are taken before the carcasses enter the processing department.

- There are 3 required sample sites or anatomical locations on the carcass, which are the **flank, brisket, and rump**.
- The frequency is based on the number of carcasses. Regulations require that carcasses for sampling be selected at **random**.
- Generic E. coli tests are reported as a quantity or bacterial concentration. The units of measure must match the testing technique used to ensure that results are reported correctly.
- Establishments are **required to keep a table or a chart of the results for at least the most recent 13 test results**.

If the Agency does not have performance criteria published for the species being tested or for the sampling technique being used, establishments must use statistical process control (SPC) to develop criteria to compare their samples results. The performance criteria in the regulations are referenced as “m” and “M” values. Thus, cattle establishments collecting excision samples must use the m/M values prescribed in the regulations. However, **most establishments use sponging, so** this means most establishments **must use SPC**. There are practically no establishments which can use m/M because it is only applied to excision sampling.

Establishments must use statistical process control (SPC), to develop their own criteria, to evaluate their test results when they slaughter species or use sampling techniques for which the Agency has not developed performance criteria. IPP are not to focus on the particular method the establishment uses to set process control criteria. Instead, they are to review the generic E. coli testing results and verify that the establishment has set generic E. coli criteria to define process control and responds to results outside those criteria.

Under the regulations, establishments are not required to take corrective actions or to document the necessary actions for E. coli test failures. However, when livestock slaughter establishments **do not evaluate their test results (9 CFR 310.25(a)(5)), they might not be maintaining slaughter process controls sufficient to prevent fecal contamination.**

Note: The livestock (other than swine) slaughter establishment's **generic E. coli testing results cannot, by themselves, support a finding of noncompliance** with 9 CFR 310.25(a) However, if the establishment's testing results indicate a failure of process control, IPP are to verify the establishment's sanitary dressing procedures.

IPP perform the livestock Generic E. coli task, select the regulatory requirement to **verify** and determine whether the establishment is in compliance or noncompliance with the regulations.

- **IPP are to verify that the establishment maintains daily records** documenting the implementation and monitoring of its procedures, makes these records of the tables and charts with generic E. coli test results available for review, and **retains these records for one year.**
- If IPP find noncompliance, they are to notify the establishment and document the noncompliance in an NR citing the appropriate regulation.
- Establishment test results that show lack of process control should be considered in conjunction with other information, like sanitary dressing procedures, zero tolerance, SSOP, and any other HACCP performance criteria.
- **Further enforcement action might be necessary if the establishment has repetitive NRs, or if the establishment's corrective actions are ineffective.** IPP are to discuss with their immediate supervisor the need to take an enforcement action outlined in FSIS Directive 5000.1.

Microbiological Sampling for Poultry (other than Ratite) and Swine Slaughter Operations
Establishments that slaughter poultry, other than ratites, and swine are required to perform microbiological sampling and analysis, for example, testing for *Salmonella*, *Campylobacter*, or indicator organisms such as aerobic plate count (APC), total coliform, *Enterobacteriaceae*, and *Escherichia coli*, Biotype I, also known as generic *E. coli*.

Because establishments have differences in their operations, each establishment has the **flexibility** to develop a sampling plan and determine the microbial organism that will accurately monitor the effectiveness of its process control procedures. **Establishments MUST incorporate their written process control procedures into their HACCP system, either in the HACCP plan itself, as sanitation SOPs, or as a prerequisite program.**

Microbiological test results that represent the level of microbiological contamination at key steps in the slaughter process are necessary for the establishment to provide comprehensive objective evidence **to demonstrate process control.** Process control consists of the programs and procedures that an establishment implements to ensure its process prevents contamination of poultry and swine carcasses, including contamination with pathogens and fecal material.

Note: The required location where the sample is collected, and frequency of sampling depend on species and size of establishment.

IPP are to **verify** that the poultry or swine slaughter establishment:

- Developed a written sampling program that identifies the specific microorganisms being tested and location/frequency where samples are collected,
- Incorporated its written sampling program for preventing contamination by enteric pathogens into its HACCP system,
- Implements and maintains its written sampling program,
- Maintains scientific and technical documentation to support the decisions that the establishment made in designing the sampling program,
- Maintains daily records documenting the implementation and monitoring of its procedures including sample results,
- Take actions to restore or improve process control when sample results indicate problems with establishment slaughter HACCP system.

Noncompliance occurs when the establishment is not meeting the prescribed regulatory requirements; is not following its written sampling and testing procedures; does not demonstrate that it is maintaining process control; or its corrective actions are not effective.

If the establishment has repetitive NRs, or the establishment's corrective actions are ineffective, IPP are to discuss with their immediate supervisor the need to take an enforcement action outlined in FSIS Directive 5000.1., Chapter V.

Evaluating Trends

When evaluating sampling results, IPP should be aware that repeated positive results from either FSIS or establishment testing can:

- Indicate a trend, even if a noncompliance has not been documented
- Indicate that an establishment is not effectively preventing insanitary conditions or direct contamination or adulteration of product
- Indicate systemic problems with an establishment's food safety system

Trends indicating systemic problems, such as positive sampling results, may not involve any NRs. If positive sample results indicate systemic problems around an establishment, or if they are associated with a noncompliance or other findings, IPP should record the association in an inspection note in PHIS and contact their supervisor.

IPP should discuss their findings during the next weekly meeting and describe to establishment management the trends or systemic problems found. IPP are to document this meeting on an MOI.

23 HUMANE HANDLING VERIFICATION FOR LIVESTOCK AND GOOD COMMERCIAL PRACTICES FOR POULTRY

Objectives:

1. Name the two approved methods of slaughter in the Humane Methods of Slaughter Act (HMSA).
2. List the steps in performing the Livestock Humane Handling Verification task using the Public Health Information System (PHIS).
3. List the Humane Activities Tracking System (HATS) categories and give one example of each.
4. Given a specific scenario, be able to identify regulatory noncompliance, whether it is egregious, and what action to take, if any.
5. Describe the actions an inspector should take when he/she observes a non-egregious incident of inhumane treatment resulting from: facility deficiencies, disrepair or equipment breakdown, establishment employee actions in handling livestock, or improper stunning.
6. Define egregious noncompliance, give examples, and describe the action taken in response.
7. Name the documents completed for non-egregious and egregious noncompliances.
8. List the steps in performing the Poultry Good Commercial Practices (GCP) task.
9. Identify regulatory noncompliance with Good Commercial Practices or mistreatment of birds and actions to take in each case.

The Humane Methods of Livestock Slaughter Act (HMSA) of 1978 made the humane slaughter and handling of livestock mandatory in connection with slaughter of all food animals slaughtered in USDA inspected establishments.

The two approved methods of slaughter are:

- Livestock must be rendered insensible to pain on the first application of the **stunning** device before being shackled, hoisted, cast, or cut. This means that the animal must be unconscious and unable to feel pain before it is “stuck” (veins and arteries severed so it bleeds out) before it is shackled and hoisted into the air, or before it is dropped onto a table/floor.
- The requirements of any religious faith that prescribes a method of slaughter whereby the animal suffers loss of consciousness by anemia of the brain caused by the simultaneous and instantaneous severance of the carotid arteries with a sharp instrument. This method is known as ritual slaughter. In **ritual slaughter**, the animal's throat is cut from side to side with a sharp knife, deeply enough for the major arteries and veins to be severed. Examples of ritual slaughter include Jewish (kosher) slaughter and Islamic (halal) slaughter.

Livestock Humane Handling Verification Task

In livestock slaughter establishments, you will verify compliance with the humane handling regulations (9 CFR part 313) by performing the Livestock Humane Handling Verification task. This task must be performed once per shift, each shift animals are slaughtered or when animals are on-site, even when slaughter operations are not occurring.

Recording Time in HATS (Humane Activities Tracking System)

You are to accurately and completely record the time that you spend on the nine specific HATS categories.

- Record the total time spent verifying each HATS category, in **quarter hour** increments, rounding up to the next quarter hour.
- There should be an entry of **at least one quarter hour** in HATS Category IV – **“Antemortem Inspection”** for every slaughter shift **except in very small establishments** (see below).
- In addition, verify one or more of the other HATS categories during each slaughter shift. Ensure that, over time, all HATS categories are verified, and the appropriate time recorded.
- During normal operations, the total maximum time entered across all HATS categories will generally not exceed the total operational hours for that respective shift.

At many very small establishments, the total amount of inspection time spent on HATS procedures, including observations at antemortem inspection, may only total .25 hour (or less). Therefore, IPP should record .25 hour per day in a different HATS category each slaughter day.

Note: Antemortem inspection **must still be performed** when animals are presented for slaughter, even if you do not record HATS time.

9 HATS Categories

- I. **Inclement Weather:** Observe how the establishment adapts its facilities and handling procedures for heat, cold, ice, snow, and rain. Some things to look for include:
 - Animals slipping or falling because of wet floors.
 - Livestock overheated because of a lack of proper shade or because of a lack of water for cooling.
 - Disabled livestock not in a covered pen protected from the elements.
- II. **Truck Unloading:** Observe animal handling during movement from trucks to the holding pens. Some things to look for include:
 - Vehicles or ramps not being properly positioned, leading to the injury of animals.
 - Handling of animals on conveyances.
 - Animals forced to move faster than a normal walking speed.

Note: If animals appear exhausted and/or dehydrated refer to the **Twenty-Eight Hour Law**. The Animal and Plant Health Inspection Service (APHIS) Twenty-Eight Hour Law requires transporters to stop at least every 28 hours to provide animals with food, water, and rest, and

those who do not are in violation of this law. Consult with your supervisor if you have concerns about the condition of the animals being delivered.

- III. **Water and Feed Availability:** Observe whether animals in holding pens have access to water at all times and are provided appropriate feed if held more than 24 hours. Some things to look for include:
- Water not accessible to livestock in holding pens.
 - Feed not provided to livestock held for longer than 24 hours.
 - Feed provided not appropriate for species and age (e.g., hay fed to bob veal calves).
- IV. **Handling during Antemortem Inspection:** Observe establishment employees' handling and restraint of animals during antemortem inspection. Some things to look for include:
- Livestock being injured because of handling practices.
 - Livestock being moved faster than a normal walking speed.
- V. **Suspect and Disabled:** Observe how the establishment handles and houses animals who are injured or ill, or otherwise designated as U.S. Suspect after antemortem examination. Some things to look for include:
- Conscious animals being dragged.
 - Disabled animals not separated from normal ambulatory animals.
 - U.S. Suspect and disabled livestock are not provided or placed in a covered pen.
- VI. **Electric Prod/Alternative Object Use:** Observe the types of instruments used to facilitate animal movement, the extent to which they are used, and whether their use is causing undue stress or pain to animals. Some things to look for include:
- Livestock being excessively prodded resulting in overexcitement or injury.
 - Use of electric prods on sensitive areas (face, ears, udder, genitals, etc.).
 - Livestock being driven with sharp objects or other means which cause pain or injury.
- VII. **Slips and Falls:** Observe animal movement from holding pens to the stunning area. Some things to look for include:
- Livestock slip and fall due to inadequate footing or improper handling practices (typically observed during movement of animals after ante-mortem inspection).
 - Livestock slip and fall because of lack of slip-resistant flooring.
- VIII. **Stunning Effectiveness:** Observe that stunning methods used are appropriate and effective. Some things to look for include:
- Livestock not rendered unconscious with a single application of the stunning methodology.
 - Use of secondary entrances with potential for injury (or actual injury) of livestock. Note that secondary entrances are not prohibited but should be safe and should not allow animals to bypass antemortem inspection prior to slaughter.

There are some general principles that apply to all stunning methods:

1. Stunning equipment must be maintained in good repair. Equipment in poor repair can interfere with the rapid and effective application of the stunning blow. This can result in an incomplete or unsuccessful stun.
2. Effective stunning requires effective restraint. If an animal is not effectively restrained, it will be much more difficult to locate the stunning blow with a high degree of accuracy. The stunning area should be designed and constructed to limit the free movement of animals.
3. A well-trained and experienced establishment employee must operate stunning devices. The employee must be able to accurately and consistently position the stunning device so that the animal is rendered immediately unconscious.
4. Animals need to be delivered to the stunning area with a minimum of excitement or discomfort. It is more difficult to place the stunning device accurately, and the method of stunning may not work as effectively, on an excited or injured animal.

With any stunning method, it is important to observe the amount of time it takes for the animal to begin bleeding out (“sticking”) after being stunned. Although there is no regulatory requirement for this time interval, if the “stun-to-stick” interval is prolonged, it could result in animals regaining or beginning to regain sensibility on the bleed rail.

The regulations describe four acceptable methods for producing a state of surgical anesthesia (surgical anesthesia is defined as a state where the animal feels no painful sensations). The four acceptable methods are:

1. Chemical (carbon dioxide - CO₂)
2. Mechanical (captive bolt)
3. Mechanical (gunshot)
4. Electrical (electrical current)

There are numerous signs IPP may observe for to indicate an animal is properly stunned. Some signs of a properly stunned animal include, but are not limited to:

- The head and neck of the animal are floppy.
- The tongue is limp and hanging straight down out of the mouth.
- There is no vocalization-bellowing or squealing.
- The eyes are wide open with a blank stare.

IX. **Conscious Animals on the Rail:** Observe animals on the bleed rail after stunning and sticking for signs they might be regaining consciousness. Some things to look for include:

- Employees processing (e.g., shackling, hoisting, cutting) livestock not rendered unconscious by the method of stunning.
- Animals regaining consciousness after being stunned. If you observe an animal regain consciousness after stunning, ensure the animal is promptly stunned, and contact your supervisor immediately.

Ritual Slaughter (HMSA - Humane Methods of Slaughter Act)

The ritual slaughter cut and the handling and restraint that immediately precedes that cut is often called the “**ritual bubble**.” The activities that occur within that “ritual bubble” fall under Section 1906 of the HMSA and are protected as part of the Constitutional right to religious freedom. This does not mean that Agency personnel are to ignore completely what happens within the “ritual bubble”—what it means is that Agency personnel do not enforce humane handling regulations during those steps of the slaughter process.

It is important to understand that ritual slaughter establishments are required to meet all the humane handling regulatory requirements except stunning prior to shackling, hoisting, throwing, cutting, or casting. A few ritual slaughter establishments elect to apply one of the approved stunning methods either before or after the ritual cut. In such establishments, IPP will also verify the stunning effectiveness HATS category VIII. All animals must be unconscious or **insensible to pain prior to any dressing procedures** such as head skinning, leg removal, ear removal, horn removal, or opening hide patterns.

Odd-Hour Verification Visits

The IIC, in conjunction with the FLS and DVMS, determines how frequently IPP need to perform odd- hour inspection to observe the livestock facilities and handling practices when animals are delivered or held outside the establishment’s regular hours of operation. These visits are unannounced and outside of operating hours.

Robust Systematic Approach

There is no regulatory requirement for an establishment to use a systematic approach to humane handling and no requirement that such approach, if used, be in writing. However, an establishment may choose to develop and implement in a robust way a written animal handling program that effectively addresses the four aspects of a systematic approach that FSIS outlined in the 2004 Federal Register Notice. For a systematic approach to be considered “robust” it would have to be written. These four steps are:

- Conduct an initial **assessment** of where, and under what circumstances, livestock may experience excitement, discomfort, or accidental injury while being handled in connection with slaughter, and of where, and under what circumstances, stunning problems may occur;
- **Design** facilities and implement practices that will minimize excitement, discomfort, and accidental injury to livestock;
- **Evaluate** periodically the handling methods the establishment employs to ensure that those methods minimize excitement, discomfort, or accidental injury and evaluate those stunning methods periodically to ensure that all livestock are rendered insensible to pain by a single blow; and
- **Respond** to the evaluations, as appropriate, by addressing problems immediately and by improving those practices and modifying facilities when necessary to minimize excitement, discomfort, and accidental injury to livestock.

If the establishment has a robust systematic approach, FSIS will take that into consideration should it be necessary to determine how to proceed when an incident occurs that involves egregious inhumane treatment.

Enforcement

The thought process that you should follow when performing the Livestock Humane Handling Verification task includes:

- Is there noncompliance?
- If so, is it egregious?
- What action should be taken?

If you observe a humane handling noncompliance, you must take immediate action if animals are being harmed. For example, if you observe an employee driving livestock with an instrument (e.g., the edge of a shovel, a pointed metal prod) that can cause injury, your first priority is to stop that action from continuing.

Once that is done, your next step is to decide if the noncompliance is egregious or non-egregious, because the actions you take will be dictated by that determination. An egregious humane handling violation is so serious that it usually warrants an immediate suspension of the assignment of inspectors under the authority of the Rules of Practice (9 CFR 500.3(b)).

Non-egregious Noncompliances

When a noncompliance is observed, 9 CFR part 313.50 specifies a progression of enforcement actions allowing for an escalating response by IPP when the establishment does not comply with the humane slaughter of livestock regulations.

- **First, notify establishment** management of the humane handling noncompliance, if not already done when addressing the needs of the animal.
- **Second, request that establishment management** immediately **correct** the situation and take the necessary steps to prevent recurrence.
- Third, document the noncompliance on a **noncompliance record (NR)**.

If necessary, take a regulatory control action (RCA) to prevent further injury to the animal(s) or to prevent injuries from occurring to other animals. You will also take the appropriate regulatory control action if you do not receive an adequate response or corrective actions to the NR or if the noncompliance observed continues to occur. The appropriate regulatory control action depends on the nature of the noncompliance. Remember that the goals of applying a tag are to control the situation and prevent further injury or distress to animals.

If the noncompliance is the result of facility deficiencies, disrepair, or equipment breakdown, but is not immediately causing injury or distress to livestock, attach a U.S. Rejected tag to the noncompliant equipment/pen/etc.

If the noncompliance is the result of establishment employee actions in the handling or movement of livestock and animals are being injured or treated inhumanely, attach the tag either at a point specific to the location and nature of the violation or to the alleyways leading to the stunning area. Noncompliance examples include animals driven faster than a normal walking speed or animals slipping and falling because of slick floors.

The tag will remain in place until the establishment operator implements appropriate immediate actions and measures to prevent recurrence. The tag shall not be removed by anyone other than an inspector. All livestock slaughtered prior to the tagging may continue to be dressed, processed, or prepared under inspection.

Whenever a non-egregious noncompliance of the humane slaughter requirements is observed, inspection personnel must document the incident on a NR and **send a copy to the DVMS** at the District Office. It is important that it clearly and specifically describe exactly what was observed, including any response by the animal (if the noncompliance involved animal discomfort or injury). Specify all the relevant regulations that pertain to the incident. At the top of Block 10 (where the noncompliance is described) on the NR, list the HATS category you were performing when you saw the noncompliance. If the noncompliance is covered by a second HATS category, note both categories on the NR. **Note:** The HATS categories do not have to be listed at the top of Block 10, but they must be clearly stated somewhere in the description narrative.

If the establishment continues to have noncompliances or does not adequately correct previously documented noncompliances, the IIC is to communicate this to the FLS and DVMS. The IIC will work with the FLS and DVMS to determine if a Notice of Intended Enforcement (NOIE) should be issued for the recurrent noncompliances.

Examples of non-egregious noncompliances (include, but not limited to):

- *There are sharp corners, holes or fence gaps in which animals may be injured.*
- *There are protruding rails or sharp objects which may injure animals.*
- *There are issues with access to water or feed.*
- *There is driving of animals off a high step, causing some to slip or fall.*
- *There is excessive use of prods, causing undue excitement but not pain or injury.*

Egregious Noncompliances

So, what is an egregious noncompliance? Webster's Dictionary defines "egregious" as "conspicuously bad or flagrant." The Agency defines it as "any act or condition that results in severe harm to animals."

If you observe a noncompliance that you believe is egregious, your next set of actions will depend on whether you are the IIC. **If you are the IIC, place a U.S. Rejected tag at the appropriate place and inform establishment management that you are communicating** with the FLS, District Office and DVMS to discuss the incident and recommend that a suspension without notification is imposed in accordance with 9 CFR 500.3(b).

If you are not the IIC, attach a U.S. Rejected tag at the appropriate place, and inform establishment management that you are taking a regulatory control action and that no more animals can be slaughtered until you contact the IIC. Whichever action is taken, all livestock slaughtered before the action may be dressed, processed, or prepared under inspection.

Note: Regardless of whether you are the IIC, your very first step—even before applying a tag—is to stop the activity that is causing harm to animals, if at all possible, without endangering yourself.

The IIC will immediately notify the FLS, District Office and the DVMS of the incident to discuss and recommend a suspension action.

The IIC will also document the facts that serve as the basis of the suspension action on a noncompliance record (NR) and promptly provide that information electronically to the DO and the DVMS for their use. The NR will form the basis of the Notice of Suspension documented by the DVMS and DO staff and of the Administrative Enforcement Report.

Examples of egregious noncompliances (include, but not limited to):

- Making cuts on or skinning conscious animals;
- Excessive beating or prodding of ambulatory or non-ambulatory disabled animals or dragging of conscious animals;
- Stunning of animals and then allowing them to regain consciousness;
- Failing to immediately (or promptly) render an animal unconscious after a failed initial stunning attempt (e.g., no planned corrective actions);
- Leaving disabled livestock exposed to adverse climate conditions while awaiting disposition.

Poultry Good Commercial Practices (GCP) Verification Activities

Poultry (chickens, turkeys, ducks, fowl, etc.) are not subject to the humane handling regulations as discussed above for livestock. Rather, compliance or noncompliance is determined based on a single regulation that prescribes that birds must be slaughtered under a well-controlled process that ensures they are bled out and no longer breathing by the time they enter a scald tank. 9 CFR 381.65(b) reads as follows:

*“Poultry must be slaughtered in accordance with good commercial practices in a manner that will result in **thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding**. Blood from the killing operation must be confined to a relatively small area.”*

FSIS has generally expanded the definition of Good Commercial Practices regulatory noncompliance to any activity or handling practice that results in large numbers of birds dying by means other than slaughter. For example:

- Large numbers of birds dying in cages due to extreme unmitigated heat or cold.
 - Large numbers of live birds run over or crushed by equipment.
 - Large numbers of birds with broken legs or wings due to practices during live hang.
- Note:** Birds showing signs that they entered the slaughter process already dead (“dead on arrival” or “DOA”) is a sanitation (SPS) issue, rather than a Good Commercial Practices issue.

IPP assigned to poultry slaughter facilities are expected on a **daily, per shift basis** when the establishment slaughters, to perform a Poultry Good Commercial Practices Verification task.

If the poultry are stunned prior to bleeding, check the stunning equipment to ensure it is functioning properly. Poultry that have been effectively stunned will have an arched neck and tucked-in wings posture. Note that while stunning of poultry is a common practice, it is not required by regulations.

Check in the bleeding area to determine if the bleeding equipment is functioning properly. One way that you might be alerted to problems with the bleeding equipment is if the line inspectors

report an increased number or clusters of cadavers at inspection stations or increased numbers of bruised wings or legs.

Once a week, IPP are to randomly select a day to review establishment records documenting adherence to good commercial practices (video footage of slaughter activities may also be counted as records). This review takes the place of observation in the receiving through pre-scald areas. Recognize that establishments are not required to maintain written records of good commercial practices. If records are not kept, IPP are to visit the receiving through pre-scald areas as above.

Enforcement

During poultry handling and slaughter, IPP are to document through NRs or MOIs establishment failure to follow GCP. From a regulatory perspective, **adherence to GCP is a process control issue** and not a bird-by-bird performance standard issue.

If the establishment is not following good commercial practices, and birds are dying other than by slaughter, you are to document a noncompliance record citing 9 CFR 381.65(b), using the Poultry Good Commercial Practices Verification task in PHIS. **IPP are to write NRs for GCP noncompliance only when they can demonstrate that an establishment has lost process control and that there is an ongoing trend of bird dying otherwise than by slaughter.** Consult with your chain of command if you are uncertain whether your observations constitute a GCP noncompliance.

Poultry Mistreatment MOIs

Poultry mistreatment MOIs are issued when the establishment is mistreating birds up until the kill step, but the mistreatment event does not demonstrate that the establishment's process is out of control. The MOI documents the discussion between IPP and the establishment management about the poultry mistreatment event, as well as any planned corrective actions by the establishment. Give a copy of the MOI to establishment management, keep a copy in the inspection file, and send a copy to the DVMS.

District Veterinary Medical Specialist

The District Veterinary Medical Specialist (DVMS) will review the MOIs and GCP NRs and determine if additional action is warranted. If you have questions or concerns about what you observe during poultry slaughter, contact the DVMS for guidance.

24 READY-TO-EAT AND SHELF-STABLE PRODUCTS PROCESS FAMILIARIZATION

Objectives

1. Define Ready-to-Eat
2. Define Shelf-Stable
3. Identify process steps that relate to the safety of fully cooked/not shelf-stable, heat-treated/shelf-stable, and not heat-treated/shelf-stable products
4. Identify factors requiring control at key process steps to meet standards for safety and product identity

When performing inspection tasks, it is important to follow the regulatory process. As discussed previously, the four components of regulatory process are inspection methodology, decision making (**GAD**), documentation, and enforcement. This module provides a list of resource material that relates to Ready to Eat meat and poultry products.

When performing the verification task to verify compliance with HACCP requirements, IPPs are review relevant regulations, review directives for instructions to perform the tasks, as well as compliance guidelines to be familiar with validated supporting information.

Ready-to-Eat (RTE) meat and poultry is defined by FSIS 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. RTE product labels do not require to bear safe-handling instructions or other labeling that directs that the product must be cooked or otherwise treated for safety and can include frozen meat and poultry products.

RTE meat and poultry products include:

1. Products with a standard of identity as required by 9 CFR 319 and 9 CFR 381 (example: hotdog), **or**
2. The intended use of the finished products is typically RTE (example: pate, pepperoni, salami).

FSIS **standards of identity** generally require the presence of certain expected ingredients in a food product or mandate how a product is to be formulated or prepared.

NOTE: A meat and poultry product receives a full-lethality treatment is not required to be RTE product unless the product has a standard of identity requiring it to be RTE (9 CFR 319 and 9 CFR 381), the establishment can consider the finished product to be NRTE. FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products ([usda.gov](https://www.usda.gov)) provide detail information on how to determine whether the product is RTE and labeling requirements for NRTE products.

Lethality is a process or combination of processes that ensures that no Salmonella organisms remain in the finished product, as well as reduces other pathogens and their toxins or toxin metabolites. Examples of lethality processes include cooking, fermentation, salt-curing, and drying.

Stabilization is a process of preventing or limiting the growth of spore-forming bacteria capable of producing toxins either in the product before consumption or in the human intestine after consumption. Establishments may use a variety different stabilization process such as cooling, hot-holding, or meeting and maintaining certain pH or water activity levels.

Post-lethality Processing Environment is the area in an establishment into which product is routed after having been subjected to an initial lethality treatment. The product may be exposed in this area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures (9 CFR 430.1).

Shelf-stable for the purposes of meat and poultry products is defined as the condition achieved when meat and poultry products can be stored under ambient temperature and humidity conditions; if the package integrity is maintained during storage, shipping, and display at retail and in the home; and the product will not spoil or become unsafe throughout the manufacturer's specified shelf-life.

In order to achieve shelf stability for food safety purposes, certain intrinsic parameters consist of either water activity and/or pH must be achieved. Not shelf stable meat and poultry products must be stored under refrigeration or frozen prior to consumption and labeled as "Keep refrigerated or frozen."

NOTE: FSIS has a regulatory definition of shelf-stability in (9 CFR 431.1) but this only applies to thermally processed, commercially sterile products and does not apply to the types of products described in this module. Information about canned foods and other commercially sterile products will be covered in thermal processing training.

There are many RTE SS fermented, salt-cured, and dried products that rely on **multi-hurdle** approaches to achieve lethality and shelf-stability. Multi-hurdle products in the context of this module are those products that rely on a combination of hurdles or processing steps to eliminate pathogens of concern and result in a RTE shelf-stable product. These hurdles typically include processing steps such as fermentation, salt-curing, and drying that use a combination of factors such as reduced pH, reduced water activity (also referred to as aw) over time, high brine, or salt concentration to kill bacteria and prevent their outgrowth during storage. Generally, one step is not sufficient on its own to eliminate pathogens of concern, instead a combination of processing steps or hurdles is needed.

Water activity, abbreviated as aw, is a measure of the concentration of moisture (i.e., water) and its availability in a food. The amount of water available in a food depends on the total concentration of all dissolved substances in the product because they bind water. Thus, if ingredients such as salt or sugar are added to food, they compete with the bacteria for available water.

Moisture Protein Ratio (MPR) expresses the percent moisture divided by the percent protein. MPR is commonly used in the U.S. to classify dried sausages and other meat products. Although MPR values indicate the degree of product drying, they are not necessarily indicative

of microbial safety or product shelf-stability because they do not take into account availability of the water.

For example, Jerky is a SS product. After drying is complete, the establishment should monitor or verify the water activity to demonstrate that the product has attained shelf-stability in accordance with the scientific support. FSIS does not have a standard of identity for jerky in its regulations. However, jerky has historically been dried to an MPR of 0.75:1 or below as described in the Food Standards and Labeling Policy Book | Food Safety and Inspection Service (usda.gov). FSIS is aware that some manufacturers rely upon the MPR, rather than water activity, for determining whether their process adequately dries the jerky to produce a SS product. MPR is an inappropriate indicator of shelf-stability. Water activity (also referred to as aw), measured by an instrument such as a water activity meter, is the more appropriate indicator to verify jerky is properly dried for food safety. This is because water activity is a better measure of available water (or water that is not bound by other components) for microbial growth than is MPR. Minimizing available water (e.g., achieving a sufficiently low water activity) is necessary to achieve shelf-stability, provided measures are taken to address mold growth. Such measures to prevent mold growth may include using short inventory pull dates, low pH, antimycotics, coatings, packaging, or any combination of these measures.

Degree-hours is the amount of time in hours above 60°F (the critical temperature at which staphylococcal growth effectively begins) an establishment's fermentation process can take at a specific temperature to reduce the pH to 5.3 or below in order to control *S. aureus* growth.

Post-lethality Considerations

For all RTE products, it is important to ensure contamination and adulteration of products is prevented after the lethality treatment is complete. Even if the product is RTE shelf-stable, pathogens may still be able to survive on the product if it becomes contaminated during handling. RTE foods implicated in foodborne illness are commonly implicated due to post-processing contamination by bacteria such as *S. aureus* and *Lm* either by food handlers or from the environment.

Establishments produces post-lethality exposed RTE meat and poultry products are required to comply with regulatory requirement of 9CFR 430 Listeria Rule. Details of the requirements are discussed in the *Lm* Regulation module.

FSIS has maintained a “zero tolerance” for *Lm* in RTE products and continues to strengthen programs and recommendations to reduce or eliminate *Lm* from RTE products.

To ensure that contamination and adulteration of products is prevented after the lethality treatment, establishments are required to:

- **Develop and implement** SSOPs (9 CFR 416.11-9 CFR 416.16).
- **Maintain** sanitation in the RTE area to ensure that food contact surfaces are free of contamination from *Lm* and other pathogens, such as *Salmonella*, in accordance with 9 CFR part 430.
- **Support** the safety of non-meat ingredients added part-way through the lethality treatment (e.g., during lard application during drying of salt-cured hams) or after the final lethality step is complete (e.g., coating dry or semi-dry sausages in pepper or rolling sausages in rice flour to give the appearance of an outer coating of mold).

RTE Products HACCP Categories

1. **Fully Cooked-Not Shelf Stable (FC, NSS).** Products produced under this category further process by using primarily a full lethality heat process step (e.g., cooking) to achieve food safety. The finished products are not shelf-stable and must be frozen or refrigerated for food safety purposes. The products must be labeled “Keep Refrigerated or Frozen” These products also meet the definition of Ready-to-Eat (RTE) as defined in 9 CFR 430.1.
2. **Heat Treated-Shelf Stable (HT, SS).** Products produced under this category further process by using a heat treatment processing step in combination with curing, drying, or fermenting processing step to achieve food safety. The finished products are SS and not required to be frozen or refrigerated for food safety purposes. The intended use of these products can be RTE and NRTE.
3. **Not Heat Treated-Shelf Stable (NHT, SS).** Products produced under this category use curing, drying, and or fermenting processing step as the sole means by which product achieves food safety. Establishments may apply a low-level heat treatment as long as the heat treatment is not used as means to achieve food safety. The finished products are SS and not required to be frozen or refrigerated for food safety purposes. The intended use of these products can be RTE and NRTE.
4. **Product with Secondary Inhibitors-Not Shelf Stable.** Products produced under this category use a curing processing step or a processing step using other ingredients that inhibit bacterial growth. The finished products are not SS and must be frozen or refrigerated for food safety purposes. The intended use of these products can be RTE and NRTE.

Pathogens of Concerns

The following section is designed to complement FSIS’s compliance guides and to further assist establishments in conducting a hazard analysis for cooked meat and poultry products as required by 9 CFR 417.2(a)(1) and for supporting decisions in their hazard analysis as required by 9 CFR 417.5(a)(1).

➤ **Cooking lethality**

- The following hazard is present in raw products whose outgrowth during the heating come-up time should be controlled: *Staphylococcus aureus* (*S. aureus*)
- The following are hazards present in raw products that the lethality treatment should be designed to destroy *Salmonella*, Shiga toxin-producing *Escherichia E. coli* (STEC) (in beef), *Campylobacter* (in poultry), *Listeria monocytogenes* (Lm), *Trichinae spiralis* and *Toxoplasma gondii* (in pork, especially feral or non-confinement raised swine)

NOTE: Although all of these hazards are a concern, *Salmonella* is considered an indicator of lethality because the thermal destruction of *Salmonella* in cooked products would indicate the destruction of most other pathogens (64 FR 732).

➤ **Stabilization**

- The primary hazards of concern during cooling and hot holding are *C. perfringens* and *C. botulinum*

➤ **For all RTE Shelf Stable and Not Shelf Stable meat and poultry products**

- The following hazards are present in raw products whose outgrowth in the finished products should be controlled during fermentation, salt-curing and drying steps: *Staphylococcus aureus* (*S. aureus*), *C. perfringens* and *C. botulinum*
- The following hazards are present in raw products which should be destroyed or reduced during fermentation, salt-curing and drying steps: *Salmonella*, Shiga toxin-producing *Escherichia E. coli* (STEC) (in beef), *Campylobacter* (in poultry), *Listeria monocytogenes* (Lm), *Trichinae spiralis* and *Toxoplasma gondii* (in pork, especially feral or non-confinement raised swine).

Per FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments, in order to achieve a shelf-stable product, a water activity critical limit of 0.85 or lower should be targeted for products stored in an aerobic or oxygen containing environment such as in ambient air, provided the establishment takes steps to prevent mold growth on the finished product. If the product is vacuum packaged in an oxygen impervious packaging (creating an anaerobic environment where no oxygen is present), then the water activity critical limit can be 0.91 or lower.

NOTE: Vacuum packaged products with a water activity level > 0.85 and ≤ 0.91 should be kept refrigerated once the package is opened because the product would no longer be considered shelf-stable once it is exposed to oxygen. Lack of shelf-stability once the product is exposed to oxygen is mainly a concern for products that would not be consumed within a single serving as these products are not likely to be vacuum packaged by the consumer between servings. Therefore, unless the establishment has support that the product is likely to be consumed in a single serving, vacuum packaged products with a water activity in the range of > 0.85 and ≤ 0.91 should be labeled with a statement such as “Refrigerate After Opening” (as described in 9 CFR 317.2(k)).

It is important to verify establishment’s operation against with their validated supporting documentations to ensure that critical operational parameters within the scientific support closely match the establishment’s actual process or provide justification for any differences to support the decisions in its hazard analysis (9 CFR 417.5(a)(1)).

FSIS Ready-to-Eat Fermented, Salt Cured, and Dried Products Guideline, Table 1. Key Steps or Hurdles Used to Achieve Lethality and Shelf-Stability by Product Group

| | Seasoning/ Marination | Fermentation | Low- Temperature Heat Step | Salt-curing/ Equalization | Drying |
|-----------------------------|-----------------------------------------------------------|----------------------------------------------------------------------|----------------------------------|-----------------------------------------|-------------------------------------------|
| Hurdle/ Product Group | Addition of salt and nitrite or nitrate/Lower pH | Lower pH/ Competitive Microflora/ Bacteriocin production | Heat | High brine/Reduced water activity | Reduced water activity over time |
| Fermented | X | X | Optional | | X |
| Salt-cured | X | | Optional | X | X |
| Dried | X | | | | X |

Overview of Fermented Products

RTE fermented meat and poultry products are products in which the raw meat or poultry are usually reduced in size by grinding or chopping, formulated with cure, starter culture, salt and seasoning mixture, stuffed in casings, fermented, sometimes heated with a low temperature heat step for food safety or smoked, and then dried. There are also RTE acidified products that are formulated with chemical acidulants, instead of starter cultures, to accelerate the acidification process by eliminating the lengthy fermentation step. This section focuses on fermented products. Products in this category include: Genoa salami, hard salami, pepperoni, turkey pepperoni, summer sausage, Abruzzese, Lebanon bologna, sopressata, thuringer, mettwurst, saucisson, chorizo, chourico, soudjouk (sujuk or soujouk), pickled pigs' feet, bologna in vinegar, and landjager.

Critical Steps and Critical Operating Parameters:

| Fermentation | Low-Temperature Heat Step (Optional) | Drying: |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">• Fermentation temperature, target pH, time to reach target pH, and smoke (if used)• Type and use of starter cultures• Product characteristics: Casing diameter, shape and product formulation including salt, sugar (type and level), and use of nitrite or nitrate | <ul style="list-style-type: none">• Time and temperature: Heating CUT, hold time, and temperature for low temperature heating step• Equipment used to generate heat• Product characteristics | <ul style="list-style-type: none">• Drying room temperature• Drying time• Target water activity• Product characteristics |

Note: Fermentation and drying alone are not particularly effective lethality treatments. When these steps are found to be effective, there are a lot of critical operational parameters that need to be implemented consistent with the scientific support. It is not enough to only meet degree-hours, follow a drying or salt-curing method for *Trichinella*, and achieve a final water activity for shelf-stability. Degree-hours are intended to control the outgrowth of *S. aureus*. To reduce levels of other pathogens such as *Salmonella*, products often need to be fermented to a lower pH than 5.3. Also, methods for controlling *Trichinella* have not been validated for controlling *Salmonella* and product may need to be dried longer to reduce levels of *Salmonella* in the product.

Overview of Salt-Cured Products

RTE salt-cured meat and poultry products are usually whole muscle products that are cured with salt and sodium nitrite or nitrate, then air dried, and sometimes smoked (if desired for certain flavor characteristics). Examples of salt-cured products include Prosciutto ham, Parma ham, Westphalian ham, Bayonne ham, Serrano ham, Black Forest ham, country ham, pancetta, coppa, capocollo, bresaola, beef prosciutto, basturma, duck prosciutto, linguica, and salchichon. Because many products rely on dry-curing, the guideline focuses on the critical operational parameters of dry-curing.

Critical Steps and Critical Operating Parameters:

| Dry-Curing: | Salt-Equalization: | Drying: |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">• Curing temperature• Curing time• Salt coverage of exposed muscle tissue• Product characteristics (e.g., product size and formulation, including salt concentration) | <ul style="list-style-type: none">• Equalization temperature• Equalization time• Brine concentration and water activity after equalization• Product size (diameter or thickness) | <ul style="list-style-type: none">• Drying room temperature• Drying time• Target water activity• Product characteristics |

Note:

- The equalization time is critical to ensuring sufficient brine concentration and water activity at the end of the process. If a process uses a shorter equalization time, then the final brine concentration and water activity may not be sufficient to prevent *S. aureus* growth when product begins drying at a higher temperature.
- If a process uses a shorter equalization time than that in the supporting documentation, then the final brine concentration and water activity may not be sufficient to prevent *S.aureus* growth when product begins drying at a higher temperature.

Overview of Dried Products

RTE dried meat and poultry products can be comminuted, sliced whole muscle, or whole muscle products that may or may not be formulated with nitrite, may be smoked, are usually heated, and are air dried or oven dried. In addition, meat and poultry products that are freeze dried are also considered by FSIS to be RTE dried products. Examples of products that are dried as the primary lethality treatment include dried beef, (some) beef jerky, beef nuggets, steak tenders, kippered beef, meat sticks, turkey jerky, tasajo, pemmican, pipi kaula, droëwors, biltong, jamon (jambon), longanisa, (some) saucisson, (some) chorizo, dried soup mixes/soup bases, freeze-dried entrees, fried pork skins/rinds/cracklings/chicharrones, and lard.

Critical Steps and Critical Operating Parameters:

| Marination/Seasoning: | Drying: |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none">• Product formulation• Antimicrobial application (e.g., concentration, pH, coverage, contact time) | <ul style="list-style-type: none">• Drying room temperature• Drying time• Target water activity• Product characteristics |

Note: Additional Interventions It is not appropriate to add up the results of two separate studies conducted for the same type of intervention (such as two acid dips) because the second time the intervention is used it will likely be less effective. This is because any bacteria that survive the first treatment are likely to be more tolerant to the second treatment.

References:

- Directive 5000.1 Verifying an Establishment's Food Safety System
- Directive 5000.6 Performance of the Hazard Analysis Verification Task
- Directive 7120.1 Safe and Suitable Ingredients Used in the Production of Meat, Poultry, and Egg Products
- FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)
- FSIS Stabilization Guideline for Meat and Poultry Products (Revised Appendix B)
- FSIS Compliance Guideline for Meat and Poultry Jerky Produced by Small and Very Small Establishments
- FSIS Ready-to-Eat Fermented, Salt-Cured, and Dried Products Guideline
- Controlling *Listeria monocytogenes* in Post-lethality Exposed Ready-to-Eat Meat and Poultry Products
- FSIS Compliance Guideline for the Prevention and Control of *Trichinella* and Other Parasitic Hazards in Pork and Products Containing Pork
- FSIS Cooking Guideline for Meat and Poultry Products (Revised Appendix A)
- HACCP Model for Full Cooked-Not Shelf Stable Roast Beef
- Food Standards and Labeling Policy Book
- Fermented, Salt-Cured, and Dried Products Guideline CSI and Supervisory Personnel Webinar
- Instructions for Training on the Ready-To-Eat Fermented, Salt-Cured, and Dried Products Guideline
- Good Manufacturing Practices for Fermented Dry & Semi-Dry Sausage Products

25 LETHALITY AND STABILIZATION

Objectives:

1. Define: Lethality, Stabilization, Performance Standard, Target, Critical Operating Parameter, and Scientific Gap.
2. State regulatory lethality and stabilization performance standards.
3. Identify compliance guidelines frequently used to support lethality, stabilization, and multiple hurdles processes.
4. Identify critical operational parameters in the FSIS guideline for lethality.
5. Describe the relationship between humidity and cooking.
6. Identify which microorganisms are controlled in the lethality and stabilization steps.
7. Explain the food safety significance of drying in the jerky process.
8. Explain how multiple hurdles are used in a food safety system.
9. Describe how inspectors verify that establishments have support for their lethality, stabilization, and multiple hurdle processes.

Ready-to-Eat (RTE) products are meat or poultry products that are edible without additional preparation to achieve food safety. Two main processes which are critical for achieving safety in RTE products are known as lethality and stabilization. They are used to control the biological hazards in RTE products.

Lethality (cooking) is defined as the process or steps used to **destroy pathogenic** microorganisms in a product to make the product safe for human consumption.

After the product is cooked, spores of ***Clostridium (C.) botulinum*** and ***C. perfringens*** that survive the cooking process can germinate, becoming vegetative cells that can multiply to hazardous levels if cooling is inadequate. Rapid cooling from 130°F to 80°F is necessary to prevent the growth of Clostridium bacteria. The processes that establishments employ to limit the growth of spore-forming bacteria are called **stabilization (cooling)**.

The most common stabilization is cooling. However, other treatments, such as lowering the product pH through fermentation or marination, prevents the growth of ***Staphylococcus aureus***. Drying or salt-curing to reduce the water activity or adding antimicrobials may also be used in combination with heating or each other to destroy pathogens. The use of multiple treatments to achieve lethality or stabilization is called the **multiple hurdle concept**.

For certain RTE products, FSIS has established regulatory performance standards because they have a higher public health risk. These products have historically been associated with foodborne illnesses caused by specific pathogenic bacteria or their toxins (*Salmonella*, *L. monocytogenes*, *E. coli* O157:H7, *C. perfringens*, and *C. botulinum*).

RTE products are adulterated if they contain pathogens of public health concern, or their toxins:

- Any ***Salmonella***, ***Lm***, or **STEC** is injurious to health.
- Any ***C. botulinum*** growth is a public health concern.
- ***C. perfringens*** at levels that could lead to toxin formation indicates product was prepared, packed, or held under insanitary conditions.

Performance standards are quantifiable pathogen reduction levels or growth limit requirements set by FSIS for lethality and stabilization of certain products.

Lethality performance standards require establishments to ensure the lethality process for certain RTE products meets a specific log-10 reduction of *Salmonella* microorganisms. The lethality performance standard requires a minimum 6.5-log reduction of *Salmonella* for roast beef, cooked beef, and corned beef, at least a 7.0-log reduction of *Salmonella* in cooked poultry products, and cooked uncured meat patties to achieve a 5-Log reduction of *Salmonella* (and other pathogens including STEC).

The **stabilization performance standards** are quantifiable pathogen growth limit requirements set by FSIS for the stabilization of certain meat and poultry products. The stabilization performance standard requires: No multiplication of *C. botulinum* and no more than 1-log increase of *C. perfringens* throughout the product shelf life.

Establishments may use alternative **lethality** or **stabilization** support for certain products. The establishment must be able to demonstrate that the alternative support achieves a different (usually lower) log reduction than what is prescribed in the regulations.

Targets are quantifiable pathogen reduction levels or growth limits set by the establishment to produce safe products in the absence of regulatory performance standards. *Salmonella* is used as a target organism because death of *Salmonella* indicates destruction of other vegetative pathogens.

Critical operating parameters are the time-temperature intervention combinations establishments apply to cooked products that affect pathogen log-10 reductions and achieve lethality. Critical operating parameters may include but are not limited to time, temperature, water activity, concentration, relative humidity, and even type of equipment necessary to achieve the critical operating parameter.

FSIS Compliance Guidelines provide guidance to industry and may be used to support CCPs and critical limits in a HACCP plan. It is not mandatory for the establishment to use these guidelines. For example, **Appendix A** provides support for lethality (time, temperature, and humidity for cooking processes) and **Appendix B** for stabilization (cooling options). These Compliance Guidelines do not cover catfish, pork rinds, lard and tallow, dried products, partially heat treated not ready-to-eat products, or the production of products that rely on multiple hurdles to achieve lethality and shelf-stability. The Jerky Guideline describes requirements for lethality (heat and humidity) prior to drying.

FSIS time-temperature tables identify **relative humidity** as a critical operating parameter to ensure moist cooking and adequate surface lethality of pathogens, especially *Salmonella*. Unless the establishment can provide additional support for why humidity would not be needed in its process to ensure lethality on the product surface, there is a concern in not maintaining humidity because:

- Product surfaces will take longer to heat.
- Product surfaces can dry out.
- Bacteria can become more heat resistant.

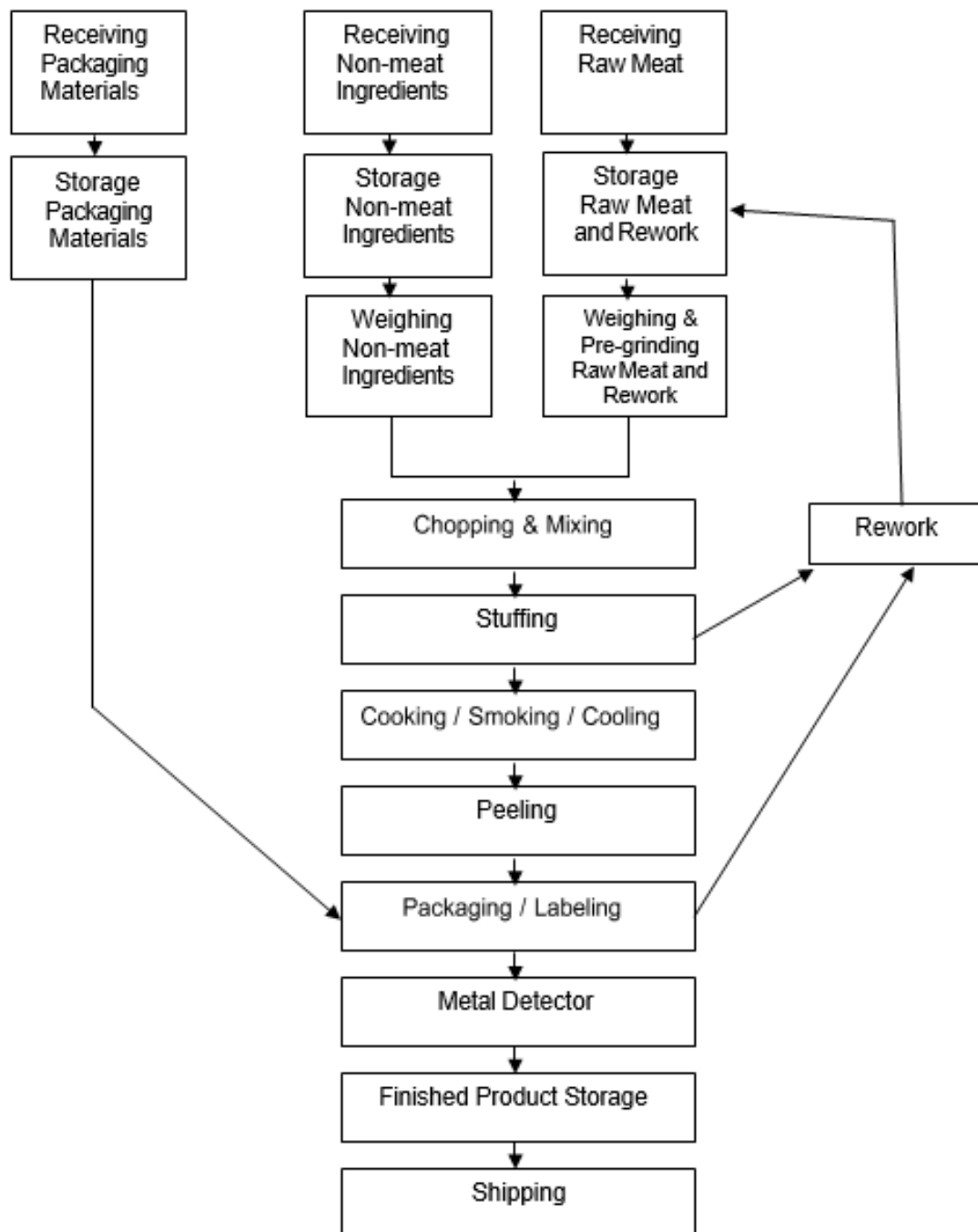
Appendix A and Appendix B have identified Scientific Gaps in several common cooking processes where adequate support for achieving critical operating parameters is lacking. Until scientific research becomes readily available, establishments may address scientific gaps by referring to recommendations from older FSIS cooking guidance for:

- Products cooked for short times at high temperatures.
- Products cooked using cooking methods, such as microwaves, that are not designed to control relative humidity.
- Other processes that may inherently maintain relative humidity around the meat and poultry filling but cannot follow one of the relative humidity options.
- Processes where the drying step comes before cooking under moist conditions.
- Products with long heating come-up-times (CUT).
- Partially heat-treated, smoked, not fully cooked products containing nitrite and either erythorbate or ascorbate that cannot follow the new cooling options due to long heating come-up and cooling times.
- Large mass, non-intact, fully cooked products, including scalded offal, that cannot cool quickly enough to follow the new cooling options.
- Fully cooked, smoked bacon containing nitrite and erythorbate/ascorbate that achieve the lethal time and temperature combinations but cannot use the new cooking options because relative humidity is not addressed.
- Immersion or dry-cured products containing nitrite that use equilibration time instead of erythorbate or ascorbate but cannot meet cooling options without nitrite.
- Products that contain nitrite and use equilibration time instead of erythorbate or ascorbate, but do not have a brine concentration of $\geq 6\%$.

Please see E13 Lethality, Stabilization, And Multiple Hurdles Workshop

26 RTE HAZARDS AND CONTROLS EXAMPLE

Hotdog Flow Diagram



No returned product accepted.

(Training Example Only)

Hotdog - Hazard Analysis – ...EXCERPT...

(Training Example Only)

| Process Step | Potential Food Safety Hazard | RLTO | Basis | If RLTO, What Control Measures? | Is this Step a CCP? |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------|---------------|-----------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|---------------------|
| Receiving - raw meat | B-Pathogen growth | No | Temperature Control Program | Vegetative pathogens and Trichinae eliminated at the Cooking CCP | No |
| | <i>Salmonella</i> , STECs, <i>Campylobacter</i> , <i>Trichinella spiralis</i> | Yes | | Clostridia growth and toxin formation prevented. with Chilling CCP and Temperature Control Program | |
| | <i>Clostridium botulinum</i> and <i>Clostridium perfringens</i> (Clostridia) | Yes | | | |
| | C-None P-Metal, rubber, plastic, wood in incoming raw product | No | Receiving Inspection Program | | |
| ... | ... | ... | ... | ... | ... |
| Cooking & Smoking | B-Pathogens and parasites C- None P-None | Yes | | Cooking at temperatures sufficient to eliminate pathogens and parasites | Yes-1B |
| Cooling | B- <i>Clostridium</i> growth B-Contamination with <i>Lm</i> and potential subsequent growth C-None P-None | Yes No | Brine SOP for salt concentration, temperature, and microbial testing for <i>Listeria</i> spp. | Rapid cooling to ensure no growth of <i>C. botulinum</i> & less than one log growth of <i>C. perfringens</i> | Yes-2B |
| ... | ... | ... | ... | ... | ... |

Hotdog HACCP Plan (Training Example Only)

| CCP | Critical Limits | Monitoring Procedures | Verification Procedures | Records | Corrective Actions |
|---------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|-------------------------------------------|
| 1B Cooking | Internal temp at least 160°F | Every 2 hours, internal temperature checked by floor supervisor using handheld digital thermometer, two temps taken from each (upper and lower) chain of continuous cooker/smoker/cooler unit checked at specified access point "B" | Accuracy of all thermometer s checked prior to each shift. Once per shift QC will observe one internal temp monitoring procedure. Daily, QC supervisor will review monitoring records and other records required by 417.5(a)(3) | Cooking log Thermometer log Corrective Actions log | QC will take Corrective Actions per 417.3 |
| 2B Cooling | Cooler brine medium kept at or below 28°F. Chain speed not to exceed 100 racks per minute. Internal temp reduced from 130°F to less than 40°F in 90 minutes or less | Every 2 hours cooler brine medium checked at specified access point "A" Every 2 hours chain speed checked Every 2 hours internal product temperature at exit checked using handheld digital thermometer, two temps taken from each (upper and lower) chain of continuous cooker/smoker/cooler All three monitoring checks done by floor supervisor | Accuracy of all thermometers checked prior to each shift Once per shift QC will observe one internal temp monitoring, one brine temp check, and one chain speed check procedure Daily, QC supervisor will review monitoring records and other records required by 417.5(a)(3) | Cooling log Thermometer log Corrective Actions log | QC will take Corrective Actions per 417.3 |

27 READY-TO-EAT (RTE) SANITATION

Objectives

1. Identify why establishments producing RTE products have a special responsibility for adequate sanitation in the RTE processing environment.
2. Describe effective methods of sanitation in RTE processing environments.
3. Identify potential sanitation issues in RTE processing environments.

Ready-to-eat product - As per 9 CFR 430.1 definitions, a meat or poultry product 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 safe-handling instructions (as required for non-RTE products by 9 CFR 317.2(i) 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.

Post-lethality Treatment - A process that eliminates or reduces levels of *Listeria monocytogenes* on or in an RTE product to make it safe for human consumption. Examples of post-lethality treatments are cooking and high-pressure processing (HPP). The application of an **antimicrobial agent** (e.g., potassium lactate; sodium diacetate) or an **antimicrobial process** (e.g., freezing; low water activity or pH) that limits or suppresses *L. monocytogenes* growth may also be used as a post-lethality treatment if it eliminates or reduces *L. monocytogenes* growth over the shelf life of the RTE product.

Post-lethality exposure - Exposure of product that has been subjected to an initial lethality treatment to the environment in the processing area as a result of slicing, peeling, re-bagging, cooling semi-permeable encased product with a brine solution, or other procedures.

Cross-contamination - The transfer of harmful bacteria among food, FCS, or NFCS environmental surfaces. 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 tabletop that has bacteria on it. Often, they are transferred indirectly, such as when a pallet placed on the floor in a raw area is subsequently used in the RTE area, or when an employee handles a pallet and then touches exposed product.

Consumed as packaged - Product eaten or consumed as it comes from the package (no heating/cooking/mixing/etc.).

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

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

Establishments are responsible for producing product that is free from any pathogen.

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

Lm is spread very easily by direct contact with a contaminated surface. ***Lm* can survive and grow in cool, damp environments**, such as those found in processing areas, coolers, or floors. Incomplete removal of product debris can provide nutrients and a place of attachment which allows bacterial growth. Maintaining dry processing equipment will help reduce the growth of *Lm*.

Lm can form biofilms on solid surfaces, such as stainless steel and rubber, and can survive adverse conditions on apparently smooth surfaces. Biofilm is a thin, slimy film of bacteria that adheres to a surface effectively protecting it from the environment. Biofilms protect the bacteria embedded in the biofilm from sanitizers. Rotating detergents and sanitizers help maintain effectiveness and keeps bacteria from building resistance. Sanitizing is done after cleaning, because a sanitizer cannot work effectively unless the equipment is cleaned first.

Lm contamination has been linked to disruptive construction. *Lm* is in the environment and the dust/debris generated during construction can carry it to many different places if not controlled. Dust generated by construction and other disruptive activities can establish contamination on food contact and other environmental surfaces.

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

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

- c) Pre-rinse equipment (rinse in same direction as product flow). Pre-rinse with warm or cold water – less than 140°F (hot water may coagulate proteins or “set soils”).
- d) Clean, foam, and scrub equipment. Always use at least the minimum contact time for the detergent/foam. Instructions should be provided on identifying possible niches and use of appropriate cleaning methods. Live steam for cleaning is not acceptable at this step since it may bake organic matter on the equipment.
- e) Rinse equipment (rinse in same direction as product flow).
- f) Visually inspect equipment to identify minute pieces of meat and biological residues.
- g) Sanitize floor and then equipment to avoid contaminating equipment with aerosols from floor cleaning. Care should be taken in using high pressure hoses in cleaning the floor so that water won't splash on the already cleaned equipment. Use hot water, at least 180°F, for about 10 seconds to sanitize equipment. Sanitizers (e.g., acidic quaternary ammonia) may be more effective than steam for *Lm* control.
- h) Rotate sanitizers periodically. Alternating between alkaline-based and acid-based detergents helps to avoid “soapstone” and biofilms. This also helps change the pH to prevent adaptation of bacteria to a particular environment.
- i) Dry. Removing excess moisture can be done most safely and efficiently by air drying. Reduced relative humidity can speed the process. Avoid any possible cross-contamination from aerosol or splash if a method other than air drying (e.g., using a squeegee or towel) is used.

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

28. *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, 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 (aw) 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 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–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)

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

- 1) Gathering information by asking questions;
- 2) Assessing the information; and
- 3) 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) allow 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 agent's 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 a 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 Alternative 1 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, referencing 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 9 CFR 430.4(b)(1) and 9 CFR 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 9 CFR 430.4(b)(1) and 9 CFR 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 9 CFR 430.4(b)(1) and 9 CFR 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 9 CFR 430.4(b)(1) and 9 CFR 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)

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:

- 1) Gathering information by asking questions;
- 2) Assessing the information; and
- 3) 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 Alternative 2 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 and reference 9 CFR 430.4(b)(2) and, depending on 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 9 CFR 430.4(b)(2), 9 CFR 416, and 9 CFR 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 9 CFR 430.4(b)(2) and 9 CFR 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 9 CFR 430.4(b)(2) and 9 CFR 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 9 CFR 430.4(b)(2) and 9 CFR 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)(2)

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

- 1) Gathering information by asking questions;
- 2) Assessing the information; and
- 3) 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 determine 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 products 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 products 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 products 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 and reference 9 CFR 430.4(b)(3) and, depending on where 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 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 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 "*Listeria* Rule" regulations.

Please see E14 *Listeria monocytogenes* Regulations Workshop

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 AND Antimicrobial Agent or Process | Post-lethality Treatment OR Antimicrobial Agent or Process | Sanitation and Testing Program | Non-deli, Non-hotdog | Deli or hot-dog product |
| | Choice 1: Post-lethality Treatment | Choice 2: Antimicrobial Agent or Process | | | |
| 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 Prerequisite Program and should demonstrate no more than 2-logs growth of <i>Lm</i> over the estimated shelf life. | X | X | | | |
| Sanitation Program Requirements | | | | | |
| Testing food contact surfaces (FCS) in the post-lethality processing environment for <i>Lm</i> or an indicator organism. | | X | X | X | X |
| State testing frequency. | | X | X | X | X |
| Identify size and location of sites to be sampled. | | X | X | X | X |
| Explain why testing frequency is sufficient to control <i>Lm</i> or an indicator organism. | | X | X | X | X |
| Identify conditions for Hold-and-Test, when FCS (+) for <i>Lm</i> or an indicator organism. | | X | 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 |

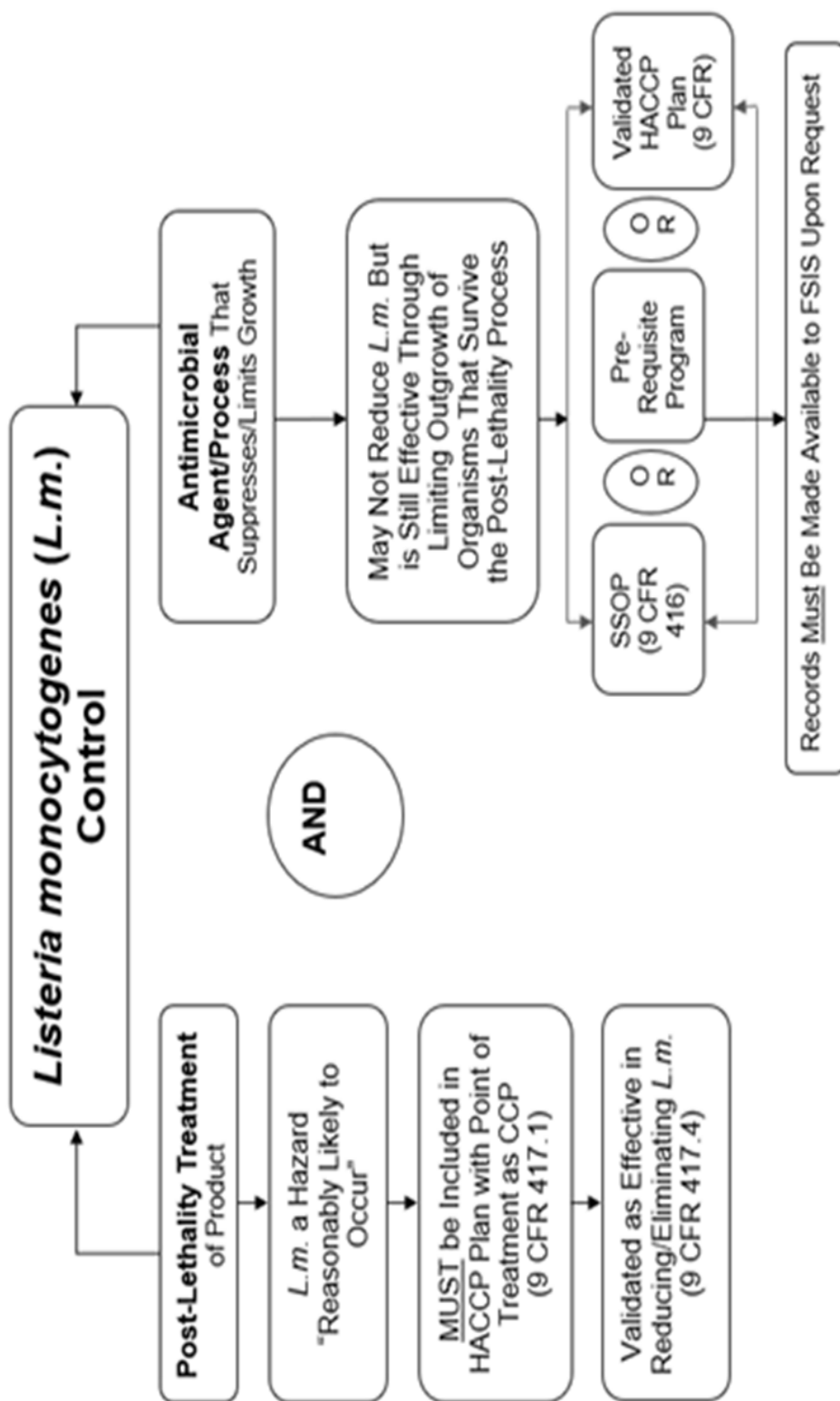
Attachment 2: Chart of RTE vs NRTE Products

| TYPE | CLASS | HACCP CATEGORY | REQUIRED LABELING | WHAT THE 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>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 a common or usual name that consumers understand to refer to RTE product and 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 Ground Raw Product Not Ground 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 | <p>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.</p> | <ul style="list-style-type: none"> Use of SHI labeling (Some establishments may have a CCP for SHI labeling application). If it is not obvious that the product is raw and needs to be cooked: 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: <ul style="list-style-type: none"> a. Cooking and preparation instructions on the product are sufficient to destroy pathogens. b. Instructions are realistic for the intended consumer. |
| | | | | |

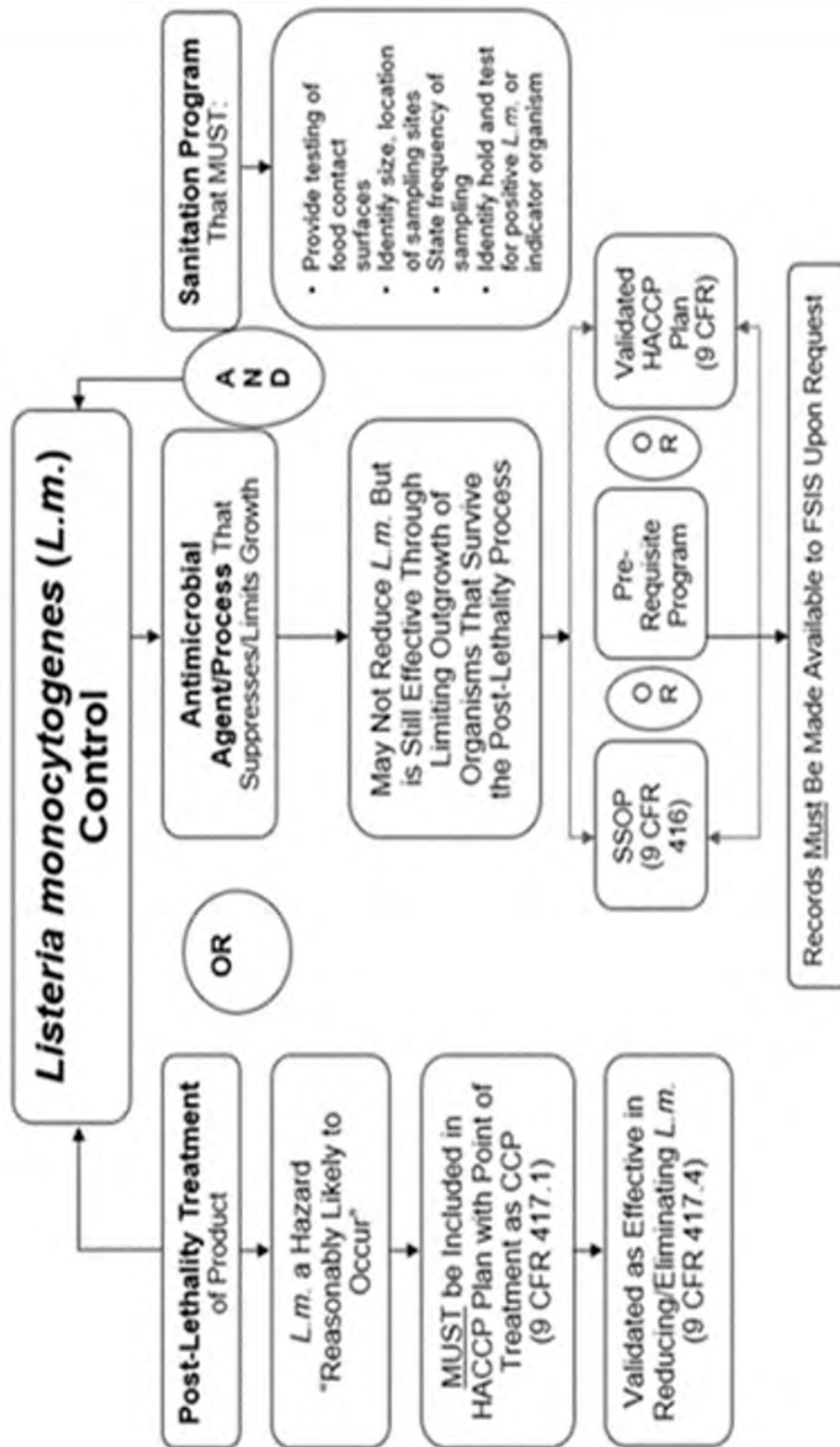
*A meat or poultry product that is edible without any additional preparation to achieve food safety.

| | | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>A product containing a meat/poultry component that is RTE in combination with non-meat/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 because it contains raw components. May include meals, dinners, and frozen entrees.</p> | <p>Not-ready-to-eat</p> | <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 (see Section 1.4). 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 (e.g., "Cook and Serve"). 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> |
| <p>A meat/poultry product that has received an adequate lethality treatment for <i>Salmonella</i> that may or may not be defined by a standard of identity or a common or usual name that consumers understand to refer to RTE product, and meets the definition of RTE in 9 CFR 430. RTE products that are post-lethality exposed must meet the requirements of 9 CFR part 430. May include hotdogs, deli meat, and RTE sausages.</p> | <p>Ready-to-eat</p> | <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 | <p>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.</p> | <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"). |

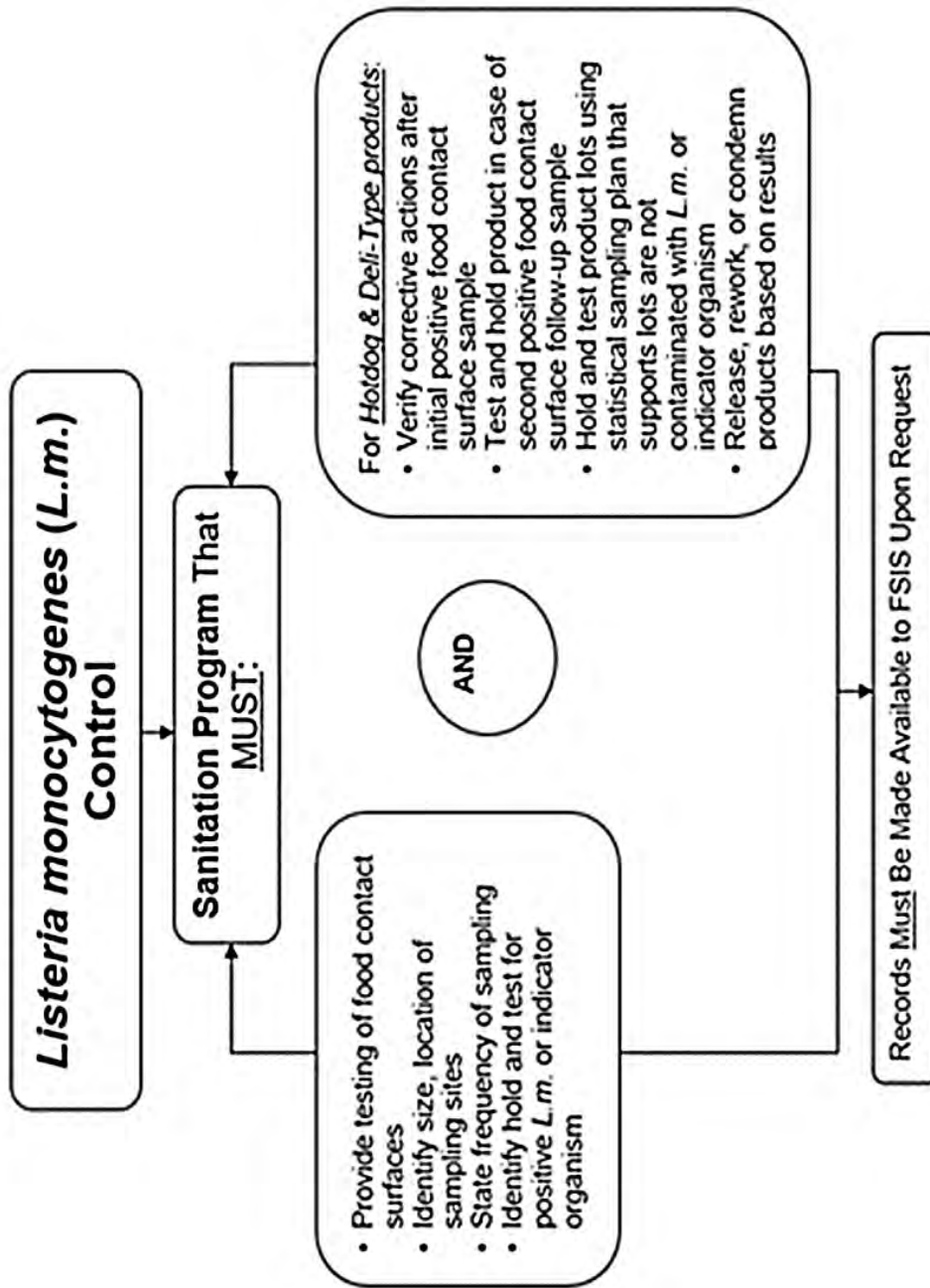
Alternative 1



Alternative 2



Alternative 3



29 SAMPLING READY-TO-EAT (RTE) PRODUCT

Objectives:

1. Identify the pathogens of concern associated with sampling of ready-to-eat (RTE) product.
2. Describe the conditions for RTE product to be considered adulterated.
3. Define the following terms:
 - a. Final package
 - b. Sampled lot
4. Describe the steps for performing a PRODRTE sampling task.
5. Explain what IPP should consider when scheduling RTE samples.
6. Describe why it is important to notify establishment management prior taking a sample.
7. Explain how FSIS samples are documented.
8. Describe the process for ensuring sample integrity, from sample collection until sample is shipped.
9. List the items that are packed into the sample container.
10. Identify how IPP obtain sample results.
11. Describe what actions IPP take when a positive FSIS RTE sample result is identified.
12. Describe the actions IPP take when establishment testing obtains a positive sample result.
13. Explain the procedures in verifying corrective actions for a positive RTE sample.
14. Identify the two sampling programs that EIAOs may perform in RTE establishments.

FSIS's microbiological testing program, RTEPROD, is designed to **verify that the establishment's food safety system is effective**, and that FSIS performance standards and regulations are met. FSIS tests RTE products for pathogens because of the potential public health impact of a breakdown in the establishment's food safety system.

The pathogens of public health concern are *Listeria monocytogenes* (*Lm*) and *Salmonella*.

- *Salmonella* usually indicates a breakdown in lethality step
- *Lm* usually indicates post-lethality contamination

RTE product is adulterated if it:

- Contains *Lm*, *Salmonella*, or any pathogen known to cause illness including *E. coli* O157:H7
- Comes into contact with a food contact surface positive for *Lm* or *Salmonella* after lethality

Final package is the packaging that is normally shipped by the establishment into commerce.

Sampled lot is the amount of product represented by the sample. The establishment is responsible for defining the sampled lot.

All RTE meat and poultry products are subject to RTEPROD including post lethality and non-post lethality exposed product.

Products that are ineligible for RTEPROD sampling include:

- Pass through product
- Oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats.
- Product labeled “For Further Processing”

There are 6 general steps in sampling RTE product:

1. Determine which product to sample and schedule the sample
2. Notify establishment management
3. Collect the sample
4. Document the sample
5. Pack and ship the sample and form
6. Respond to the results

Before collecting a sample, IPP are to officially notify the establishment management that they will be collecting a sample and explain the reason they are collecting the sample.

IPP will collect the sample from the current day’s production after the establishment has applied all interventions except any microbiological testing intervention. If the establishment intends to test the product for *Lm* or *Salmonella*, IPP are not to wait for the establishment to receive the test results.

IPP are to collect a **one- pound** sample of product in an intact package.

On the day of sample collection, IPP will enter sample collection data and additional product info in PHIS as directed in PHIS Directive 13,000.2. IPP are to complete a questionnaire in PHIS for each RTEPROD sample request and are to ensure that all requested information is entered completely and accurately.

IPP are to safeguard the integrity of samples during submission according to FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications.

Pack the sample in this order:

1. Absorbent pad
2. Gel pack
3. Cardboard separator
4. Zip-lock bag containing the identified sample and paperwork
5. Extra small bar code sticker that was not used
6. Foam plug
7. Close shipper with Container Seal (7355-2A)

If any RTE product sample collected by IPP under the RTEPROD sampling project tests positive for *Lm* or *Salmonella*, product in the sampled lot is adulterated. IPP are to follow the instructions in FSIS PHIS Directive 5000.1 when taking enforcement actions in response to positive sampling results.

If the sample is positive for non-*Lm* *Listeria* spp. but negative for *Lm*, IPP are to be aware that establishments must take corrective actions per 9 CFR 416.15.

If FSIS finds a product or food contact surface positive for *Lm* or *Salmonella*, IPP are to verify that the establishment takes the appropriate corrective actions by performing a directed HACCP Verification Task.

- When performing a directed HACCP Verification Task in response to a *Lm* positive result, IPP are to review the same information they review during a routine HACCP Verification Task. IPP are also to verify that the establishment implemented corrective actions according to 9 CFR 417.3 (a) and (b) if the measures for addressing *Lm* are included in the HACCP plan or prerequisite program, or 9 CFR 416.15 if the measures are incorporated in the Sanitation SOP. FSIS will also perform an IVT/FSA for *Lm*, as described in FSIS Directive 10,300.1.
- When performing a directed HACCP Verification Task in response to a *Salmonella* positive result, IPP are to verify that the establishment took the appropriate corrective actions according to 9 CFR 417.3(a) or (b), or 9 CFR 416.15.

EIAOs trained in the IVT methodology collect samples under the Intensified Verification Testing (IVT) program which involves collecting product, food contact, and environmental (non-food contact) samples. This sampling is typically done “for cause” (e.g., positive sample results).

EIAOs trained in the IVT methodology also collect samples under the Routine Risk-based *Lm* (RL*m*) sampling program when conducting routine FSAs in establishments that produce RTE products.

NOTE: When evaluating sampling results, IPP should be aware that repeated positive results from either FSIS or establishment testing can:

- Indicate a trend, even if a noncompliance has not been documented
- Indicate that an establishment is not effectively preventing insanitary conditions or direct contamination or adulteration of product
- Indicate systemic problems with an establishment’s food safety system

Trends indicating systemic problems, such as positive sampling results, may not involve any NRs. If positive sample results indicate systemic problems around an establishment, or if they are associated with a noncompliance or other findings, IPP should record the association in an inspection note in PHIS and contact their supervisor.

IPP should discuss their findings during the next weekly meeting and describe to establishment management the trends or systemic problems found. IPP are to document this meeting on an MOI.

References:

https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/10240.4.pdf

https://www.fsis.usda.gov/sites/default/files/media_file/2022-03/10240.3.pdf

Other Tasks

30 EXPORT CERTIFICATION

Objectives:

1. Describe how to perform the Inspection Verification.
2. Describe where to locate current export requirements.
3. List the reasons why a Certifying Official would not sign an export certificate.
4. List the reasons when a replacement export certificate can be issued.
5. Describe when to write a Memorandum of Interview related to export certification.
6. Who administers the Export Verification, Quality System Assessment Program (EV/QSA)?
7. How to navigate through PHIS Electronic Export module.

For phase six through eight countries (see future Notices also), IPP are to print the approved export certificates on standard white copy paper (8.5" x 11") from the View Export Records (9060) grid, but only for establishments that do not have functional printers or PHIS access, as indicated in Section VI below. All other establishments will print the approved export certificates on standard white copy paper (8.5" x 11") from the Create/View 9060-6 Export Applications (9060) grid in PHIS, as indicated in Section III below. IPP are not to print from PHIS on FSIS security paper (item number ECP-11) except for countries that require it as documented in the **Export Library**.

The certifying official (CO), any FSIS official who signs the completed export certificate (9060-5), verifies the information on the export certificate comparing to the information on the signed export application (9060-6) and the country requirements in the FSIS Export Library. The CO may not be directly associated with the production or inspection of exported product. IPP perform a physical check of containers, labels, and product. If after checking the Export Library and the product you believe that products listed on the application are not eligible for export to the country listed on the application, first discuss your concerns with the exporter. Then, write a memorandum of interview (MOI) detailing your discussions and whether your concerns were addressed adequately. Give a copy of the completed MOI to the exporter and file a copy in the inspection file.

Means of stamping

The USDA export stamp is an accountable item that must be held under control. The stamp is applied to the container. Establishments may also use computer-generated stickers. Stickers must be the exact size and impression as the export stamp, must be printed with authorization, must be based on assigned export number, and the establishment must identify number of stickers produced prior to applying. They must give all unused stickers to the inspector upon completion. Establishments may also perform direct inkjet printing of the export mark to the carton or container. You are to verify that the inkjet mark is equal in size and an exact

impression of the FSIS rubber export stamp. They should also not be printed on the cartons or containers until authorized by you, should only be applied in the quantity needed for application to the consignment, and the establishment should notify you in advance of the quantity of cartons or containers to be printed. Applying the export mark to the cartons or to the containers should be done under the supervision of a designated plant employee.

A unique identifier (UI) is an alternate export mark that may be used for export consignments instead of using the standard USDA export mark that contains the export certificate number. The UI may be any combination of numbers or letters. IPP are not to certify export consignments marked with a UI unless the importing country allows containers to be marked with a UI. The applicant should link the UI to the corresponding export certificate by including the following statement in the remarks section of the export certificate or on FSIS Form 9060-5B (remarks continuation page); "The products covered by this certificate are marked with the Unique Identifier X#X#X#X#X#XX#X#."

Pre-stamping

Under some conditions, establishments can pre-stamp the product. Pre-stamping occurs when the establishment stamps the boxes and completes the export certificate when you are not present.

FSIS Form 9060-5 (Export Certificate of Wholesomeness) are accountable items and should be maintained secured. Keep a record of the issued and voided certificate numbers at the establishment. When completed, the CO reviews the certificate. The country requirements show if the importing country needs additional certificates, which are usually hyperlinked in the Export Library.

Before signing the certificate, the CO should check the certificate for corrections, check for attachments and ensure that the exporting firm has lined-out any unused space. If you have questions about the information on the application, the export certificate, or other supplemental documents, do not to sign the certificate until you seek clarification. If you still have concerns about signing the export certificate after reviewing the completed export documents and performing product re-inspection or export verification activities, discuss the concerns with establishment management. Document the discussion with establishment management in an MOI and identify any of their concerns that cannot be resolved. Provide a copy of the MOI to establishment management and retain a copy for the government file. Document any regulatory noncompliances by issuing an NR, notify the supervisor of your concerns, and describe the establishment's plan to address the concerns. Do not sign the export certificate.

A replacement certificate is to be issued for one of the following reasons:

- Original certificate did not contain required information.
- Original certificate contained incorrect information, importer, exporter, consignee, or consignor has changed, but is within the same country that appears on the certificate.

If the certificate is lost, IPP are not to issue a replacement certificate unless the exporter provides a letter of assurance to the CO stating the certificate will be returned if found. The replacement certificate only restates the information contained on the original certificate or if the country of destination has changed. The exporter may split or consolidate a shipment with stamped pallet or conveyance. The Remarks section for a replacement certificate must contain

the statement as follows: "This certificate replaces certificate number (insert original certificate number(s) dated (insert date(s) of the original certificate(s)). The export mark covered by the certificate shows certificate number (insert original certificate number)."

Not all countries require establishments to submit a 9080-3 to be listed as eligible. It is the applicant's responsibility to find out if it is required by the importing country, fill out the application, and submit it to inspection personnel, including attaching any required supplemental documentation.

All 9080-3s must be submitted in PHIS. This is, whether or not the applicant currently has access to PHIS industry component or not. It is for every country that requires this form to list eligible establishments in the Export Library, not just those active in PHIS.

If the applicant does not have access, the applicant will submit a paper application to the FSIS Proxy and the Proxy will enter it into PHIS.

In PHIS, the application will be routed for approval in administrative order, and when the 9080-3 application is approved, the establishment will be included in the eligible establishments list in the Export Library.

The 3 levels of approval are The Inspector-In-Charge (IIC), Public Health Veterinarian (PHV) or Consumer Safety Inspector (CSI), the Frontline Supervisor (FLS), and District Manager (DM), or designee, and they are to use the instructions to review and either approve or reject the 9080-3 once it has been submitted in PHIS by establishment management.

If IPP find that all foreign country requirements have not been met or that the species/product/product category is not eligible for export to the foreign country, IPP are to reject the "Establishment Application for Export" (9080-3).

Export Verification/Quality System Acceptance (EV/QSA)

Establishments which want to participate in this program must first contact the Agricultural Marketing Service (AMS), who approves by auditing and notifies FSIS Office Program and Policy Development (OPPD) and Import/Export Policy Development Staff (IEPDS), then notifies the appropriate DO. You will need to check the country requirements in the Export Library to verify the receiving country participates in EV/QSA. IPP check that the product codes are approved for export and if the country requires a Statement of Verification (SOV) for the exported product. IPP also check that the applicant supplied a copy of the SOV with the completed export application, completed additional certificates, and completed export certification when presenting for IPP signature. In addition, IPP check if supporting documents such as lab sampling results are available, although not all countries will require all these steps. The exporting facility must obtain the SOV confirming that the EV/QSA program met the country requirements and that the products are eligible for export before the FSIS certifying official signs the completed export certificate. Establishments that need to obtain an SOV for export must contact AMS directly. If there is improper execution of the EV/QSA, notify AMS with the following information: establishment name, address, product type, product code, quantity of product, date of production, lot number, shift produced, date and nature of observation, name of country for which product is intended, export certificate number, any other information to verify claim, and name of IPP documenting concerns. If any of the problems with the EV/QSA

requirements are also regulatory non-compliances, take the appropriate enforcement actions and issue an NR.

Reimbursable export activities include familiarizing with requirements in the Export Library, conducting and documenting inspection or certification activities required by an EV/QSA program, conducting, and documenting any other additional inspection or certification activities, reviewing foreign country label requirements and certifications requiring a PHV signature, and approval and issuance of all replacement export certificates.

Export activities are recorded in PHIS. Each day IPP issue an export certificate at an official establishment, they are to schedule and document **one** domestic Export Certification task in PHIS. Regardless of the number of export certificates issued or the number of IPP that issue certificates on a given day, IPP are only to record the task as performed **once each day, per shift** and not for each inspector or export certificate they issue. If performing export certification activities in PHIS, each export application will appear as a separate task.

References:

FSIS Export Library - <https://www.fsis.usda.gov/inspection/import-export/import-export-library>

Directive 9000.1 – Export Certification

Directive 12,600.1 – Voluntary and Other Reimbursable Inspection Services Directive 13,000.5 – Public Health Information System Export Certification

Notice 09-23 – Seven-Digit Export Stamp, Enhanced Digital Signature, Plain Paper Printing, and Statements Module for Use With the Export Module of the Public Health Information System - Phase Eight

31 FOOD DEFENSE

Objectives

1. Explain the risk that intentional contamination presents to FSIS-regulated products.
2. Define the following terms:
 - a. Food safety
 - b. Food defense
 - c. Food defense practices
 - d. Supply chain
 - e. Food defense vulnerability
3. List the characteristics of a functional food defense plan.
4. Recognize examples of vulnerabilities and associated food defense practices.
5. Describe the purpose of the food defense task.
6. Identify measures an establishment can take to protect their product from intentional contamination.
7. Explain how inspectors are to perform the Food Defense task and document food defense vulnerabilities in the Public Health Information System (PHIS).

Food Defense Terminology

Food Defense – The protection of food products from intentional contamination or adulteration intended to cause public health harm or economic disruption. Food Defense is an integral part of FSIS's mission in protecting public health. The mission of the FSIS Food Defense Program is to protect the U.S. food supply from dynamic and evolving threats.

Food Security – Ensuring all people at all times have both physical and economic access to enough food for an active, healthy life. Food security includes both physical and economic access to food that meets people's dietary needs and food preferences.

Therefore, the concept of food security certainly includes but encompasses much more than the idea of food defense.

Food Safety – Guarding against unintentional contamination of food. HACCP plans and Sanitation SOPs, which are developed based on what can be predicted to happen if we do not put safety measures at critical points, are used to guard against unintentional contamination.

Food Defense Practices – Policies, procedures, or countermeasures to mitigate vulnerability to intentional contamination.

Critical Infrastructure – Defined in the Patriot Act of 2001 as systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters. The Food and Agriculture Sector is one of 16 critical infrastructures identified by the Patriot Act.

Supply Chain – Continuous process, including every step involved in food production and food reaching the consumer; often referred to as “farm-to-table” or “farm-to-fork.”

Food Defense Vulnerabilities And Food Defense Practices

A **vulnerability** can be any part of the food production or storage system where a protective measure should be implemented to protect a product from intentional adulteration, but such a measure is found to be missing or not in place.

Food defense vulnerabilities are weaknesses within the food production process that make it easy to intentionally contaminate product.

An establishment can put **food defense practices** (also called mitigation strategies) into place to reduce the likelihood that intentional contamination will occur. **Food defense is not a one-size-fits-all approach!** Food defense practices that are implemented to protect products within a large establishment may not be effective or may not be necessary in a small or very small establishment. This should be considered when inspection program personnel (IPP) conduct their food defense activities.

Food Defense In FSIS-Regulated Establishments

Food defense is **voluntary** for FSIS-regulated establishments.

A **functional food defense plan** is an approach to identify and mitigate vulnerabilities; it can help an establishment prevent, protect against, respond to, and recover from an intentional contamination incident. A food defense plan is functional when it meets all four of the following criteria:

1. Developed – The plan is documented and signed.
2. Implemented – Food defense practices identified in the plan are actually implemented.
3. Tested – Food defense measures are monitored and validated to ensure they are working.
4. Reviewed and maintained – The plan is reviewed at least annually and revised as needed.

Note: An establishment must be *implementing* the elements of its food defense plan in order for FSIS to consider it “functional.”

IPP are responsible for maintaining the functional food defense plan status for an establishment in the Establishment Profile in PHIS. This status should be updated per the frequency identified in Directive 5300.1, Managing the Establishment Profile in the Public Health Information System, or when IPP become aware of a change in the establishment’s functional food defense plan status.

National Terrorism Advisory System

The National Terrorism Advisory System (NTAS) is a system managed by the Department of Homeland Security (DHS) to communicate information about terrorist threats by providing information to the American public.

Performing Food Defense Tasks In PHIS

IPP in meat and poultry establishments are to perform the Food Defense task as assigned in PHIS. PHIS will automatically generate one routine Food Defense task per quarter to the establishment Task List. This task has a priority 3 in the establishment Task List, including a start/end date window of three months. Only one questionnaire is to be completed per establishment. The task is to only be performed on one shift in multi-shift establishments. The supervisor should determine which shift performs the task. The shift that does not complete the task should mark the task as not performed with a justification of ‘Task assigned to another inspector.’

IPP perform the Food Defense task to identify vulnerabilities within establishments that may lead to intentional contamination of FSIS-regulated products.

In the case of a NTAS alert identifying an elevated or imminent threat to food or agriculture, the inspector-in-charge (IIC) will receive specific instructions through supervisory channels on other measures to take.

Summary

Defending the food supply against intentional contamination is a critical function. IPP, both in and outside of establishments, serve as the Agency’s eyes and ears to help identify vulnerabilities that may lead to intentional contamination. IPP are responsible for three activities related to food defense:

1. Updating the functional food defense plan status in the PHIS establishment profile and ensuring it is accurate;
2. Performing food defense tasks;
3. Submitting a food defense MOI when food defense vulnerability is observed and discuss with establishment management.

Implementation of Food Defense tasks serves to protect the public, which is essential to our mission, and ensures the security of our food, a vital component of homeland security.

Report any suspicious activities in establishments to your District Manager through supervisory channels or call the FSIS 24-hour emergency hotline at 1-866-395-9701.

32 NON-FOOD SAFETY CONSUMER PROTECTION (NFSCP)

Objectives:

1. Identify the statutes, regulations and primary directives that relate to non-food safety consumer protection responsibilities.
2. Explain what to do when noncompliance is observed with the Non-Food Safety Consumer Protection Tasks.
3. Explain the regulatory requirements for products that are subject to standards of identity.
4. Explain the purpose of the Non-Food Safety Consumer Protection Tasks.

The Non-Food Safety Consumer Protection (NFSCP) requirements are verified by **Other Consumer Protection** tasks to determine that establishments are complying with regulatory requirements designed to protect the consumer in ways other than ensuring food safety, such as **economic adulteration** and **misbranding**.

Statutes

Let's start by reviewing the statutes in the Federal Meat Inspection Act (FMIA) related to NFSCP requirements. The term "misbranded" is defined in 21 U.S.C. 601(n) of the FMIA. There are twelve parts to this definition. Misbranded is defined in the FMIA as a meat product that:

- Part (1) has labeling which is false or misleading.
- Part (2) is offered for sale under the name of another food.
- Part (3) is an imitation of another food.
- Part (4) has a container that is misleading.
- Part (5) has a label that fails to show the name and place of business that produced the product or fails to contain an accurate statement of the quantity of the contents of the meat product.
- Part (6) contains a label that is missing required information.
- Part (7) has a label that purports that it was produced in a manner that follows a standard of identity, but the product does not conform to those standards.
- Part (8) does the amount of product in the container fall below the fill standard.
- Part (9) contains ingredients that are not represented on the label by common names of the food.
- Part (10) makes special dietary claims but does not list the corresponding dietary properties and information required on the label.
- Part (11) contains artificial flavoring, coloring, or chemical preservatives that are not listed on the label.
- Part (12) requires some type of handling for a wholesome condition to be maintained but the label fails to contain that information.

The terms “label” and “labeling” are also defined in the FMIA as follows.

- FMIA 601(o) – The term “label” means a display of written, printed, or graphic matter upon the immediate container of any article.
- FMIA 601(p) – The term “labeling” means all labels and other written, printed, or graphic matter upon any article or any of its containers or wrappers or accompanying such article.

Section 607 of the FMIA covers labeling, marking, and container requirements. Section 607(e) states that when there is reason to believe the marking or labeling or container is false or misleading, FSIS has the authority to withhold its use until it is modified so that it is no longer false or misleading.

There are similar provisions in the poultry statutes. The Poultry Products Inspection Act (PPIA) 453 (h) contains similar definitions of “misbranded” and 457 contains labeling and container standards.

Labeling & Standards of Identity

There are certain general labeling requirements that apply to all product that bear a label. Some of these basic requirements include:

- The label must list the name of the product and ingredients.
- The ingredients statement should be accurate (i.e., that all ingredients are listed in descending order of predominance and any proteinaceous substances used in the formulation are declared in the ingredients statement).
- The name and place of business of the manufacturer must be shown.
- It must contain an accurate statement of the net weight or quantity.
- The label must not be false or misleading.
- It must list any handling (refrigeration) of the product that is required in order to maintain the product in a wholesome condition.
- There are also very specific requirements for safe handling instructions for raw or not ready-to-eat meat and meat products.
- Restricted ingredients (if any) are used as per regulatory requirements.
- The label is used on appropriate product.
- There is a label approval on file.

The term **Standard of Identity**, however, refers to certain regulatory requirements that must be met in order to label specific types of products. These regulations dictate that products for which standards of identity exist must have a label showing the product name and ingredients statement and any other information as listed in the standard of identity regulations.

The 9 CFR 319.15-319.881 (Subparts B through U) cover the specific requirements for various meat products – from raw products that have only a few ingredients, to products such as cooked sausage that may have a number of ingredients and may go through numerous processing steps.

Here's an outline of all the regulations covering the definitions and standards of identity or composition (Part 319) for meat products:

- Subpart A – General
- Subpart B – Raw meat products
- Subpart C – Cooked meats
- Subpart D – Cured meat, unsmoked and smoked
- Subpart E – Sausage generally: fresh sausage
- Subpart F – Uncooked, smoked sausage
- Subpart G – Cooked sausage
- Subpart K – Luncheon meat, loaves, jellied products
- Subpart L – Meat specialties, puddings, nonspecific loaves
- Subpart M – Canned, frozen, dehydrated meat food products
- Subpart N – Meat food entrée products, pies, and turnovers
- Subpart O – Meat snacks, hors d'oeuvres, pizza, and specialty items
- Subpart P – Fats, oils, shortenings
- Subpart Q – Meat soups, soup mixes, broths, stocks, extracts
- Subpart R – Meat salads and meat spreads
- Subpart U – Miscellaneous (breaded and liver meat products)

9 CFR 381 Subpart P covers the labeling requirements for poultry products that have standards of identity. 9 CFR 381.156 covers the requirements for using terms such as light or dark meat on a label containing poultry products. Like the regulations related to meat products, these regulations covering poultry products specify percent of poultry light/dark meat required for the product to meet the standard, and in some cases the type of ingredients required/allowed, such as binders or extenders.

Here are the 9 CFR §381 Subpart P regulations covering the standards of identity for poultry products:

- 381.155 – General
- 381.156 – Poultry meat content standards for certain poultry products
- 381.157 – Canned boned poultry and baby or geriatric food
- 381.158 – Poultry dinners (frozen) and pies
- 381.159 – Poultry rolls
- 381.160 – (Kind) burgers; (Kind) patties
- 381.161 – “(Kind) A La Kiev”
- 381.162 – “(Kind) steak or fillet”
- 381.163 – “(Kind) baked” or “(Kind) roasted”
- 381.164 – “(Kind) barbecued”
- 381.165 – “(Kind) barbecued prepared with moist heat
- 381.166 – Breaded products
- 381.167 – Other poultry dishes and specialty items
- 381.168 – Maximum percent of skin in certain poultry products
- 381.169 – Ready-to-cook poultry products to which solutions are added
- 381.170 – Standards for kind and classes, and for cuts of raw poultry
- 381.171 – Definitions and standards for “Turkey Ham”
- 381.173 – Mechanically Separated (Kind of Poultry)
- 381.174 – Limitations with respect to use of Mechanically Separated (Kind of Poultry)

Verification Methodology for Non-Food Safety Tasks

FSIS Directive 7000.1 provides general instructions for how IPP are to perform specific verification tasks related to non-food safety requirements. The PHIS system will assign other consumer protection tasks to establishment task lists based on the product information recorded in the establishment profile. As with other tasks, IPP are to schedule the tasks on the dates most appropriate for performing the particular verification task.

The NFSCP Tasks include the Economic/Labeling Tasks, Labeling Tasks, Livestock Finished Product Standards Task, Poultry Finished Product Standards Task, Economic Sampling Task, and Species Specific Sampling Tasks. IPP will perform the appropriate verification procedures by:

- Observing establishment product formulation;
- Verifying the accuracy of labeling;
- Observing processing procedures;
- Reviewing establishment records;
- Examining product;
- Checking product identification, condition, and temperature;
- Performing a variety of other in-plant measurements, testing and calculations; or
- Observing slaughter practices.

Product compliance determinations are made based on non-food safety regulatory requirements, including product standards, net weight standards, regulatory minimum or maximum limits of ingredients or components, or product defects. If product is found to exceed any of the maximum limits, falls below the minimum requirements, or fails to meet any of the other regulatory requirements, there is noncompliance. As mentioned before, determinations of noncompliance should be based on production lots or process controls rather than on individual units of product.

When noncompliance is found, take the appropriate regulatory control actions, such as retention of product, rejection of equipment or facilities, stopping lines, or refusing to allow the processing of specifically identified product (9 CFR 500.1(a)) if it is determined that misbranded or economically adulterated product would otherwise enter commerce or be shipped from the establishment. Additionally, FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes, or forms of any container for use with any meat or poultry product per 9 CFR 500.8. If it is determined that economically adulterated or misbranded product has entered commerce, FSIS will expect establishments to implement recall procedures.

Supplemental Content

REGULATIONS

Up to date as of 3/29/2024

This content is from the eCFR and is authoritative but unofficial.

Title 9 —Animals and Animal Products

Chapter III —Food Safety and Inspection Service, Department of Agriculture

Subchapter E —Regulatory Requirements Under the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act

PART 500 RULES OF PRACTICE

§ 500.1 Definitions.

§ 500.2 Regulatory control action.

§ 500.3 Withholding action or suspension without prior notification.

§ 500.4 Withholding action or suspension with prior notification.

§ 500.5 Notification, appeals, and actions held in abeyance.

§ 500.6 Withdrawal of inspection.

§ 500.7 Refusal to grant inspection.

§ 500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.

§ 500.9 Procedures for the filing of appeals.

§ 500.1 Definitions.

- (a) A “**regulatory control action**” is the retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.
- (b) A “**withholding action**” is the refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.
- (c) A “**suspension**” is an interruption in the assignment of program employees to all or part of an establishment; and
- (d) An establishment subject to Federal inspection or facility receiving voluntary inspection services under the regulations is “adversely affected” when that person has a legally cognizable interest, and the decision or action has caused or is substantially likely to cause injury to that interest.

§ 500.2 Regulatory control action.

- (a) FSIS may take a regulatory control action because of:
 - (1) Insanitary conditions or practices;
 - (2) Product adulteration or misbranding;
 - (3) Conditions that preclude FSIS from determining that product is not adulterated or misbranded; or
 - (4) Inhumane handling or slaughtering of livestock.
- (b) If a regulatory control action is taken, the program employee will immediately notify the establishment orally or in writing of the action and the basis for the action.
- (c) An establishment may appeal a regulatory control action, as provided in §§ 306.5, 381.35, and 590.310 of this chapter.

§ 500.3 Withholding action or suspension without prior notification.

- (a) FSIS may take a withholding action or impose a suspension without providing the establishment prior notification because:
 - (1) The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453, 21 U.S.C. 602, or 21 U.S.C. 1033;
 - (2) The establishment does not have a HACCP plan as specified in § 417.2 of this chapter;
 - (3) The establishment does not have Sanitation Standard Operating Procedures as specified in §§ 416.11-416.12 of this chapter;
 - (4) Sanitary conditions are such that products in the establishment are or would be rendered adulterated;
 - (5) The establishment violated the terms of a regulatory control action;
 - (6) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS employee; or
 - (7) The establishment did not destroy a condemned meat or poultry carcass, or part or product thereof, or egg product, that has been found to be adulterated and that has not been reprocessed, in accordance with part 314 or part 381, subpart L, or part 590 of this chapter within three days of notification.
- (b) FSIS also may impose a suspension without providing the establishment prior notification because the establishment is handling or slaughtering animals inhumanely.

§ 500.4 Withholding action or suspension with prior notification.

FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because:

- (a) The HACCP system is inadequate, as specified in § 417.6 of this chapter, due to multiple or recurring noncompliances;
- (b) The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§ 416.13 through 416.16 of this chapter;
- (c) The establishment has not maintained sanitary conditions as prescribed in §§ 416.2-416.8 of this chapter due to multiple or recurring noncompliances;
- (d) The establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results in accordance with § 310.25(a) or § 381.94(a) of this chapter;
- (e) The establishment did not meet the *Salmonella* performance standard requirements prescribed in § 310.25(b) or § 381.94(b) of this chapter.

§ 500.5 Notification, appeals, and actions held in abeyance.

- (a) If FSIS takes a withholding action or imposes a suspension, the establishment will be notified orally and, as promptly as circumstances permit, in writing. The written notification will:
 - (1) State the effective date of the action(s),
 - (2) Describe the reasons for the action(s),
 - (3) Identify the products or processes affected by the action(s),
 - (4) Provide the establishment an opportunity to present immediate and corrective action and further planned preventive action; and
 - (5) Advise the establishment that it may appeal the action as provided in §§ 306.5, 381.35, and 590.310 of this chapter.
- (b) The prior notification provided for in § 500.4 of this part will:
 - (1) State the type of action that FSIS may take;
 - (2) Describe the reason for the proposed action;
 - (3) Identify the products or processes affected by the proposed action;
 - (4) Advise the establishment of its right to contact FSIS to contest the basis for the proposed action or to explain how compliance has been or will be achieved; and
 - (5) Advise the establishment that it will have three business days from receipt of the written notification to respond to FSIS unless the time period is extended by FSIS.
- (c) An establishment may appeal the withholding action or suspension, as provided in §§ 306.5, 381.35, and 590.310 of this chapter.

- (d) If FSIS suspends inspection and does not hold the suspension action in abeyance as provided in paragraph (e) of this section, the establishment may request a hearing pursuant to the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H. Upon such request, the Administrator will file a complaint that will include a request for an expedited hearing.
- (e) FSIS may hold a suspension in abeyance and allow the establishment to operate under the conditions agreed to by FSIS and the establishment.

§ 500.6 Withdrawal of inspection.

- (a) The FSIS Administrator may file a complaint to withdraw a grant of Federal inspection in accordance with the Uniform Rules of Practice, 7 CFR subtitle A, part 1, subpart H because:
 - (1) An establishment produced and shipped adulterated product;
 - (2) An establishment did not have or maintain a HACCP plan in accordance with part 417 of this chapter;
 - (3) An establishment did not have or maintain Sanitation Standard Operating Procedures in accordance with part 416 of this chapter;
 - (4) An establishment did not maintain sanitary conditions;
 - (5) An establishment did not collect and analyze samples for *Escherichia coli* Biotype I and record results as prescribed in § 310.25(a) or § 381.94(a) of this chapter;
 - (6) [Reserved]
 - (7) An establishment did not slaughter or handle livestock humanely;
 - (8) An establishment operator, officer, employee, or agent assaulted, threatened to assault, intimidated, or interfered with an FSIS program employee; or
 - (9) A recipient of inspection or anyone responsibly connected to the recipient is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA, section 18(a) of the PPIA, or section 18 of the EPIA.
- (b) [Reserved]

§ 500.7 Refusal to grant inspection.

- (a) The FSIS Administrator may refuse to grant Federal inspection because an applicant:
 - (1) Does not have a HACCP plan as required by part 417 of this chapter;
 - (2) Does not have Sanitation Standard Operating Procedures as required by part 416 of this chapter;
 - (3) Has not demonstrated that adequate sanitary conditions exist in the establishment as required by part 308, subpart H of part 381, part 416, or part 590 of this chapter;
 - (4) Has not demonstrated that livestock will be handled and slaughtered humanely; or
 - (5) Is unfit to engage in any business requiring inspection as specified in section 401 of the FMIA or section 18(a) of the PPIA.
- (b) If the Administrator refuses to grant inspection, the applicant will be provided the opportunity for a hearing in accordance with the Uniform Rules of Practice, 7 CFR Subtitle A, part 1, subpart H.

§ 500.8 Procedures for rescinding or refusing approval of marks, labels, and containers.

- (a) FSIS may rescind or refuse approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat, poultry, or egg product, under section 7 of the FMIA, under section 8 of the PPIA, or under sections 7 or 14 of the EPIA.
- (b) FSIS will provide written notification that:
 - (1) Explains the reason for rescinding or refusing the approval;
 - (2) Provides an opportunity for the establishment to modify the marking, labeling, or container so that it will no longer be false or misleading; and
 - (3) Advises the establishment of its opportunity to submit a written statement to respond to the notification and to request a hearing.
- (c) If FSIS rescinds or refuses approval of false or misleading marks, labels, or sizes or forms of any container for use with any meat, poultry, or egg product, an opportunity for a hearing will be provided in accordance with the Uniform Rules of Practice, 7 CFR subtitle A, part 1, subpart H.

§ 500.9 Procedures for the filing of appeals.

- (a) Any establishment subject to Federal inspection or facility under voluntary inspection and adversely affected by a decision or action of an inspector or other Agency employee related to an inspection activity mandated under the FMIA, PPIA, or EPIA or related to voluntary reimbursable inspection services allowed under the AMA may appeal the decision or action. Initial appeals of an applicable decision or action, as well as subsequent appeals of denied appeals through final Agency action, must be made within 30 calendar days after receipt of written notification of the contested decision or action. Appeals may be supported by any argument or evidence that the appellant may wish to offer as to why the contested decision or action should be reconsidered.
- (b) Any initial appeal of a decision or action of an inspector or other Agency employee must be made to his/her immediate supervisor having jurisdiction over the subject matter of the appeal.

PART 416 SANITATION

- § 416.1 General rules.
- § 416.2 Establishment grounds and facilities.
- § 416.3 Equipment and utensils.
- § 416.4 Sanitary operations.
- § 416.5 Employee hygiene.
- § 416.6 Tagging insanitary equipment, utensils, rooms, or compartments.
- § 416.11 General rules.
- § 416.12 Development of Sanitation SOP's.
- § 416.13 Implementation of SOP's.
- § 416.14 Maintenance of Sanitation SOP's.
- § 416.15 Corrective Actions.
- § 416.16 Recordkeeping requirements.
- § 416.17 Agency verification.

§ 416.1 General rules.

Each official establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions and to ensure that product is not adulterated.

§ 416.2 Establishment grounds and facilities.

- (a) **Grounds and pest control.** The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.
- (b) **Construction.**
 - (1) Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

- (2) Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.
 - (3) Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.
 - (4) Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.
- (c) **Light.** Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained, and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in hand-washing areas, dressing and locker rooms, and toilets.
- (d) **Ventilation.** Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.
- (e) **Plumbing.** Plumbing systems must be installed and maintained to:
 - (1) Carry sufficient quantities of water to required locations throughout the establishment;
 - (2) Properly convey sewage and liquid disposable waste from the establishment;
 - (3) Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment;
 - (4) Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor;
 - (5) Prevent back-flow conditions in and cross-connection between piping systems that discharge wastewater or sewage and piping systems that carry water for product manufacturing; and
 - (6) Prevent the backup of sewer gases.
- (f) **Sewage disposal.** Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.
- (g) **Water supply and water, ice, and solution reuse.**
 - (1) A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.
 - (2) Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.
 - (3) Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that which has come into contact with raw product may not be used on ready-to-eat product.

- (4) Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.
- (5) Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.
- (6) Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.
- (h) ***Dressing rooms, lavatories, and toilets.***
 - (1) Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.
 - (2) Lavatories with running hot and cold water, soap, and towels, must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.
 - (3) Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

§ 416.3 Equipment and utensils.

- (a) Equipment and utensils used for processing or otherwise handling edible product or ingredients must be of such material and construction to facilitate thorough cleaning and to ensure that their use will not cause the adulteration of product during processing, handling, or storage. Equipment and utensils must be maintained in sanitary condition so as not to adulterate product.
- (b) Equipment and utensils must not be constructed, located, or operated in a manner that prevents FSIS inspection program employees from inspecting the equipment or utensils to determine whether they are in sanitary condition.
- (c) Receptacles used for storing inedible material must be of such material and construction that their use will not result in the adulteration of any edible product or in the creation of insanitary conditions. Such receptacles must not be used for storing any edible product and must bear conspicuous and distinctive marking to identify permitted uses.

§ 416.4 Sanitary operations.

- (a) All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned, and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.
- (b) Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.
- (c) Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions. Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.
- (d) Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

§ 416.5 Employee hygiene.

- (a) *Cleanliness.* All persons working in contact with product, food-contact surfaces, and product-packaging materials must adhere to hygienic practices while on duty to prevent adulteration of product and the creation of insanitary conditions.
- (b) *Clothing.* Aprons, frocks, and other outer clothing worn by persons who handle product must be of material that is disposable or readily cleaned. Clean garments must be worn at the start of each working day and garments must be changed during the day as often as necessary to prevent adulteration of product and the creation of insanitary conditions.
- (c) *Disease control.* Any person who has or appears to have an infectious disease, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, must be excluded from any operations which could result in product adulteration and the creation of insanitary conditions until the condition is corrected.

§ 416.6 Tagging insanitary equipment, utensils, rooms, or compartments.

When an FSIS program employee finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he will attach to it a "U.S. Rejected" tag. Equipment, utensils, rooms, or compartments so tagged cannot be used until made acceptable. Only an FSIS program employee may remove a "U.S. Rejected" tag.

§ 416.11 General rules.

Each official establishment shall develop, implement, and maintain written standard operating procedures for sanitation (Sanitation SOP's) in accordance with the requirements of this part.

§ 416.12 Development of Sanitation SOP's.

- (a) The Sanitation SOP's shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).
- (b) The Sanitation SOP's shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOP's as specified and will maintain the Sanitation SOP's in accordance with the requirements of this part. The Sanitation SOP's shall be signed and dated upon initially implementing the Sanitation SOP's and upon any modification to the Sanitation SOP's.
- (c) Procedures in the Sanitation SOP's that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.
- (d) The Sanitation SOP's shall specify the frequency with which each procedure in the Sanitation SOP's is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).

§ 416.13 Implementation of SOP's.

- (a) Each official establishment shall conduct the pre-operational procedures in the Sanitation SOP's before the start of operations.
- (b) Each official establishment shall conduct all other procedures in the Sanitation SOP's at the frequencies specified.
- (c) Each official establishment shall monitor daily the implementation of the procedures in the Sanitation SOP's.

§ 416.14 Maintenance of Sanitation SOP's.

Each official establishment shall routinely evaluate the effectiveness of the Sanitation SOP's and the procedures therein in preventing direct contamination or adulteration of product(s) and shall revise both as necessary to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel.

§ 416.15 Corrective Actions.

- (a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOP's or the procedures specified therein, or the implementation or maintenance of the Sanitation SOP's, may have failed to prevent direct contamination or adulteration of product(s).
- (b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOP's and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOP's or the procedures specified therein.

§ 416.16 Recordkeeping requirements.

- (a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOP's and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOP's as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOP's shall authenticate these records with his or her initials and the date.
- (b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.
- (c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

§ 416.17 Agency verification.

FSIS shall verify the adequacy and effectiveness of the Sanitation SOP's and the procedures specified therein by determining that they meet the requirements of this part. Such verification may include:

- (a) Reviewing the Sanitation SOP's;
- (b) Reviewing the daily records documenting the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken;
- (c) Direct observation of the implementation of the Sanitation SOP's and the procedures specified therein and any corrective actions taken or required to be taken; and
- (d) Direct observation or testing to assess the sanitary conditions in the establishment.

PART 417 HAZARD ANALYSIS AND CRITICAL CONTROL POINT (HACCP) SYSTEMS

§ 417.1 Definitions.

§ 417.2 Hazard Analysis and HACCP Plan.

§ 417.3 Corrective actions.

§ 417.4 Validation, Verification, Reassessment.

§ 417.5 Records.

§ 417.6 Inadequate HACCP Systems.

§ 417.7 Training.

§ 417.8 Agency verification.

§ 417.1 Definitions.

For purposes of this part, the following definitions shall apply:

Corrective action. Procedures to be followed when a deviation occurs.

Critical control point. A point, step, or procedure in a food process at which control can be applied and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.

Critical limit. The maximum or minimum value to which a physical, biological, or chemical hazard must be controlled at a critical control point to prevent, eliminate, or reduce to an acceptable level the occurrence of the identified food safety hazard.

Food safety hazard. Any biological, chemical, or physical property that may cause a food to be unsafe for human consumption.

HACCP System. The HACCP plan in operation, including the HACCP plan itself.

Hazard. SEE Food Safety Hazard.

Preventive measure. Physical, chemical, or other means that can be used to control an identified food safety hazard.

Process-monitoring instrument. An instrument or device used to indicate conditions during processing at a critical control point.

Responsible establishment official. The individual with overall authority on-site or a higher level official of the establishment.

§ 417.2 Hazard Analysis and HACCP Plan.

(a) Hazard analysis.

- (1) Every official establishment shall conduct, or have conducted for it, a hazard analysis to determine the food safety hazards reasonably likely to occur in the production process and identify the preventive measures the establishment can apply to control those hazards. The hazard analysis shall include food safety hazards that can occur before, during, and after entry into the establishment. A food safety hazard that is reasonably likely to occur is one for which a prudent establishment would establish controls because it historically has occurred, or because there is a reasonable possibility that it will occur in the particular type of product being processed, in the absence of those controls.
- (2) A flow chart describing the steps of each process and product flow in the establishment shall be prepared, and the intended use or consumers of the finished product shall be identified.
- (3) Food safety hazards might be expected to arise from the following:
 - (i) Natural toxins;
 - (ii) Microbiological contamination;
 - (iii) Chemical contamination;
 - (iv) Pesticides;
 - (v) Drug residues;
 - (vi) Zoonotic diseases;
 - (vii) Decomposition;
 - (viii) Parasites;
 - (ix) Unapproved use of direct or indirect food or color additives; and
 - (x) Physical hazards.

(b) The HACCP plan.

- (1) Every establishment shall develop and implement a written HACCP plan covering each product produced by that establishment whenever a hazard analysis reveals one or more food safety hazards that are reasonably likely to occur, based on the hazard analysis conducted in accordance with paragraph (a) of this section, including products in the following processing categories:
 - (i) Slaughter—all species.
 - (ii) Raw product—ground.
 - (iii) Raw product—not ground.
 - (iv) Thermally processed—commercially sterile.
 - (v) Not heat treated—shelf stable.
 - (vi) Heat treated—shelf stable.
 - (vii) Fully cooked—not shelf stable.
 - (viii) Heat treated but not fully cooked—not shelf stable.
 - (ix) Product with secondary inhibitors—not shelf stable.

- (2) A single HACCP plan may encompass multiple products within a single processing category identified in this paragraph, if the food safety hazards, critical control points, critical limits, and procedures required to be identified and performed in paragraph (c) of this section are essentially the same, provided that any required features of the plan that are unique to a specific product are clearly delineated in the plan and are observed in practice.
- (3) HACCP plans for thermally processed/commercially sterile products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of part 431 of this chapter.
- (c) ***The contents of the HACCP plan.*** The HACCP plan shall, at a minimum:
 - (1) List the food safety hazards identified in accordance with paragraph (a) of this section, which must be controlled for each process.
 - (2) List the critical control points for each of the identified food safety hazards, including, as appropriate:
 - (i) Critical control points designed to control food safety hazards that could be introduced in the establishment, and
 - (ii) Critical control points designed to control food safety hazards introduced outside the establishment, including food safety hazards that occur before, during, and after entry into the establishment;
 - (3) List the critical limits that must be met at each of the critical control points. Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met;
 - (4) List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;
 - (5) Include all corrective actions that have been developed in accordance with § 417.3(a) of this part, to be followed in response to any deviation from a critical limit at a critical control point; and
 - (6) Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.
 - (7) List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with § 417.4 of this part.
- (d) ***Signing and dating the HACCP plan.***
 - (1) The HACCP plan shall be signed and dated by the responsible establishment individual. This signature shall signify that the establishment accepts and will implement the HACCP plan.
 - (2) The HACCP plan shall be dated and signed:
 - (i) Upon initial acceptance;
 - (ii) Upon any modification; and
 - (iii) At least annually, upon reassessment, as required under § 417.4(a)(3) of this part.
- (e) Pursuant to 21 U.S.C. 456, 463, 608, and 621, the failure of an establishment to develop and implement a HACCP plan that complies with this section, or to operate in accordance with the requirements of this part, may render the products produced under those conditions adulterated.

§ 417.3 Corrective actions.

- (a) The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:
 - (1) The cause of the deviation is identified and eliminated;
 - (2) The CCP will be under control after the corrective action is taken;
 - (3) Measures to prevent recurrence are established; and
 - (4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

- (b) If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall:
 - (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met;
 - (2) Perform a review to determine the acceptability of the affected product for distribution;
 - (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce;
 - (4) Perform or obtain reassessment by an individual trained in accordance with § 417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.
- (c) All corrective actions taken in accordance with this section shall be documented in records that are subject to verification in accordance with § 417.4(a)(2)(iii) and the recordkeeping requirements of § 417.5 of this part.

§ 417.4 Validation, Verification, Reassessment.

- (a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.
 - (1) **Initial validation.** Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.
 - (2) **Ongoing verification activities.** Ongoing verification activities include, but are not limited to:
 - (i) The calibration of process-monitoring instruments;
 - (ii) Direct observations of monitoring activities and corrective actions; and
 - (iii) The review of records generated and maintained in accordance with § 417.5(a)(3) of this part.
 - (3) continue
 - (i) **Reassessment of the HACCP plan.** Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with § 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of § 417.2(c) of this part.
 - (ii) Each establishment must make a record of each reassessment required by paragraph (a)(3)(i) of this section and must document the reasons for any changes to the HACCP plan based on the reassessment, or the reasons for not changing the HACCP plan based on the reassessment. For annual reassessments, if the establishment determines that no changes are needed to its HACCP plan, it is not required to document the basis for this determination.

- (b) **Reassessment of the hazard analysis.** Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.

§ 417.5 Records.

- (a) The establishment shall maintain the following records documenting the establishment's HACCP plan:
- (1) The written hazard analysis prescribed in § 417.2(a) of this part, including all supporting documentation;
 - (2) The written HACCP plan, including decision making documents associated with the selection and development of CCP's and critical limits, and documents supporting both the monitoring and verification procedures selected and the frequency of those procedures.
 - (3) Records documenting the monitoring of CCP's and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.
- (b) Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded, and shall be signed or initialed by the establishment employee making the entry.
- (c) Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with § 417.7 of this part, or the responsible establishment official.
- (d) Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.
- (e) Record retention.
- (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated product, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years.
 - (2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.
- (f) Official review. All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

§ 417.6 Inadequate HACCP Systems.

A HACCP system may be found to be inadequate if:

- (a) The HACCP plan in operation does not meet the requirements set forth in this part;
- (b) Establishment personnel are not performing tasks specified in the HACCP plan;
- (c) The establishment fails to take corrective actions, as required by § 417.3 of this part;
- (d) HACCP records are not being maintained as required in § 417.5 of this part; or
- (e) Adulterated product is produced or shipped.

§ 417.7 Training.

- (a) Only an individual who has met the requirements of paragraph (b) of this section, but who need not be an employee of the establishment, shall be permitted to perform the following functions:
 - (1) Development of the HACCP plan, in accordance with § 417.2(b) of this part, which could include adapting a generic model that is appropriate for the specific product; and
 - (2) Reassessment and modification of the HACCP plan, in accordance with § 417.3 of this part.
- (b) The individual performing the functions listed in paragraph (a) of this section shall have successfully completed a course of instruction in the application of the seven HACCP principles to meat, poultry, or egg products processing, including a segment on the development of a HACCP plan for a specific product and on record review.

§ 417.8 Agency verification.

FSIS will verify the adequacy of the HACCP plan(s) by determining that each HACCP plan meets the requirements of this part and all other applicable regulations. Such verification may include:

- (a) Reviewing the HACCP plan;
- (b) Reviewing the CCP records;
- (c) Reviewing and determining the adequacy of corrective actions taken when a deviation occurs;
- (d) Reviewing the critical limits;
- (e) Reviewing other records pertaining to the HACCP plan or system;
- (f) Direct observation or measurement at a CCP;
- (g) Sample collection and analysis to determine the product meets all safety standards; and
- (h) On-site observations and record review.

PART 418 RECALLS

§ 418.1 [Reserved]

§ 418.2 Notification.

§ 418.3 Preparation and maintenance of written recall procedures.

§ 418.4 Records.

§ 418.1 [Reserved]**§ 418.2 Notification.**

Each official establishment must promptly notify the local FSIS District Office within 24 hours of learning or determining that an adulterated or misbranded meat, meat food, poultry, or poultry product received by or originating from the official establishment has entered commerce, if the official establishment believes or has reason to believe that this has happened. The official establishment must inform the District Office of the type, amount, origin, and destination of the adulterated or misbranded product.

§ 418.3 Preparation and maintenance of written recall procedures.

Each official establishment must prepare and maintain written procedures for the recall of any meat, meat food, poultry, or poultry product produced and shipped by the official establishment. These written procedures must specify how the official establishment will decide whether to conduct a product recall, and how the establishment will effect the recall, should it decide that one is necessary.

§ 418.4 Records.

All records, including records documenting procedures required by this part, must be available for official review and copying.

PART 430 REQUIREMENTS FOR SPECIFIC CLASSES OF PRODUCT

§ 430.1 Definitions.

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

§ 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.

§ 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 that is contaminated with *L. monocytogenes*. Establishments must not release into commerce product that contains *L. monocytogenes* or that has been in contact with a food contact surface contaminated with *L. monocytogenes* without first reworking the product using a process that is destructive of *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 § 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 § 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 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 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 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) In order to release into commerce product held under this section, 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 § 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 § 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) [Reserved]
- (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.

REGULATION CHART

| ROP RULES OF PRACTICE | | HACCP HAZARD ANALYSIS CRITICAL CONTROL POINT | |
|-----------------------------------------------|-----------------------------------------------------------------------------------------------------|----------------------------------------------|--------------------------------------------------------------------------------------|
| 500.1 | Definitions | 417.1 | Definitions |
| 500.2 | Regulatory control action | 417.2 | Hazard Analysis and HACCP Plan |
| 500.3 | Withholding/Suspension WITHOUT prior notification | (a) | Hazard analysis |
| 500.5(a) | Notification | (1) | Determine RLTO hazards, identify preventive measures |
| 500.4 | Withholding/Suspension WITH prior notification | (2) | Flow chart |
| 500.5(b) | Notification | (3) | Expected food safety hazards |
| 500.6 | Withdrawal | (b) | HACCP plan |
| 500.7 | Refusal to grant inspection | (1) | Develop and implement for each process/product if hazard RLTO |
| 500.8 | Rescinding labels, marks | (2) | Requirements for single HACCP Plan |
| SPS SANITATION PERFORMANCE STANDARDS | | (3) | Requirements for thermally processed |
| 416.1 | General rules | (c) | Contents of HACCP Plan |
| 416.2 | Establishment grounds and facilities | (1) | List of food safety hazards |
| (a) | Grounds and pest control | (2) | List of CCP's |
| (b) | Construction | (3) | List of critical limits |
| (c) | Light | (4) | List of procedures & frequency |
| (d) | Ventilation | (5) | Corrective actions |
| (e) | Plumbing | (6) | Record keeping system |
| (f) | Sewage disposal | (7) | List of verification procedures/frequency |
| (g) | Water supply and water, ice, and solution reuse | (d) | Signing and dating HACCP plan |
| (h) | Dressing rooms, lavatories & toilets | (1) | Signed and dated by responsible person |
| 416.3 | Equipment and utensils | (2) | Sign and date frequency |
| (a) | Constructed to facilitate cleaning | (e) | Failure to Develop and Implement HACCP Plan |
| (b) | Accessibility for inspection | 417.3 | Corrective Actions |
| (c) | Receptacles for storing inedible material | (a) | Describe action after deviation |
| 416.4 | Sanitary operations | (1) | Cause is identified & eliminated |
| (a) | Food contact surface, cleaning & sanitizing | (2) | CCP is under control |
| (b) | Non-food contact surface, cleaning & sanitizing | (3) | Prevent recurrence |
| (c) | Cleaning compounds and sanitizers | (4) | No adulterated product shipped |
| (d) | Product protected | (b) | Unforeseen hazard |
| 416.5 | Employee Hygiene | (1) | Segregate, hold product |
| (a) | Cleanliness | (2) | Perform review |
| (b) | Clothing | (3) | Actions to ensure product not shipped |
| (c) | Disease control | (4) | Reassessment of HACCP plan |
| 416.6 | Tagging equipment, rooms, or compartments | (c) | Document corrective actions |
| SSOP SANITATION STANDARD OPERATING PROCEDURES | | 417.4 | Validation, Verification, Reassessment |
| 416.11 | General Information | (a) | Every establishment shall validate HACCP plan/s |
| 416.12 | Development of SSOP's | (1) | Initial validation |
| (a) | Describe all procedures | (2) | Ongoing verification to include, |
| (b) | Signed and dated | (i) | calibration |
| (c) | Procedures for pre-op | (ii) | direct observation |
| (d) | Frequency of procedures & responsible individual | (iii) | review of records |
| 416.13 | Implementation of SSOP's | (3) | Reassessment, (i) at least annually or when change is made, (ii) record reassessment |
| (a) | Conduct pre-op | (b) | Reassessment of hazard analysis |
| (b) | Conduct all other procedures | 417.5 | Records |
| (c) | Monitors implementation of SSOP procedures | (a) | Establishment shall maintain |
| 416.14 | Maintenance of SSOP's routinely evaluate | (1) | Written hazard analysis |
| 416.15 | Corrective Actions | (2) | Written HACCP plan |
| (a) | Conduct corrective actions, including | (3) | Records of CCP's, temps., corrective actions |
| (b) | Disposition of contaminated product restores sanitary conditions prevent recurrence | (b) | Made at time event occurs |
| 416.16 | Record Requirements | (c) | Pre-shipment review |
| (a) | Daily records required, responsible individual, initialed and dated | (d) | Records on computer |
| (b) | Records on computers | (e) | Record retention |
| (c) | Location and retention of records maintained | (f) | Official review |
| 416.17 | Agency Verification | 417.6 | Inadequate HACCP System |
| | Review SSOP's, daily records, direct observation of SSOP procedures & direct observation of testing | (a) | Plan doesn't meet requirements |
| Recall | | (b) | HACCP tasks not accomplished |
| 418.2 | Notification | (c) | Fails to take corrective actions |
| 418.3 | Preparation and maintenance of written procedures | (d) | No records |
| 418.4 | Records | (e) | Adulterated product shipped |
| | | 417.7 | Training |
| | | (a) | Trained individual develops/reassesses |
| | | (b) | Course of instruction |
| | | 417.8 | Agency Verification |
| | | (a) | Review HACCP plan/s |
| | | (b) | Review CCP records |
| | | (c) | Review adequacy of corrective actions |
| | | (d) | Review critical limits |
| | | (e) | Review other records pertaining to HACCP plan/s |
| | | (f) | Direct observation of CCP |
| | | (g) | Sample collection |
| | | (h) | On-site observation & records review |

ACRONYM AND INITIALISMS LISTING

| | |
|-------|-----------------------------------------------------------------------------|
| AA | Assistant Administrator |
| ACS | Acidified Calcium Sulfate |
| ADR | Animal Disposition Reporting |
| AER | Administrative Enforcement Report |
| AM | Antemortem Inspection |
| AMA | Antimicrobial Agent |
| AMAP | Antimicrobial Agents and Processes |
| AMP | Antimicrobial Process |
| AMS | Agricultural Marketing Service |
| AOAC | Association of Official Analytical Chemists (Now called AOAC International) |
| APC | Aerobic Plant Count |
| APHIS | Animal and Plant Health Inspection Service |
| AMR | Advanced Meat Recovery |
| ASC | Acidified Sodium Chlorite |
| ATP | Adenosine Triphosphate |
| aw | Water Activity |
| BITES | Biological Information Transfer Email System |
| BSE | Bovine Spongiform Encephalopathy |
| CA | Corrective Actions |
| CCMS | Consumer Complaint Monitoring System |
| CCP | Critical Control Point |
| CDC | Centers for Disease Control and Prevention |
| CFL | Center for Learning |
| CFR | Code of Federal Regulations |
| CFU | Colony Forming Units |
| CIP | Clean in Place |
| CL | Critical Limit |
| COA | Certificate of Analysis |
| CPS | Coagulase Positive Staph |
| CSI | Consumer Safety Inspector |
| CSO | Consumer Safety Officer |
| DM | District Manager |
| DDM | Deputy District Manager |
| DCS | District Case Specialist |
| DJE | Dual Jurisdiction Establishment |
| DO | District Office |
| DRO | District Recall Officer |
| DVMS | District Veterinary Medical Specialist |
| EARO | Executive Associate for Regulatory Operations |
| EIAO | Enforcement Investigations and Analysis Officer |

| | |
|-----------|-------------------------------------------------------------------------|
| EMC | Emergency Management Committee |
| EPA | Environmental Protection Agency |
| EPIA | Egg Products Inspection Act |
| FCS | Food Contact Surface |
| FDA | Food and Drug Administration |
| FDIB | Foodborne Disease Investigation Branch |
| FFDCA | Federal Food, Drug, and Cosmetic Act |
| FI | Food Inspector |
| FIFRA | Federal Insecticide Fungicide and Rodenticide Act |
| FLS | Frontline Supervisor |
| FMIA | Federal Meat Inspection Act |
| FNS | Food and Nutrition Service |
| FO | Field Operations |
| FOIA | Freedom of Information Act |
| FPS | Finished Product Standard |
| FR | Federal Register |
| FSA | Food Safety Assessment |
| FSIS | Food Safety and Inspection Service |
| GAD | Gather Assess Determine |
| GMP | Good Manufacturing Practice |
| GRAS | Generally Recognized as Safe |
| HA | Hazard Analysis |
| HACCP | Hazard Analysis and Critical Control Point |
| HATS | Humane Activities Tracking System |
| HAV | Hazard Analysis Verification |
| HCG | Hazards Control Guide |
| HEP | High Event Period (with regard to STECs) |
| HH | Humane Handling |
| HIMP | HACCP-based Inspection Models Project |
| HMSA | Humane Methods of Slaughter Act |
| HPP | High Pressure Processing |
| HRI | Hotels, Restaurants, and Institutions |
| HUS | Hemolytic Uremic Syndrome |
| ICMSF | International Commission on the Microbiological Specification for Foods |
| IIC | Inspector in Charge |
| IKE | Interactive Knowledge Exchange |
| IPP | Inspection Program Personnel |
| IVT | Intensified Verification Testing |
| KIS | Kidney Inhibition Swab |
| LIMS | Laboratory Information Management System Direct |
| <i>Lm</i> | <i>Listeria monocytogenes</i> |
| LOG | Letter of Guarantee |

| | |
|--------|-----------------------------------------------------------------------|
| LOI | Letter of Information |
| LOW | Letter of Warning |
| LPDS | Labeling and Program Delivery Staff |
| LTD | Less Than Daily |
| MOI | Memorandum of Interview |
| MOU | Memorandum of Understanding |
| MPCM | Microbial Pathogen Computer Modeling |
| MPN | Most Probable Number |
| MPR | Moisture Protein Ratio |
| NACMCF | National Advisory Committee on the Microbiological Criteria for Foods |
| NACMPI | National Advisory Committee on Meat and Poultry Inspection |
| NFCS | Non Food Contact Surface |
| NFSCP | Non-Food Safety Consumer Protection |
| NIST | National Institute of Standards and Technology |
| NOIE | Notice of Intended Enforcement |
| NOL | No Objection Letter |
| NOS | Notice of Suspension |
| NPDW | National Primary Drinking Water NR Noncompliance Record |
| NRLTO | Not Reasonably Likely to Occur |
| NRTE | Not Ready to Eat |
| OCP | Other Consumer Protection |
| OFO | Office of Field Operations |
| OIG | Office of Inspector General |
| OM | Office of Management |
| OEED | Office of Employee Experience and Development |
| OPACE | Office of Public Affairs and Consumer Education |
| OPARM | Office of Planning, Analysis, and Risk Management |
| OIEA | Office of Investigation, Enforcement, and Audit |
| OPHS | Office of Public Health Science |
| OPPD | Office of Policy and Program Development |
| OSHA | Occupational Safety and Health Administration/Act |
| PDS | Policy Development Staff |
| PFGE | Pulsed Field Gel Electrophoresis |
| PHV | Public Health Veterinarian |
| PHIS | Public Health Information System |
| PLE | Post Lethality Exposed |
| PLT | Post Lethality Treatment |
| PM | Postmortem Inspection |
| PMP | Pathogen Modeling Program |
| PMP | Pest Management Program |
| PPIA | Poultry Products Inspection Act |
| PPM | Parts Per Million |

| | |
|--------|-------------------------------------------------------------|
| PR | Pathogen Reduction |
| PRP | Pre-Requisite Program |
| QA | Quality Assurance |
| QC | Quality Control |
| QRG | Quick Reference Guide |
| RCA | Regulatory Control Action |
| RD | Regional Director (OIEA) |
| REC | Recall Effectiveness Check |
| RMIS | Risk Management and Innovation Staff |
| RLm | Risk Based <i>Listeria monocytogenes</i> Testing |
| RLTO | Reasonably Likely to Occur |
| RMA | Resource Management Analyst |
| RMS | Resource Management Specialist |
| RMTAD | Recall Management and Technical Analysis Division |
| ROP | Rules of Practice |
| RTE | Ready to Eat |
| RTE/SS | Ready to Eat/Shelf Stable |
| SCSI | Supervisory Consumer Safety Inspector |
| SEIAO | Supervisory Enforcement Investigations and Analysis Officer |
| SIP | Salmonella Initiative Program |
| SOP | Standard Operating Procedures |
| SPC | Statistical Process Control or Standard Plate Count |
| SPHV | Supervisory Public Health Veterinarian |
| SPS | Sanitation Performance Standards |
| SRM | Specified Risk Materials |
| SSOP | Sanitation Standard Operating Procedures |
| STEC | Shiga toxin-producing <i>E. coli</i> |
| STEPS | System Tracking <i>E. coli</i> Positive Suppliers |
| SVMO | Supervisory Veterinary Medical Officer |
| TA | Talmadge-Aiken Act |
| TCOE | Training as a Condition of Employment |
| TDT | Thermal Death Time |
| TPC | Total Plate Count |
| TSP | Trisodium Phosphate |
| TT | Time Temperature |
| USC | United States Code |
| USDA | United States Department of Agriculture |
| vCJD | Variant Creutzfeldt-Jakob disease |
| VMO | Veterinary Medical Officer |
| VP | Verification Plan |

