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

Inspection Methods

Student Study Guide

2 of 3

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16 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


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, or any additional trimming, washing, or application of any interventions.

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 either pre-chill testing station or any location after final trimming prior to the chiller 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 from the same cause or indicate a systemic issue, the current NR is to be associated with the most recent zero tolerance or related NR. When associating NRs for the same cause, IPP are to follow the methodology set out in FSIS Directive 5000.1.

If the findings do not show the same cause, IPP are NOT to associate the NRs.
17 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.
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 screw-cap 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_LBW01):

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 ± 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 ± 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_COM01):

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 product 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.

**PERFORMANCE STANDARDS – FSIS DIRECTIVE 10,250.2**

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.

<table>
<thead>
<tr>
<th>Product</th>
<th>Max Acceptable % Positive</th>
<th>Performance Standard</th>
<th>Minimum # of Samples to Assess Process Control</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>Salmonella</em></td>
<td><em>Campylobacter</em></td>
<td><em>Salmonella</em></td>
</tr>
<tr>
<td>Broiler Carcass</td>
<td>9.8</td>
<td>15.7</td>
<td>5 of 51</td>
</tr>
<tr>
<td>Turkey Carcass</td>
<td>7.1</td>
<td>5.4</td>
<td>4 of 56</td>
</tr>
<tr>
<td>Comminuted Chicken</td>
<td>25.0</td>
<td>1.9</td>
<td>13 of 52</td>
</tr>
<tr>
<td>Comminuted Turkey</td>
<td>13.5</td>
<td>1.9</td>
<td>7 of 52</td>
</tr>
<tr>
<td>Chicken Parts</td>
<td>15.4</td>
<td>7.7</td>
<td>8 of 52</td>
</tr>
</tbody>
</table>

**Performance Categorization**

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

**Category 3 – Highly Variable Process Control**: Establishments that have exceeded the maximum allowable percent positive during the most recent 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.
18 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 day’s notice (if it does not cause undue hardship to the plant), 1 day’s 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 product. 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.

<table>
<thead>
<tr>
<th># of containers in each specific production</th>
<th># of sample pieces to select from each container</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>12 pieces</td>
</tr>
<tr>
<td>4</td>
<td>15 pieces</td>
</tr>
<tr>
<td>3</td>
<td>20 pieces</td>
</tr>
<tr>
<td>2</td>
<td>30 pieces</td>
</tr>
<tr>
<td>1</td>
<td>60 pieces</td>
</tr>
</tbody>
</table>

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-
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 product 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.
**Objective:** To review performance of certain steps of the HAV task.

**Scenario:** You recently submitted a sample of raw ground beef which was confirmed positive result for *E. coli* O157:H7. You decide to perform a directed HAV task as one follow-up. Excerpt of establishment documents provided.

Consider:

- What documents and records should you review?

- What will you look for when reviewing these documents and records?

- What findings would be evidence of noncompliance?

---

**Product Description**

<table>
<thead>
<tr>
<th>Common Name:</th>
<th>Ground Beef Patties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Formulation:</td>
<td>Fresh beef trimmings from Open Beef</td>
</tr>
<tr>
<td>Packaging:</td>
<td>Bulk (frozen patties) in 20 lb box</td>
</tr>
<tr>
<td>Shelf Life:</td>
<td>3-6 months if frozen</td>
</tr>
<tr>
<td>Intended Use:</td>
<td>Restaurants</td>
</tr>
</tbody>
</table>

For Training Purposes Only
### Raw Non-Intact Product Hazard Analysis (Ground Beef Patties) …EXCERPT…

<table>
<thead>
<tr>
<th>Process Step</th>
<th>Food Safety Hazard</th>
<th>Reasonably Likely to Occur</th>
<th>Basis</th>
<th>Measures Applied to Prevent, Eliminate, or Reduce the Hazard to an Acceptable Level</th>
</tr>
</thead>
</table>
| Receiving-Raw Beef Trimmings     | Biological: Pathogens:  
E. coli O157:H7  
Salmonella  
BSE / SRMs | No | E. coli O157:H7 is a known pathogen in raw beef products  
(Interventions for E. coli should also reduce Salmonella) | Receiving Inspection Program  
Supplier will provide documentation that product is derived from animals less than 30 months of age and the SRMs are removed |
| Chemical: None                   | Physical: Foreign Materials | No | Damaged containers can result in product exposure to foreign material or cross contamination. | Visual inspection for damaged containers at receiving – (Receiving log) |

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For Training Purposes Only
**RECEIVING INSPECTION PROGRAM**

**Required Documents**

Before unloading beef trimmings from truck trailer, the receiving manager will verify there is documentation accompanying the shipment stating that:

1. Intervention(s) were applied to the source materials of the beef trimmings in compliance with the supplier’s HACCP program.
2. The beef trimmings are derived from cattle that are less than 30 months of age and SRMs have been removed.
3. Each lot of beef trimmings has been tested and found to be negative for *E. coli* O157:H7, each lot has an associated letter of guaranty.

**Measuring Receiving Temperature**

The surface temperature of the beef trimmings must be ≤ 40°F. Temperature is monitored in at least 2 containers per trailer by receiving foreman at the receiving dock for each delivery of beef trimmings.

**Inspection of Containers**

100% visual inspection of shipping container condition by the receiving foreman.

**Corrective Actions**

If the required documentation does not accompany the shipment of beef trimmings, placed on “hold” until the required documentation is received.

If the temperature of beef trimmings is above 40°F, the supplier may provide evidence which demonstrates the temperature of the beef trimmings from time of shipping to receipt was above 40°F for no more than 2 hours but never above 50°F.

Beef trimmings with damaged containers are segregated and placed in “Product Reinspection” area for further evaluation.

**Records**

1. Receiving Log
2. Bills of Lading
3. Letters of Guaranty

---

**Receiving Log**

<table>
<thead>
<tr>
<th>Date</th>
<th>Supplier</th>
<th>Product</th>
<th>Lot Codes</th>
<th>Temperature (trimmings)</th>
<th>Condition (Acc or UnAcc)</th>
<th>Receiving Initials</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-25-2019</td>
<td>Open Beef</td>
<td>5combos beef trim</td>
<td>Lot 012416AC</td>
<td>38, 40</td>
<td>Acc</td>
<td>EP</td>
</tr>
<tr>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
</tbody>
</table>

Corrective Actions:
STRAIGHT BILL OF LADING

Open Beef Co, Inc.

8305 Hawthorne Way
Petaluma, CA 94954

CONSIGNED TO:
Groveton Meats, Inc.
1200 Presley Drive
Los Angeles, CA 94852

SPECIAL INSTRUCTIONS
Trailer Temp: 34 degrees F

<table>
<thead>
<tr>
<th>Pallets Used</th>
<th>S.O. Number</th>
<th>Seal Numbers</th>
<th>Ship Date</th>
<th>Delivery Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>799</td>
<td>23012/931</td>
<td></td>
<td>1-24-19</td>
<td>1-25-19</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Piece Count</th>
<th>Description</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Combos – Beef Trimmings Lot 012416AC</td>
<td>2476 lbs.</td>
</tr>
</tbody>
</table>

Total Pc Cnt: 5  Driver Initials: JT  Total Wt: 2476 lbs.

Note: This shipment contains beef products derived only from animal determined to be less than 30 months of age and contains no SRM’s such as tonsils or distal ileum.

SHIPPER: Open Beef Co.
PER: JT

CARRIER: Open Beef Co.
PER: JT
DATE: 1-25-19
Dear Customer,

As part the Food Safety System at Open Beef, we apply a validated antimicrobial organic acid rinse to all of our carcasses and variety meats. This letter is to convey the results of Open Beef Co, Inc. *E. coli* O157:H7 “Verification” testing. We perform verification testing of trimmings that will be used as raw ground beef components to provide ongoing validation of our Food Safety system. We use the N-60 sampling method to collect our samples and the contract lab utilizes test methods which are equivalent in sensitivity to FSIS methods.

**Current Results:**

Lot Number – 012416AC  
Production Date: 01/23/19  
Sample Date: 01/23/19  
Shipment Number – 25744  
Trailer Number – T43  
N60 Sample Result: NEGATIVE for *E. coli* O157:H7  
Result Received: 01/24/19  
Contract Lab: JDL Laboratories, Inc.

Please contact me if you have any further questions.

*Bert Earnest*  
Bert Earnest  
Director of Quality Assurance
20 Sampling Requirements to Demonstrate Process Control in Slaughter Operations

Objectives:

1. Explain why generic *E. coli* sampling and analysis is performed in livestock (other than swine) slaughter operations.
2. Explain why microbiological sampling and analysis is performed in swine and poultry slaughter (other than ratite) operations.
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.

Generic *E. coli* Testing for Livestock, (other than swine)

Each official establishment that slaughters livestock, other than swine, or ratites is required to test for *Escherichia coli* Biotype I, also known as “generic *E. coli*.”

Note: Swine and poultry (other than ratite) will be covered in the next section.

Fecal material is one of the principal sources of pathogenic organisms (*Salmonella*, *Campylobacter*, and *E. coli* O157:H7) that contaminate carcasses. The best indicator of fecal contamination is *Escherichia coli*, Biotype I, also called generic *E. coli*, because it is commonly found in the intestinal tract of food animals. The purpose of generic *E. coli* testing is to verify the effectiveness of sanitation and process control in slaughter establishments.

Note: Generic *E. coli* is not a pathogen.
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.
  - Hide-on carcasses are **not** excised – The regulations are specific that these are only sponged.

**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.
21 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 **ritual** 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 by performing the Livestock Humane Handling Verification task. This task must be performed once per shift, every shift animals are slaughtered or on-site.

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: 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: Some things to look for include:
   - Vehicles or ramps not being properly positioned, leading to the injury of animals.
   - Animals forced to move faster than a normal walking speed.

III. Water and Feed Availability: 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.
Note: If animal appears 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.

IV. Handling 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: Some things to look for include:
- Conscious animals being dragged.
- Disabled animals not separated from normal ambulatory animals.
- US Suspect and disabled livestock are not provided or placed in a covered pen.

VI. Electric Prod/Alternative Object Use: Some things to look for include:
- Livestock being excessively prodded resulting in overexcitement or injury.
- Livestock being driven with sharp objects or other means which cause pain or injury.

VII. Slips and Falls: 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: 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.

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 devices 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 period, 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)

Some signs of a properly stunned animal (but 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: Some things to look for include:

- 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, you must 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 of 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 don’t enforce humane handling regulations within that “ritual bubble”.

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. 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. 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 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 managers of the humane handling noncompliance, if not already done when addressing the needs of the animal.
- **Second**, request that establishment managers 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. Retained / Rejected tag to the noncompliant equipment/pen/etc. Noncompliance examples include holes in pen floors or fences that can trap/injure an animal’s legs or feet.

- 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 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 multiple noncompliances.

More 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 or not you are the IIC. **If you are the IIC, place a U.S. Retained/Rejected tag at the appropriate place** and inform establishment managers 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. Retained/Rejected tag at the appropriate place**, and inform establishment managers 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 or not you are the IIC, your very first step—even before applying a tag—is to stop the activity that is causing harm to animals.

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.”

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 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.

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. 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 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.
**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. In addition, you are to document the discussion and any planned actions on the part of the establishment in a MOI. Give a copy of the MOI to establishment managers, keep a copy in the inspection file, and send a copy to the DVMS.

**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.
22 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 hazards 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, bunging, 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.
23 Review of Establishment Data Task

Objectives:
1. Explain the purpose of the Review of Establishment Data task
2. Identify the kinds of records that are subject to review during this task
3. Describe how to assess the significance of information gathered during this task
4. Explain how to follow-up on questions or concerns identified
5. Explain how to document the task in PHIS
6. Describe what is done if the establishment management refuses access to records

What Data do IPP Review and Why?

Establishments may conduct certain testing or monitoring activities that are not a part of their HACCP plans or Sanitation SOPs. For example, establishments may perform testing or monitoring activities as a part of a prerequisite program or conduct product testing to comply with certain specifications of its customers. Data generated by such activities may not even be referenced in a hazard analysis. Nonetheless, these activities may provide information relevant to the effectiveness of establishments’ food safety systems. In other words, the data may raise questions or concerns about the adequacy of an establishment’s hazard analysis.

Whenever the results of testing and monitoring activities provide information relevant to the adequacy of decisions made in a hazard analysis, FSIS considers records of these results to be supporting documentation for that hazard analysis. Such records must be maintained by the establishment and made available for FSIS review. A prudent establishment will consider the significance of this information with respect to the overall effectiveness of its food safety system and respond to the results as necessary.

IPP should be aware of all monitoring and testing related to food safety conducted by an establishment, including monitoring and testing not referenced in the hazard analysis and not included as components of the establishment’s Sanitation SOPs or HACCP plan. FSIS Directive 5000.2 specifies that at least once per week, IPP are to review the results of any such monitoring and testing. In this training module, we discuss the methodology for reviewing such data. The Review Establishment Data task helps IPP gain a full understanding of the establishment’s food safety system. Considering the significance of this information in the context of the establishment’s food safety system may identify potential vulnerabilities that otherwise may not be recognized when performing other HACCP and sanitation inspection tasks.
Records Subject to the Review Establishment Data Task

The Federal Meat Inspection Act (Section 642) and the Poultry Products Inspection Act (Section 460(b)) both establish the legal authority for requiring establishments to maintain a broad range of records. In addition, the Acts provide FSIS the authority to access any required records as necessary. FSIS has made clear to the regulated industries that IPP have the authority to access all establishment records that could disclose the existence of an insanitary condition which needs to be addressed in an establishment’s HACCP plan, Sanitation SOPs, or prerequisite programs.

The regulatory authority to have access to records, which may have some bearing on the hazard analysis, derives directly from 9 CFR 417.5(a)(1), which states that an establishment must maintain the written hazard analysis prescribed in 9 CFR 417.2(a) and all supporting documentation. Furthermore, establishments are required by 9 CFR 417.5(f) to make all records required by 9 CFR 417 available for official review.

The purpose of a hazard analysis is to identify all relevant hazards and to determine which are reasonably likely to occur (RLTO) in the production process (9 CFR 417.2(a)(1)). A hazard analysis (and any documentation supporting the decisions in that hazard analysis) is not intended to be a static document. At any time, additional information or data may call into question the adequacy of an establishment’s hazard analysis. This information or data may not be specifically referenced in the hazard analysis or generated through implementation of the establishment’s HACCP plan or Sanitation SOPs.

FSIS Directive 5000.2 specifies that IPP have access to any type of record maintained by the establishment if the record relates to the establishment maintaining its food safety system. Establishments must decide what type and frequency of testing is necessary to support the decisions made in its hazard analysis. Thus, the establishment decides which testing programs are necessary to ensure food safety and which testing programs are unrelated to food safety. However, the establishment would have to explain to IPP why certain test records are not related to food safety and do not impact the hazard analysis. If IPP learn of a testing program and have questions about whether records of that testing program should be included in the Review Establishment Data task, they should seek guidance from their supervisors and ask FSIS.
NOTE: The Review Establishment Data task targets records of monitoring and testing results that bear on food safety, not product quality concerns. Certain regulatory product quality concerns would be verified through non-food safety, other consumer protection (OCP) tasks instead of the Review Establishment Data task.

Obviously, IPP should question why the results of any testing for pathogens conducted to meet purchase specifications or for other purposes would not affect the hazard analysis. It is not unusual, though, for many establishments to conduct testing of non-product contact surfaces or finished product for generic microbes such as aerobic plate counts (APCs), generic coliform bacteria, or other non-pathogenic microbes. Establishments may use such testing to provide information about product quality (e.g., shelf life) or to meet certain customer purchase specifications. Generally, such test results can also have implications for food safety. For example, if non-pathogen test results are used to ensure that the production process controls the overall level of microbes in the product, such test results may affect the hazard analysis, because the production process may be modified in response to microbial levels. In these situations, the test results should be made available to IPP for review. If purchase specifications call for testing of non-pathogens and the results are for information purposes only, those results would not affect the hazard analysis and generally would not have to be made available to IPP for review.

The types of records subject to the Review Establishment Data task are not limited to records of microbial testing. For example, some establishments may include metal detection in their process to meet some customer purchase specification. The establishment’s hazard analysis may reference preventive maintenance programs and visual checks for metal contamination as support for metal being not reasonably likely to occur, but not include the customer-required metal detection program as additional support. Nonetheless, the metal detection program has implications for food safety in such an establishment, and records associated with the metal detection program should be made available to IPP for review.

In addition to the results of any monitoring or test results, IPP also have access to any written procedures associated with those results. This would include information such as the methods of sample collection and analysis or the procedure for conducting some monitoring activity.
Performing the PHIS Review Establishment Data Task

At least once a week IPP should schedule and perform the Review Establishment Data task in PHIS. IPP review the results of any testing that the establishment has performed that may have an impact on the establishment’s hazard analysis.

Gathering Information

When reviewing such monitoring and test results, inspection program personnel are to consider questions such as:

1. Is there documentation (paperwork) that supports the frequency of the testing that the establishment employs?
2. If the establishment uses the testing to reflect the effects of a prerequisite program do the results support the decision-making for the design of the program?
3. At what point in the process does the testing occur?
4. Does the establishment use the test results in a manner that checks the proper execution of some activity at the point in the process where the testing occurs?
5. Do the results indicate that a food safety concern may be developing?
6. Is the establishment reacting to the situation? If so, what is it doing?
7. Do results indicate that a potential food safety concern is decreasing?
8. If pathogen or indicator organism positive results have decreased, does the establishment plan to reduce testing frequencies? If so, how it will ensure that such modifications to its testing program will not affect the likelihood of finding pathogens?
9. Are there operational results that correlate with the testing results? For example, does a reduction in microbial counts coincide with a new cleaning regimen, or conversely, has there been an increase in microbial counts during a time when the establishment failed to adequately implement some Sanitation SOP activities?
Assessing Information

A negative response to any of the questions above does not automatically mean there is a noncompliance or inadequate hazard analysis. IPP are to **consider all available information** in order to make any determination as to whether there is a basis for concern about how the establishment is implementing its system, or about how it is reacting to the results of its testing. However, IPP are **not** to write a noncompliance record on the basis of their review of these records. IPP should keep in mind that the Agency’s policy is to encourage establishments to do testing and to address any problems that exist.

At weekly meetings with establishment management (see FSIS Directive 5000.1 and FSIS Directive 5010.1, Rev. 1), IPP are to raise any questions they have regarding any tests results that may have an impact on the establishment’s hazard analysis. When necessary, inspection IPP are to raise concerns through supervisory channels to the District Office.

Documenting the Review Establishment Testing Data Task

As part of documenting the weekly Memorandum of Interview (MOI), IPP are to indicate that they conducted the Review Establishment Data task, and that they discussed any concerns with the establishment at the weekly meeting. In the MOI, IPP are to:

1. Briefly list what tests results they reviewed and for what time period;
2. Describe the specific concerns, if any, that they discussed with the establishment; and
3. State how the establishment responded.

Anytime IPP have concerns about how an establishment responds to what was discussed at the weekly meeting or have questions about whether a particular type of data is available to the Agency, they are to raise those concerns or questions through supervisory channels. Frontline Supervisors will periodically review the documentation above and raise any concerns with the In-plant team and, as necessary, the District Office. Based on the concerns raised by IPP through supervisory channels, District Offices may determine that an Enforcement Investigation Analysis Officer (EIAO) needs to conduct a food safety assessment (FSA). The FSA assesses factors such as what the tests results reveal about food safety, and whether the design of testing, procedures or prerequisite programs are adequately supported by the decisions made in the hazard analysis.
Once IPP have conducted the Review Establishment Data task, discussed any concerns with plant management, and included the items above in the MOI, they are to indicate within PHIS that the inspection task has been completed.

**Refusal of Access to Records**

IPP have reported that establishments have refused to give them access to the results of equipment swab tests, microbiological testing of marinade solutions that are to be reused, and *Salmonella* testing. Establishments have refused to give access to these testing results on the grounds that the results are trade secrets—the testing is done for customers who do not want the results shared with the Agency, and the Agency is only entitled access to records upon which the establishment affirmatively relies.

The argument that the testing is a trade secret does not provide a basis not to share the information with FSIS. FSIS has authority and responsibility to protect trade secret information under the *Freedom of Information Act*. Such authority is meaningless unless the Agency has access to such information. The fact that a customer does not want the information shared with the Agency is irrelevant. The Agency’s HACCP regulations have the force and effect of law and must be followed by the establishment.

If the IPP have questions about whether a particular type of data is available to the Agency, they are to advise their supervisor of the situation. As indicated above, an establishment is obligated to provide access to HACCP plans and other establishment data in accordance with 9 CFR 417.5(f). If an establishment refuses to provide access to its HACCP plan or other supporting documentation for review and recording of information into PHIS, IPP are to record a noncompliance, citing 9 CFR 417.5(f). IPP are then to discuss this noncompliance with establishment management at the next weekly meeting, and document that fact and any establishment response in the MOI. If the establishment continues in its refusal, IPP are to immediately contact their Frontline Supervisor, who will in turn inform the District Manager (DM) of the establishment's refusal. The DM, or designee, will contact establishment management and discuss the issue. If the establishment continues to refuse, the DM will instruct IPP to take an official control action by withholding inspection as defined under 9 CFR 500.1(b). The DM will then document the incident in a letter to the establishment, officially informing it that FSIS has withheld inspection under 9 CFR 500.3(a)(6) because the establishment has interfered with an FSIS inspector performing his/her inspection duties. The DM will lift the withholding action when the establishment has provided its HACCP plan and supporting documentation to IPP for review.
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

**Fully-Cooked, Not Shelf-Stable.** This category applies to establishments that further process products 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.

**RTE (Ready-to-Eat) product** is 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 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.

**Shelf-Stable (SS) product** is free of microorganisms (pathogens and spoilage) capable of growing in the product at non-refrigerated conditions at which the product is intended to be held during distribution and storage. Shelf-stability is primarily achieved through drying or low water activity ($a_w$).

**Heat-Treated, Shelf-Stable.** This category applies to establishments that further process by using a heat treatment processing step as the primary means to achieve food safety, in combination with curing, drying, or fermenting processing steps. The finished products are shelf-stable and are not required to be frozen or refrigerated for food safety purposes.

**Not Heat-Treated, Shelf-Stable.** This category applies to establishments that further process by curing, drying, or fermenting to achieve food safety. The finished products are shelf-stable and not required to be frozen or refrigerated for food safety purposes.
Cooking is a very important step, because it is here that any pathogens (e.g., *Salmonella*) that may be in the product will be eliminated and the numbers of spoilage bacteria will be lowered to an acceptable level. This is called a *lethality* treatment. The cooling process is also known as *stabilization*.

Shelf-stable dried meat snacks have a low moisture content (22-24%) and low water activity. A water activity limit of $\leq 0.85$ should control growth of all bacterial pathogens of concern as well as mold for products stored in the presence of oxygen; however, if the product is vacuum packaged in an oxygen-impervious packaging (anaerobic environment), the water activity limit could be $\leq 0.91$.

**Dried Whole Muscle Meat Products**
- Mostly dry cured
- Treated with salt or salt brines to achieve shelf stability
- **Primary factor affecting shelf stability is aw**
  - Examples include:
    - Dry hams (Prosciutto, Parma, Country Ham)
    - Dry pork shoulders (Coppa)
    - Dry pork bellies (Pancetta)
    - Dry beef rounds (Bresaola, Beef Prosciutto, Basturma)

**Dry and Semi-Dry Sausages**
- Probably the largest group of dried products
- Further broken down into:
  - **Fermented products** (acidified by adding a starter culture of acid producing bacteria to the product) such as pepperoni, hard salami, and summer sausage
  - **Acidified with chemical acidulants** (faster process than fermentation) such as meat sticks made without starter culture
  - **Non-acidified cooked products** such as formed and extruded jerky products, or cooked and dried salami for export to Japan

Establishments can apply the *multiple hurdles concept*, which uses a combination of critical operational parameters to achieve lethality (i.e., multiple steps to kill pathogens) to control a food safety hazard. Examples of multiple hurdles include the combination of high salt content and drying in the dry-cured ham process, and the combination of fermentation (increased acidity to control *Staphylococcus aureus*), cooking or smoking (optional), and drying in the fermented, dry sausage process (controls multiple pathogens including *Clostridium botulinum* and *Clostridium perfringens*). Drying in the fermented, dry sausage process is also important because it helps the products meet their standard of identity and controls the outgrowth of *Clostridium botulinum* and *Clostridium perfringens* so that drying achieves stabilization and the cooling step is unnecessary.
25 Lethality and Stabilization

Objectives:


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 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 ≥ 6%.
26 Food Ingredients of Public Health Concern

Objectives:

1. List the “Big 8” food allergens.
2. Distinguish between a food allergy and a food intolerance.
3. List examples of food ingredients to which some individuals are intolerant.
4. Describe establishment responsibilities for controlling ingredients of public health concern.
5. Identify situations that may lead to cross-contact with a food allergen.
6. Identify situations that may result in mislabeling of a product containing an ingredient of public health concern.
7. Distinguish between labeling requirements for ingredients of public health concern and voluntary labeling declarations.
8. Describe when an establishment can include factual statements about the processing environment on a finished product label.
9. Perform and document the “Big 8” Formulation Verification task.
10. Identify additional labeling concerns that require a directed General Labeling task and documentation of general labeling noncompliance.

Introduction

FSIS is responsible for verifying that establishments have adequate in-plant ingredient controls and appropriate product labeling that lists ingredients in descending order of predominance by common or usual name.

Food Allergies

Exposure to specific proteins in certain food ingredients, not a direct harmful effect from the ingredient itself, can trigger a severe immune system reaction in individuals with food allergies. An allergic reaction is a hypersensitive, aggressive immune system response with symptoms that include tingling in the mouth, tongue and throat swelling, breathing difficulty, hives, vomiting, abdominal cramps, diarrhea, drop in blood pressure, and unconsciousness. In severe cases, life-threatening allergic responses called “anaphylactic reactions” may result in death. No conclusive scientific evidence exists that defines a necessary minimum threshold level for a food allergen to cause an adverse reaction. In most cases, the presence of an undeclared substance that is a known allergen, even in trace amounts, poses a significant public health risk and a potentially catastrophic allergic reaction in an allergic individual.
The FDA has identified eight foods (“Big 8”) and any ingredients that contain protein derived from these eight foods as major food allergens. The foods that account for approximately 90% of food allergies are:

- Milk
- Eggs
- Fish (e.g., bass, cod, or flounder)
- Crustacean shellfish (e.g., crab, lobster, or shrimp)
- Tree nuts (e.g., almonds, pecans, or walnuts)
- Peanuts
- Wheat
- Soybeans

**NOTE:** Attachment 1 in FSIS Directive 7230.1 provides a comprehensive list of ingredients and products that may be derived from the “Big 8” food allergens.

According to FDA estimates, food allergies result in 30,000 emergency room visits, 2,000 hospitalizations, and 150 deaths each year. While these reactions can be treated, there is no cure for food allergies. To avoid consequences, consumers with a food allergy rely on accurate labeling of food products to strictly avoid foods containing the allergen.

**Food Intolerances**

Some individuals may be intolerant of certain food and color additives. The adverse effects of food intolerances, which are often confused with allergic reactions, are generally not life-threatening and do not involve the same immunological mechanisms. Nevertheless, they can have significant public health consequences.

**Lactose** is a sugar molecule in milk and milk product derivatives. Some people are deficient in lactase, an enzyme in the intestinal tract that breaks down lactose. People with lactose intolerance experience gas, bloating, cramping, and sometimes diarrhea.

**Sulfites** are added ingredients used as to preserve food and prevent browning of processed fruits, vegetables, and shellfish. People with sulfite intolerance can experience chest tightness, hives, stomach cramps, diarrhea, breathing problems, and an increased risk of having asthma symptoms for sensitive people with asthma.
FD&C Yellow No. 5, a color additive also known as tartrazine, is used in a variety of food products. Tartrazine can cause symptoms similar to an allergic reaction (i.e., hives and swelling) in intolerant consumers.

Monosodium Glutamate (MSG) is added to a number of meat and poultry products as a flavor enhancer. Some individuals report headache, chest tightness, nausea, diarrhea, and sweating following consumption of MSG-containing products.

Gluten is the protein found in cereal grains (e.g., barley, rye, oats) that helps give dough its elasticity. Individuals who are intolerant to gluten have a condition known as celiac disease. Symptoms may include fatigue, bloating, cramping, chronic diarrhea, nutrient malabsorption, and, although not an allergic reaction, inflammation and damage to the lining of the small intestine.

Nitrate and nitrites are different nitrogenous compounds used as curing agents in many meat and poultry products (e.g., hotdogs, bologna, salami, other processed meats) to inhibit the growth of Clostridium spp. and contribute to the characteristic flavor and color of cured products. Consuming nitrate or nitrite compounds may cause headache and hives in some people. The amount of nitrite or nitrate added to a product is restricted by regulation because excessive concentrations can be toxic.

Some product formulations include only naturally occurring sources of nitrite or nitrate (e.g., celery juice powder, parsley, cherry powder, beet powder, spinach, sea salt) and must be labeled appropriately (e.g., “uncured” bacon product that includes a declaration on the product label stating, “Uncured Bacon, No Nitrates or Nitrites added except those naturally occurring in ________”) because naturally occurring sources of nitrite or nitrate do not inhibit the outgrowth of Clostridium spp. as well as the highly purified chemical forms. In addition, cured products generally bear a statement such as "Not Preserved, Keep Refrigerated Below 40°F at All Times." Exceptions to the refrigeration handling statement include finished products that have been sufficiently dried according to other requirements or contain an amount of salt sufficient to achieve an internal brine concentration of ≥10%.

NOTE: FD&C coloring agents (e.g., Red No. 3 and Red No. 40 added to cures as a tint to distinguish nitrite-containing compounds from salt) do not need to be declared on the product label since their use is considered incidental and does not function as a color additive in the meat or poultry product. Similarly, release agents used on grills, loaf pans, cutters, or other hard production surfaces are generally considered to be a processing aid and their incidental use is not required to be declared on the product label.
Establishment Responsibilities

The establishment is responsible for researching all ingredients used in its product formulations and determining if an ingredient may trigger a food allergy. FSIS expects establishments to employ appropriate food safety procedures (i.e., HACCP plans, SSOPs, or other prerequisite programs) that ensure added ingredients match the product formula and all ingredients are properly and accurately disclosed on the product label.

Ongoing sanitary measures must prevent cross-contact between allergenic and non-allergenic products, equipment, and utensils, and ensure accurate label declarations on products that contain allergens. Cross-contact can be avoided through effective controls and appropriate use of ingredients, such as checking ingredient containers at receiving for damage, ensuring proper identification and control of allergenic ingredients and products throughout production, effective sanitation measures, training employees to work with allergens, and adhering to product formulations.

In addition to inadequate sanitary controls, accidental application of inaccurate labels to properly formulated products poses a threat to sensitive consumers. The establishment can ensure accurate product labeling by changing labels when changing product formulations, reviewing incoming non-meat/non-poultry ingredient labels for changes, discarding obsolete labels after a change in product formulation, reviewing newly printed labels for accuracy, controlling labels to ensure application of the correct label, maintaining adequate identification controls of product containing an allergenic ingredient that is intended for rework, and declaring an allergen indirectly added to the product.

NOTE: When reviewing an establishment’s hazard analysis and supporting documentation regarding the use of highly refined edible oils, be aware that highly refined edible oils (e.g., soybean oil, peanut oil) are plant-based oils that have been processed and rendered virtually free of allergenic proteins and are safe for the food-allergic population to consume. However, allergen-containing products cooked or par-fried in highly refined edible oils may leave traces of allergenic proteins behind in the oil. Establishments that reuse the same oil to cook or par-fry products should consider the potential hazard oil reuse might pose to food-allergic consumers.

Avoiding cross-contact between products containing a food allergen and those that do not is critically important. Cross-contact could result from inadequate control or inappropriate use of ingredients of public health concern.
Situations that may allow for cross-contact to occur include the establishment failing to:

- Check ingredient containers for damage at receiving to prevent allergen contamination within the establishment.
- Implement a program to ensure proper identification and control of allergenic ingredients, allergen containing products, and allergen containers through receiving, weighing, formulation, and packaging.
- Ensure effective sanitation measures are in place to address the potential for cross-contact when producing multiple products with different formulations.
- Implement adequate sanitation procedures for cleaning of utensils and equipment used in formulating and processing both products containing an allergen and products without allergens.
- Train employees on the appropriate use of ingredients and the need to be especially careful when working with allergens.
- Appropriately identify/store products to be reworked that contain an allergen.
- Manufacture a product in accordance with the intended product formulation.

In addition to inadequate controls to prevent cross-contact, accidental application of inaccurate labels to properly formulated products could pose a threat to consumers sensitive to any ingredients in the formulation. **Examples of how inaccurate labeling of a product can occur include the establishment failing to:**

- Declare ingredients listed in the product formula on the product label by common or usual name.
- Change labels when changing over from one product formulation to another.
- Review the labels on incoming non-meat/non-poultry ingredient mixes at receiving for changes.
- Discard obsolete labels after a change in product formulation.
- Review newly printed labels to ensure accuracy.
- Control labels for products with similar appearance but different ingredients to ensure application of the correct label (e.g., storing mixed bundles of labels for similar products with different ingredient formulas which could lead to a mix-up of labels).
- Maintain adequate production controls over a product that contains an allergenic ingredient and is intended for rework, allowing it to be reworked into a product not labeled to contain that ingredient.
• Declare an allergen that was indirectly added to the product. An example would be an establishment that is producing product on a food contact surface sprayed with a non-stick coating (a release agent intended to prevent product from adhering to the food contact surface) containing soy lecithin and is not properly declaring the soy lecithin on its finished product label. Note that substances used as release agents on surfaces, including grills, loaf pans, cutters, or other hard surfaces, are generally considered to be processing aids and are not required to be declared in the ingredients statement on the meat or poultry product label. However, if a particular release agent contains a known allergen, such as soy lecithin, official establishments must list the allergenic ingredient in the ingredients statement on the product label. Many cooking sprays (e.g., PAM®) used as release agents will contain soy lecithin as an emulsifier. Some may contain other allergenic ingredients as well.

Label Declarations

Under FMIA and PPIA, all ingredients used to formulate meat or poultry products generally must be declared by its common or usual name in the ingredients statement on the product label.

With few exceptions, a meat or poultry product is considered to be misbranded if it contains permitted ingredients that are not declared on product labels.

The need for accurate, informative product labeling is especially important for individuals with allergies or food intolerances. FSIS supports the use of voluntary statements on labels to further alert people with sensitivities or intolerances to the presence of specific ingredients (e.g., a label statement such as, “Contains: milk, wheat gluten” or a product label specifying, “Contains sodium caseinate (from milk)” to alert milk allergic consumers that an ingredient contains or is derived from milk).

On a limited case-by-case basis, the FSIS Labeling and Program Delivery Staff (LPDS) may permit the use of factual labeling statements about a product’s manufacturing environment. However, the Agency does not consider the casual use of an elective statement about a product’s manufacturing environment as helpful to consumers and does not promote good manufacturing practices under a HACCP system.
Factual Labeling Statements

With the exception of ingredients consistent with the FDA’s definition of a processing aid or incidental additive, all ingredients listed on labels of incoming food and food ingredients must be declared on finished product containers. Official establishments must list an allergenic ingredient in the product label ingredients statement if a formulation component used contains a known allergen (e.g., soy lecithin in a release agent). All ingredients listed in a “may contain” or “produced in a facility” statement must be listed on the final label unless the establishment has (1) contacted the supplier and confirmed, preferably in writing, that the statement is a cautionary statement, and no such ingredient is in the product; and (2) included a written statement in its hazard analysis supporting why the “may contain” or “produced in a facility” statement is not documented on the finished meat or poultry product label.

FSIS will consider any non-misleading symbols, statements, or logos to inform consumers of the presence of ingredients of public health concern in meat or poultry products. An establishment may submit such a request to the Agency as a policy inquiry but not as label-approval submission.

NOTE: Some chemicals mentioned in this handout may be classified as “generally recognized as safe” (GRAS) for human consumption. Although this module focuses on the addition of ingredients reported to cause adverse health effects in some individuals, establishments must consider all potential chemical food safety hazards, including ingredients that are GRAS, in their hazard analyses.

Factual Labeling Statement Example:

An official establishment uses chopped peanuts in making a dry, Thai-style meat sauce mix. The processing environment must remain dry during operations. Since the production equipment cannot be washed, peanut dust may become airborne and unavoidably contaminate other meat or poultry products manufactured in the same production area. In such situations, a statement about the manufacturing environment as described above or the use of a “may contain (name of allergenic ingredient)” statement has been approved by LPDS. However, it is not acceptable to use this type of statement to address poor SSOPs, such as potential cross-contamination between different products due to inadequate equipment wash between production.
Inspection Program Personnel Responsibilities

Establishments are expected to have effective controls and preventive measures to address all potential chemical hazards, including food allergens and other ingredients of public health concern. IPP will verify that the establishment addressed allergens as a potential chemical food hazard in its hazard analysis, has support for decisions made in its hazard analysis, and implemented effective controls based on those decisions.

IPP must be up to date and aware of the establishment's controls and preventive measures for allergens and ingredients of public health concern. Multiple inspection activities (e.g., HAV task, HACCP Verification task, Review of Establishment Testing Data task, Pre-operational and Operational SSOP tasks, General Labeling Task, and “Big 8” Formulation Verification task) may be necessary to verify that an establishment’s food safety system meets regulatory requirements for allergens and ingredients of public health concern. IPP will issue an NR under the appropriate inspection task if the establishment:

- Fails to address a potential chemical food safety hazard in its process.
- Does not have adequate documentation on file to support decisions made in its hazard analysis for hazards that are not reasonably likely to occur.
- Fails to adequately implement its SSOPs or other prerequisite programs to support a decision that a chemical food safety hazard is not reasonably likely to occur.
- Fails to appropriately declare any allergen or other ingredient of public health concern on the product label.

“Big 8” Formulation Verification Task

The “Big 8” Formulation Verification task provides IPP with a method for verifying that establishments are accurately controlling and labeling the eight most common food allergens. Performing the task as described in FSIS Directive 7230.1 includes reviewing records, observing production processes, and responding to specific task-related questions in PHIS.

IPP assigned to establishments that produce products in any of the HACCP processing categories other than slaughter must determine whether the establishment produces any products that may contain any of the “Big 8” food allergens. Review the preventive and control measures developed by the establishment to verify that such measures are being effectively implemented and product label ingredients are consistent with product formulation records.
Depending on its processes and decisions made in its hazard analysis, an establishment’s preventive and control measures to control allergens may be in its HACCP plan, Sanitation SOPs, or a prerequisite program.

For establishments in which the “Big 8” Formulation Verification task is relevant, the task will appear monthly as a routine Priority 3 task on the Establishment Task List in PHIS. IPP will perform the routine verification task on each shift in establishments with multiple shifts. In establishments that produce more than one product, IPP are to use the chart from Directive 7230.1 (page 5) to prioritize product selection. Whether or not the establishment produces products containing a “Big 8” allergen, IPP are to apply the priority list to all products in an eligible establishment.

NOTE: Examples of multi-ingredient components include sauces, condiments (e.g., ketchup, mustard), seasoning packets, flavorings, spice mixes, soup bases, or other combinations of two or more ingredients mixed together. Additional considerations regarding multi-ingredient seasonings or spices, processing aids, incidental additives, release agents, and “may contain” or “produced in a facility” statements on incoming food and food ingredients are outlined in FSIS Directive 7230.1.

To perform a routine “Big 8” Formulation Verification task, IPP must first schedule the task in advance and determine which products will be produced on that date. Next, they must select a product for the task, which may require coordinating with IPP on other shifts to avoid selecting the same product for consecutive tasks. Always attempt to select products that have not been selected previously unless there has been a change in supplier, ingredients, formulation, or the establishment produces a very limited number of products.

NOTE: If FSIS Directive 7230.1 task criteria does not apply to the operation, IPP are to find the “Big 8” Formulation Verification task on the Establishment Profile/Inspection Tasks page for the establishment and disable the task in accordance with FSIS Directive 13,000.1.

After selecting a product, IPP are to obtain that product’s specific product formulation from the establishment for verification in accordance with 9 CFR 318.6 and 9 CFR 381.180. The “Big 8” Formulation Verification task may be performed using a combination of the recordkeeping and review and observation inspection components.
Performing the task involves:

1. Reviewing product formulation records and observing product formulation process steps to verify that all ingredients used in the production of the product are consistent with the intended product formulation.
2. Reviewing the product label to verify that all ingredients used in formulating the product are declared in the ingredients statement by common or usual name and in descending order of predominance.
3. Observing that the appropriate label is applied to the product.
4. Observing that the applied label is consistent with the establishment’s label approval on file.

As part of documenting the task in PHIS, IPP will respond to specific questions related to this task located on the “additional info” tab of the task documentation page. Attachment 2 of FSIS Directive 7230.1 provides more information regarding these questions.

If there are any indications of increased risk of undeclared allergens in the establishment, the “Big 8” Formulation Verification task may be performed more frequently as a “for cause” directed task. Before scheduling additional “Big 8” Formulation Verification tasks, IPP should discuss with their supervisor the circumstances and any concerns of increased risk of undeclared allergens.

**Documenting Noncompliance with the “Big 8” Formulation Verification Task**

IPP are to document noncompliance on an NR in PHIS under the “Big 8” Formulation Verification task whenever they determine that a meat or poultry product contains a “Big 8” allergen not declared in the ingredients statement on the product label. IPP will cite the relevant safety regulation(s) in 9 CFR 317.2(f) for products bearing the meat inspection legend or 9 CFR 381.118 for products bearing the poultry inspection legend. In addition, IPP must always notify their supervisor when they identify such noncompliance so that a recall request determination can be made.

**The establishment’s food safety system has failed anytime it ships product containing an undeclared allergen in commerce.**

**NOTE:** If IPP identify concerns when performing the “Big 8” Formulation Verification task and believe a directed HAV task should be performed, they are to discuss those concerns with their supervisor.
Documenting Noncompliance for Other Undeclared Ingredients

If IPP determine that a product contains an ingredient not declared in the ingredients statement but it is not a “Big 8” allergen, a directed General Labeling task should be scheduled to document General Labeling noncompliance with 9 CFR 317.2(f) for products bearing the meat inspection legend or 9 CFR 381.118 for products bearing the poultry inspection legend.

Other Actions

IPP may need to take regulatory control of product at the official establishment as necessary to prevent the product from entering commerce. IPP should always contact the FLS for guidance any time they have reason to believe any product bearing labels that fail to declare one of the “Big 8” food allergens or any other ingredient of public health concern has entered commerce. An immediate withholding action on the process may be necessary and a product recall may be requested by the Recall Management and Technical Analysis Division (RMTAD). Refer to FSIS Directive 8080.1 for more information on recalls.
No returned product accepted.
(Training Example Only)
<table>
<thead>
<tr>
<th>Process Step</th>
<th>Potential Food Safety Hazard</th>
<th>RLTO</th>
<th>Basis</th>
<th>If RLTO, What Control Measures?</th>
<th>Is this Step a CCP?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Receiving - raw meat</td>
<td>B-Pathogen growth</td>
<td>No</td>
<td>Temperature Control Program</td>
<td>Vegetative pathogens and Trichinae eliminated at the Cooking CCP</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella</em>, STECs, <em>Campylobacter</em>, <em>Trichinella spiralis</em></td>
<td>Yes</td>
<td></td>
<td>Clostridia growth and toxin formation prevented with Chilling CCP and Temperature Control Program</td>
<td></td>
</tr>
<tr>
<td></td>
<td><em>Clostridium botulinum</em> and <em>Clostridium perfringens</em> (Clostridia)</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C-None</td>
<td>No</td>
<td>Receiving Inspection Program</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P-Metal, rubber, plastic, wood in incoming raw product</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td>…</td>
<td>…</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Cooking &amp; Smoking</td>
<td>B-Pathogens and parasites</td>
<td>Yes</td>
<td></td>
<td>Cooking at temperatures sufficient to eliminate pathogens and parasites</td>
<td>Yes-1B</td>
</tr>
<tr>
<td></td>
<td>C-None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P-None</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Cooling</td>
<td>B-<em>Clostridium</em> growth</td>
<td>Yes</td>
<td></td>
<td>Rapid cooling to ensure no growth of <em>C. botulinum</em> &amp; less than one log growth of <em>C. perfringens</em></td>
<td>Yes-2B</td>
</tr>
<tr>
<td></td>
<td>B-Contamination with <em>Lm</em> and potential subsequent growth</td>
<td>No</td>
<td>Brine SOP for salt concentration, temperature, and microbial testing for <em>Listeria</em> spp.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>C-None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>P-None</td>
<td></td>
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</tr>
</tbody>
</table>
### Hotdog HACCP Plan (Training Example Only)

<table>
<thead>
<tr>
<th>CCP</th>
<th>Critical Limits</th>
<th>Monitoring Procedures</th>
<th>Verification Procedures</th>
<th>Records</th>
<th>Corrective Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>1B</td>
<td>Internal temp at least 160°F</td>
<td>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”</td>
<td>Accuracy of all thermometers 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)</td>
<td>Cooking log Thermometer log Corrective Actions log</td>
<td>QC will take Corrective Actions per 417.3</td>
</tr>
<tr>
<td>2B</td>
<td>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</td>
<td>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</td>
<td>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)</td>
<td>Cooling log Thermometer log Corrective Actions log</td>
<td>QC will take Corrective Actions per 417.3</td>
</tr>
</tbody>
</table>
28 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 bacteria, possibly including pathogenic bacteria, to the exposed RTE product after the lethality treatment. These bacteria can come from the environment, from the employees, or from the equipment. They can be transferred directly, such as when an exposed RTE product is placed on a 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.
29 Listeria monocytogenes (Lm) Regulations

Objectives

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 “Listeria Rule Verification Activities.”

Introduction

Listeria monocytogenes (Lm) is a widespread pathogen capable of surviving under various environmental conditions. It has been isolated from the soil, plant materials, animal feedstuffs, the intestinal tract of various mammals and birds, and has also been found in some species of fish and shellfish. Lm is very tolerant of freezing, drying, salt, and heat, and can grow at temperatures from 31.3°F up to 113°F. It can adapt to significant changes in pH values and reproduce at a pH range between 4.39 and 9.4. Lm can also reproduce with a water activity (aw) as low as 0.92.

Listeriosis, a disease caused by consuming food products contaminated with Lm, can occur from a few days up to six weeks after ingestion. The infective dose of Lm is believed to be fewer than 1,000 organisms. Lm is especially pathogenic to high risk populations, including pregnant women and their fetuses, young children, the elderly, and immunocompromised individuals. An individual with a mild Lm infection may have general flu-like symptoms, including nausea, vomiting, and diarrhea. However, severe infections can lead to septicemia, meningitis, encephalitis, and death. Infections during pregnancy may result in a miscarriage or stillbirth.

A common link in Lm outbreaks is contamination of RTE products in the post-lethality environment prior to packaging. Lm can contaminate a food processing environment from animals, ingredients, equipment, personnel, environmental reservoirs, or other means. Once Lm contaminates the processing environment, it can establish in drains, on processing equipment, and in refrigeration units. The organism can also form a durable biofilm.

Lm may cross-contaminate RTE product exposed to the post-lethality environment due to inadequate sanitary practices. Dust, movement of personnel, and equipment associated with construction projects (e.g., air handling system repairs, removal of walls, repairs to plumbing systems) create opportunities for Lm to cross-contaminate post-lethality exposed product. An establishment may need to implement additional sanitation practices and containment procedures for any construction projects in or around processing areas where post-lethality exposed products are handled and packaged.
FSIS considers \textit{Lm} to be a significant foodborne pathogen of great potential public health concern that must be controlled by establishments producing post-lethality exposed RTE products. FSIS has developed regulatory requirements specifically for controlling \textit{Lm} in post-lethality exposed RTE products. In addition, the agency has developed \textit{Lm} sampling programs as part of its public health strategy for protecting consumers against \textit{Lm}.

\textbf{Listeria Rule}

On June 6, 2003, FSIS published an interim final i.e., 9 CFR Part 430 “Listeria Rule” that requires establishments producing post-lethality exposed RTE products to prevent adulteration by \textit{Lm}. 9CFR 430.4(a) identifies \textit{Lm} as a hazard that establishments producing RTE products exposed to the post-lethality environment must control through a HACCP plan or prevent in the processing environment through an SSOP or other prerequisite program. It states that RTE product is adulterated if it contains \textit{Lm} or comes into direct contact with a food contact surface contaminated with \textit{Lm}. 9 CFR 430.4(b) identifies three alternatives that establishments are to choose from in order to control \textit{Listeria} in post-lethality exposed RTE product. IPP are responsible for using appropriate HACCP or SSOP verification tasks to verify establishment compliance with §430.4(b).

\textbf{Definitions}

9 CFR 430.1 provides several definitions that are specific to ready-to-eat (RTE) products. Two RTE product definitions are \textbf{deli products} and \textbf{hotdog products}. A \textit{deli product} is an RTE meat or poultry product that is typically sliced, either in an official establishment or after distribution, and assembled in a sandwich for consumption. A \textit{hotdog product} is an RTE meat or poultry frank, frankfurter, or wiener product with a standard of identity defined in 9 CFR 319.180 and 319.181. 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 \textit{Lm}.

\textbf{A lethality treatment} is the initial process RTE meat and poultry product undergoes to eliminate or reduce the number of pathogenic microorganisms on or in a product. Examples of lethality treatments that will make an RTE product safe for human consumption include cooking or the application of an antimicrobial agent or process that eliminates or reduces pathogenic microorganisms.

The \textbf{post-lethality processing environment} is the area in an establishment into which product subjected to an initial lethality treatment has been routed. The product may be exposed to the environment through slicing, peeling, re-bagging, cooling semi-permeable encased product in a brine solution, or other procedures.

\textbf{Post-lethality exposed product} is RTE product that comes into direct contact with a food contact surface in the post-lethality processing environment after an initial lethality treatment. Only post-lethality exposed RTE products are subject to 9 CFR 430.
The following three terms are associated with the three *Listeria* control alternatives used to control or prevent *Lm* in an RTE product in the post-lethality environment:

- **Post-lethality treatment** (PLT) - an additional lethality treatment, following the initial lethality treatment, applied to the final product or sealed package of product to reduce or eliminate the risk of *Lm* contamination during post-lethality exposure. Examples of post-lethality treatments include steam pasteurization, hot water pasteurization, radiant heating, and high-pressure processing (HPP). Some antimicrobial agents may also function as post-lethality treatments.

- **Antimicrobial agent** - a substance in or added to an RTE product that suppresses or limits growth of *Lm* in the product throughout the shelf life of the product. Examples of antimicrobial agents used in RTE products are sodium lactate, potassium lactate, and sodium diacetate. FSIS Directive 7120.1 identifies additional antimicrobial agents approved for use in the production of RTE meat and poultry products.

- **Antimicrobial process** - an operation (e.g., freezing) applied to an RTE product that suppresses or limits 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*.

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

While not defined in §430.1, *indicator organism* is defined in 9 CFR 430 as a species of bacterium used to determine if the sanitary conditions of food processing equipment, production areas, or storage rooms will allow for the presence of pathogenic microorganisms.

**Establishment Responsibilities**

An establishment that produces post-lethality exposed RTE meat and poultry products must maintains its facility in a sanitary manner. The sanitation program must be designed and implemented to prevent contamination of food contact surfaces (FCS) and adulteration of RTE product with *Lm* and other pathogens in the post-lethality environment. The establishment must conduct a hazard analysis designed to control FCS contamination and adulteration of RTE products. Any hazards considered reasonably likely to occur must be included in a HACCP plan and the effectiveness of the RTE processes validated. The establishment should incorporate procedures for accurately labeling RTE products, including identifying product for rework. The hazard analysis, HACCP plan, supporting documentation, and prerequisite programs should be maintained and made available to FSIS upon request.

**Sampling Program**

Under §430.4(b)(2)(iii)(A) and (3)(i)(A), establishments that produce post-lethality exposed RTE products are required to provide for FCS testing in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or indicator organism.
While sampling is not required under Alternative 1 or Alternative 2, Choice 1, FSIS recommends the establishment collect from each post-lethality exposed production line a minimum of 2 \( Lm \) FCS samples per year (every 6 months) under Alternative 1 and a minimum of 4 \( Lm \) FCS samples per year (quarterly) under Alternative 2, Choice 1. FCS sampling is required for Alternative 2, Choice 2 and Alternative 3. The minimum required sampling frequency from each post-lethality exposed production line under Alternative 2, Choice 2 is 4 \( Lm \) FCS samples per year (quarterly) and once per month (monthly) under Alternative 3. For establishments that produce RTE deli products and hotdogs under Alternative 3, the minimum FCS sampling frequency from each post-lethality exposed production line is monthly in very small establishments, every 2 weeks for small establishments, and weekly in large establishments. 9 CFR 430.4 requires establishments to identify the size, location, and frequency of the FCS sites to be sampled and provide an explanation of why the testing frequency is sufficient to ensure that \( Lm \) will be effectively controlled.

**IPP Responsibilities for Verifying Compliance with 9 CFR Part 430.4**

In order to verify compliance with 9 CFR 430.4, IPP must be familiar with the establishment’s RTE products and processes. If necessary, establishment management should be asked if they produce any RTE product that is exposed to the environment following the initial lethality step.

IPP should ask the establishment which of the three *Listeria* control alternatives was chosen for each post-lethality exposed RTE product produced. If necessary, plant management should be advised that initial validation results supporting the effectiveness of the selected alternative must be made available to FSIS upon request.

IPP should verify that the establishment is meeting the requirements of the alternative it selected by performing the appropriate SSOP or HACCP tasks. If the establishment decides to produce different products using different alternatives, the inspector should verify that each post-lethality exposed RTE product meets the requirements for the alternative selected.

In addition to verifying the effectiveness of the *Listeria* control alternatives selected, IPP will verify that the establishment is maintaining sanitary conditions sufficient to prevent product contamination, including \( Lm \). Sanitation is the foundation for controlling \( Lm \) and without it, no alternative will successfully control \( Lm \).

**Note:** See Attachment 1 for *L. monocytogenes* control requirements and Attachment 2 for summaries of the *Listeria* control alternatives and their requirements.

**Alternative 1 - 9 CFR 430.4(b)(1)**

Alternative 1 uses a post-lethality treatment (which may also be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product AND an antimicrobial agent or process that suppresses or limits the growth of \( Lm \).
Alternative 1 Compliance Example

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

Alternative 2 - 9 CFR 430.4(b)(2)

Alternative 2 uses either a post-lethality treatment (which may be an antimicrobial agent or process) that reduces or eliminates microorganisms on the product or an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

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

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

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

Alternative 2 Compliance

**Example 1:** An establishment's product line includes chicken salad and ham salad in hermetically seals containers under Alternative 2, Choice 1. The cooked, sealed containers are batch loaded into cylinders and the cylinders are loaded into a chamber, to undergo High Pressure Processing (HPP) as a post-lethality treatment. 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 (RLTO) in the post-lethality processing environment. The establishment identified the HPP as a post-lethality treatment and included it in its HACCP plan as a CCP. The critical limit for HPP is time at a specific pressure level. In reviewing supporting documents for the CCP, you determine 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°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 high pressure process. You conclude that the establishment is in compliance with 9 CFR 430.4(b)(2).

**Example 2:** You are verifying that an establishment is meeting the requirements of §430 and Alternative 2, Choice 2. You review the establishment’s hazard analysis for fully cooked frozen breaded chicken products and verify that the cooking and chilling steps have been identified as CCPs in the hazard analysis and were incorporated into a HACCP plan. In addition to these CCPs, *Lm* was considered a potential hazard not reasonably likely to occur (NRLTO) at the packaging step because of the *Listeria* control measures in the establishment’s SSOP designed to prevent *Lm* in the post-lethality processing environment. You request the supporting documentation for decisions made in the hazard analysis and the establishment provides a scientific document that identifies freezing as an antimicrobial process that would inhibit *Lm* growth in the finished product throughout the shelf life of the product. The establishment also provides the verification procedures and associated records it uses to demonstrate that products are frozen below the level that the scientific validation document establishes as effective in 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 verify 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* is maintained. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(2).

**Alternative 3 - 9 CFR 430.4(b)(3)**

Alternative 3 involves the use of sanitation measures alone to prevent *Lm* in the processing environment and on the RTE product. There are separate FCS sampling requirements for deli meat and hotdogs produced under this alternative.

**Alternative 3 Compliance**

**Example 1:** You are verifying that the establishment is meeting 9 CFR 430 and Alternative 3 requirements. You review the establishment’s hazard analysis for fully cooked, not shelf stable breakfast type products (e.g., bacon, sausage patties, sausage links, etc.). You verify that the cooking and chilling steps have been identified as CCPs in the hazard analysis and were incorporated into a HACCP plan. *Lm* was considered a potential hazard NRLTO at the packaging step because the establishment has implemented sanitary measures to control *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is NRLTO in the post-lethality environment. You review the establishment’s
SSOP program and records. You verify 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 also 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 frequency of testing. The establishment provided a thought process documenting why the testing frequency selected is sufficient to ensure that effective control of *Lm* 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 9 CFR 430 and Alternative 3. You review the establishment’s hazard analysis for fully cooked, not shelf stable deli and hotdog type products (e.g., franks, sliced ham, sliced bologna, sliced roast beef, sliced turkey breast, etc.). You verify that the cooking and chilling steps were identified as CCPs in the hazard analysis and incorporated into a HACCP plan. The establishment considered *Lm* a food safety hazard NRLTO at the packaging step because of *Listeria* control measures in its SSOP intended to prevent *Lm* from occurring in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is NRLTO in the post-lethality environment. You review the establishment’s SSOP and records and verify 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 documenting why the testing frequency selected is sufficient to ensure that effective control of *Lm* is maintained.

You determine that the establishment verifies the effectiveness of the corrective actions taken with respect to sanitation after an initial positive test result. The corrective actions require 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. You verify that if the establishment obtains a second positive test during follow-up testing, it will hold the lots of product that may be contaminated from contact with the food contact surface until a subsequent test result indicates that the sanitation problem is corrected. After a second positive *Lm* sample result, the establishment will also test each lot of product that may have become contaminated with *Lm*. The establishment will release the implicated product into commerce only after it has been tested and found free of *Lm*. If the sampled product tests positive for *Lm*, the establishment considers the product adulterated and withholds it from distribution. The establishment will then either destroy the held product or rework it using a process that is destructive to *Lm*. The establishment will also document the test results and product disposition. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(3).
VERIFYING COMPLIANCE

Gather Information

IPP should use the GAD thought process to verify compliance with Alternatives 1, 2, or 3. Alternative 2 is based on the same requirements as Alternative 1 except that the establishment can choose to use only a post-lethality treatment (Choice 1) or an antimicrobial agent or process (Choice 2). When verifying compliance with Alternative 1 and Alternative 2 requirements, IPP should seek answers to the following questions:

1. Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in a HACCP plan?
2. Does the establishment have scientific documentation supporting the effectiveness of its post-lethality treatment in accordance with §417.5(a)(2)?
3. Does the establishment have validation data for the post-lethality treatment in accordance with §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 \textit{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?
7. Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of \textit{Lm} in its HACCP plan, its Sanitation SOPs, or a prerequisite program?
8. Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

When verifying compliance with Alternative 2, Choice 2, or Alternative 3 requirements, IPP should seek answers to these questions regarding the establishment’s sanitation procedures.

1. Has the establishment incorporated sanitation measures in a HACCP plan, SSOP, or other prerequisite program?
2. Is the establishment’s food contact surface testing used to verify the on-going effectiveness of its sanitation procedures?
3. Does testing of food contact surfaces in the post-lethality processing environment ensure
that the surfaces are sanitary and free of Lm or of an indicator organism?

4. Did the establishment identify the conditions under which it will implement hold-and-test procedures following a positive test of a food contact surface for an indicator organism?

5. Did the establishment state the frequency with which testing will be done?

6. Did the establishment identify the size and location of the sites that will be sampled?
   
   NOTE: establishments should identify all possible FCS sites (AskFSIS QA dated 2-17-12)

7. Did the establishment include an explanation of why the testing frequency is sufficient to ensure that effective control of Lm, or an indicator organism, is maintained?

If an establishment produces a RTE deli product or hotdog product under Alternative 3, IPP should verify that the establishment:

1. Effectively implemented corrective actions (with respect to sanitation after an initial positive result on a food contact surface in the post-lethality processing environment) 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. Holds product lots 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 follow-up testing until the problem is corrected as indicated by negative follow-up test results.

3. Sample and test product 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.

4. Documents testing results.

5. Reworks held product using a process that is destructive to Lm.

Assess Information

To answer these questions, IPP 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).
- Review Sanitation SOP and/or prerequisite program records (as necessary).
Determine Compliance

IPP must determine regulatory compliance after all available information pertaining to the Listeria Control Alternative selected has been gathered and assessed. There is no noncompliance if the establishment has met all regulatory requirements. If the establishment has not met all regulatory requirements, the noncompliance should be documented on an NR under the appropriate PHIS task as described in FSIS Directive 5000.1, citing the appropriate sections of §430.4(b), §417 for HACCP and prerequisite programs, and/or §416 for sanitation. IPP should verify that the establishment has taken effective corrective and preventive actions 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.

Alternative 1 Noncompliance Examples:

1. The establishment has a post-lethality treatment to reduce or eliminate Lm incorporated into the HACCP plan but does not have the use of the antimicrobial agent or process to suppress or limit the growth of Lm incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program. (Cite §430.4(b)(1), 417.5(a)(1) & (2))

2. The establishment has the use of the antimicrobial agent or process to suppress or limit the growth of Lm incorporated into its HACCP plan, its Sanitation SOP, or a prerequisite program, but does not have a post-lethality treatment to reduce or eliminate Lm incorporated into the HACCP plan. (Cite §430.4(b)(1), 417.5(a)(1) & (2))

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

Alternative 2 Noncompliance Examples

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 included in a HACCP plan OR an antimicrobial agent or process to suppress or limit the growth of Lm incorporated into a HACCP plan, SSOP, or a prerequisite program. Cite §430.4(b)(2), 417.2, 417.5(a)(1) & (2)

2. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 only addresses the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of Lm or of an indicator organism. Cite §430.4(b)(2), 416, 417.5(a)(1) & (2)

3. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the conditions under which or at what point hold-and-test
procedures following a positive test of a food-contact surface for Lm or an indicator organism will be initiated. Cite §430.4(b)(2), 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 sites to be sampled or explain why the testing frequency selected is sufficient to ensure that effective control of Lm or an indicator organism is maintained. Cite §430.4(b)(2), 417.5(a)(1) & (2)

Alternative 3 Noncompliance Examples

1. The establishment does not have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program. Cite §430.4(b)(3), 417.5(a)(1) & (2)

2. An establishment that produces deli and hotdog products does not conduct follow-up testing of target sites on the FCS 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), 417.5(a)(1) & (2)

3. An establishment that produces deli and hotdog 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), 417.5(a)(1) & (2)

Documentation and Enforcement

If noncompliance with the Lm regulations is found, IPP are to issue an NR under the appropriate HACCP or SSOP task as described in FSIS Directive 5000.1, citing 9 CFR 430.4(b)(1), (2), or (3) and the appropriate sections of 9 CFR 417 or 416 if applicable. IPP are to verify that the establishment has taken effective corrective actions 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, IPP 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 9 CFR 430.
## ATTACHMENT 1: CONTROL REQUIREMENTS for Listeria MONOCYTOGENES

### Requirements

<table>
<thead>
<tr>
<th>Post-lethality Treatment AND Antimicrobial agent or Process</th>
<th>Post-lethality Treatment OR Antimicrobial agent or Process</th>
<th>Sanitation and Testing Program</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Choice 1:</strong> Post-lethality Treatment</td>
<td><strong>Choice 2:</strong> Antimicrobial Agent or Process</td>
<td>Non-deli, Non-hotdog</td>
</tr>
</tbody>
</table>

- **Increasing Risk Levels and Frequency of FSIS Verification Testing**

### 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 \( Lm \) prior to distribution of the product into commerce.

### Document effectiveness of antimicrobial agent or process:
- Must be included as part of the establishment’s HACCP, Sanitation SOP, or Pre-requisite Program and should demonstrate no more than 2-logs growth of \( Lm \) over the estimated shelf life.

### Sanitation Program Requirements

- Testing food contact surfaces (FCS) in the post-lethality processing environment for \( Lm \) or an indicator organism.
- State testing frequency.
- Identify size and location of sites to be sampled.
- Explain why testing frequency is sufficient to control \( Lm \) or an indicator organism.
- Identify conditions for Hold-and-Test, when FCS (+) for \( Lm \) or an indicator organism.

### Additional Sanitation Program Requirements

- Effective after 1st FCS (+) for \( Lm \) or an indicator organism. Includes testing of targeted FCS as most likely source and additional testing of the surrounding area.
- If follow-up testing yields 2nd FCS (+), hold products that may be contaminated until problem is corrected as shown by FCS (-) in follow-up testing.
- Hold and test product lots using a sampling plan that provides statistical confidence that the lots are not contaminated with \( Lm \) or an indicator organism. Release, rework or condemn products based on results.
- Document results and product disposition.

### Establishments in all three alternatives must maintain sanitation in accordance with 9 CFR 416.
30 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. Food contact surface
   b. Intact package
   c. Sampled lot
4. Describe the steps for performing a RTE sampling task.
5. Explain the difference between the RTEPROD_RAND and the RTEPROD_RISK sampling project codes.
6. Explain what IPP should consider when scheduling RTE samples.
7. Describe why it is important to notify establishment management prior to taking a sample.
8. Explain how FSIS samples are documented.
9. Describe the process for ensuring sample integrity, from sample collection until sample is shipped.
10. List the items that are packed into the sample container.
11. Identify how IPP obtain sample results.
12. Describe what actions IPP take when a positive FSIS RTE sample result is identified.
13. Describe the actions IPP take when establishment testing obtains a positive sample result.
14. Explain the procedures in verifying corrective actions for a positive RTE sample.
15. Identify the two sampling programs that EIAOs may perform in RTE establishments.

FSIS’s microbiological testing program 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* 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*

A **food contact surface** is the equipment or utensil surface with which exposed RTE product has direct contact (for example, conveyor belt, tabletop, knife blade).

**Intact package.** This is product in the final packaged form (immediate container) in which it will be shipped.

**Sampled lot** is the amount of product represented by the sample.

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

**RTEPROD_RAND:** For this sample program, IPP will randomly select any RTE product produced at the time of collection, regardless of whether the product has been exposed post-lethality; and make every effort to randomly sample all the RTE products produced at the establishment by rotating through the products over time (i.e., through subsequent sample requests).

**RTEPROD_RISK:** For this sample program, IPP are to select a post-lethality-exposed product based on the highest risk level.

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.

For both RTEPROD_RAND and RTEPROD_RISK samples, 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_RAND or RTEPROD_RISK sampling projects 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.

Establishments under Alternative 2 Choice 2 and Alternative 3 are required to conduct sampling of food contact surfaces. Establishments may also choose to conduct sampling of product. If an establishment’s product or food contact surface test result is positive for *Lm*, IPP should not issue an NR unless the establishment failed to hold the affected product and did not implement corrective actions, which includes proper disposition of the sampled product lot.
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* (RLm) sampling program when conducting routine FSAs in establishments that produce RTE products.

31 HACCP System and Recall Verification

Objectives

1. Explain the regulatory thought process, define its four components, and identify key aspects of each component.

2. Understand four essential questions to consider in determining when to document a failure to meet HACCP regulatory requirements.

3. Use the regulatory thought process to determine if a food safety system is inadequate.

4. Identify three types of enforcement actions taken when a noncompliance determination is made.

5. Identify two scenarios when a HACCP verification plan is necessary.

6. Verify that establishments maintain written recall procedures per 9 CFR 418.3 requirements.

Introduction

The HACCP system, referenced in 9 CFR 417.4, is defined in 9 CFR 417.1 as “the HACCP plan in operation, including the HACCP plan itself.” The HACCP plan in operation includes ALL of the following:

- Hazard analysis.
- HACCP plan.
- Supporting documentation including prerequisite programs used to make decisions in the hazard analysis.
- HACCP records generated on an ongoing basis.

In using the regulatory thought process to determine if wholesome, unadulterated products are being produced, IPP are actually verifying the overall effectiveness of the establishment’s HACCP system. Verifying whether individual product units are wholesome is less important than determining the overall effectiveness of the establishment’s comprehensive HACCP system.

HACCP Regulatory Process

The diagram in module 13 (HACCP Regulatory Process) shows the HACCP regulatory process, which includes the following four components:

- **Inspection Methodology**
  - Performing HACCP inspection tasks
  - Verifying specific HACCP regulatory requirements by performing the HACCP inspection task
• **Decision-making (GAD)**
  - **Gathering** information, making observations, reviewing documentation, **assessing** the gathered information, arriving at a supportable compliance **determination**

• **Documentation**
  - Entering HACCP inspection task results (observations and determinations) in PHIS
  - Documenting noncompliance on a Noncompliance Record (NR)
  - Associating noncompliance from the same cause

• **Enforcement**
  - Following the Rules of Practice (ROP)
  - Providing the establishment with due process

**FSIS Responsibilities**

FSIS responsibilities for verifying an establishment’s food safety system are outlined in FSIS Directives 5000.1 and 5000.6. IPP are responsible for understanding and properly performing in PHIS the HACCP inspection tasks described in these Directives.

**Inspection Methodology**

To verify that establishments are complying with 9 CFR Part 417, IPP perform two HACCP inspection tasks: The Hazard Analysis Verification (HAV) task and the HACCP Verification Task. The HAV Task directs IPP to review the establishment’s hazard analysis, prerequisite programs, and other supporting documentation for one HACCP plan. The HACCP Verification Task focuses on verifying the implementation of the establishment’s HACCP plans, prerequisite programs, and other supporting programs. Both of the HACCP verification tasks, which can be performed as a routine or directed task, has two verification components:

- Recordkeeping (RK)
- Review and Observation (RO)

IPP may use either component or a combination of the components to verify regulatory compliance.

**Decision-Making (GAD)**

IPP should use the regulatory **GAD** (Gather, Assess, and Determine) thought process to perform the HACCP inspection tasks. IPP are to gather all available information to help them determine regulatory compliance. This may include:

- Reviewing hazard analyses, HACCP plans, prerequisite programs, supporting documentation, and ongoing monitoring records, HACCP plans, SSOPs, prerequisite programs, and other supporting programs or procedures.

- Observing establishment employees performing or implementing HACCP, SSOP, or prerequisite program or other supporting program procedures, and occasionally taking measurements as specified in HACCP system documents.
After reviewing the gathered information, IPP are to assess the significance and meaning of information gathered by:

- Comparing the information gathered to HACCP regulatory requirements.
- Considering how each piece of information, either taken separately or with other findings, supports that the HACCP system is functioning as intended.
- Considering the information in the context of past findings to identify any patterns or trends (e.g., Is this an isolated or recurring problem? Are conditions getting worse? Is the establishment responding effectively and in a timely manner to problems?)

HACCP system noncompliance is a failure to meet any of the regulatory requirements outlined in 9 CFR Part 417. If a HACCP system noncompliance is identified, the establishment is expected to take immediate and further planned actions to come back into compliance. Before IPP determine whether or not they should document the failure to meet the HACCP regulatory requirements as a noncompliance, they should consider the following four questions:

1. Did the establishment identify the failure to meet regulatory requirements or deviations from a critical limit?
2. If product is involved, has the establishment ensured product safety?
3. Has the establishment taken immediate and further planned actions to correct the failure to meet regulatory requirements, or has it taken corrective actions to address the deviation in accordance with 9 CFR 417.3?
4. Is a trend developing (i.e., has the establishment failed to carry out the actions in 1 through 3 above for similar situations)?

**Note:** When answering these questions, it may be necessary for the IPP to gather additional information (e.g., ongoing verification records).

There is no noncompliance if the answer to questions 1, 2, and 3 is “yes” and “no” for question 4 because the establishment identified and addressed the situation. IPP would verify and document compliance with the applicable regulations in PHIS because the establishment’s response included the further planned actions and preventive measures for the noncompliance or deviation. The ability to track developing trends would not be adversely affected by not issuing an NR.

However, if the answer to questions 1, 2, or 3 is “no” or question 4 is “yes,” a noncompliance exists. IPP would document the noncompliance in PHIS and generate an NR. IPP should discuss with their supervisor any concerns whether the information supports a particular compliance determination.

**HACCP System Compliance**

The purpose of the HACCP verification task is more than to just identify isolated instances of noncompliance. IPP must also consider what their positive, negative, or inconclusive findings indicate about the overall effectiveness of the establishment’s HACCP system. It is important that each piece of information be considered in the context of the HACCP system and the potential for product adulteration. The following questions will help IPP to consider the significance of each finding for the HACCP system:
• **Is this information part of a pattern or trend?** For example, is the establishment missing a measurement for a prerequisite program an isolated incident or has the establishment regularly failed to implement its prerequisite programs?

• **Is there other information to indicate that the HACCP system is working or is not working?** For example, if an establishment’s prerequisite program specifies product will be received with supplier certificates of analysis (COA) and periodically tested but the establishment failed to receive a COA for a particular product, how did they respond on whether or not to use the product?

• **Does the information seem to agree with the other available information about the food safety system?** For example, an establishment uses a prerequisite program to prevent a hazard in incoming products, and the records appear to show that a particular hazard is being prevented. However, the establishment’s testing of finished product for the particular hazard finds positive results.

• **Do these results support each other or is there an apparent contradiction?** For example, an establishment that uses a prerequisite program to prevent *E. coli* O157:H7 in incoming beef has COAs and verification test results on incoming trim that indicate the hazard is not reasonably likely to occur, but the establishment gets a positive test result on a finished product lot. The finished product test result calls into question the effectiveness of the prerequisite program as means of supporting the decision that *E. coli* O157:H7 is not reasonably likely to occur.

### Inadequate HACCP System Determination

By considering the preceding questions, IPP can determine whether the information supports a finding of HACCP system regulatory compliance:

- Has adulterated product been produced or shipped?
- Is the HACCP system effectively controlling the relevant food safety hazards?
- Has the establishment failed to meet one or more HACCP regulatory requirements?

If noncompliance is found, IPP need to determine if it indicates an inadequate HACCP system.

Depending on the problems identified, the establishment may need to reassess the hazard analysis and HACCP plan. For example, if an establishment has not identified *E. coli* O157:H7 as a food safety hazard reasonably likely to occur, tests outside the HACCP plan or SSOP, and gets a positive result, a reassessment of its HACCP plan and hazard analysis would then be required by 9 CFR 417.4(a)(3). The establishment must support the decisions made during the reassessment as specified in 9 CFR 417.5(a)(1) & (2).

If the establishment did not reassess its HACCP plan and hazard analysis as required by 9 CFR 417.3(b)(4) and §417.4(a)(3)(i) or does not have supporting documentation required by §417.5(a)(1) & (2), IPP cannot determine that the HACCP system meets the requirements of 9 CFR 417.6. Consider the following questions to determine if there is an inadequate HACCP system:

1. **Does the HACCP plan meet the regulatory requirements of 9 CFR Part 417?**

   If an establishment did not implement all or some of its HACCP plan or did not meet regulatory requirements, IPP would be unable to determine whether or not the establishment was producing unadulterated product in compliance with 9 CFR Part 417. For example, the HACCP
A system is inadequate if an establishment does not maintain any records associated with its HACCP plan, does not monitor critical limits at any CCP, or did not reassess or modify its HACCP plan when necessary.

2. Was adulterated product produced or shipped?

The HACCP system is inadequate if it did not prevent the production and distribution of adulterated product. For example, if an establishment failed to meet a critical limit for a CCP and did not take corrective actions per 9 CFR 417.3 but performed a pre-shipment review, the HACCP system is inadequate.

3. Is there a trend in establishment noncompliance?

Trends in the regulations cited on NRs are a key factor in determining if an establishment’s HACCP system is inadequate. Two or more NRs citing the same regulations and recurring noncompliance descriptions addressing similar causes may be a trend that indicates the HACCP system is inadequate.

No specific number of incidents constitutes a trend because of the variabilities in processing environments and HACCP plans. IPP should closely review the noncompliance descriptions contained in Block 10 of the NR form and not rely solely on the number of linked NRs to indicate a possible trend in noncompliance. Careful analysis of the regulations cited and written descriptions of noncompliance are necessary when determining if a trend indicates that the HACCP system may be inadequate.

Action to Take If an Inadequate System Exists

After determining that an inadequate HACCP system exists, IPP would take action and notify the District Office via supervisory channels. If adulterated product was produced and shipped in commerce, IPP would take an immediate withholding action according to the Rules of Practice.

DOCUMENTATION

Completing a Noncompliance Record

When documenting noncompliance on an NR, identify each noncompliance. Be specific, thorough, and include the time and location. Explain that establishment management received notification and state any regulatory control actions taken. Consult FSIS Directive 5000.1 and the PHIS User Guide for further information about completing the NR.

Throughout this course, you have learned that noncompliance is documented when it is observed, and the same causes of noncompliance are associated when they are identified. Documenting and associating noncompliance is not only useful in identifying trends, it also enables the Agency to provide establishments with due process and to take enforcement action when necessary.

If IPP document multiple or recurring noncompliance, they could request (through their chain of command) that the DO issue a Notice of Intended Enforcement Action (NOIE) to the establishment per §500.4. A request for an NOIE should come as no surprise. In reaching this conclusion, IPP should have been discussing the noncompliance trend with the establishment during weekly meetings and keeping the FLS or IIC apprised of what was happening.
Enforcement Rules of Practice

The Rules of Practice (ROP) in 9 CFR 500 provide establishments with due process. They also describe how and under what circumstances the Agency progresses with further enforcement actions. Enforcement action may be necessary to prevent adulterated product from being produced and shipped. In accordance with the Rules of Practice, enforcement action could be one of three types.

1. **Regulatory Control Action** - The retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.

2. **Withholding Action** - 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.

3. **Suspension** - An interruption in the assignment of program employees to all or part of an establishment.

Withholding actions affect whether the mark of inspection may be applied, while suspensions affect whether inspection verification activities will be performed.

**Regulatory Control Actions**

FSIS may take a regulatory control action (RCA) for insanitary conditions or practices, product adulteration or misbranding, conditions that preclude FSIS from determining that product is not adulterated or not misbranded, or inhumane handling or slaughtering of livestock.

An RCA allows IPP to prevent the movement of the affected product or use of the equipment or facility involved until the noncompliance has been corrected. IPP are not required to give the establishment prior notification that they are about to execute a RCA. IPP will take the RCA (e.g., retaining product, rejecting the equipment or room with a tag) and then complete an NR. RCAs should remain in effect until the establishment has brought itself back into regulatory compliance.

If there is SPS or SSOP noncompliance with direct product contamination or adulteration, IPP will verify that the establishment addressed the noncompliance by meeting the requirements of either 9 CFR 416 or 9 CFR 417, including corrective actions. An NR will be written, citing the appropriate SSOP or HACCP regulations. The establishment may need to re-evaluate the effectiveness of its procedures in its HACCP plan or SSOP and modify them if they are no longer effective in preventing contamination or adulteration of product.

If the direct product contamination poses a food safety hazard, IPP will verify that the establishment effectively implemented corrective actions that meet the requirements of §417.3(b). These corrective actions should include a reassessment to determine whether the unforeseen hazard should be incorporated into a HACCP plan. Regulatory control actions are not frequently used for HACCP regulatory noncompliance unless control is necessary to prevent shipment of contaminated or adulterated product.

Examples of common regulatory control actions related to slaughter include stopping a line or retaining a carcass as a result of a slaughter food safety standard finding.
Withholding Actions Without Prior Notice

It may be necessary for IPP to take immediate enforcement actions without giving the establishment prior notice to prevent an imminent threat to public health. For example, IPP would need to take an immediate withholding action if an establishment produced and shipped adulterated product. In this situation, the immediate withholding action would be taken and then the District Office and supervisor would be notified as soon as possible. Refer to the ROP module for additional information.

Withholding and Suspension Actions With Prior Notification

Some withholding and suspension actions require prior notification according to the ROP. The most common withholding or suspension actions related to HACCP noncompliance are those in which the HACCP system is inadequate due to multiple or recurring noncompliance. Withholding or suspending inspection for this cause requires prior notification to the establishment. The prior notice is in the form of a written Notice of Intended Enforcement Action (NOIE). Remember that a suspension may only be issued by a District Manager or higher FSIS official.

District Office Notification

After determining that an inadequate HACCP system may exist, IPP should notify the District Office and request that a Notice of Intended Enforcement (NOIE) be issued to the establishment. The DO will provide direction about any further actions that may need to be taken. The DO may assign an EIAO to evaluate the establishment's HACCP system.

District Office Determines Enforcement Action

After evaluating all of the facts of the case, the District Office will determine the appropriate enforcement action based upon the ROP.
Corrective actions were either not fully implemented or were ineffective. FSIS closes out the NOIE by suspending the assignment of program employees to all or part of the establishment.

Establishment responds including proposed corrective actions

FSIS defers enforcement to allow the establishment to implement proposed corrective actions

Establishment’s response does not adequately address the issues addressed in the NOIE

FSIS prepares a verification plan based on the establishment’s proposed corrective actions

Corrective actions are implemented by the establishment and are effective. FSIS closes out the NOIE with a Letter of Warning (LOW)

Establishment does not respond to the NOIE

FSIS suspends the assignment of program employees to all or part of the establishment

Establishment responds including proposed corrective actions

FSIS holds the suspension in abeyance to allow the establishment time to implement proposed corrective actions

FSIS prepares a verification plan based on the establishment’s proposed corrective actions

Corrective actions were either not fully implemented or were ineffective. FSIS reinstates the suspension

FSIS prepares a verification plan based on the establishment’s proposed corrective actions

Corrective actions are implemented by the establishment and are effective. FSIS closes out the suspension with a Letter of Warning (LOW)
Verification Plan

When FSIS defers an enforcement action or holds a suspension in abeyance, the establishment is allowed time to implement proposed corrective actions. A verification plan (VP) is developed by the EIAO with input from the in-plant inspection team, FLS, and DO. A VP captures all of the corrective actions the establishment stated they would do and provides a systematic means for FSIS to verify that an establishment is effectively implementing the proffered corrective measures.

A Verification Plan:

- Describes the verification activities to be performed by inspection personnel based on the establishment’s corrective measures.
- Lists the procedures and frequency for each verification activity.
- Identifies the regulatory citation for each verification activity.

IPP schedule and perform the directed verification activities identified in the VP, which typically lasts for 90 days and is updated every 30 days. On a weekly basis, the in-plant team reports the results of the activities conducted under the VP, via e-mail to the District Office. The in-plant inspection team has the flexibility to increase the frequency of the verification activities based on its findings. Any failure to meet the conditions of the proposed corrective measures would support FSIS imposing further enforcement actions.

RECALLS

Recalls are initiated when there is evidence of adulterated or misbranded product in commerce (e.g., a positive pathogen sample result is obtained for product the establishment already has shipped). FSIS Directive 8080.1, “Recall of Meat and Poultry Products,” details all verification requirements for recalls.

NOTE: Product is “in commerce” if it is out of the producing establishment’s direct control and is in distribution (e.g., in a warehouse, distribution center, retail facility, restaurant, or other institution).

Establishment Recall Requirements

On May 8, 2012, FSIS published the final rule “Requirements for Official Establishments to Notify FSIS of Adulterated or Misbranded Product, Prepare and Maintain Written Recall Procedures, and Document Certain Hazard Analysis and Critical Control Points System Plan Reassessments” (77 FR 26929). The rule requires official establishments to:

1. Notify the local FSIS DO within 24 hours of learning or determining that an adulterated or misbranded meat or poultry product received by or originating from the official establishment has entered commerce (9 CFR 418.2). The 24-hour period begins once an establishment believes that a product in commerce is adulterated or misbranded under the FMIA or PPIA (e.g., final results of a laboratory analysis show that raw ground beef contains E. coli O157:H7 or product contains an allergen that is not declared on the product label).

2. Prepare and maintain written procedures for the recall of all meat and poultry products produced and shipped by the establishment (9 CFR 418.3).
3. Prepare written recall procedures as required by 9 CFR 418.3 before being granted Federal inspection (9 CFR 304.3(a) and 381.22(a)).

**NOTE:** There may be situations in which laboratory results are not available, but epidemiological evidence indicates there may be a probability of harm from consuming the product. Under these circumstances, official establishments should consider the strength of the epidemiological evidence to determine whether there is reason to believe that the product is adulterated or misbranded.

When notifying the DO that an adulterated or misbranded meat or poultry product was received by or originated from the official establishment, establishment officials should provide the type, amount, origin, and destination of the adulterated or misbranded product.

The DO is to notify the Recall Management and Technical Analysis Division (RMTAD) as soon as possible after notification. If establishments contact other FSIS personnel, those employees are to contact RMTAD promptly through supervisory channels.

The DO and possibly the RMTAD evaluate each situation on a case-by-case basis (see FSIS Directive 8080.1, “Recall of Meat and Poultry Products”). The RMTAD coordinate any recall activities and are to be notified immediately if product has left the establishment’s control. The RMTAD is also notified so that a press release can be issued and recall effectiveness checks can be performed.

More or less product may be determined to be “affected product” when all factors are considered (e.g., whether some or all products produced under the same or a substantially similar HACCP plan have been affected, what pathogens are involved, whether there have been any other incidents of contamination in the establishment associated with the pathogen, and whether there have been persistent and recurring noncompliance in the establishment).

**The establishment is expected to perform a voluntary recall of any unsafe product in commerce.** If the establishment does not voluntarily recall product, the DO will coordinate actions to detain or seize affected product.

Meat and poultry establishments must have written procedures for the recall of any meat or poultry product produced and shipped by the official establishment. FSIS Directive 5000.8, “Verifying Compliance with Requirements for Written Recall Procedures,” dated 12/18/2013, outlines the details of how to verify the requirements of 9 CFR 418.3.

**FSIS Verification**

At least once a year, IPP are to perform a directed Other Inspection Requirements task to verify that establishments have written recall procedures. If IPP determine that the establishment has written recall procedures, they are to document in PHIS that they performed the task, and that the establishment complies with 9 CFR 418.3. If IPP determine that the establishment does not have written recall procedures, they are to document the noncompliance in PHIS on a noncompliance record, citing 9 CFR 418.3.
HACCP Regulatory Process

1. Perform HAV Task

2. Perform HACCP verification Task

3. Noncompliance Found? Yes

4. Stop

5. Inadequate

6. Complete NR

7. Complete NR

8. Follow ROP

9. Notify District Office through supervisory channels

10. District Office will determine appropriate enforcement action based on the ROP

Yes

No

No

Yes
32 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.

Resources:
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

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#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 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).”
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.
33 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 1-866-395-9761.
34 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 product. 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 entree 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.
RULES OF PRACTICE

500.1 Definitions
500.2 Regulatory control action
500.3 Withholding/Suspension WITHOUT prior notification
500.4 Withholding/Suspension WITH prior notification
500.5(b) Notification
500.6 Withdrawal
500.7 Refusal to grant inspection
500.8 Rescinding labels, marks

SANITATION PERFORMANCE STANDARDS

416.1 General rules
416.2 Establishment grounds and facilities
(a) Grounds and pest control
(b) Construction
(c) Light
(d) Ventilation
(e) Plumbing
(f) Sewage disposal
(g) Water supply and water, ice, and solution reuse
(h) Dressing rooms, lavatories & toilets
416.3 Equipment and utensils
(a) constructed to facilitate cleaning
(b) accessibility for inspection
(c) receptacles for storing inedible material
416.4 Sanitary operations
(a) food contact surface, cleaning & sanitizing
(b) non-food contact surface, cleaning & sanitizing
(c) cleaning compounds and sanitizers
(d) product protected
416.5 Employee Hygiene
(a) Cleanliness
(b) Clothing
(c) Disease control
416.6 Tagging equipment, rooms or compartments

SANITATION STANDARD OPERATING PROCEDURES

416.11 General Information
416.12 Development of SSOP's
(a) describe all procedures
(b) signed and dated
(c) procedures for pre-op
(d) frequency of procedures & responsible individual
416.13 Implementation of SSOP's
(a) conduct pre-op
(b) conduct all other procedures
(c) monitors implementation of SSOP procedures
416.14 Maintenance of SSOP's routinely evaluate
416.15 Corrective Actions
(a) conduct corrective actions, including
(b) disposition of contaminated product
(c) restore sanitary conditions
416.16 Record Requirements
(a) daily records required, responsible individual, initialed and dated
(b) records on computers
(c) location and retention of records maintained
416.17 Agency Verification review SSOP’s, daily records, direct observation of SSOP procedures & direct observation of testing

HAZARD ANALYSIS CRITICAL CONTROL POINT

417.1 Definitions
417.2 Hazard Analysis and HACCP Plan
(a) Hazard analysis
(1) Determine RLTO hazards, identify preventive measures
(2) Flow chart
(3) Expected food safety hazards
(b) HACCP plan
(1) develop and implement for each process/product, if hazard RLTO
(2) requirements for single HACCP Plan
(3) requirements for thermally processed
(c) Contents of HACCP Plan
(1) List of food safety hazards
(2) List of CCP’s
(3) List of critical limits
(4) List of procedures & frequency
(5) Corrective actions
(6) Record keeping system
(7) List of verification procedures/frequency
(d) Signing and dating HACCP plan
(1) Signed and dated by responsible person
(2) Sign and date frequency
(e) Failure to Develop and Implement HACCP Plan

417.3 Corrective Actions
(a) Describe action after deviation
(1) Cause is identified & eliminated
(2) CCP is under control
(3) Prevent recurrence
(4) No adulterated product shipped
(b) Unforeseen hazard
(1) Segregate, hold product
(2) Perform review
(3) Actions to ensure product not shipped
(4) Reassessment of HACCP plan
(c) Document corrective actions

417.4 Validation, Verification, Reassessment
(a) Every establishment shall validate HACCP plan/s
(1) Initial validation
(2) Ongoing verification to include, (i) calibration
(ii) direct observation (iii) review of records
(3) Reassessment, (i) at least annually or when change is made, (ii) record reassessment
(b) Reassessment of hazard analysis

417.5 Records
(a) Establishment shall maintain
(1) Written hazard analysis
(2) Written HACCP plan
(3) Records of CCP’s, temps., corrective actions
(b) Made at time event occurs
(c) Pre-shipment review
(d) Records on computer
(e) Record retention
(f) Official review

417.6 Inadequate HACCP System
(a) Plan doesn't meet requirements
(b) HACCP tasks not accomplished
(c) Fails to take corrective actions
(d) No 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
Additional Resources

**Acronym 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
$\text{aw}$ 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
Lm  Listeria monocytogenes
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
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 E. coli
STEPS System Tracking E. coli 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