

Inspection Methods Refresher Course Student Handout



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Sanitation Performance Standards (SPS)

9 CFR 416.1- 416.6

Purpose:

Proper and effective sanitation is vital to every step of the food manufacturing process. This section will focus on helping the IPP develop a working knowledge of the Sanitation Performance Standards (SPS) regulations in the 9 CFR 416.1 through 416.5. IPP will learn how to perform the Sanitation Performance Standards Verification Task using the “GAD” process that is used by FSIS. The GAD process involves gathering information, assessing the information, and determining if the establishment complies with the regulations. IPP will also understand the regulatory responsibilities of IPP (9 CFR 416.6).

Facilities that must comply with the SPS regulations:

- Federal and State inspected meat and poultry establishments
- Import/Export facilities
- Identification (ID) warehouses
- Custom-exempt operations

Sanitation Requirements:

• 9 CFR 416.1 - 416.5

• **FSIS Directive 5000.1 Rev. 5** addresses the Sanitation Performance Standards (SPS) regulations and the SPS Verification Task

Purpose: To verify compliance with the Sanitation Performance Standards (9 CFR 416.1 - 416.5), IPP will inspect conditions in and around the official premises of the establishment, review documents, and inspect the facility and equipment for overall sanitary conditions. The establishment designates the official premises during the grant of application process. IPP must conduct all inspection activities within the physical boundaries designated as the official premises of the establishment.

When performing the SPS task to verify SPS requirements:

IPP should directly observe conditions in one or more areas of the establishment. IPP or the IIC will select standards based on the SPS noncompliance history of the establishment. When necessary, IPP will review the following documents: water potability certificate; pesticide use information; EPA registrations, labels, and instructions for proper use; sewage disposal approval letter (when the establishment has a private sewer system); cleaning compounds, sanitizing agents, processing aids, etc.; and documentation describing the safe and correct use of chemicals that are in the establishment.

When performing the task, IPP should:

- Have a working knowledge of specific SPS regulations;
- Ask questions specific to the regulations;
- Directly observe areas relevant to the regulations; and
- Assess the establishment's answers to those questions

How to determine compliance or noncompliance? Use professional knowledge and good judgement.

- Gather information
- Assess each situation
- Determine if an insanitary condition has occurred.

9 CFR 416.1 General Rules

Sets overall requirement for the SPS, i.e., establishments must ensure operations in and around the establishments do not lead to insanitary conditions that would contaminate or adulterate product.

9 CFR 416.1 is to be cited in situations where findings indicate that an establishment systematically fails to maintain sanitary conditions and that product adulteration may occur as a result. In fact, it is inappropriate to use in every single SPS non-compliance that will be documented.

What does “insanitary” mean? A state, condition, or occurrence which may lead to the contamination or adulteration of edible meat or poultry product when it is exposed, processed, handled, stored, or packaged”.

Sanitation Performance Standards: FSIS Directive 5000.1 -Verifying an Establishment's Food Safety System

SPS Regulations: 9 CFR Part 416.2 - 416.6:

416.2(a) Grounds and Pest Control- The grounds about an establishment must be maintained to prevent conditions that could lead to insanitary conditions, adulteration of product, or interfere with inspection by FSIS program employees. Establishments must have in place a pest management program to prevent the harborage and breeding of pests on the grounds and within establishment facilities. Pest control substances used must be safe and effective under the conditions of use and not be applied or stored in a manner that will result in the adulteration of product or the creation of insanitary conditions.

416.2(b) Construction

- **416.2(b)(1)** Establishment buildings, including their structures, rooms, and compartments must be of sound construction, be kept in good repair, and be of

sufficient size to allow for processing, handling, and storage of product in a manner that does not result in product adulteration or the creation of insanitary conditions.

- **416.2(b)(2)** Walls, floors, and ceilings within establishments must be built of durable materials impervious to moisture and be cleaned and sanitized as necessary to prevent adulteration of product or the creation of insanitary conditions.
- **416.2(b)(3)** Walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice.
- **416.2(b)(4)** Rooms or compartments in which edible product is processed, handled, or stored must be separate and distinct from rooms or compartments in which inedible product is processed, handled, or stored, to the extent necessary to prevent product adulteration and the creation of insanitary conditions.

416.2(c) Lighting- Lighting of good quality and sufficient intensity to ensure that sanitary conditions are maintained, and that product is not adulterated must be provided in areas where food is processed, handled, stored, or examined; where equipment and utensils are cleaned; and in handwashing areas, dressing and locker rooms, and toilets

416.2(d) Ventilation- Ventilation adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of product and the creation of insanitary conditions must be provided.

416.2(e) Plumbing- Plumbing systems must be installed and maintained to:

- **416.2(e)(1)** Carry sufficient quantities of water to required locations throughout the establishment.
- **416.2(e)(2)** Properly convey sewage and liquid disposable waste from the establishment.
- **416.2(e)(3)** Prevent adulteration of product, water supplies, equipment, and utensils and prevent the creation of insanitary conditions throughout the establishment.
- **416.2(e)(4)** Provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor.
- **416.2(e)(5)** Prevent back-flow conditions in and cross-connection between piping systems that discharge wastewater or sewage and piping systems that carry water for product manufacturing.
- **416.2(e)(6)** Prevent the back up of sewer gases.

416.2(f) Sewage- Sewage disposal -Sewage must be disposed into a sewage system separate from all other drainage lines or disposed of through other means sufficient to prevent backup of sewage into areas where product is processed, handled, or stored. When the sewage disposal system is a private system requiring approval by a State or local health authority, the establishment must furnish FSIS with the letter of approval from that authority upon request.

416.2(g) Water supply, water, ice, solution reuse

- **416.2(g)(1)** A supply of running water that complies with the National Primary Drinking Water regulations (40 CFR part 141), at a suitable temperature and under pressure as needed, must be provided in all areas where required (for processing product, for cleaning rooms and equipment, utensils, and packaging materials, for employee sanitary facilities, etc.). If an establishment uses a municipal water supply, it must make available to FSIS, upon request, a water report, issued under the authority of the State or local health agency, certifying or attesting to the potability of the water supply. If an establishment uses a private well for its water supply, it must make available to FSIS, upon request, documentation certifying the potability of the water supply that has been renewed at least semi-annually.
- **416.2(g)(2)** Water, ice, and solutions (such as brine, liquid smoke, or propylene glycol) used to chill or cook ready-to-eat product may be reused for the same purpose, provided that they are maintained free of pathogenic organisms and fecal coliform organisms and that other physical, chemical, and microbiological contamination have been reduced to prevent adulteration of product.
- **416.2(g)(3)** Water, ice, and solutions used to chill or wash raw product may be reused for the same purpose provided that measures are taken to reduce physical, chemical, and microbiological contamination so as to prevent contamination or adulteration of product. Reuse that has come into contact with raw product may not be used on ready-to-eat product.
- **416.2(g)(4)** Reconditioned water that has never contained human waste and that has been treated by an onsite advanced wastewater treatment facility may be used on raw product, except in product formulation, and throughout the facility in edible and inedible production areas, provided that measures are taken to ensure that this water meets the criteria prescribed in paragraph (g)(1) of this section. Product, facilities, equipment, and utensils coming in contact with this water must undergo a separate final rinse with non-reconditioned water that meets the criteria prescribed in paragraph (g)(1) of this section.
- **416.2(g)(5)** Any water that has never contained human waste and that is free of pathogenic organisms may be used in edible and inedible product areas, provided it does not contact edible product. For example, such reuse water may be used to move heavy solids, to flush the bottom of open 24 evisceration troughs, or to wash antemortem areas, livestock pens, trucks, poultry cages, picker aprons, picking room floors, and similar areas within the establishment.
- **416.2(g)(6)** Water that does not meet the use conditions of paragraphs (g)(1) through (g)(5) of this section may not be used in areas where edible product is handled or prepared or in any manner that would allow it to adulterate edible product or create insanitary conditions.

416.2(h) Dressing rooms, Lavatories, and Toilets:

- **416.2(h)(1)** Dressing rooms, toilet rooms, and urinals must be sufficient in number, ample in size, conveniently located, and maintained in a sanitary condition and in good

repair at all times to ensure cleanliness of all persons handling any product. They must be separate from the rooms and compartments in which products are processed, stored, or handled.

- **416.2(h)(2)** Lavatories with running hot and cold water, soap, and towels must be placed in or near toilet and urinal rooms and at such other places in the establishment as necessary to ensure cleanliness of all persons handling any product.
- **416.2(h)(3)** Refuse receptacles must be constructed and maintained in a manner that protects against the creation of insanitary conditions and the adulteration of product.

416.3 Equipment & Utensils

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

416.4 Sanitary Operations:

- **416.4(a)** All food-contact surfaces, including food-contact surfaces of utensils and equipment, must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.

NOTE: Many establishments will comply with the requirements of 416.4(a) through SSOP activities.

- **416.4(b)** Non-food-contact surfaces of facilities, equipment, and utensils used in the operation of the establishment must be cleaned and sanitized as frequently as necessary to prevent the creation of insanitary conditions and the adulteration of product.
- **416.4(c)** Cleaning compounds, sanitizing agents, processing aids, and other chemicals used by an establishment must be safe and effective under the conditions of use. Such chemicals must be used, handled, and stored in a manner that will not adulterate product or create insanitary conditions.

Documentation substantiating the safety of a chemical's use in a food processing environment must be available to FSIS inspection program employees for review.

- **416.4(d)** Product must be protected from adulteration during processing, handling, storage, loading, and unloading at and during transportation from official establishments.

416.5 Employee Hygiene:

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

Custom Exempt 303.1a(2)(i) Establishments that conduct custom exempt operations must be maintained and operated in accordance with the provisions of §416.1 through 416.6, except for §416.2(g)(2) through (6) of this chapter, regarding the water reuse and any provisions of Part 416 of this chapter relating to inspection or supervision of specified activities or other action by a program employee. If custom exempt operations are conducted in an official establishment, however, all of the provisions of

Part 416 of this chapter shall apply to those operations.

Sanitation Standard Operating Procedures (SSOP)

Objectives

After completion of this module, the participant will be able to:

1. List the 4 regulatory requirements for Sanitation SOPs.
2. State the steps taken by IPP to verify Sanitation SOP implementation and monitoring, maintenance, recordkeeping, and corrective actions.
3. Identify the required corrective actions the establishment must take and record for noncompliances involving direct contamination or adulteration of product.
4. List the record retention, authentication, data integrity, and daily documentation requirements for Sanitation SOP records.
5. Discuss the enforcement action that could be taken when FSIS observes a noncompliance during a pre-operational or operational sanitation inspection.

General Rules

§416.11 General Rules

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

Sanitation Standard Operating Procedures (Sanitation SOPs) are written procedures that an establishment develops and implements to prevent direct contamination or adulteration of product. The establishment is required to maintain these written procedures on file, and they must be available to FSIS upon request. It is the establishment's responsibility to implement the procedures as written in the Sanitation SOPs. The establishment must maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective action taken. When the establishment or FSIS determines that the Sanitation SOPs may have failed to prevent direct contamination or adulteration of product, the establishment must implement corrective actions that include the appropriate disposition of product, restore sanitary conditions, and develop measures to prevent recurrence.

Development of Sanitation SOPs

§416.12 Development of Sanitation SOPs

- (a) *The Sanitation SOPs shall describe all procedures an official establishment will conduct daily, before and during operations, sufficient to prevent direct contamination or adulteration of product(s).*
- (b) *The Sanitation SOPs shall be signed and dated by the individual with overall authority on-site or a higher level official of the establishment. This signature shall signify that the establishment will implement the Sanitation SOPs as specified and will maintain the Sanitation SOPs in accordance with the requirements of this part. The Sanitation SOPs shall be signed and dated upon initially implementing the Sanitation SOPs and upon any modification to the Sanitation SOPs.*

- (c) *Procedures in the Sanitation SOPs that are to be conducted prior to operations shall be identified as such, and shall address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.*
- (d) *The Sanitation SOPs shall specify the frequency with which each procedure in the Sanitation SOPs is to be conducted and identify the establishment employee(s) responsible for the implementation and maintenance of such procedure(s).*

Establishment Responsibilities

The establishment has the responsibility to develop written Sanitation SOPs that clearly describe procedures the establishment will implement to prevent direct contamination or adulteration of product. The establishment and inspection personnel should understand that there are not separate Sanitation SOPs for different operations or different shifts. The Sanitation SOPs cover the entire establishment and all shifts of operation.

These written procedures must:

- contain all the procedures the establishment will conduct daily, before and during operation.
- identify the procedures to be conducted prior to operations (pre-op) and address, at a minimum, the cleaning of food contact surfaces of facilities, equipment, and utensils.
- specify the frequency with which each procedure in the Sanitation SOP is to be conducted and identify the establishment employee or position responsible for the implementation and maintenance of the procedures.
- be signed and dated by the individual with overall authority on-site or a higher-level official of the establishment. This signature signifies that the establishment will implement the Sanitation SOPs as written and will maintain the Sanitation SOPs in accordance with the requirements of this part.

Inspection Verification for the Sanitation SOP Design

All USDA-FSIS inspected establishments must have written Sanitation SOPs that meet the development (basic design) requirements listed in §416.12 before a Grant of Inspection is given. The FLS, or designee, will ensure that new establishments have written Sanitation SOPs in place prior to recommending approval for a Grant of Inspection to the District Office. IPP will address basic design noncompliance while performing Sanitation SOP verification tasks.

To effectively verify compliance with the Sanitation SOP regulations, IPP are to understand the Sanitation SOP regulations (§416.11 - §416.16), be familiar with the establishment's current written Sanitation SOPs, and perform the verification tasks as described in FSIS Directive 5000.1 and FSIS Directive 5000.4.

NOTE: If IPP find that an establishment has not developed written Sanitation SOPs, they should contact their supervisor immediately.

Sanitation SOP Verification Tasks

The following table lists four tasks used to verify compliance with Sanitation SOP requirements.

Inspection Tasks	General Description
Pre-Operational Sanitation SOP Record Review	Use the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations.
Pre-Operational Sanitation SOP Review and Observation	Use the Review and Observation verification activity and the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations. In PHIS, IPP should select the “Both” option on the Activity tab.
Operational Sanitation SOP Record Review	Use the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products during operations.
Operational Sanitation SOP Review and Observation	Use the Review and Observation verification activity and the Recordkeeping verification activity to verify that the establishment implements the procedures in the Sanitation SOP effectively to prevent contamination of food contact surfaces or adulteration of products during operations. In PHIS, IPP should select the “Both” option on the Activity tab.

Regardless of which Sanitation SOP task is performed, IPP will verify that establishments meet all **four** of the following regulatory requirements **in addition to the design requirements §416.12:**

- a. Implementation and monitoring of Sanitation SOP (§416.13);
- b. Maintenance of Sanitation SOP (ensuring its effectiveness) (§416.14);
- c. Sanitation SOP corrective actions (§416.15); and
- d. Sanitation SOP recordkeeping (§416.16).

The Record Review Tasks: Pre-Operational and Operational

IPP use the recordkeeping verification activity to verify all **four** Sanitation SOP requirements (implementation, maintenance, corrective actions, and recordkeeping) while performing the Pre-Operational and Operational Sanitation SOP Record Review tasks.

During the Sanitation SOP record review tasks, IPP perform the following:

- 1) Review the written Sanitation SOP to be familiar with the establishment's current pre-operational or operational sanitation procedures.
- 2) Verify that the SSOP continues to meet the design requirements of §416.12.
- 3) Verify that the establishment has maintained daily records that demonstrate that the establishment has implemented the pre-operational and operational procedures as written, monitored those procedures at least daily or at the specified frequency, and taken immediate or corrective action when necessary.

For instance, IPP verify that the records indicate that the establishment conducted monitoring daily prior to the start of operations. If the establishment observed a contaminated food contact surface (residue from previous day's product) during pre-operational inspection, IPP verify that the establishment documented that the contaminated surface was re-cleaned, re-inspected and released before product passed over the surface. Similarly, if the establishment has documented the finding of contaminated product or food contact surfaces during operations, IPP verify that the documented corrective actions meet regulatory requirements.

NOTE: In most cases, product does not contact equipment surfaces prior to the start of operations. However, if the establishment found contaminated product during pre-operational inspection, IPP will verify that the establishment has documented corrective actions that meet the requirements of §416.15(b).

- 4) Verify all the recordkeeping requirements of §416.16.

For instance, IPP verify that the establishment employee responsible for the implementation and monitoring of the procedure has authenticated the records with their initials and date.

The Review and Observation Tasks: Pre-Operational and Operational

IPP use **both** the review and observation verification activity and the recordkeeping verification activity when performing the Pre-Operational and Operational Sanitation SOP Review and Observation tasks. IPP are to verify that all **four** Sanitation SOP requirements (implementation, maintenance, corrective actions, and recordkeeping).

Each time IPP perform the review and observation tasks, they:

- 1) should review the written Sanitation SOP so they are familiar with the establishment's current pre-operational or operational sanitation procedures,
- 2) verify that the SSOP continues to meet the requirements of §416.12,

- 3) observe the establishment conducting its monitoring activities and implementing corrective action when they find that the pre-operational or operational procedures have failed to effectively clean and sanitize food contact surfaces,
- 4) inspect one or more areas and perform an organoleptic examination of some of the establishment's facilities, equipment, and utensils to assess sanitary conditions (sometimes referred to as "hands-on" inspection),
- 5) compare their findings with the establishment records/findings, (which may not be documented until the start of the next production day for that specific shift), and
- 6) verify that the establishment meets the corrective action requirement of 9 CFR 416.15 when they find that the establishment's Sanitation SOP has failed to prevent product contamination or adulteration.

Selecting Production Areas and Equipment for Pre-Op Sanitation SOP Review and Observation Verification Task (FSIS Directive 5000.4)

In both slaughter and processing establishments, IPP follow the same methodology or thought process to plan their Pre-Op Sanitation SOP verification. IPP are to select the production area(s) and equipment to examine using a risk-based approach. The area(s) and equipment selected are those that present the highest risk of becoming insanitary or causing product contamination.

The following factors indicate a higher risk to public health:

- 1) Equipment that will contact exposed product.
- 2) Equipment that will contact RTE product post-lethality.
- 3) Equipment that is difficult to clean.
- 4) Equipment that FSIS has not verified recently.
- 5) Equipment/area(s) with a history of noncompliance; and
- 6) Testing results that suggest that specific pieces of equipment may present a risk to public health.

IPP review test results and other records relevant to the food safety system weekly per FSIS Directive 5000.2. Based on information gathered from test results, establishment sanitation records or other records, establishment pre-op sanitation findings, or repetitive noncompliances, IPP are to consider whether to increase the extent of pre-op sanitation verification activities (i.e., how much equipment and how many areas).

IPP are encouraged to discuss their thought processes for making their selections on an on-going basis with their IIC or FLS. They are not expected to put their thought process in writing, nor to share it with establishment management.

Pre-Op Sanitation SOP Review and Observation Task

To perform the Pre-Op Sanitation SOP Review and Observation task, IPP should have:

- A functional flashlight.
- A pen or pencil.
- U.S. Rejected/U.S. Retained tags and some means (tape, string, rubber bands) of affixing these tags to equipment, departments, product, etc.
- A notepad to record their pre-operational findings.

IPP not trained in lockout/tagout (FSIS Directive 4791.11) methodology shall not perform pre-op sanitation inspection on any piece of equipment requiring lock out. If IPP select a ready-to-eat (RTE) production area for pre-operational inspection, they should start in the RTE department first to prevent introduction of microorganisms from the raw product areas.

After establishment management informs IPP that an area is ready for FSIS pre-op inspection, IPP perform the review component of Pre-Op Sanitation SOP Review and Observation verification task. They are to inspect areas in the establishment, equipment and utensils, and places on equipment that, if insanitary, would present the greatest risk of transferring pathogens or other contaminants to product (e.g., direct food contact surfaces that are difficult to clean or may serve as microbial harborage sites). Establishments can elect to reassemble equipment after they complete their monitoring and implementation of the Sanitation SOPs. However, IPP can request that the establishment disassemble the piece of equipment so that the IPP will be able to perform their pre-op sanitation verification.

IPP perform “hands-on” inspection to verify that direct food contact surfaces are organoleptically clean. This means that the surfaces look clean, feel clean, and smell clean. IPP visually examine the food contact surfaces for product residues from previous days’ operations. They feel the contact surfaces to determine if there are residues or foreign materials (e.g., grit, dust, etc.) present from previous days’ operations that are not visible. IPP detect any odors in these area(s) that may indicate insanitary conditions.

If direct food contact surfaces are contaminated with residues from previous days’ operations, it is likely that these conditions will harbor microorganisms and/or have a chemical residue present. The surfaces should be free of foreign material such as fat, blood, hair, rust, dust, grease, and cleaning chemicals.

IPP are to focus on food contact surfaces and not on surfaces or areas that do not directly contact product. They are to look at selected pieces of equipment rather than all equipment. When there are large numbers of simple equipment such as pans, buckets, trays, or hand tools, IPP are to select a representative sample (e.g., one or two each).

Although the focus is on food contact surfaces, IPP should remain aware of other insanitary conditions such as unclean non-food contact surfaces; condensation; peeling paint; and scaling rust from overhead fixtures in areas where products are processed, handled, or stored.

When IPP have completed their examination of the selected area(s) and equipment, IPP should compare their findings to the establishment's sanitation findings. If the written records are not yet completed, IPP may ask the establishment about its pre-operational findings and any actions taken. However, IPP must verify the recordkeeping requirements before completing the task.

When IPP observe contaminated direct food contact surfaces during the pre-op sanitation verification, they are to reject the affected equipment. The establishment has the responsibility to restore sanitary conditions (clean the contaminated food contact surface) and document the restoration of sanitary conditions under §416.16(a). **Preventive measures do not need to be developed and documented unless product has been contaminated or adulterated by the unclean surface.** IPP should not remove the USDA reject tag until the establishment has restored sanitary conditions.

In rare situations in which product has been contaminated or adulterated before the start of operations, the establishment must take corrective actions that meet the requirements in §416.15(b). Furthermore, IPP should not remove the regulatory control action until the establishment has proposed corrective actions, either verbally or in writing, that meet these requirements.

In some cases, the establishment might conduct monitoring of the implementation of the Sanitation SOP procedures before inspection personnel arrive at the establishment. In these situations, the FLS or IIC will decide how frequently IPP will directly observe the establishment conducting their monitoring procedures. The supervisor will consider several factors when making this decision: 1) establishment compliance history, 2) documentation in the FSIS file, and 3) information from Sanitation SOP records.

Operational Sanitation SOP Review and Observation Task

IPP should select area(s) of the establishment and equipment that presents the **highest risk** for insanitary conditions or product contamination. If a RTE production area is selected, IPP should start in the RTE area to prevent introducing microorganisms from the raw product areas into the RTE area.

IPP are to have:

- a functional flashlight.
- a pen or pencil.
- U.S. Rejected/U.S. Retained tags and some means (tape, string, rubber bands) of affixing these tags to equipment, departments, product, etc.
- a notepad to record their operational findings.

IPP should observe the equipment, employees, and facilities to verify that product

contamination is not occurring during operation. For example, employees might contact contaminated surfaces with their hands and/or clothing and return to handling product without first cleaning their hands or changing their outer clothing. If IPP observe contaminated direct food contact surfaces or contaminated product, there is Sanitation SOP noncompliance whether there is a procedure written in the establishment's Sanitation SOP to cover that situation or not.

IPP should inspect direct food contact surfaces of equipment, facilities, and utensils. Although the task focuses on verifying product and food contact surfaces are not contaminated during operation, IPP should be aware of other potential sources of product contamination such as condensation, peeling paint, dead-end pipes, and scaling rust from overhead fixtures where products are processed, handled, or stored can contaminate products.

When possible, IPP should also observe the establishment conducting its monitoring activity. Some establishments conduct the monitoring of operational sanitation at a frequency of once or twice daily. Therefore, it might be difficult for the IPP to observe this activity

When IPP have completed their assessment of the sanitation in one or more areas of the establishment, they should compare their findings with the establishment's sanitation findings. If the records are not complete at the time, IPP might ask the establishment if it has conducted monitoring and what observations were made. However, IPP must verify the recordkeeping requirements prior to completion of the task.

IPP should be aware that there are times the responsible establishment employee might not be able to propose permanent preventive measures immediately. However, in these situations, the establishment should propose a tentative preventative measure of what they will do until they determine a permanent solution.

Frequencies for Performing the Sanitation SOP Verification Tasks

IPP are to perform pre-operational and operational Sanitation SOP verification tasks at frequencies scheduled by PHIS, or an adjusted frequency based on relevant information (e.g., a developing trend of noncompliance). IPP are to:

1. perform two pre-operational Sanitation SOP verifications per week at each establishment in an assignment, including one Pre-Op SSOP Review and Observation and one Pre-Op SSOP Record Review task. These two pre-operational tasks are to be performed at an approximately equal amount;
2. perform one operational Sanitation SOP verification task at each establishment in an assignment during each shift – either an Operational SSOP Review and Observation or Operational SSOP Records Review task. These two operational tasks are to be performed at an approximately equal amount; and
3. perform “inspector directed” Sanitation SOP verification tasks as warranted by conditions observed at the establishment. For example: During the performance of other verification

tasks unrelated to sanitation, if inspection personnel observe insanitary conditions, they are to perform an Operational SSOP Review and Observation verification task. IPP are also to perform Sanitation SOP tasks as directed by their supervisor.

In patrol assignments, there are times when inspection personnel cannot perform the Pre-Op SSOP Review and Observation task in each establishment once per week due to simultaneous start times or having more than five establishments on the patrol. In such cases, IPP are to use good judgment and their knowledge of the establishments' compliance histories with sanitation requirements to decide where and when to do Pre-Op Sanitation SOP verification tasks.

When an establishment operates on Saturdays, Sundays, and holidays, IPP are to conduct pre-operational and operational sanitation tasks in the same manner and frequency as they do during the week. Whenever IPP performed a task on reimbursable overtime, IPP are to check the appropriate box on the task's Activity tab to document this fact.

IMPLEMENTATION AND MONITORING

§416.13 Implementation (Monitoring) Requirement

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

1. Establishment Responsibilities

The establishment is responsible for developing written procedures that are sufficient to prevent direct contamination or adulteration of product. The establishment also has the responsibility for implementing the procedures in the written Sanitation SOPs. If the establishment writes a procedure in its Sanitation SOP, it must implement that procedure and monitor it daily. In other words, the establishment is responsible for doing what it said it would do.

2. Inspection Verification

IPP should verify that the establishment is meeting these regulatory requirements by performing the recordkeeping, and the review and observation task.

When verifying the implementation requirement while performing the pre-operational Sanitation SOP task, IPP are verifying that the establishment is meeting the regulatory requirements for implementation of the procedures that will be conducted before the start of operations. When

verifying the implementation requirement while performing the operational Sanitation SOP task, IPP are verifying that the establishment is implementing the procedures that will be conducted during operations.

When verifying compliance with §416.13, IPP should seek answers to the following type of questions:

- Is the establishment implementing the pre-operational procedures in the Sanitation SOP prior to the start of operations?
- Is direct contamination or adulteration of product, or unclean direct food contact surfaces observed by FSIS or the establishment?
- Is the establishment conducting the procedures in the Sanitation SOP as written?
- Does the Sanitation SOP contain monitoring frequencies?
- If the Sanitation SOP does not contain monitoring frequencies, is the establishment monitoring the implementation of the procedures in the Sanitation SOP daily?

3. Environmental Sampling

There are no regulatory requirements to include environmental sampling in an establishment's Sanitation SOP. However, if environmental sampling is included in the Sanitation SOP, IPP should verify that the establishment is following those procedures. IPP should observe the establishment collecting samples, review sample results, and verify that the corrective actions specified in the Sanitation SOP are taken when necessary. The verification should be completed as part of the Sanitation SOP review & observation task. If the establishment is conducting environmental testing but the procedures are not included in the Sanitation SOP, IPP will review the establishment's testing results weekly as described in FSIS Directive 5000.2. Information gathered from such testing results should be used in the IPP's thought process for selecting the areas and equipment examined and the extent of inspection (i.e., how much equipment and several areas) during the Operational Sanitation SOP review and observation task in establishments that process meat and poultry products.

MAINTENANCE

§416.14 Maintenance Requirement

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

1. Establishment Responsibilities

Before federally inspected meat or poultry establishments are permitted to operate, they must develop Sanitation SOPs that prescribe sanitation measures to prevent product adulteration or contamination. This means establishments can only speculate about which sanitation measures should be included in their Sanitation SOPs to prevent the occurrence of insanitary conditions in their production process. The effectiveness of these measures is unknown

initially. Therefore, it is necessary for establishments to evaluate the effectiveness of their Sanitation SOPs once they are implemented.

Each establishment must meet two primary obligations to comply with the requirements for the Sanitation SOP maintenance regulation. The first responsibility requires establishments to evaluate the effectiveness of all Sanitation SOPs that have been implemented in their production operations and the second requires that the establishment to revise the Sanitation SOP as needed to ensure that it is reflective of the operation and that the Sanitation SOP is effective. This regulatory requirement encourages establishments to develop a system for the evaluation of their written Sanitation SOPs to prevent direct contamination or adulteration of product.

Although establishments must identify the members of their management team who will be responsible for implementation and evaluation of their Sanitation SOPs, they are not required to identify the method the individuals employ to perform the evaluations. The regulation only requires that establishments perform an evaluation of the effectiveness of their Sanitation SOPs; it does not dictate how establishments should perform this evaluation. The establishment must sign and date the Sanitation SOPs any time modifications are made. However, there is no regulatory requirement that the establishment personnel should notify FSIS inspection personnel of the change.

It is also a responsibility of the establishments to revise their Sanitation SOPs to keep them effective and current with respect to changes in facilities, equipment, utensils, operations, or personnel. These regulations list examples of changes that may occur within an establishment that could alter the effectiveness of an established Sanitation SOP. However, the methodologies used to evaluate their Sanitation SOPs and to determine their effectiveness do not need to be recorded. If the establishment determines the Sanitation SOPs are no longer effective and current, the Sanitation SOPs must be revised.

2. Inspection Verification

FSIS is responsible for verifying the establishment meets the maintenance regulatory requirements. IPP should verify this requirement while performing the Pre-Operational and Operational Sanitation SOP tasks. When verifying this requirement, IPP must understand that IPP should review the establishment's Sanitation SOP records and NRs over a period of time to determine whether this requirement is met. Just because IPP find an unclean food contact surface while performing the review and observation task for pre-operational sanitation does not mean that the establishment needs to evaluate the effectiveness of the Sanitation SOPs.

However, if IPP look at several weeks of Sanitation SOP records, IPP might see that the Sanitation SOPs have repeatedly been ineffective in preventing direct contamination or adulteration of product. During this same period of time IPP might also find that there have been several NRs documenting the ineffectiveness of the Sanitation SOPs in preventing direct contamination or adulteration of product. IPP will have to use their professional knowledge and good judgment to determine whether the Sanitation SOP is meeting the maintenance regulatory requirement. IPP should discuss and document their concerns with the

establishment. If the establishment does not modify the Sanitation SOP and IPP observe contaminated product, IPP should take a regulatory control action. IPP might not accept preventive measures that do not include re-evaluation of the Sanitation SOP as an effective means of preventing direct contamination or adulteration of product.

When verifying compliance with §416.14, IPP should seek answers to questions similar to the following:

- Has the establishment routinely evaluated the effectiveness of the Sanitation SOPs in preventing direct contamination or adulteration?
- If changes were made in the facilities, equipment, utensils, operations, or personnel, have the Sanitation SOPs been revised to keep them effective?
- Does the establishment routinely review the Sanitation SOP records to determine if there are trends occurring indicating that the Sanitation SOP needs revising?

NOTE: In addition to determining if the establishment has met the maintenance requirement, information gathered from reviewing the establishment's Sanitation SOP records and NRs may be used in the thought process for selecting the areas and equipment examined and the extent of inspection (i.e., how much equipment and how many areas) during the Pre-Operational Review and Observation task in establishments that process meat and poultry products. For instance, IPP could determine from the Sanitation SOP records and NRs which processing areas or rooms and equipment are typically found to be unclean and if noncompliances are increasing during pre-op verification.

Keep in mind, the establishment needs to revise the procedures as necessary to keep them current and effective. The Sanitation SOP may be changed frequently. The establishment is not obligated to notify FSIS when it revises its written Sanitation SOPs since FSIS does not approve the Sanitation SOP or Sanitation SOP revisions. However, the Sanitation SOP must be signed and dated when any modification is made.

CORRECTIVE ACTION

§416.15 Corrective Action Requirement

(a) Each official establishment shall take appropriate corrective action(s) when either the establishment or FSIS determines that the establishment's Sanitation SOPs or the procedures specified therein, or the implementation or maintenance of the Sanitation SOPs, may have failed to prevent direct contamination or adulteration of product(s).

(b) Corrective actions include procedures to ensure appropriate disposition of product(s) that may be contaminated, restore sanitary conditions, and prevent the recurrence of direct contamination or adulteration of product(s), including appropriate reevaluation and modification of the Sanitation SOPs and the procedures specified therein or appropriate improvements in the execution of the Sanitation SOPs or the procedures specified therein.

1. Establishment Responsibilities

These regulations require the establishment to take corrective actions when either the establishment **OR** FSIS determines the **Sanitation SOPs fail to prevent direct contamination or adulteration of product**. Regardless of the type or cause of the failure, corrective actions must be taken. There are three parts to corrective action and all three of these requirements must be met and recorded each time product contamination occurs. The corrective actions also include appropriate disposition of product.

NOTE: Most of the time product will not be involved during pre-operational sanitation monitoring. When the establishment finds direct food contact surfaces that are unclean during its monitoring of pre-operational sanitation and cleans the surfaces before product passes over that surface, this is compliance. In these situations, FSIS believes the establishment's Sanitation SOP has worked as intended. Implementing and documenting preventative measures are not required.

The establishment is not required to notify inspection personnel when product contamination occurs but has the responsibility to implement corrective actions that will meet the requirements of §416.15(b). The establishment should take full responsibility for the corrective actions meeting the three requirements of the regulation. Those regulatory requirements are:

- Appropriate disposition of products that may be contaminated;
- Restoration of sanitary conditions; and
- Prevention of recurrence of direct contamination or adulteration of products.

Reconditioning Product

Although there is no regulatory requirement, establishments may have a procedure in its Sanitation SOPs for reconditioning product that incidentally comes in contact with a non-food contact surface (such as the floor). The procedure usually consists of the following steps; an establishment employee will remove product from the floor in a timely manner, trim contaminants from the surface area, wash the product at a product wash station, and inspect it before returning it to production. This procedure is used for occasional instances of product contamination. If the establishment is following its written procedures and monitoring these procedures, the establishment would not be required to take corrective action that meets the requirements of §416.15 every time product falls on the floor. If the establishment does not have a reconditioning procedure in its Sanitation SOP, it would be required to take and document corrective actions that meet the requirements of §416.15 each time product falls on the floor.

2. Inspection Verification

IPP should verify this regulatory requirement when performing the Sanitation SOP verification tasks. Every time the establishment implements corrective actions due to product contamination, IPP should verify that the regulatory requirements in §416.15 are met. IPP can verify this requirement by performing any of the verification tasks. When performing the Pre-

Operational Sanitation SOP Record Review task, IPP should request the daily pre-operational sanitation records that they want to review. IPP should review the monitoring records to determine if the establishment documented occasions in which product was contaminated. If there is documentation showing the establishment had found product contamination during pre-operational monitoring, there should also be documentation of the corrective actions taken for these situations. IPP should review these corrective actions and compare them to the regulatory requirements to verify that they have been met. Did the establishment have adequate documentation to demonstrate appropriate disposition of the affected product? Did the establishment document corrective actions that were adequate to restore sanitary conditions? Did the establishment document corrective actions to prevent recurrence of direct contamination or adulteration of product?

When performing the Operational Sanitation SOP Record Review task, IPP should request from the establishment the daily operational sanitation records that they want to review. IPP should review the monitoring records to determine if there were instances of direct food contact surfaces or product being contaminated. If there is documentation showing the establishment had found a contaminated food contact surface that had contacted product or product contamination during the operational monitoring, there should also be documentation of the corrective actions taken for these situations. IPP should review these corrective actions and compare them to the regulatory requirements to verify that they have been met. Did the establishment have adequate documentation to demonstrate appropriate disposition of the affected product? Did the establishment document corrective actions that were adequate to restore sanitary conditions? Did the establishment document corrective actions to prevent recurrence of direct contamination or adulteration of product?

When IPP are performing the Pre-Operational Sanitation SOP Review and Observation task and find direct food contact surfaces that are contaminated, IPP should take a regulatory control action on the piece or pieces of equipment. There is an insanitary condition which is noncompliance with §416.13(a). In most cases product is not coming into contact with equipment surfaces during pre-operational sanitation inspection. The establishment must clean the surface (re-establish sanitary conditions) and document the restoration of sanitary conditions according to §416.16(a). FSIS would expect the establishment to consider how to make appropriate improvements in the execution of its pre-operational procedures because the establishment must be operated and maintained in a manner sufficient to prevent the creation of insanitary conditions as stated in §416.1. However, establishing and documenting preventive measures **are not** required.

If IPP are observing the establishment performing the monitoring as part of the Pre-Operational Sanitation SOP Review and Observation task and the monitor finds a contaminated food contact surface, this provides an opportunity for IPP to observe the establishment implementing actions to restore sanitary conditions.

When IPP are performing the Operational Sanitation SOP Review and Observation task and find direct food contact surfaces or product that is contaminated, IPP should take a regulatory control action of that equipment or product. IPP should keep that control action in place until the establishment has given IPP the corrective actions and preventive measures they plan to

implement to restore sanitary operations and prevent recurrence. They must also implement corrective actions to ensure the appropriate disposition of affected product. If what they are proposing does not meet these regulatory requirements, the regulatory control action should be left in place until the establishment proposes corrective actions that will meet these requirements. This also provides IPP the opportunity to verify that the establishment implements the corrective actions that they proposed. IPP should also verify that the corrective actions they document are the same as those they implemented.

If IPP are observing the establishment performing the monitoring as part of the Operational Sanitation SOP Review and Observation task and the monitor finds a food contact surface or product contaminated, this provides an opportunity for IPP to observe the establishment implementing the corrective actions. IPP can observe the establishment taking actions that restore sanitary conditions. IPP can observe the establishment to verify that they make appropriate disposition of product. If they put preventive measures in place immediately, IPP can verify these preventive measures.

NOTE: IPP should realize that many times the establishment might not be able to propose preventive measures until later because decisions might involve others in the establishment. For example, if IPP have identified a problem and the person in that area cannot propose the preventive measures because of the amount of capital involved, they should inform IPP that they will have a meeting with top management. This should be documented on the Sanitation SOP records. After the meeting, when the preventive measures have been decided, the establishment needs to document those preventive measures in the Sanitation SOP records.

Example:

For example, you identify a condensation problem in an area of the establishment that is contaminating product. You retain the product in the area and reject that area for use. When you notify the responsible establishment employee of the problem, he tells you that there is a structural problem in that area that will cost several thousand dollars to repair. He further explains that he does not have the authority to have the structure repaired. He states he will bring it to the attention of the establishment owner and will inform you of the preventive measures that the owner proposes. You agree this is logical and when the appropriate disposition is made on the product and sanitary conditions in that area are restored, you relinquish the regulatory control actions. All these corrective actions should be recorded in the establishment records. You should keep notes of your findings while performing this verification task so that you can accurately document them on the NR.

When verifying compliance with §416.15, IPP should seek answers to the following:

- When FSIS or the establishment determines that the Sanitation SOPs fail to prevent the direct contamination or other adulteration of product during operation, does the establishment implement corrective actions that ensure appropriate disposition is made of any product that may be contaminated?

- When FSIS or the establishment determines that the Sanitation SOPs fail to prevent the direct contamination or other adulteration of product during operation, does the establishment implement corrective actions that restore sanitary conditions?
- When FSIS or the establishment determines that the Sanitation SOPs fail to prevent the direct contamination or other adulteration of product during operation, does the establishment implement corrective actions that prevent recurrence?
- Do the corrective actions include the reevaluation and modification of the Sanitation SOPs or improvements in the execution of the procedures when trends are occurring?

NOTE: If the establishment is monitoring the pre-operational sanitation procedures, finding unclean food contact surfaces, and taking actions to restore sanitary conditions, and IPP **are not** finding direct food contact surfaces unacceptable, the establishment is in compliance with the regulations. Now, IPP should focus on whether the establishment is making improvements to the execution of its pre-operational sanitation procedures sufficient to prevent the creation of insanitary conditions and preventing direct contamination or adulteration of product. The requirement for preventive measures only applies when the Sanitation SOP fails to prevent direct contamination or adulteration of product. However, when IPP find unclean food contact surfaces during pre-operational sanitation inspection or direct contamination or adulteration of product during operations, IPP should take a regulatory control action. The regulatory control action should not be relinquished until the establishment has cleaned the food contact surface or taken corrective actions in §416.15 for contaminated product including proposing an **acceptable** preventive measure. The IPP should not accept the same preventive measures previously proposed by the establishment if those preventative measures were ineffective in preventing recurrence.

NOTE: If the establishment finds direct contamination or adulteration of product and takes appropriate corrective actions as per §416.15(b), then there is no need to initiate a regulatory control action or document an NR. These corrective actions include restoring sanitary conditions, making appropriate disposition of product, and implementing measures to prevent recurrence. If the establishment finds a contaminated food contact surface during preoperational sanitation inspection and cleans and sanitizes the surface before product goes across that surface, then there is no need to initiate a regulatory control action or document an NR.

RECORDKEEPING

§416.16 Recordkeeping Requirement

(a) Each official establishment shall maintain daily records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The establishment employee(s) specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedure(s) specified in the Sanitation SOPs shall authenticate these records with his or her initials and the date.

(b) Records required by this part may be maintained on computers provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

(c) Records required by this part shall be maintained for at least 6 months and made available to FSIS. All such records shall be maintained at the official establishment for 48 hours following completion, after which they may be maintained off-site provided such records can be made available to FSIS within 24 hours of request.

1. Establishment Responsibilities

§416.16(a) requires the establishment to maintain **daily** records sufficient to document the implementation and monitoring of the Sanitation SOPs and any corrective actions taken. The establishment must have records documenting that monitoring has been conducted daily for each of the procedures specified in the Sanitation SOPs. If the establishment has specified a monitoring frequency in the Sanitation SOP that is more frequent than daily, the documentation would have to reflect that the monitoring activities had been conducted at the specified frequencies. The establishment employee specified in the Sanitation SOPs as being responsible for the implementation and monitoring of the procedures shall authenticate these records with initials or signature and the date.

There must also be a written record of any corrective actions required by §416.15. These records must be maintained daily.

Note: The establishment has until the beginning of the same shift the next business day to complete SSOP records.

§416.16(b) provides the establishment the flexibility to maintain these records on a computer system provided the establishment implements appropriate controls to ensure the integrity of the electronic data.

§416.16(c) states that the records must be kept on-site for 48 hours and must be maintained for at least 6 months. After the initial 48 hours, the records may be kept off-site as long as they can be retrieved for a program employee within 24 hours of the request.

2. Inspection Verification

IPP should perform the Pre-Operational Sanitation SOP Record Review task when verifying compliance with the pre-operational sanitation recordkeeping requirements and Operational Sanitation SOP Record Review task when verifying compliance with the operational sanitation recordkeeping requirements. IPP should verify that these daily records contain:

- Documentation of the monitoring of the Sanitation SOPs;
- Documentation of any corrective actions taken; and
- Authentication (initials or signature of responsible person and the date).

IPP should also verify that:

- The establishment has appropriate controls to ensure the integrity of electronic data maintained on computers;
- The Sanitation SOP records are accessible to FSIS;
- The Sanitation SOP records are maintained for at least 6 months;
- The Sanitation SOP records are maintained on-site for 48 hours after

Completion; and

- The Sanitation SOP records are available to FSIS with 24 hours of request if they are maintained off-site.

Some of the questions that IPP need to consider when evaluating the establishment's records are listed below. As in all the other evaluations of the establishment's Sanitation SOP system, IPP will need to be very familiar with exactly what the Sanitation SOP says in relation to the records they are keeping. In addition to knowing what is in the Sanitation SOP, IPP will also need to understand the regulatory aspect of recordkeeping.

- Are the Sanitation SOP records available to FSIS upon request?
- Are the records completed prior to the start of the same shift the next operating day?
- Are the records completed in the manner specified in the Sanitation SOP?
- Are the records' entries legible?
- Was all monitoring done and recorded at the prescribed frequency?
- Are the records initialed or signed and dated?

Documentation and Enforcement

After completing a SSOP verification task, IPP are to use PHIS to document findings of compliance or noncompliance.

If the establishment is in compliance with all Sanitation SOP regulatory requirements, IPP will mark the regulations that were verified and check the "Inspection Completed" box.

When IPP determine that an establishment does not meet one of the regulatory requirements in 9 CFR §416.11 through §416.16, IPP should immediately notify the establishment's management about the Sanitation SOP noncompliance and take a regulatory control action, if one is necessary. IPP will need to document the findings of the Sanitation SOP noncompliance on a Noncompliance Record (NR), FSIS Form 5400-4.

When IPP become aware that an establishment was required to take corrective actions per 9 CFR 416.15, IPP must verify that the establishment met the requirement and document in PHIS that they verified the requirements.

When IPP observe contamination of product or direct food contact surfaces during an Operational Sanitation SOP verification task, they are to take a regulatory control action on the affected equipment or product. IPP are to remove the regulatory control action only after the establishment has taken corrective actions that 1) ensure appropriate disposition of products, and 2) restore sanitary conditions, and at least proposed 3) prevent recurrence of direct contamination or adulteration of products.

When IPP observe contamination of direct food contact surfaces during a Pre-Operational Sanitation SOP verification task, they are to take a regulatory control action on the affected equipment. During pre-operational sanitation, there should be no affected product. IPP are to

remove the regulatory control action only after the establishment has restored sanitary conditions

If the establishment has found the contaminated contact surface or product and taken the corrective actions required, there is no noncompliance. IPP are to verify that the establishment is implementing the corrective actions specified in 9 CFR 416.15 when the establishment finds direct contamination or adulteration of products or contact surfaces.

When IPP observe Sanitation SOP noncompliance that does not result in contamination of product or food contact surfaces (e.g., failure to initial records), they are not to take a regulatory control action.

If IPP observe **both** Sanitation SOP and SPS noncompliance while performing a Sanitation SOP verification task, they document both noncompliances on a single Sanitation SOP NR by recording a result of noncompliance for each applicable regulatory citation.

EXAMPLE: *While performing the Pre-Op Sanitation SOP Review and Observation verification task in the fabrication department, IPP observe product residue and grease on several meat hooks, in addition to fat particles and hog hair from the previous days' production on the wall behind the dehairing machine. IPP are to document each noncompliance and cite §416.13(a) and §416.2(b) under the Pre-Op Sanitation SOP Review and Observation verification task and record the result on a single NR.*

If IPP observe **only** SPS noncompliance while performing a Pre-Op Sanitation SOP verification task, record the noncompliance under the task being performed at the time of the observation. In this example, the noncompliance would be documented under a Pre-Op Sanitation SOP task even though the regulatory citation is an SPS regulation.

NOTE: If IPP determine that a Sanitation SOP noncompliance represents a systematic or repetitive failure by the establishment to prevent product contamination or maintain sanitary conditions, they are to document noncompliance with 9 CFR 416.1 in addition to the applicable Sanitation SOP regulation.

Application of the Rules of Practice

The Rules of Practice regulations describe the enforcement actions that can be taken if establishments do not meet regulatory requirements. Sections 500.3 and 500.4 of the Rules of Practice regulations describe the enforcement actions that can be imposed on an establishment when the Sanitation SOP regulatory requirements are not met.

§500.3(a)(1) states that FSIS may take a withholding action or impose a suspension without providing the establishment prior notification if 1) *The establishment produced and shipped adulterated or misbranded product as defined in 21 U.S.C. 453 or 21 U.S.C. 602, or 2) The establishment does not have Sanitation Standard Operating Procedures as specified in §416.11-416.12 of this chapter.*

1. Shipping contaminated or adulterated product

If the Sanitation SOP does not prevent contaminated or adulterated product from being produced and shipped, IPP should impose a withholding action as described in §500.3.

Since contaminated or adulterated product was shipped, there is an imminent threat to the public health and IPP should take an immediate withholding action. When contaminated or adulterated product has been produced and shipped, IPP are not required to notify the establishment in advance that IPP are taking the withholding action. FSIS will provide the establishment written notification later. An NR is written documentation of the noncompliance. The District Office will review the circumstances and advise the FLS or IIC on how to proceed when further enforcement actions are necessary.

2. Failure to meet the design regulatory requirements

Before inspection is granted, the establishment must have developed a written Sanitation SOP that meets the requirements of §416.11-416.12. However, if an existing establishment modifies its Sanitation SOP or fails to maintain the Sanitation SOP such that it no longer meets the basic design requirements, IPP should notify the establishment about the noncompliance and contact their supervisor regarding possible enforcement specified in §500.3.

Section 500.4 of the Rules of Practice states: *FSIS may take a withholding action or impose a suspension after an establishment is provided prior notification and the opportunity to demonstrate or achieve compliance because: The Sanitation Standard Operating Procedures have not been properly implemented or maintained as specified in §§416.13 through 416.16 of this chapter.*

3. Repetitive Sanitation SOP failures

This means that IPP must have adequate documentation to support the determination that the Sanitation SOPs have repeatedly not been implemented and maintained to be effective in preventing direct contamination or adulteration of product. It is not necessary for IPP to determine that contaminated or adulterated product has been shipped to impose the enforcement actions described in §500.4. It is necessary that IPP have adequate documentation to demonstrate that the establishment is unable to prevent repeated failures of the Sanitation SOPs. There are two reasons why Sanitation SOP failures can occur. (1) Either the Sanitation SOP is not designed adequately to prevent contamination or adulteration of product, or (2) the Sanitation SOPs are not properly implemented.

IPP must associate the Sanitation SOP failures to the same cause identified within the NRs generated at the establishment. For this reason, accurate documentation is very important. Each associated NR should reference the previous NR number, the NR date, and list the specific preventive measures that were not implemented or were ineffective in preventing the recurrence of the Sanitation SOP failures.

When IPP determine there is adequate documentation to support an enforcement action as specified in §500.4, IPP should contact the District Office, via supervisory channels, and request the assistance of an EIAO for the issuance of a Notice of Intended Enforcement

action (NOIE). There is no specific number of NRs required for the issuance of an NOIE, but their documentation should support their requested enforcement action. Based on the EIAO's recommendations, the District Office will issue the Notice of Intended Enforcement action to the establishment.

IPP must verify compliance and noncompliance with the SPS regulations. Noncompliance is the failure of an establishment to meet one or more regulatory requirements. Every time the IPP determines that the establishment is not meeting the SPS requirements, the IPP must document the noncompliance on an NR. If the IPP determines that the SPS noncompliance is due to the establishment's repeated failure to maintain sanitary conditions, the IPP should consult with their FLS or IIC to determine if 416.1 should be added to the noncompliance record. When the IPP finds that any equipment, utensil, room, or compartment at an official establishment is insanitary or that its use could cause the adulteration of product, he or she will attach to it a "U.S. Rejected" tag. Equipment, utensils, rooms, or compartments tagged cannot be used until made acceptable. Only an FSIS program employee may remove a "U.S. Rejected" tag.

Hazard Analysis and Critical Control Point (HACCP)

HACCP Seven Principles

FSIS requires all establishments that produce federally inspected meat and poultry products to design and operate HACCP (**Hazard Analysis and Critical Control Point**) systems. The seven principles of HACCP, which encompass a systematic approach to the identification, prevention, and control of food safety hazards include:

1. Conduct a Hazard Analysis
2. Determine Critical Control Points
3. Establish Critical Limits
4. Establish Monitoring Procedures
5. Establish Corrective Actions
6. Establish Recordkeeping and Documentation Procedures
7. Establish Verification Procedures

Principle 1: Conduct a Hazard Analysis.

- **A thorough hazard analysis** is the **key** to preparing an effectively designed HACCP plan.
- **A hazard is a biological, chemical, or physical** agent that is reasonably likely to occur and will cause illness or injury in the absence of its control.
- During the development and design of the hazard analysis, establishments must consider all three types of hazards – biological, chemical, and physical – at each step they identify in the production process. Once the establishment has identified potential hazards, these hazards are evaluated to determine if each one is reasonably likely to occur (RLTO), or not reasonably likely to occur (NRLTO).
- If the establishment determines that **the hazard is reasonably likely to occur, a critical control point must be developed** to address the hazard, either at that step or later in the process.
- If the establishment determines the hazard is not reasonably likely to occur, they must provide justification for this decision.
- **A Prerequisite Program** is a procedure or set of procedures that is designed to provide basic environmental or operating conditions necessary for the production of safe, wholesome food. The programs provide a foundation for the development and implementation of an effective HACCP system.

Principle 2: Determine Critical Control Points

- A **critical control point** is defined as a point, step, or procedure in a food process at which control can be applied, and, as a result, a food safety hazard can be prevented, eliminated, or reduced to acceptable levels.
- For **each** hazard that is determined to be reasonably likely to occur, the establishment must identify critical control points and corresponding critical limits that are measurable or observable.

Principle 3: Establish Critical Limits

- **Critical limits (CL)** are the parameters that indicate whether the control measure at the CCP is in or out of control.

- **CL is a maximum or minimum value** to which a biological, chemical, or physical parameter must be controlled at a CCP to prevent, eliminate, or reduce to an acceptable level the occurrence of a food safety hazard. Critical limits must be actual values that can be measured or quantified.

Principle 4: Establish Monitoring Procedures

- **Monitoring is a planned sequence of observations or measurements** to assess whether a **CCP is under control** and to produce an accurate record for future use in verification. Every CCP that is in the HACCP plan must be monitored to ensure that the critical limits are consistently met and that the process is producing safe product. Establishments must determine how often they need to monitor CCPs.
- **There are three objectives to monitoring:**
 - To track control of the process. This allows the establishment to identify trends in the process that may be leading to loss of process control. If monitoring detects a trend, establishments can take appropriate measures to restore process control before there is a deviation from the critical limit;
 - To determine when the process has deviated from the critical limit. This information lets the establishment know that process control has been lost and that appropriate corrective actions must be taken;
 - To provide a written document to be used in verification. Monitoring results must be recorded on official HACCP records, and such records serve as the basis for verification activities.

Principle 5: Establish Corrective Actions

- The corrective actions must be determined for each CCP in cases where the CL is not met.

Principle 6: Establish Recordkeeping and Documentation Procedures

- Establishment must ensure that the HACCP system has an effective recordkeeping system.

Principle 7: Establish Verification Procedures

- HACCP systems must be systematically verified.

HACCP Regulatory Process

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 the:

- Hazard analysis;
- HACCP plan;
- supporting documentation including prerequisite programs used to make decisions in the hazard analysis, and

- HACCP records generated on an ongoing basis.

IPP must focus on the overall effectiveness of the establishment's HACCP system.

HACCP Regulatory Process

- **Inspection Methodology**
 - Performing HACCP inspection tasks
 - Verifying specific HACCP regulatory requirements during the performance of the HACCP inspection task
- **Decision-making (GAD)**
 - Gathering information, making observations, reviewing documentation, assessing the gathered information and arriving at a supportable compliance or noncompliance 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 food safety system are outlined in **FSIS Directives 5000.1 and 5000.6**.

The HACCP inspection tasks appear on the establishment's inspection Task List as **routine** tasks according to the specific HACCP process categories (listed in 9 CFR 417.2(b)) entered in the Establishment Profile in PHIS. IPP may initiate **directed** HACCP inspection tasks when they observe HACCP regulatory noncompliance or are instructed to do so by their supervisor.

HACCP Inspection Tasks

IPP perform two HACCP inspection tasks to verify that establishments are complying with 9CFR Part 417:

- **The Hazard Analysis Verification (HAV) task** directs the IPP to review the establishment's hazard analysis for one HACCP plan, the HACCP plan, and any prerequisite programs or other documentation used to support the decision that a food safety hazard is not reasonably likely to occur in the process.
- **The HACCP verification task** focuses the attention of the IPP on the execution or implementation of the establishment's HACCP plans, prerequisite programs and other supporting programs, i.e., implementation of the establishment's HACCP system. IPP perform a HACCP verification task for each of the HACCP process categories listed in the establishment's profile.

Both HACCP verification tasks can be performed as a routine or directed task.

Each HACCP task has two verification components:

- ***A recordkeeping component, and***
- ***A review and observation component***

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

Regulation 9 CFR 417.5(f) requires the establishment to make all such records available for official review.

Regulatory Decision-Making - A Thought Process

When IPP perform both of the HACCP inspection tasks, they need to use the regulatory thought process described below.

Gather, Assess, and Determine or GAD

IPP are to **gather** all available information to help them determine regulatory compliance.

IPP are to **assess** the significance and meaning of information gathered.

IPP are to **determine** whether the information supports a finding of regulatory compliance.

The Hazard Analysis Verification (HAV) Task

The **Hazard Analysis Verification (HAV) Task** is a work method that provides IPP with a powerful approach to verifying compliance with certain requirements of 9 CFR 417, specifically those that pertain to certain foundational elements of an establishment's HACCP system.

These foundational elements are:

- A flow chart and hazard analysis that **matches the actual production processes** in the establishment;
- A hazard analysis in which the establishment accurately considers **applicable food safety hazards** given the nature of the process, product, and intended use of the product and determines whether each hazard is reasonably likely to occur (RLTO);
- Critical control points (**CCPs**) for hazards that are **reasonably likely to occur** in the process and documentation supporting those CCPs;
- Documentation (prerequisite programs) **supporting any decision** that a food safety hazard is not reasonably likely to occur (NRLTO) in the process;
- Evidence supporting the validity of the HACCP system; and
- Reassessment of the HACCP system annually and anytime changes occur that could affect the hazard analysis or HACCP plan.

Examples of technical and scientific support the establishment can use are

Regulations, Pathogen Modeling Program (PMP), Processing Authority (PA), Challenge Studies, In-plant data, Agency compliance guidance documents, and other decision-making documents.

Examples of support documents the establishment can use to support a decision that a hazard is not reasonably to occur are: LOG (Letters of Guarantee); COA (Certificates of Analysis); product temperature controls; and microbial testing programs. IPP are to review the support documents while performing the HAV task.

Examples of Non-compliances IPP may find while performing the HAV task are:

- The establishment's flow chart does not accurately represent all the steps in the establishment's production process. Noncompliance with 417.2(a)(2).
- The establishment's flow chart does not accurately describe product flow. Noncompliance with 417.2(a)(2).
- The hazard analysis identifies a hazard reasonably likely to occur (RLTO) but does not have an associated CCP at or after the point where the hazard is introduced. Noncompliance with 417.2(c)(2).
- The establishment does not have documentation to support the development of CCPs, critical limits, or monitoring and verification procedures. Noncompliance with 417.5(a)(2).
- The establishment does not maintain validation data. Noncompliance with 417.4(a)(1).
- The establishment did not perform a reassessment at least once in the previous calendar year. Noncompliance with 417.4(a)(3).

HAV Task Summary Table

Refer to Directive 5000.6 for additional information about each step.

Step	Description	Verification Questions	Regs
1	Review flow chart and compare to production process.	<ul style="list-style-type: none"> Does the flow chart represent the actual production process? 	417.2(a)(2)
	Review the hazard analysis and consider guidance in the FSIS Meat and Poultry Hazards and Controls Guide (HCG).	<ul style="list-style-type: none"> Does the flow chart or hazard analysis identify the intended use or consumers of the product? Does the hazard analysis appear to consider the relevant food safety hazards for the establishment's process, product, and intended use? For each hazard, does the establishment consider it RLTO or NRLTO? 	417.2(a)(2) 417.2(a)(1)
3	For each hazard, the establishment considers RLTO, verify that the HACCP plan includes one or more CCPs to control it. <i>If no hazards are reasonably likely to occur, skip to step 4.</i>	<ul style="list-style-type: none"> Does the establishment have one or more CCPs to control the hazard in each product or process where it is reasonably likely to occur? Does the establishment have information to support the CCPs, CLs, monitoring and verification procedures? 	417.2(c)(2) 417.5(a)(2)
4	For each hazard the establishment considers NRLTO, determine what evidence the establishment uses to support the decision, including prerequisite programs and other supporting programs (e.g., written programs, records, and employee activities).	<ul style="list-style-type: none"> Does the establishment prevent the hazard by implementing a prerequisite or other supporting program (SSOP, GMP, SOP, etc.)? – <i>proceed to step 5.</i> Does the establishment support the decision with other documentation besides a prerequisite or other supporting program? – <i>proceed to step 6.</i> Does the written program appear to be designed to prevent the relevant hazard? Do the records and your observations indicate the program is consistently being implemented as written? 	417.5(a)(1)

		<ul style="list-style-type: none"> Do the records and your observations indicate that the program continues to prevent the relevant hazard on an ongoing basis? 	
Step	Description	Verification Questions	Regs
5	Review other supporting documentation	<ul style="list-style-type: none"> Does the establishment have copies of the documents referenced in the hazard analysis? Do the documents appear to apply to the current establishment process? 	417.5(a)(1)
6	Review establishment validation documents, including scientific supporting documents and validation data.	<ul style="list-style-type: none"> Does the establishment maintain documents to support the scientific or technical basis for the CCPs and prerequisite programs used to support decisions in the hazard analysis? Does the establishment maintain in-plant validation data for the life of the plan? 	417.4(a)(1)
7	Verify reassessment requirements. Check most recent signature date for each HACCP plan.	<ul style="list-style-type: none"> Has the establishment reassessed at least once in the most recent calendar year? Has the establishment reassessed, if necessary, in response to any changes that could affect the hazard analysis? 	417.4(a)(3)
		<ul style="list-style-type: none"> Has the establishment reassessed, if necessary, in response to any unforeseen hazard? 	417.3(b)
		<ul style="list-style-type: none"> Has the establishment documented the results of the reassessment? 	417.4(a)(3)(ii)
8	Document your findings in PHIS.	<ul style="list-style-type: none"> No problems detected – document HAV task results in PHIS. Clear case of noncompliance – document HAV task results and NR in PHIS and notify your supervisor. Concerns about the establishment HACCP system <p>– discuss situation with your supervisor for assistance in determining how to proceed. Document HAV task results in PHIS.</p>	

HACCP Verification Task

Introduction

The HACCP verification task is for verifying that an establishment complies with the requirements of 9 CFR Part 417. There are nine HACCP verification tasks. Each task represents a specific HACCP processing category.

The HACCP Verification Task

Expectations of IPP in Conducting the HACCP Verification Task

IPP are to verify that the establishment implements its HACCP system in accordance with the regulations in 9 CFR Part 417 by performing the HACCP verification task.

IPP must be familiar with the establishment's hazard analysis, HACCP plan, and any prerequisite or other programs that the establishment uses to support the decision(s) that specific food safety hazards are not reasonably likely to occur.

IPP use the recordkeeping and/or the review and observation components to verify that an establishment is effectively implementing the procedures set out in its HACCP plan.

IPP are to verify that establishments are meeting all the HACCP regulatory requirements.

IPP will document their findings in PHIS, including any noncompliance they find when performing their verification activities.

If IPP cannot complete the HACCP verification task in one day, know the steps to take until the task can be completed.

4 Regulatory Requirements

- Monitoring
- Verification
- Recordkeeping
- Corrective Actions

Performing the HACCP Verification Task

1. Select a product type within the specified HACCP process category and a specific production for the selected product type.

Specific production is a term that is used to refer to whatever method the establishment uses to group product, e.g., product produced during a specific period of time, a specific production lot, or other designated product. FSIS does not determine the method used to define specific production; this is an establishment's responsibility.

2. Review the HACCP plan for the selected product type.
- 3-5. Verify that the monitoring, verification, and recordkeeping HACCP regulatory requirements have been met for **all CCPs** in the HACCP plan for that **specific production**.
6. Verify the implementation of any **prerequisite programs** or other programs that apply to the specific production.
7. Verify that the **corrective action** HACCP regulatory requirement has been met.
8. Verify that the **pre-shipment review** requirement for that specific production has been met.
9. Consider any implications of noncompliance and document the HACCP verification task in PHIS.

Regulatory Reference

Requirement	Regulatory References	Component
Monitoring	417.2(c)(4) <u>Monitoring Requirement</u>	Rk R& O
Verification	417.2(c)(7) <u>Verification Requirement</u> 417.4(a)(2)(i)(ii)(iii) <u>Verification Activities</u>	Rk R& O
Recordkeeping	417.2(c)(6) <u>Recordkeeping System</u>	Rk
	417.5(a)(3) <u>HACCP Records</u>	Rk
	417.5(b) <u>Records Authenticity</u>	Rk R& O
	417.5(d) <u>Computerized Records</u>	Rk
	417.5(e)(1) and (2) <u>Record Retention</u>	Rk
	417.5(f) <u>Official Review</u>	Rk
	(Prerequisite Program Implementation) 417.5(a)(1) <u>Supporting Documentation</u>	Rk R& O
	417.5(c) <u>Pre-Shipment Review</u>	Rk R&O (on occasion)
Corrective Action	417.3(a) Deviation from a critical limit 417.3(b) Deviation not covered by a specified corrective action/unforeseen	Rk R&

	hazard	O
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Monitoring

NACMCF Monitoring Definition

- Monitoring is a planned sequence of observations or measurements taken to assess whether a CCP is under control and produce an accurate record for future verification.

The regulation that applies to monitoring is:

9 CFR 417.2(c)(4)—List the procedures, and the frequency with which those procedures will be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits.

Methodology

IPP may decide to use the recordkeeping component to verify the monitoring requirement to determine if the establishment is performing the monitoring procedures at the frequency specified in the HACCP plan.

Taking Measurements at Critical Control Points

IPP should occasionally take measurements at certain critical control points in the process (i.e., perform a hands-on – review component) to verify that product meets the critical limit. When IPP take measurements to verify that product meets the critical limit, they are to use the calibrated instrument that the establishment uses for the monitoring or verification activities.

FSIS Responsibilities

- IPP verify HACCP regulatory requirements.
- IPP should be familiar with the monitoring procedures and frequencies in the current HACCP plan.
- Visualize what is occurring at the CCP, seek clarification.

Observing Establishment Employees

IPP should observe an establishment employee performing HACCP monitoring activities in the process to determine whether the procedures are being carried out as written in the HACCP plan.

Verification

Verification activities are tools that the establishment uses to ascertain that the HACCP plan is being followed correctly.

The regulations that apply to verification procedures and frequencies are:

9 CFR 417.2(c)(7)—*List the verification procedures, and the frequency with which those procedures will be performed, that the establishment will use in accordance with §417.4 of this part.*

9 CFR 417.4(a)(2)(i)(ii)(iii)—*Ongoing verification activities include, but are not limited to:*
(i) the calibration of process-monitoring instruments; (ii) direct observations of monitoring activities and corrective actions; and (iii) the review of records generated and maintained in accordance with §417.5(a)(3) of this part.

Methodology

IPP verify the verification requirement by performing the HACCP verification tasks. They can use either the recordkeeping, or review and observation component, or both.

Thought Process

- Gathering information by asking questions
- Assessing the information
- Determining regulatory compliance

Review Verification Records

- IPP should review the verification records to determine compliance.
- IPP should verify that it contains the actual values and observations.

Review the HACCP Plan

- Every HACCP Plan must contain verification procedures.
- Establishment sets frequencies.
- Establishments must calibrate instruments.

Assess Information

- Look at the establishment's HACCP plan.
- Review HACCP plan.
- Review HACCP records.
- Observe establishment employees.

Observing Establishment Employees

- IPP must observe establishment employees performing the verification activities listed in the plan.
- Is the establishment verifier doing activity as per the regulations?
- Is the establishment performing verification at the infrequency set out in the HACCP plan?
- Directly observe any corrective actions that need to be taken.

Observe Product Sampling

- Even if the product sampling is not included in the HACCP plan, we would

review results.

Recordkeeping

IPP verify the recordkeeping requirements when performing HACCP verification tasks. IPP verify recordkeeping requirements by reviewing the following:

- **The HACCP plan**
- **HACCP records**

Components

- IPP may use the recordkeeping and review and observation components.

Thought Process

- Gathering information by asking questions
- Assessing the information
- Determining regulatory compliance

Recordkeeping System

The regulatory requirement for a recordkeeping system is:

9 CFR 417.2(c)(6)—Provide for a recordkeeping system that documents the monitoring of the critical control points. The records shall contain the actual values and observations obtained during monitoring.

IPP verify this requirement using the recordkeeping component while performing the HACCP verification task.

- Verify compliance with 417.2(c)(6).
- Verify that HACCP Plan lists all records used to document the monitoring of critical control points.
- Verify that it contains the actual values and observations.

HACCP Records Requirement

The regulatory requirement for HACCP records is:

9 CFR 417.5(a)(3)—The establishment shall maintain: Records documenting the monitoring of CCP and their critical limits, including the recording of actual times, temperatures, or other quantifiable values, as prescribed in the establishment's HACCP plan; the calibration of process-monitoring instruments; corrective actions, including all actions taken in response to a deviation; verification procedures and results; product code(s), product name or identity, or slaughter production lot. Each of these records shall include the date the record was made.

IPP will verify compliance with this regulation by performing the HACCP verification task. IPP will use the recordkeeping component to verify this regulation.

Records Authenticity

The regulatory requirement for record authenticity is:

9 CFR 417.5(b)—Each entry on a record maintained under the HACCP plan shall be made at the time the specific event occurs and include the date and time recorded and shall be signed or initialed by the establishment employee making the entry.

IPP will verify compliance with this regulation by performing the HACCP verification task. They are going to use the recordkeeping and the review and observation components.

Computerized Records

The regulatory requirement for computerized records is:

9 CFR 417.5(d)—Records maintained on computers. The use of records maintained on computers is acceptable, provided that appropriate controls are implemented to ensure the integrity of the electronic data and signatures.

IPP will verify compliance with this regulation by performing the HACCP verification task using the recordkeeping component.

Record Retention

The regulatory requirements for record retention and off-site storage of records are:

9 CFR 417.5(e)(1) and (2)—Record retention. (1) Establishments shall retain all records required by paragraph (a)(3) of this section as follows: for slaughter activities for at least one year; for refrigerated products, for at least one year; for frozen, preserved, or shelf-stable products, for at least two years. (2) Off-site storage of records required by paragraph (a)(3) of this section is permitted after six months, if such records can be retrieved and provided, on-site, within 24 hours of an FSIS employee's request.

IPP will verify compliance with this regulation by performing the HACCP verification task using the recordkeeping component.

Official Review Records

The regulatory requirement for making establishment records available to IPP upon request for official review is:

9 CFR 417.5(f) Official Review—All records required by this part and all plans and procedures required by this part shall be available for official review and copying.

IPP will verify compliance with this regulation by performing the HACCP verification task using the recordkeeping component.

Supporting Documentation - Prerequisite Programs and Other Supporting Programs

The regulatory requirement that addresses the use of prerequisite programs to support decisions in the hazards analysis is:

9 CFR 417.5(a)—the establishment shall maintain the following records documenting the establishment's HACCP plan: (1) the written hazard analysis prescribed in §417.2(a) of this part, including all supporting documentation

IPP verify this requirement using both the review and observation and the recordkeeping components while performing the HACCP verification task.

If a hazard is reasonably likely to occur, **must have a CCP**. If the hazard is considered not reasonably likely to occur, a prerequisite program may be used as support.

Regulatory Requirements

- Regulatory requirement - 9 CFR 417.2(a)(2) and 9 CFR 417.5(a)(1).
- Results of testing and monitoring activities related to the production of product are subject to FSIS review.
- Prerequisite program data and records are also reviewed during the Review Establishment Data procedure.

Prerequisite Programs

- Used by establishments to support the decision in their hazard analyses that a particular potential hazard is not one that is reasonably likely to occur.

NRLTO

- There is no regulatory requirement that the prerequisite program must be written.
- If not in writing, establishment would probably not be able to support the decision the hazard is not reasonably likely to occur.

Monitoring

- Establishments are not required to “monitor” or “verify” prerequisite programs.
- IPP cannot cite a “monitoring” noncompliance in prerequisite program.
- IPP **do not** verify compliance with specific regulatory requirements for monitoring, verification, and recordkeeping.
- There are no specific regulations for monitoring activities or recordkeeping practices for prerequisite programs.

Less Than Perfect

- Less-than-perfect execution may or may not be a threat to product safety.

- IPP should discuss less-than-perfect implementation of supporting programs with establishment management at weekly meeting.
- The establishment's response should be documented in the Memorandum of Interview (MOI).

Corrective Actions

Establishment must implement the corrective actions when

1. There is a deviation from a critical limit.
2. Unforeseen hazard has occurred.
3. Whenever an event occurs that requires corrective action.

IPP are to verify that the establishment implements corrective actions that meet the regulatory requirements.

A deviation from a critical limit is the failure to meet the applicable value determined by the establishment for a CCP. If a deviation from a critical limit occurs, an establishment is required to take corrective actions in accordance with 9 CFR 417.3.

A HACCP noncompliance is the failure to meet any of the regulatory requirements of 9 CFR Part 417. If a HACCP noncompliance occurs, an establishment is expected to take immediate and further planned actions to bring itself back into compliance with regulations.

9 CFR Part 417.3(a)—*The written HACCP plan shall identify the corrective action to be followed in response to a deviation from a critical limit. The HACCP plan shall describe the corrective action to be taken, and assign responsibility for taking corrective action, to ensure:*

(1) The cause of the deviation is identified and eliminated; (2) The CCP will be under control after the corrective action is taken; (3) Measures to prevent recurrence are established; and

(4) No product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce.

9 CFR 417.3(b)—*If a deviation not covered by a specified corrective action occurs, or if another unforeseen hazard arises, the establishment shall: (1) Segregate and hold the affected product, at least until the requirements of paragraphs (b)(2) and (b)(3) of this section are met; (2) Perform a review to determine the acceptability of the affected product for distribution; (3) Take action, when necessary, with respect to the affected product to ensure that no product that is injurious to health or otherwise adulterated, as a result of the deviation, enters commerce; (4) Perform or obtain reassessment by an individual trained in accordance with §417.7 of this part, to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.*

Pre-Shipment Review Requirement

The regulatory requirement for pre-shipment review is:

9 CFR 417.5(c)--Prior to shipping product, the establishment shall review the records associated with the production of that product, documented in accordance with this section, to ensure completeness, including the determination that all critical limits were met and, if appropriate, corrective actions were taken, including the proper disposition of product. Where practicable, this review shall be conducted, dated, and signed by an individual who did not produce the record(s), preferably by someone trained in accordance with §417.7 of this part, or the responsible establishment official.

Produced and Shipped

- Product is “**produced and shipped**” when the establishment completes the pre-shipment review, even if the product is still at the establishment.

Methodology

- Mostly, record keeping will be used.
- There is a lot of flexibility in meeting this requirement.
- **No regulation addresses how the review is to be conducted or when the review must be done.**

Regulatory Requirement

The pre-shipment review must be signed and not just initialed. Recording the time when the review is performed is not a regulatory requirement.

Ready-to-Eat/Shelf Stable

Objectives

1. Identify process steps that relate to the safety of Fully Cooked-Not SS, Heat Treated-SS, and Not Heat Treated-SS products.
2. Identify factors requiring control at key process steps to meet standards for safety and product identity.
3. State the compliance guidelines frequently used to support lethality, stabilization, and multiple hurdles in the establishment's food safety systems.
4. Explain how multiple hurdles are used in a food safety system.
5. Describe how inspectors verify that establishments have support for their lethality, stabilization, and multiple hurdle food safety systems.
6. Describe effective methods of sanitation in RTE processing environments.
7. Describe how to verify compliance with Part 430 regulations.
8. Identify the pathogens of concern associated with sampling of Ready-to-Eat (RTE) product.
9. Describe the steps for performing a RTE sampling task.

RTE/SS Process Familiarization

Unit Objectives

Define Ready-to-Eat (RTE).

Define Shelf-Stable (SS).

Identify process steps relating to the safety of Fully Cooked/Not Shelf-Stable (FC/NSS), Heat Treated/Shelf-Stable (HT/SS), and Not Heat Treated/Shelf-Stable (NHT/SS) products.

Identify factors requiring control at key process steps to meet standards for safety and product identity.

Terminology

Ready-to-eat (RTE): 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.

Not required to bear safe-handling instructions. No labeling directing that product must be cooked or treated for food safety.

Shelf Stable Products

- Store under ambient temperature and humidity conditions
- Microorganisms (pathogens and spoilage) will not grow throughout the manufacturer's specified shelf-life

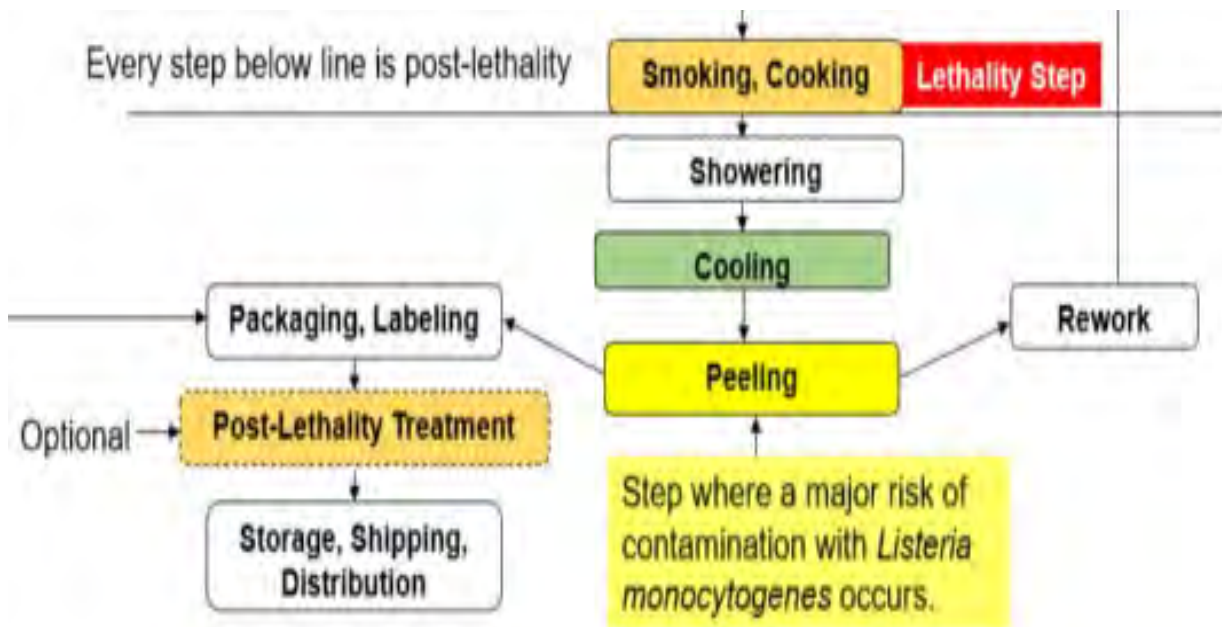
Not Shelf Stable Products

- Refrigerate or freeze prior to consumption
- Microorganisms (pathogens and spoilage) will grow if not refrigerated

Processes that can be RTE-Fully Cooked-Not Shelf Stable, Products with Secondary Inhibitors-Not Shelf Stable, Heat Treated-Shelf Stable, Not Heat Treated-Shelf Stable

Products with Secondary Inhibitors-NSS-This process category applies to establishments that further process by using a curing processing step or a processing step using other ingredients that inhibit bacterial growth. These products are generally refrigerated or frozen throughout the product's shelf life. Depending on the process and ingredients, these products **may or may not meet the definition of RTE as defined in 9 CFR 430.1.**

Hotdog flow chart close-up. Lethality and post-lethality steps.



Jerky

Jerky is cooked is cooked first, then dried. When cooking it is important to have **adequate time, temperature, and humidity**.

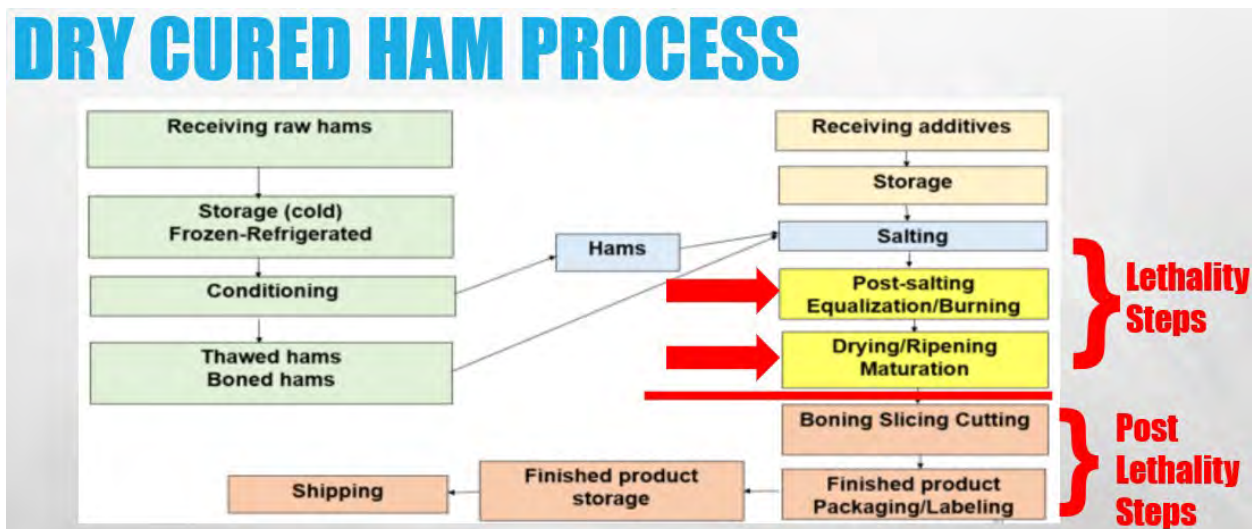
After cooking, jerky is dried. Drying stabilizes the product so that spore-forming bacteria will not grow. Drying is important to achieve shelf-stability and to meet the product identity of jerky. Moisture Protein Ratio (MPR) must be $\leq 0.75:1$ to meet the standard of identity for jerky.

Water activity (a_w) ≤ 0.85 controls bacterial pathogen and mold growth in presence of oxygen

If vacuum packed (no oxygen) $a_w \leq 0.91$ controls *Staphylococcus aureus* (*S. aureus*) growth and toxin production (Refrigerate after opening).

Water activity (a_w) is the important measurement for food safety, not MPR.

Whole muscle cured products



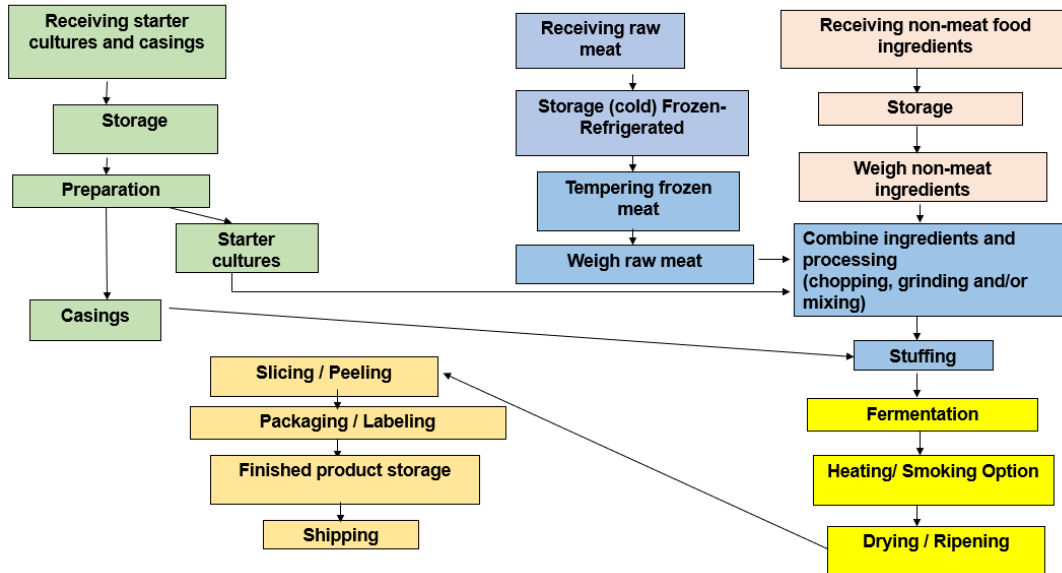
Lethality Steps

Lethality steps start with salting. But Post-salting /Equalization / Burning and Drying / Ripening / Maturation are steps that achieve both lethality and shelf stability

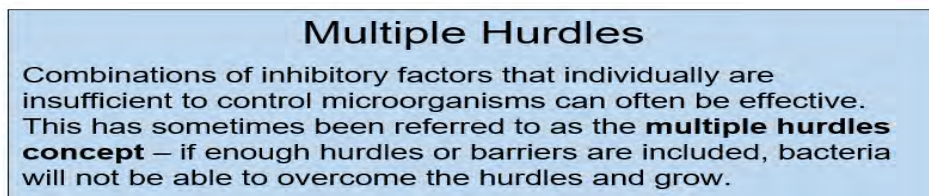
Hams must be kept cold to prevent pathogen and spoilage organism growth while salted and complete coverage with salt is important.

Fermented, Dry Sausage

Fermented Dry Sausage Flow Chart



Fermentation, Optional Heating/Smoking, and Drying/Ripening steps are lethality steps and examples of multiple hurdle concept.



Important to keep product cold throughout pre-fermentation steps to minimize fat-smearing which can slow drying. Starter culture added and is a culture of lactic acid producing bacteria and sugar. This starts the fermentation process. Starter culture can be added before or after cure, but if starter culture added after cure, thoroughly mix cure before adding as concentrated cure can inactivate bacteria in the starter culture.

Lactic acid producing bacteria (LAB) consume sugar and excrete lactic acid. The pH decreases as the sausage environment becomes more acid which produces a tangy taste. Lower pH inhibits *Staphylococcus aureus*, which can produce enterotoxin and *Micrococcus*. pH < 5.3 *Staphylococcus aureus* cannot multiply or produce toxins!

The heating/smoking step is optional. If used, may add a further layer of safety to process.

Drying- Goal is to remove moisture from the surface at the same rate as moisture migration from the product center (if surface dries first, will not adequately dry interior).

Stabilization (prevention of spore-forming bacteria from growing) is accomplished through fermentation and drying rather than cooling quickly.

Fermented, semi-dry sausages

Same basic process as fermented, dry sausage production, but without the drying step. Fermentation and cooking used as the lethality steps.

Non-acidified (not fermented) dry meat sticks

Cooked first, then dried to aw <.85 (Cooking and Drying steps critical)

Lethality, Stabilization, and Multiple Hurdles

Unit objectives

Define: Lethality, Stabilization, Performance Standard, and Target.

State regulatory lethality and stabilization performance standards.

Identify critical operational parameters in the FSIS guideline for lethality.

Describe the relationship between humidity and cooking.

Explain the food safety significance of drying in the jerky process.

Explain how multiple hurdles are used in a food safety system.

Describe how inspectors verify that establishments have support for their lethality, stabilization, and multiple hurdle processes.

FSIS Directive 7111.1, Rev 2, VERIFICATION PROCEDURES FOR LETHALITY AND STABILIZATION, is used when verifying lethality and stabilization.

Definitions

Lethality is the step used to destroy pathogens, often cooking.

Stabilization is the process used to prevent or limit the growth of spore-forming bacteria, often cooling.

Multiple hurdles concept is when multiple treatments are used to achieve lethality or stabilization.

Appendix A (new)-Lethality compliance guideline-non-regulatory-used for support

Appendix B (new)- Stabilization compliance guideline-non-regulatory-used for support

Pathogens of concern-Adulterants in RTE products

Any *Salmonella*, *Listeria monocytogenes* (Lm) and STEC.

Clostridium perfringens-Spore former controlled during stabilization. With *C. perfringens* it is outgrowth to the point where toxin is produced that would cause product to be adulterated.

Any *Clostridium botulinum* (*C. botulinum*) growth-Spore former controlled during stabilization.

Performance standards: Quantifiable pathogen reduction levels or growth limits set by FSIS regulations. Performance standards are in FSIS regulations. Set by FSIS.

Targets: Limits set by establishments to produce safe products in the absence of performance standards set by FSIS. Targets are not in FSIS regulations. Set by establishments.

9 CFR 417.2(c)(2): "Critical limits shall, at a minimum, be designed to ensure that applicable targets or performance standards established by FSIS, and any other requirement set forth in this chapter pertaining to the specific process or product, are met."

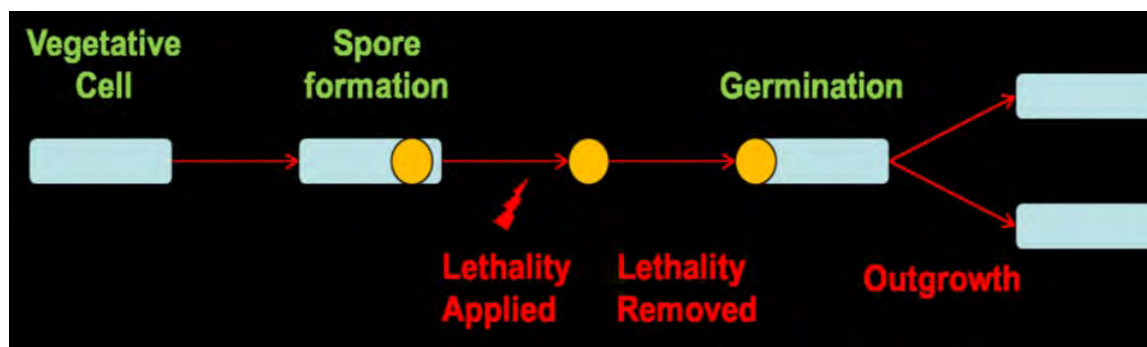
Lethality Performance Standard

Uses *Salmonella* as target organism. *Salmonella* was chosen as the pathogen of concern because it has been traditionally associated with certain types of RTE products. Death of *Salmonella* indicates destruction of other vegetative pathogens. No requirement to use any particular cooking time and temperature. For products under a performance standard, establishments can use a combination of treatments as long as a heat treatment is one of them.

Alternative Lethality: May use treatment other than ones prescribed in regulations, provided support demonstrates no viable *Salmonella* will remain in the finished product.

Log Reduction	Number of CFUs Remaining	Log Number of CFUs Remaining	Percentage Reduction
0 log	1,000,000	10 ⁶	0%
1 log	100,000	10 ⁵	90%
2 log	10,000	10 ⁴	99%
3 log	1,000	10 ³	99.9%
4 log	100	10 ²	99.99%
5 log	10	10 ¹	99.999%
6 log	1	10 ⁰	99.9999%

- Stabilization Performance Standard based on preventing growth of *C. botulinum* and *C. perfringens*. *C. botulinum* produces toxin in the product and causes botulism, which is deadly. *C. perfringens* is the target organism because the other spore-formers are slower growing.



Spores are like seeds. The plant (vegetative cell) is killed by cooking, but the seed (the spore) remains and can sprout (create a new vegetative cell) and multiply if the conditions for growth are right.

Products which are warm after cooking create an ideal environment for the growth of spore-forming pathogens. It is important to cool quickly between 130° to 80° Fahrenheit.

Some products DO have regulatory performance standards for cooking or cooling.

Cooked Beef, Cooked Roast Beef, Cooked Corned Beef

Lethality = 6.5-log reduction in *Salmonella*

Some products are without regulatory performance standards, so **targets** must be established by establishments.


Establishments must address hazards that are likely to occur with a CCP.

Establishments must identify in the HACCP system:


Lethality **pathogen reduction target** (e.g., 6.5-log reduction in *Salmonella*)


Stabilization outgrowth controls to control *Clostridium* growth.


If an establishment produces...	Lethality Performance Standard Then its lethality treatment...	Stabilization Performance Standard Then its stabilization treatment...
RTE cooked beef RTE roast beef RTE cooked corned beef 	Is to achieve a 6.5-log reduction of <i>Salmonella</i> or an alternative lethality per 9 CFR 318.17(a)(1). NOTE: The regulations allow establishments to set targets using an alternative lethality if establishments have additional support (e.g., testing of raw materials or a validated intervention).	Is not to allow multiplication of toxigenic microorganisms such as <i>C. botulinum</i> and no more than 1-log multiplication of <i>C. perfringens</i> per 9 CFR 318.17(a)(2). NOTE: Establishments may submit a waiver per 9 CFR 303.2(h) to use a process that allows ≤ 2 -logs growth <i>C. perfringens</i> provided there are additional controls in place to ensure safety of the product (see Section V.D.) More information about waivers can be found in FSIS Directive 5020.1, Verification Activities for the Use of New Technology in Meat and Poultry Establishment and Egg Products Plants.


If an establishment produces...	Lethality Performance Standard Then its lethality treatment...	Stabilization Performance Standard Then its stabilization treatment...
RTE uncured meat patties 	Is to follow one of the time/temperature combinations in 9 CFR 318.23(b)(1). These time/temperature combinations achieve a 5-log lethality of <i>Salmonella</i> in the product.	Is not to allow multiplication of toxigenic microorganisms such as <i>C. botulinum</i> and no more than 1-log multiplication of <i>C. perfringens</i> per 9 CFR 318.23(c). NOTE: Establishments may submit a waiver to use a process that allows \leq 2-logs growth of <i>C. perfringens</i> .

If an establishment produces...	Then its lethality treatment...	Then its stabilization treatment...
Other RTE cooked meat products 	Is to determine the food safety hazards that are reasonably likely to occur in its lethality process and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2(a)(1)). NOTE: FSIS recommends establishments set targets to achieve a 6.5 or 5-log reduction of <i>Salmonella</i> in their process. To use a 5-log reduction, establishments should provide additional support (see Section V.C.).	Is to consider the food safety hazards that are reasonably likely to occur in its stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2). NOTE: FSIS recommends establishments set a target to \leq 1-log or \leq 2-logs growth of <i>C. perfringens</i> in the product. To use a process that allows \leq 2-logs growth, establishments should provide additional support (see Section V.D.).

If an establishment produces...	Then its lethality treatment...	Then its stabilization treatment...
RTE shelf stable meat products 	Is to consider the food safety hazards that are reasonably likely to occur in its lethality process and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2(a)(1)). NOTE: FSIS recommends that establishments achieve a 5-log reduction of <i>Salmonella</i> , a 5-log reduction of <i>E. coli</i> , and sufficient reduction of <i>Lm</i> in their process or an alternative lethality as described in Section V.C. 2.	Is to consider the food safety hazards that are reasonably likely to occur in its stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2). NOTE: FSIS recommends establishments allow \leq 1-log or \leq 2-logs growth of <i>C. perfringens</i> in the product. To use a process that allows \leq 2-logs growth, establishments should provide additional support (see Section V.D.). For shelf-stable products, establishments should limit the growth of <i>S. aureus</i> to \leq 2-logs growth during the process, especially during the drying step and ensure no growth of <i>S. aureus</i> can occur during storage.

If an establishment produces...	Performance Standard Then its lethality treatment...	Performance Standard Then its stabilization treatment...
RTE cooked poultry 	Is to achieve a 7- log ₁₀ reduction of <i>Salmonella</i> or an alternative lethality to comply with 9 CFR 381.150(a)(1).	Is not to allow multiplication of toxigenic microorganisms such as <i>C. botulinum</i> and no more than 1- log ₁₀ multiplication of <i>C. perfringens</i> per 9 CFR 381.150(a)(2). NOTE: Establishments may submit a waiver to use a process that allows no more than 2-logs growth of <i>C. perfringens</i> .

RTE shelf stable poultry 	Is to achieve a 7-log ₁₀ reduction of <i>Salmonella</i> or an alternative lethality to comply with 9 CFR 381.150(a)(1). NOTE: The regulations allow establishments to set targets using an alternative lethality that ensures no viable <i>Salmonella</i> organisms remain in the finished product. FSIS recommends achieving ≥ 5-log reduction as an alternative lethality for shelf-stable products. No additional support is needed to use this alternative lethality with shelf-stable products as described in Section V.C.2. □	Is to consider the food safety hazards that <i>Salmonella</i> <u>are</u> reasonably likely to occur in its stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2). NOTE: FSIS recommends establishments allow ≤1-log or ≤ 2-logs growth of <i>C. perfringens</i> in the product. To use a process that allows ≤ 2-logs of growth, establishments should provide additional support (see Section V.D.). For shelf stable products, establishments should limit the growth of <i>S. aureus</i> to ≤ 2.0 logs during the process, especially during the drying step and ensure no growth of <i>S. aureus</i> can occur during storage.
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If an establishment produces...	Then its lethality treatment...	Then its stabilization treatment...
<p>NRTE partially cooked and char-marked meat patties, and partially cooked poultry strips</p> 	<p>No lethality required, will be cooked by consumer.</p> <p>NOTE: Establishments should ensure controls and preventative measures are in place to limit growth of <i>Salmonella</i> so that customary lethality processes (such as cooking) used by consumers will be adequate.</p>	<p>Must allow no multiplication of toxigenic microorganisms such as <i>C. botulinum</i> and no more than 1-log₁₀ multiplication of <i>C. perfringens</i> per 9 CFR 318.23(c)(1) and 9 CFR 381.150(b).</p> <p>NOTE: Establishments may submit a waiver to use a stabilization process that allows ≤ 2-logs growth of <i>C. perfringens</i> and no multiplication of <i>C. botulinum</i>.</p>

<p>NRTE, heat treated not fully cooked products other than partially cooked and char-marked patties and partially cooked poultry breakfast strips</p>	<p>No lethality required, will be cooked by the consumer.</p> <p>NOTE: Establishments should ensure controls and preventative measures are in place to limit growth of <i>Salmonella</i> so that customary lethality processes (such as cooking) used by consumers will be adequate to eliminate the food safety hazard.</p>	<p>Is to consider the food safety hazards that are reasonably likely to occur in <u>it</u> stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level (9 CFR 417.2).</p> <p>NOTE: FSIS recommends establishments allow ≤ 1-log or ≤ 2-logs growth of <i>C. perfringens</i> in the product. To use a process that allows ≤ 2-logs of growth, establishments should provide additional support (see Section V.D.). Establishments should also limit the growth of <i>S. aureus</i> to ≤ 2-logs during the process.</p>
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RTE and Cooked Product Validation Compliance

Establishments must decide how to design their process to control hazards. Establishments may use FSIS guidelines, published processes, or develop customized processes. Whichever support they chose, establishments must implement all critical operational parameters into their process.

Important: all critical operational parameters match the process and are implemented.

Must be validated!!

Process must be validated, it must be based on scientific literature and supported by data showing the process can be implemented as designed in the establishment.

FSIS Compliance Guidelines-Provide guidance and information to industry.

Not regulatory - not mandatory. Establishments are not required to use the compliance guidelines to support their critical limits or parameters – they may have other support. May be used to support the selection of CCPs and critical limits in the HACCP plan, or critical operational parameters in a prerequisite program.

List of Important FSIS Compliance Guidelines

Lethality Guideline - Appendix A

Stabilization Guidelines- Appendix B

Lebanon Bologna Compliance Guidelines

Jerky Compliance Guidelines

Lethality Guidelines-Appendix A- The new guideline, (still called Appendix A) incorporates the old Appendix A and includes the Time-Temperature Tables for Cooking poultry, & 5-log table, that used to be separate guidelines.

If the FSIS Lethality Guideline, known as Appendix A, is used as supporting documentation for the selection of CCPs and critical limits, all the conditions listed must be addressed.

Three critical operating parameters must be met!

Time

Temperature

Humidity

Contains time and temperature combinations for cooked beef that achieve the required 6.5-log reduction in *Salmonella*.

Temperatures are internal product temperatures.

Appendix A Compliance Guidelines for Meeting Lethality Performance Standards for certain Meat and Poultry Products (Appendix A)

Meat products can be prepared using one of the following time and temperature combinations. The stated temperature is the minimum that must be achieved and maintained in all parts of each piece of meat for at least the stated time. **Establishments should apply humidity when using this table or additional support should be provided for the process.**

<i>Degrees Fahrenheit</i>	<i>Degrees Centigrade</i>	<i>6.5-log₁₀ lethality</i>	<i>7-log₁₀ lethality</i>
130	54.4	112 min.	121 min.
131	55.0	89 min.	97 min.
132	55.6	71 min.	77 min.
133	56.1	56 min.	62 min.
134	56.7	45 min.	47 min.
135	57.2	36 min.	37 min.
136	57.8	28 min.	32 min.
137	58.4	23 min.	24 min.
138	58.9	18 min.	19 min.
139	59.5	15 min.	15 min.
140	60.0	12 min.	12 min.
141	60.6	9 min.	10 min.
142	61.1	8 min.	8 min.
143	61.7	6 min.	6 min.
144	62.2	5 min.	5 min.
145	62.8	4 min.	4 min.
146	63.3	169 sec.	182 sec.
147	63.9	134 sec.	144 sec.
148	64.4	107 sec.	115 sec.
149	65.0	85 sec.	91 sec.
150	65.6	67 sec.	72 sec.
151	66.1	54 sec.	58 sec.
152	66.7	43 sec.	46 sec.
153	67.2	34 sec.	37 sec.
154	67.8	27 sec.	29 sec.
155	68.3	22 sec.	23 sec.
156	68.9	17 sec.	19 sec.
157	69.4	14 sec.	15 sec.
158	70.0	0 sec.**	0 sec.**
159	70.6	0 sec.**	0 sec.**
160	71.1	0 sec.**	0 sec.**

** The required lethalties are achieved instantly when the internal temperature of a cooked meat product reaches 158° F or above.

Other processes may also use Appendix A

Appendix A can be used to support critical limits for cooking or heat treatment CCPs for other RTE meat, including pork. Establishments that produce other types of RTE meat may use Appendix A to support their critical limits, times and temperatures, applied at the cooking or heat treatment CCPs in their HACCP plans.

In addition to time and temperature, **humidity is another critical heating factor in Appendix A, which is often overlooked.** The time and temperature combinations are based on moist (wet) heat!

Humidity is a critical parameter for lethality of pathogens, especially *Salmonella*. If not maintained product surface will not heat as quickly, product surfaces can dry out, and bacteria become more heat resistant.

Options for maintaining relative humidity in Appendix A include, for meat and poultry products of any size, when the cooking time is at least 1 hour, and process temperature is above 145°F

Option 1-Introducing steam for 50% of the cooking time but not less than 1 hour.

Option 2-Sealing oven for 50% of the cooking time but not less than 1 hour.

Option 3-Introducing steam to achieve humidity at 90% for at least 25% of the cooking time or 1 hour.

When Humidity Controls are Not Needed

Some processes inherently maintain required humidity. Immersing the product in the liquid cooling medium, cooking product in sealed, impervious bag, applying direct heat, using an impermeable or semi-permeable product casing.

Other processes, like direct heat-grilling, flames in direct contact, heating coil, get lethal effect before the surface dries out. This is usually the case for patties.

The humidity recommendations in Appendix A apply to heat processes that can evaporate moisture from the surface of the product and surface drying can occur before the destruction of the pathogens.

Humidity is **NOT** needed for large roasts, products that are 10 pounds or more, cooked at 250 or higher, because they have a low surface to mass ratio, the surface dries slower and *Salmonella* is less likely to become heat resistant.

Options if the cooking temperature is below 145° F

Option 4-At least 90% Relative Humidity for at least 25% of the cooking time, or 1 hour, whichever is longer.

Option 5-At least 90% RH for the entire cooking time.

Note: For any time/temperature combination, if your products' total cooking time is less than 1 hour, maintain Relative Humidity.

Time-Temperature Tables for Cooking RTE Poultry

Contains time and temperature recommendations for chicken and turkey to achieve a 7.0-log₁₀ reduction in *Salmonella*. Establishments should consider the use of humidity

The Poultry Time-Temperature Tables, included in the lethality compliance guidelines, provide establishments with time and temperature combinations that can be used to cook chicken and turkey products with 1 to 12% fat levels.

Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products (Poultry Time-Temperature Tables)

Times for given temperature and fat level for Chicken needed to obtain 7-log lethality of *Salmonella**

Degrees Fahrenheit	Degrees Centigrade	1% fat	2% fat	3% fat	4% fat	5% fat	6% fat	7% fat	8% fat	9% fat	10% fat	11% fat	12% fat
136	57.8	63.3 min	64.5 min	65.7 min	67 min	68.4 min	69.9 min	71.4 min	73 min	74.8 min	76.7 min	78.9 min	81.4 min
137	58.3	50.1 min	51 min	52.1 min	53.2 min	54.3 min	55.5 min	56.8 min	58.2 min	59.7 min	61.4 min	63.3 min	65.5 min
138	58.9	39.7 min	40.5 min	41.3 min	42.2 min	43.2 min	44.2 min	45.3 min	46.4 min	47.7 min	49.2 min	50.9 min	52.9 min
139	59.4	31.6 min	32.2 min	32.9 min	33.6 min	34.4 min	35.2 min	36.2 min	37.2 min	38.3 min	39.6 min	41.1 min	43 min
140	60.0	25.2 min	25.7 min	26.2 min	26.8 min	27.5 min	28.2 min	29 min	29.8 min	30.8 min	32 min	33.4 min	35 min
141	60.6	20.1 min	20.5 min	21 min	21.5 min	22 min	22.6 min	23.2 min	24 min	24.9 min	25.9 min	27.1 min	28.7 min
142	61.1	16.1 min	16.4 min	16.8 min	17.2 min	17.6 min	18.1 min	18.7 min	19.4 min	20.1 min	21 min	22.1 min	23.5 min
143	61.7	13 min	13.2 min	13.5 min	13.8 min	14.2 min	14.6 min	15.1 min	15.6 min	16.3 min	17.1 min	18.1 min	19.3 min
144	62.2	10.4 min	10.6 min	10.8 min	11.1 min	11.4 min	11.8 min	12.2 min	12.6 min	13.2 min	13.9 min	14.8 min	15.9 min
145	62.8	8.4 min	8.6 min	8.7 min	8.9 min	9.2 min	9.5 min	9.8 min	10.2 min	10.7 min	11.3 min	12.1 min	13 min
146	63.3	6.8 min	6.9 min	7 min	7.2 min	7.4 min	7.6 min	7.9 min	8.2 min	8.6 min	9.1 min	9.8 min	10.6 min
147	63.9	5.5 min	5.5 min	5.6 min	5.7 min	5.9 min	6.1 min	6.3 min	6.6 min	6.9 min	7.4 min	7.9 min	8.6 min
148	64.4	4.4 min	4.4 min	4.5 min	4.5 min	4.7 min	4.8 min	5 min	5.2 min	5.5 min	5.8 min	6.3 min	6.8 min
149	65.0	3.5 min	3.5 min	3.5 min	3.6 min	3.6 min	3.8 min	3.9 min	4.1 min	4.3 min	4.6 min	4.9 min	5.4 min
150	65.6	2.7 min	2.7 min	2.7 min	2.7 min	2.8 min	2.9 min	3 min	3.1 min	3.3 min	3.5 min	3.8 min	4.2 min
151	66.1	2.1 min	2 min	2 min	2.1 min	2.1 min	2.1 min	2.2 min	2.3 min	2.5 min	2.6 min	2.9 min	3.1 min
152	66.7	1.5 min	1.5 min	1.5 min	1.6 min	1.6 min	1.6 min	1.7 min	1.7 min	1.8 min	1.9 min	2.1 min	2.3 min
153	67.2	1.2 min	1.2 min	1.2 min	1.2 min	1.3 min	1.3 min	1.3 min	1.3 min	1.4 min	1.4 min	1.4 min	1.6 min
154	67.8	55.9 sec	56.9 sec	58 sec	59.1 sec	1 min	1 min	1 min	1.1 min	1.1 min	1.1 min	1.1 min	1.1 min
155	68.3	44.2 sec	45 sec	45.9 sec	46.8 sec	47.7 sec	48.6 sec	49.5 sec	50.4 sec	51.4 sec	52.4 sec	53.4 sec	54.4 sec
156	68.9	35 sec	35.6 sec	36.3 sec	37 sec	37.7 sec	38.4 sec	39.2 sec	39.9 sec	40.7 sec	41.4 sec	42.2 sec	43 sec
157	69.4	27.7 sec	28.2 sec	28.7 sec	29.3 sec	29.8 sec	30.4 sec	31 sec	31.6 sec	32.2 sec	32.8 sec	33.4 sec	34 sec
158	70.0	21.9 sec	22.3 sec	22.7 sec	23.2 sec	23.6 sec	24 sec	24.5 sec	25 sec	25.4 sec	25.9 sec	26.4 sec	26.9 sec
159	70.6	17.3 sec	17.6 sec	18 sec	18.3 sec	18.7 sec	19 sec	19.4 sec	19.8 sec	20.1 sec	20.5 sec	20.9 sec	21.3 sec
160	71.1	13.7 sec	14 sec	14.2 sec	14.5 sec	14.8 sec	15 sec	15.3 sec	15.6 sec	15.9 sec	16.2 sec	16.5 sec	16.9 sec
161	71.7	10.8 sec	11 sec	11.2 sec	11.5 sec	11.7 sec	11.9 sec	12.1 sec	12.4 sec	12.6 sec	12.8 sec	13.1 sec	13.3 sec
162	72.2	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	9.6 sec	9.8 sec	10 sec	10.2 sec	10.3 sec	10.5 sec
163	72.8	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec
164	73.3	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec
165	73.9	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec

* The required lethality is achieved instantly at the internal temperature in which the holding time is < 10 seconds. Establishments should apply humidity when using this table or additional support should be provided for the process.

Times for given temperature and fat level of Turkey needed to obtain 7-log lethality of *Salmonella**

Degrees Fahrenheit	Degrees Centigrade	1% fat	2% fat	3% fat	4% fat	5% fat	6% fat	7% fat	8% fat	9% fat	10% fat	11% fat	12% fat
136	57.8	64 min	64.3 min	64.6 min	64.9 min	65.3 min	65.8 min	66.3 min	66.9 min	67.6 min	68.4 min	69.5 min	70.8 min
137	58.3	51.9 min	52.2 min	52.4 min	52.8 min	53.2 min	53.6 min	54.1 min	54.7 min	55.3 min	56.2 min	57.2 min	58.5 min
138	58.9	42.2 min	42.5 min	42.7 min	43 min	43.4 min	43.8 min	44.2 min	44.8 min	45.4 min	46.2 min	47.2 min	48.5 min
139	59.4	34.4 min	34.6 min	34.9 min	35.1 min	35.4 min	35.8 min	36.2 min	36.7 min	37.3 min	38.1 min	39.1 min	40.4 min
140	60.0	28.1 min	28.3 min	28.5 min	28.7 min	29 min	29.3 min	29.7 min	30.2 min	30.8 min	31.5 min	32.5 min	33.7 min
141	60.6	23 min	23.2 min	23.3 min	23.5 min	23.8 min	24.1 min	24.4 min	24.9 min	25.5 min	26.2 min	27.1 min	28.2 min
142	61.1	18.9 min	19 min	19.1 min	19.3 min	19.5 min	19.8 min	20.1 min	20.5 min	21.1 min	21.7 min	22.6 min	23.7 min
143	61.7	15.5 min	15.6 min	15.7 min	15.9 min	16.1 min	16.3 min	16.6 min	17 min	17.4 min	18 min	18.8 min	19.8 min
144	62.2	12.8 min	12.8 min	12.9 min	13 min	13.2 min	13.4 min	13.7 min	14 min	14.4 min	15 min	15.7 min	16.6 min
145	62.8	10.5 min	10.6 min	10.6 min	10.7 min	10.8 min	11 min	11.3 min	11.5 min	11.9min	12.4 min	13 min	13.8 min
146	63.3	8.7 min	8.7 min	8.7 min	8.8 min	8.9 min	9 min	9.2 min	9.5 min	9.8 min	10.2 min	10.8 min	11.5 min
147	63.9	7.1 min	7.1 min	7.1 min	7.2 min	7.3 min	7.4 min	7.5 min	7.7 min	8 min	8.4 min	8.8 min	9.4 min
148	64.4	5.8 min	5.8 min	5.8 min	5.8 min	5.9 min	6 min	6.1 min	6.3 min	6.5 min	6.8 min	7.2 min	7.7 min
149	65.0	4.7 min	4.7 min	4.7 min	4.7 min	4.7 min	4.8 min	4.9 min	5 min	5.2 min	5.4 min	5.8 min	6.2 min
150	65.6	3.8 min	3.7 min	3.7 min	3.7 min	3.7 min	3.8 min	3.9 min	4 min	4.1 min	4.3 min	4.5 min	4.9 min
151	66.1	3 min	2.9 min	2.9 min	2.9 min	2.9 min	2.9 min	3 min	3.1 min	3.2 min	3.3 min	3.5 min	3.8 min
152	66.7	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.3 min	2.4 min	2.5 min	2.7 min	2.8 min
153	67.2	1.8 min	1.8 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	1.9 min	2.1 min
154	67.8	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.5 min	1.6 min	1.6 min	1.6 min
155	68.3	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.2 min	1.3 min	1.3 min	1.3 min	1.3 min	1.3 min
156	68.9	59 sec	59.3 sec	59.5 sec	59.8 sec	1 min	1 min	1 min	1 min	1 min	1 min	1 min	1 min
157	69.4	47.9 sec	48.1 sec	48.3 sec	48.5 sec	48.8 sec	49 sec	49.2 sec	49.5 sec	49.7 sec	49.9 sec	50.2 sec	50.4 sec
158	70.0	38.8 sec	39 sec	39.2 sec	39.4 sec	39.6 sec	39.8 sec	40 sec	40.1 sec	40.3 sec	40.5 sec	40.7 sec	40.9 sec
159	70.6	31.5 sec	31.7 sec	31.8 sec	32 sec	32.1 sec	32.3 sec	32.4 sec	32.6 sec	32.7 sec	32.9 sec	33 sec	33.2 sec
160	71.1	25.6 sec	25.7 sec	25.8 sec	26 sec	26.1 sec	26.2 sec	26.3 sec	26.4 sec	26.6 sec	26.7 sec	26.8 sec	26.9 sec
161	71.7	20.8 sec	20.9 sec	21 sec	21.1 sec	21.2 sec	21.3 sec	21.4 sec	21.5 sec	21.6 sec	21.7 sec	21.8 sec	21.9 sec
162	72.2	16.9 sec	16.9 sec	17 sec	17.1 sec	17.2 sec	17.3 sec	17.3 sec	17.4 sec	17.5 sec	17.6 sec	17.7 sec	17.7 sec
163	72.8	13.7 sec	13.7 sec	13.8 sec	13.9 sec	13.9 sec	14 sec	14.1 sec	14.1 sec	14.2 sec	14.3 sec	14.3 sec	14.4 sec
164	73.3	11.1 sec	11.2 sec	11.2 sec	11.3 sec	11.3 sec	11.4 sec	11.4 sec	11.5 sec	11.5 sec	11.6 sec	11.6 sec	11.7 sec
165	73.9	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec	<10.0 sec

*The required lethalties are achieved instantly at the internal temperature in which the holding time is < 10 seconds. Establishments should apply humidity when using this table or additional support should be provided for the process.

Appendix "B" Stabilization (Cooling)

Appendix B provides guidance for processors that cook meat and poultry products to meet FSIS's stabilization (cooling) performance standard.

FSIS provided proven time and temperature requirements in Appendix B for establishments to use to meet the required stabilization performance standard without having to do extensive research to support their process.

Appendix B is a guideline. However, if followed precisely, Appendix B is a validated process schedule because the guideline contains processing methods already accepted by the Agency as effective in safely cooling cooked meat and poultry products.

Remember that FSIS performance standard is less than 1.0 log growth of *C. perfringens*. All four of the Appendix B cooling options, if incorporated into the establishments HACCP system, will support that standard.

Rapid cooling between 130°F and 80°F is extremely important. Data has shown that 80°F is the approximate transition between rapid growth and slower growth of many food-borne pathogenic bacteria, including *C. perfringens* and *C. botulinum*.

If the establishment cannot rapidly cool the product in accordance with the one of the cooling options in the guideline, it can develop custom stabilization (cooling) procedures provided they met the performance standard when the product they produce is subject to 9 CFR 318.17, 318.23 and 381.150. Of course, this would require the establishment to have documentation other than Appendix B to support its cooling data. The supporting documentation could be a challenge study or inoculated test pack study performed by a processing authority.

Option 1 ($\leq 1.0 \log_{10}$): During cooling, the product's maximum internal temperature should not remain between 130°F to 80°F for more than 1.5 hours nor between 80°F and 40°F for more than 5 hours (6.5 hours total cooling time). This option applies to:

- Fully cooked products (including intact or non-intact meat or poultry) and
- Partially cooked, small-mass products provided the establishment can support the heating come-up time (CUT) to the final heating temperature for partially cooked small mass products is ≤ 1 hour.
- Products may be cured or uncured although there is a larger safety margin if cured.

Appendix B- Option 2

Start chilling product **within 90 minutes** of the end of cooking

Cool product temperature from:

- **120°F to 80°F in 1 hour**
- **80°F to 55°F in 5 hours**

Continue chilling until 40°F

Fully cooked, cured, and uncured processes may use this option

Appendix B-Cured Products-Option 3

Fully Cooked *cured* product must have at least 100 ppm of ingoing sodium nitrite and 250 ppm erythorbate or ascorbate.

Cool the product temperature from:

- **130°F to 80°F in 5 hours**
- **80°F to 45°F in 10 hours**

Natural sources of nitrite and ascorbate may be used per FSIS Directive 7120.1.

Option 4 ($\leq 1.0 \log_{10}$): The following process may be used for the slow cooling of **fully cooked meat and poultry products cured with nitrite or salt**. During cooling, the product's maximum internal temperature should **not remain between 120°F to 40°F for more than 20 hours and the cooling process:**

- **causes a continuous drop in product temperature; or**
- **controls the product's temperature so that it does not stay between 120°F and 80°F for more than 2 hours**

This option applies to:

- Fully cooked products (including intact or non-intact meat or poultry)
- **Formulated with ≥ 40 ppm of sodium nitrite or its equivalent and a brine concentration of 6% or more; or**
- **Formulated with or without nitrite (such as salt cured product), but with a maximum water activity of 0.92.**

Lethality & Stabilization for Jerky Products

Jerky- Lethality Treatment

Meat cooking (lethality) process should achieve at least 5.0-log reduction of both *Salmonella* and shiga-toxin-producing *E. coli* (STEC).

Poultry process should achieve at least 5.0 log reduction of *Salmonella*

The drying (stabilization) step results in reduced water activity to prevent the outgrowth of pathogens such as *S. aureus* and *C. perfringens*.

a_w or Water Activity is used for food safety $\leq .85$ in aerobic environment. $\leq .91$ if vacuum packaged (anaerobic environment).

Multiple Hurdle Concept

Combinations of inhibitory factors that individually are insufficient to control microorganisms can often be effective. This has sometimes been referred to as the multiple hurdles concept – if enough hurdles or barriers are included, bacteria will not be able to overcome the hurdles and grow.

FSIS recommends lethality of 5.0-log₁₀ reduction of *Salmonella* and 5.0-log₁₀ reduction of STEC for products containing beef.

FSIS expects establishments to include the lethality pathogen reduction targets, and stabilization log outgrowth controls for *C. perfringens* and *C. botulinum*, in its HACCP plan or supporting documentation.

For most shelf-stable products, the **pH (≤ 4.6)** or **water activity (0.93)** preclude the growth of the primary hazards of concern (i.e., *Clostridium perfringens* and *Clostridium botulinum*).

Food Ingredients of Public Health Concern

Unit Objectives

1. List the “Big 8” food allergens.
2. Distinguish between a food allergy and food intolerance.
3. Describe establishment responsibilities for controlling ingredients of public health concern.
4. Identify situations that could lead to cross contact with a food allergen.
5. Identify situations that may result in mislabeling of a product containing an ingredient of public health concern.
6. Distinguish between labeling requirements for ingredients of public health concern and voluntary labeling declarations.
7. Explain when an establishment can include factual statements about a product's processing environment on the product label.
8. Describe how to perform and document the "Big 8" Formulation Verification task.

Definitions:

A **food allergy** is a specific type of adverse immune system reaction to a particular food or food ingredient which can be life threatening.

“Big 8” Allergens make up 90% of all allergic reactions to foods.

Food intolerances are non-allergic sensitivities to some food or color additives which produce gas, bloating, and digestive upsets, but are rarely life threatening.



Food intolerances to lactose, sulfites, FD&C No. 5-FD&C (Yellow) No. 5 or tartrazine, Monosodium glutamate (MSG), gluten, and nitrates/nitrites are common.

<u>Food Allergies</u>	<u>Food Intolerances</u>
<ul style="list-style-type: none">◦ An allergic reaction is potentially life threatening.◦ Trace amounts of an allergen could trigger a severe reaction.◦ Consumers must rely on accurate product labeling.	<ul style="list-style-type: none">◦ A non-allergic sensitivity to some food or color additive.◦ Usually not life-threatening.◦ Can still have public health significance.

Establishment Responsibilities

In the Hazard Analysis, establishments determine if any ingredients used in product formulation are of public health concern and consider the controls necessary to prevent cross contact and assure accurate labeling. These can be included in the establishment's HACCP plan, SSOPs, or other prerequisite program.

Cross contact may result from:

Inadequate control of ingredients

Inappropriate use of ingredients

Inadequate implementation of sanitation procedures

Inaccurate Labeling

Inaccurate labeling of properly formulated product is also a threat to consumers sensitive to any ingredients.

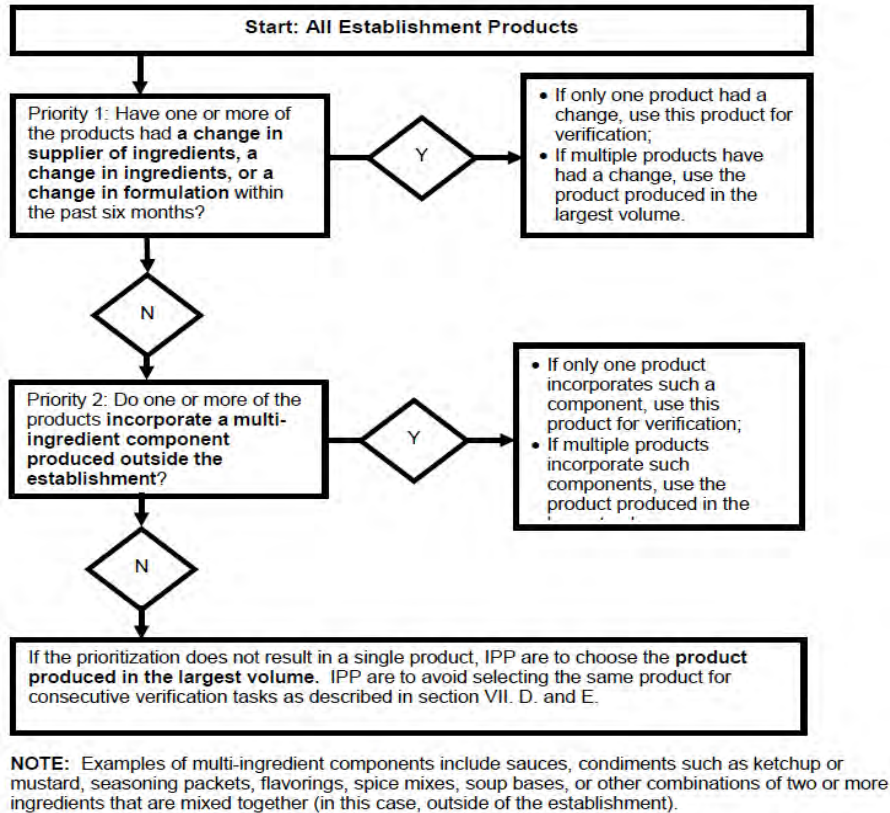
Ingredients of public health concern must be declared in the ingredients statement.

Voluntary statements on labels alert consumers to the presence of specific ingredients but are not required. Examples include: "Contains wheat", "Contains milk", "Contains sodium caseinate (from milk)".

Statements About Processing Environment may only be used when GMPs and Sanitation SOPs cannot reasonably be expected to eliminate possibility of cross - contact. Not a substitute for good sanitation. Example: "Produced in a plant that uses peanuts."

Big Eight Allergen Formulation Verification task-FSIS Directive 7230.1, Rev 2

A method used to verify that establishments accurately control and label the "Big 8" allergens. Applies to all HACCP processing categories EXCEPT slaughter.



Ready to Eat SS Sanitation

Unit Objectives

After completion of this module, the student will be able to:

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.

Terminology

Lethality Treatment-A process, including the application of an antimicrobial agent, that eliminates or reduces the number of pathogenic microorganisms on or in a product throughout the shelf life of the product.

Post-Lethality Exposure involves the handling of RTE product that comes into direct contact with a food contact surface after it has been subjected to an initial lethality treatment.

Cross-contamination is the transfer of bacteria to exposed RTE product after the lethality treatment.

Listeria monocytogenes (Lm) is of particular concern because it has potentially fatal consequences. Listeriosis can lead to septicemia, meningitis, and spontaneous abortion. It is especially pathogenic to

high-risk populations, including pregnant women, newborns, elderly, and people with weakened immune systems. Spread by direct food contact with contaminated surfaces. Grows in cool, damp environments. Gets nutrients from product debris. Can make **biofilms** to protect itself (a biofilm is a thin, slimy film of bacteria that adheres to a surface, effectively protecting it from the environment). It is hardy; can survive and grow in packaged refrigerated product, resists salt, nitrite, and acid. Illnesses and deaths linked to products adulterated with *Lm*. Adulteration of product occurs through cross-contamination from environmental sources after cooking (or other lethality steps).

Verification Sampling

Definitions:

Environmental surfaces-These are areas where product does not make contact like walls, ceilings, floors, underneath tables - carts, employee shoes, electrical cables/switches/outlets, etc...

Food Contact Surfaces - These are surfaces that have direct contact with product, such as tabletops, hands, gloves, aprons, knives, packaging material/film, conveyor belts, brine (when product is not in a cook-in-the-bag), etc...

Product - These are samples of the actual product after it has gone thru the lethality step. The amount and number of samples will depend on the type of product, testing procedure and amount represented.

Cleaning is the removal of product residue from the equipment and environment.

Sanitizing is the application of either heat or chemicals to substantially reduce the numbers of microorganisms to an acceptable level.

Pre-operational Sanitation General Steps

Rotating Detergents & Sanitizers helps maintain effectiveness by keeping bacteria "off balance".

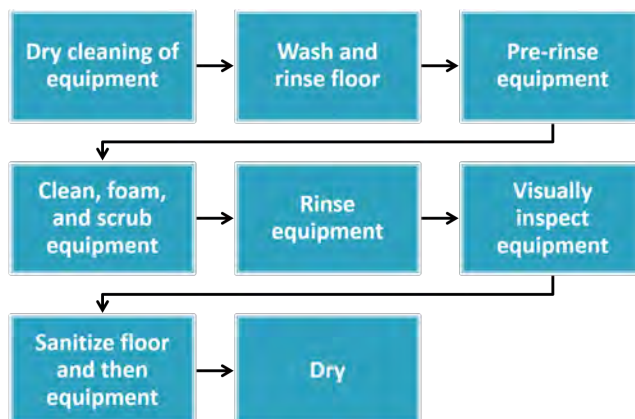
Control air/product/employee traffic flow so they do not bring *Lm* and other adulterants into the RTE environment.

Lm and Construction

Lm has been linked to disruptive construction. *Lm* is in the environment. Dust/debris generated can carry *Lm* all over the equipment and facilities, if not controlled. Dust carried by the air currents and/or employees could bring *Lm* and other adulterants to the RTE environment.

Disruptive construction includes removal of drains, floors, and walls, movement of materials, exposure of areas not typically cleaned. Establishments are responsible for controlling food safety issues resulting from construction.

Testing for *Listeria monocytogenes* vs. *Listeria* spp.



Listeria monocytogenes (Lm) = pathogen

Listeria species (spp.) = indicator organism

The term *Listeria* spp. (spp. = species) refers to all strains of *Listeria*. Because *Lm* may be present only in very low numbers, it can be difficult to detect with the available testing capabilities. Therefore, many establishments use a testing plan for *Listeria* spp. because it is easier and faster to find *Listeria* spp. since the method is testing for more than one species of *Listeria*. **Positive test results for *Listeria* spp. should be viewed as an indication that *Lm* may be present** and alert the establishment that there are **possibly insanitary conditions in the facility. Finding *Lm* is direct evidence of a pathogen and the product contacting any contaminated food contact surfaces would be considered adulterated.** Positive test of product with *Listeria* spp. means product MAY be adulterated. Positive test of product with *Listeria monocytogenes* means product IS adulterated.

***Listeria monocytogenes* Regulations**

Unit Objectives

After completion of this module, the student will be able to:

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

L. monocytogenes is a major foodborne pathogen of significant potential public health concern. *Lm* is widespread in the environment and can be found in soil, on plant materials, in animal feedstuffs, and the intestinal tracts of various mammals and birds. It tolerates a variety of environmental conditions and can reproduce at temperatures just below freezing or as high as 113°F, water activity as low as 0.92, and pH ranging from 4.39 to 9.4. Pregnant women and their fetuses, young children, the elderly, and immune-compromised individuals are most susceptible to illness.

For these reasons, FSIS considers *Lm* a hazard which must be controlled by establishments that produce post-lethality exposed RTE products. Public health strategies for protecting consumers against *Lm* include specific regulatory requirements (9 CFR Part 430) intended to control *Lm* in areas where RTE products are post-lethality exposed.

9 CFR 430.1 Definitions

Ready-to-Eat (RTE) Product – edible meat or poultry product that does not require any additional preparation by the consumer to achieve food safety.

Deli Product – RTE meat or poultry product that is typically sliced either in an official establishment or after distribution and assembled in a sandwich for consumption. NOTE: USDA regulates closed-face sandwiches and FDA has jurisdiction over open-faced sandwiches.

Hotdog Product – RTE meat or poultry frank, frankfurter, wiener, or other product that complies with a standard of identity as defined in 9 CFR 319.180 and 319.181.

Lethality Treatment – a process an establishment uses to eliminate or reduce the number of pathogenic microorganisms on or in a product for that product to be safe for human consumption.

Antimicrobial Agent – a substance in or added to RTE product that will suppress or inhibit *Lm* growth in the product throughout the entire shelf life of that product.

Antimicrobial Process – an operation (e.g., freezing, fermentation) applied to RTE product that suppresses or limits *Lm* growth in the product throughout the entire shelf life of that product.

Prerequisite Program (PRP) – a procedure or set of procedures designed to provide the basic environmental or operating conditions necessary for the production of safe, wholesome food.

Indicator Organism – a type of bacteria (often *Listeria* spp. in RTE establishments) used to determine when objectionable microbial conditions occur either in food or processing, production areas, or storage rooms. The presence of these microorganisms means pathogens may be present in the product or the processing environment.

Additional terms:

Post-lethality Treatment (PLT) – additional lethality treatment following the initial lethality process that is applied to either post-lethality exposed final product or the sealed product package to reduce or eliminate *Lm* contamination in the post-lethality environment.

Post-lethality Processing Environment – an area in an establishment where product that has been subjected to an initial lethality treatment is conveyed for further processing or packaging.

Post-lethality Exposed (PLE) Product – RTE product that comes into direct contact with an FCS in a post-lethality processing environment after the lethality treatment has been applied.

Lm Regulation 430:

Applies to RTE product exposed to the environment following the lethality process.

Not ready-to-eat (NRTE) product and product not post-lethality exposed is NOT subject to *Lm* regulation 9 CFR 430.4.

The fully cooked not shelf stable HACCP processing category applies to establishments that further process products by using a lethality treatment that includes a cooking step. “Lethality” is a process that reduces or eliminates pathogenic microorganisms to achieve food safety. An effective lethality process should reach at least a 7-log reduction for *Salmonella* in cooked poultry products, a 6.5 log reduction for cooked meat products, and at 5 log reduction in other products with adequate support. FCNSS products meet the RTE definition but are not shelf stable and must be kept frozen or refrigerated to maintain food safety. Certain RTE products (e.g., **fully cooked sausages, barbecued meats, roast beef**) are required by a standard of identity to be fully cooked.

Some establishments may produce fully cooked products (casserole, meat balls, etc.) that have no standard of identity requirement or customary or usual identity and choose to label it as NRTE (Not Ready-to-Eat).

Classify these under Heat-Treated-Not Fully Cooked-Not Shelf Stable (HT-NFC-NSS).

Verifying 9 CFR 430 Compliance

Verify RTE processing alternative selected.

Verification results demonstrate effectiveness of establishment control measures and made available upon request.

Verify establishment compliance with chosen alternative through appropriate SSOP or HACCP tasks in PHIS.

***Listeria* Regulation 9 CFR 430**

Intended to further reduce incidence of *Lm* in post-lethality exposed RTE meat and poultry products.

Includes 3 alternatives establishments use to control *Lm*.

Establishments required to maintain sanitary conditions.

Contact DO if establishment subject to Part 430 fails to meet requirements.

***Listeria* Control Alternative 1**

9 CFR 430.4(b)(1) Alternative 1:

Post-lethality treatment (may also be antimicrobial agent or process)

Reduces or eliminates *Lm* on product

-AND-

Antimicrobial agent or process

Suppresses or limits *Lm* growth throughout product shelf life **AND**

Sanitation

Alternative 1 requires use of a post-lethality treatment (i.e., an antimicrobial agent or process) to reduce or eliminate (kills) *Lm* on the product **and** an antimicrobial agent or process that suppresses or limits *Lm* growth. **The word AND is key here!!!** Antimicrobial Agent is abbreviated AMA. Antimicrobial Process is abbreviated AMP.

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

Alternative 1: Post-lethality treatment and anti-microbial agent/process verification questions:

Is the post-lethality treatment incorporated in the HACCP plan? Must be a CCP.

Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4 and 430.4(b)(1)(ii)? Must be validated.

Is the establishment implementing the post-lethality treatment as described in the HACCP plan?

Are they conducting monitoring, verification, meeting recordkeeping requirements, and taking HACCP corrective actions when required?

Alternative 1: Post-lethality treatment and anti-microbial agent/process:

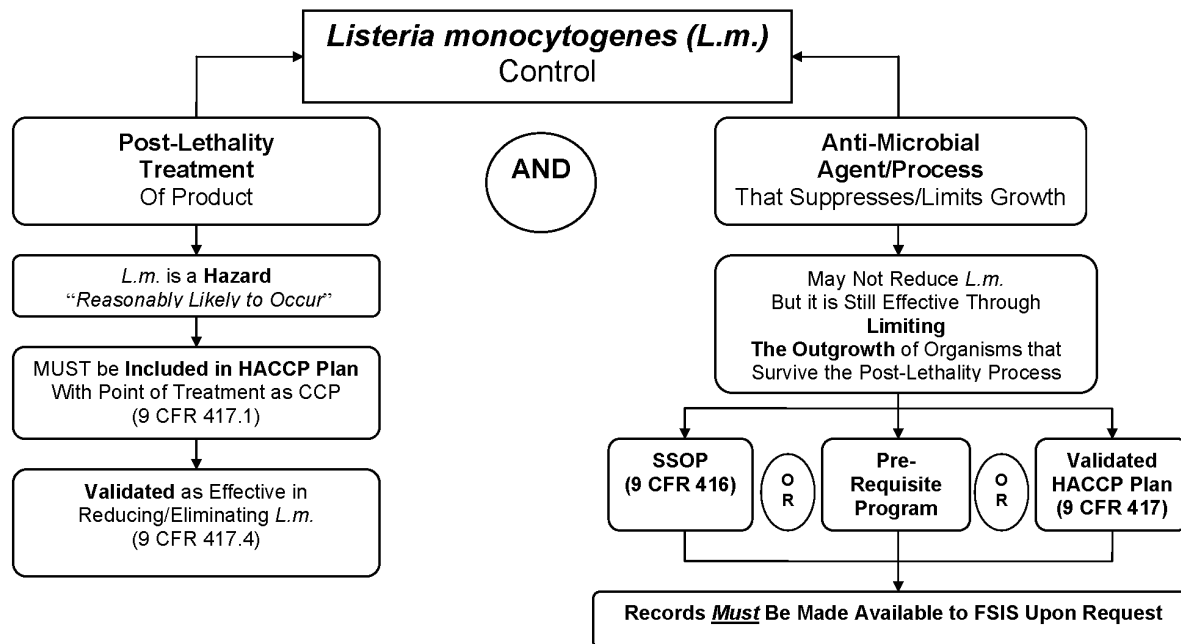
Has the establishment incorporated the use of the anti-microbial agent or process to suppress or limit the growth of *L. monocytogenes* in its HACCP plan, its Sanitation SOPs, or a pre-requisite program?

Some AMAs or AMPs may also act as a PLT if they reduce or eliminate the pathogen AND control its growth over the shelf life of the product. An example of an AMP that also acts as a PLT is a process such as drying or fermenting, which renders an RTE product shelf stable.

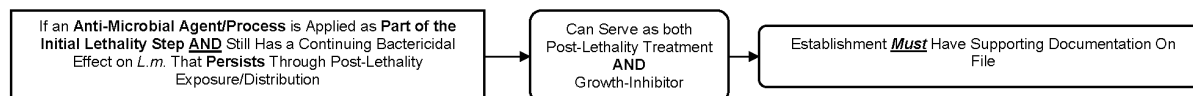
FSIS Directive 10,240.4 includes that IPP are to be aware that the *Listeria* Guideline recommends that the PLT will be validated to achieve at least a 1-log reduction of *Lm* before the product leaves the establishment. Furthermore, it states that IPP are to be aware that the *Listeria* Guideline recommends that the AMAP will allow no more than 2-log outgrowth of *Lm* over the shelf life of the product.

Food contact surface or product testing for *Lm* or *Listeria* spp. is not required for Alternative 1. FSIS recommends FCS testing at least 2 times/year/line (every 6 months).

Alternative 1



Note:



If you find that the establishment has not met all regulatory requirements (you answered “no” to one or more of the GAD questions), there is noncompliance.

You should issue an NR, and reference 9 CFR 430.4(b)(2) and, depending on where the use of the antimicrobial agent or process is addressed, either the appropriate section of 417 (for HACCP and prerequisite programs) or the appropriate section of 416 (Sanitation SOP).

Listeria Control Alternative 2

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

Alternative 2 Options

Alternative 2, Choice 1 or Choice 2

Choice 1 – Post-lethality treatment

-OR-

Choice 2 – Antimicrobial agent or process + Sanitation, including FCS testing

Requirements	Alternative 2	
	Post-lethality Treatment OR Antimicrobial Agent or Process	
	Choice 1 Post-lethality Treatment to reduce or eliminate <i>Lm</i> on product	Choice 2 Antimicrobial Agent or Process to suppress or limit growth
Validate effectiveness of post-lethality treatment (PLT). Must be included as a CCP in the establishment's HACCP Plan and should show at least a 1-log reduction in <i>Lm</i> prior to distribution of the product into commerce	X	
Document effectiveness of antimicrobial agent or process: Must be included as part of the establishment's HACCP, Sanitation SOP, or Prerequisite Program and should demonstrate no more than 2-logs growth of <i>Lm</i> over the estimated shelf life.		X
Sanitation Program Requirements		X
Testing food contact surfaces (FCS) in the post-lethality processing environment for <i>Lm</i> or an indicator organism.		X
State testing frequency.		X
Identify size and location of sites to be sampled.		X
Explain why testing frequency is sufficient to control <i>Lm</i> or an indicator organism.		X
Identify conditions for Hold-and-Test, when FCS (+) for <i>Lm</i> or an indicator organism.		X
Additional Sanitation Program Requirements		
Follow-up testing to verify corrective actions are effective after 1st FCS (+) for <i>Lm</i> or an indicator organism. Includes testing of targeted FCS as most likely source and additional testing of the surrounding area.		
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 <i>Lm</i> 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.	X	X

Under Choice 1, the establishment selects to use a post-lethality treatment that reduces or eliminates *Lm* on the product. As with Alternative 1, the effectiveness of the post-lethality treatment must be validated.

For Choice 2, the establishment uses an antimicrobial agent or process that suppresses or limits *Lm* growth.

When no post lethality treatment is used (Alternative 2, Choice 2), the establishment relies more on sanitary practices and must verify sanitation effectiveness with a sampling program.

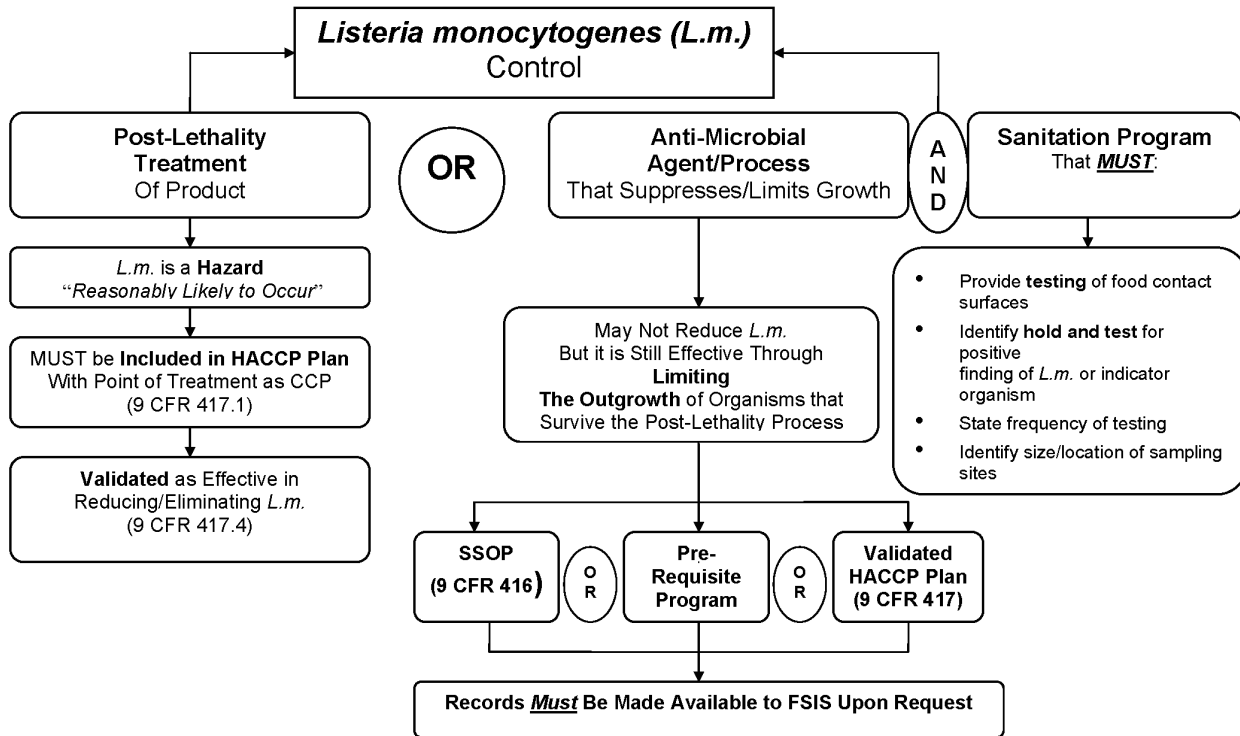
Listeria Control Testing Requirements

The establishment must identify:

- **Target organism** (either *Lm* or an indicator organism).
- **Size and location** of Food Contact Surface (FCS) test sites.
- **Frequency** of testing.
- **Support for the testing frequency** selected.
- **Conditions to hold-and-test product for positive sample results.**

Non-food contact surfaces such as walls, floors, drains, refrigeration units, etc. **may be tested** for indicator organisms, aerobic plate count (APC), or total plate count (TPC) **in addition to FCS testing**, but these results **cannot** be used to indicate the presence/absence of *Lm* **in lieu of FCS testing**.

Alternative 2



Alternative 2 Choice 1 Verification Questions

Is the post-lethality treatment (which may be an antimicrobial agent) incorporated in the HACCP plan? It must be a CCP.

Does the establishment have validation data for the post-lethality treatment in accordance with 9 CFR 417.4? It must be validated.

Is the establishment implementing the post-lethality treatment as described in the HACCP plan?

Monitoring, Verification, Corrective Actions, Recordkeeping requirements met?

Alternative 2 Choice 2 Verification Questions

Has the establishment incorporated the use of the antimicrobial agent or process to suppress or limit the growth of *L. monocytogenes* in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

To select Choice 2, the establishment **MUST** utilize an antimicrobial agent or process to limit the growth of *Lm* in the product during the shelf-life of the product.

Is the establishment using the antimicrobial agent or process as described in its HACCP plan, its Sanitation SOPs, or a prerequisite program?

You verify that the establishment is using the antimicrobial agent or process in accordance with HACCP regulatory requirements while performing the appropriate HACCP verification task if the establishment has incorporated the use of the agent or process into the HACCP plan.

Alternative 2 Choice 2: How does the establishment demonstrate that the sanitation procedures are preventing *Lm* from being in the post-lethality processing environment? It uses a microbial sampling program.

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

The establishment **must** test FCSs for either *Lm* or an indicator organism. It may test **non-food contact surfaces** such as walls, floors, drains, refrigeration units, etc., for indicator organisms or conduct aerobic plate count (APC) or total plate count (TPC) tests but these results cannot be used to indicate the presence/absence of *Lm* in the post-lethality processing environment **in place** of testing FCSs for *Lm* or an indicator organism!!!

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

- State the frequency with which testing will be done?
- Identify the size and location of the sites that will be sampled?
- Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?
- Identify the conditions under which the establishment will implement Hold & Test procedures following a positive test of an FCS for *Lm* or an indicator organism?

The establishment must identify what conditions trigger implementation of hold-and-test procedures, e.g., the first positive result for *Lm*, the first positive result for an indicator organism, 2 consecutive positive results for an indicator organism, etc.

For establishments producing RTE products under Alternatives 1 and 2, there is no magic number; rather, the establishment is free to select at what point hold and test procedures will be initiated, **provided it can be supported**. here is a suggested sampling frequency table in the *Listeria* guidelines. Some establishments will use those guidelines for the frequency of testing and cite them as support.

In determining the size, for a FCS, the establishment should take into account that the FCS on any piece of equipment will vary. For this reason, **the establishment's written program must state the size and location of the sites that will be sampled**. For example, for equipment with FCS less than 1 sq. ft., the entire surface should be sampled. For FCS larger than 1 sq. ft., a contiguous area of at least that size should be sampled.

Samples taken after 3 hours of the start of production would provide the most efficient time to detect contamination with *Lm* or an indicator organism.

9 CFR 430.4(b)(3): Alternative 3-Sanitation Measures Only

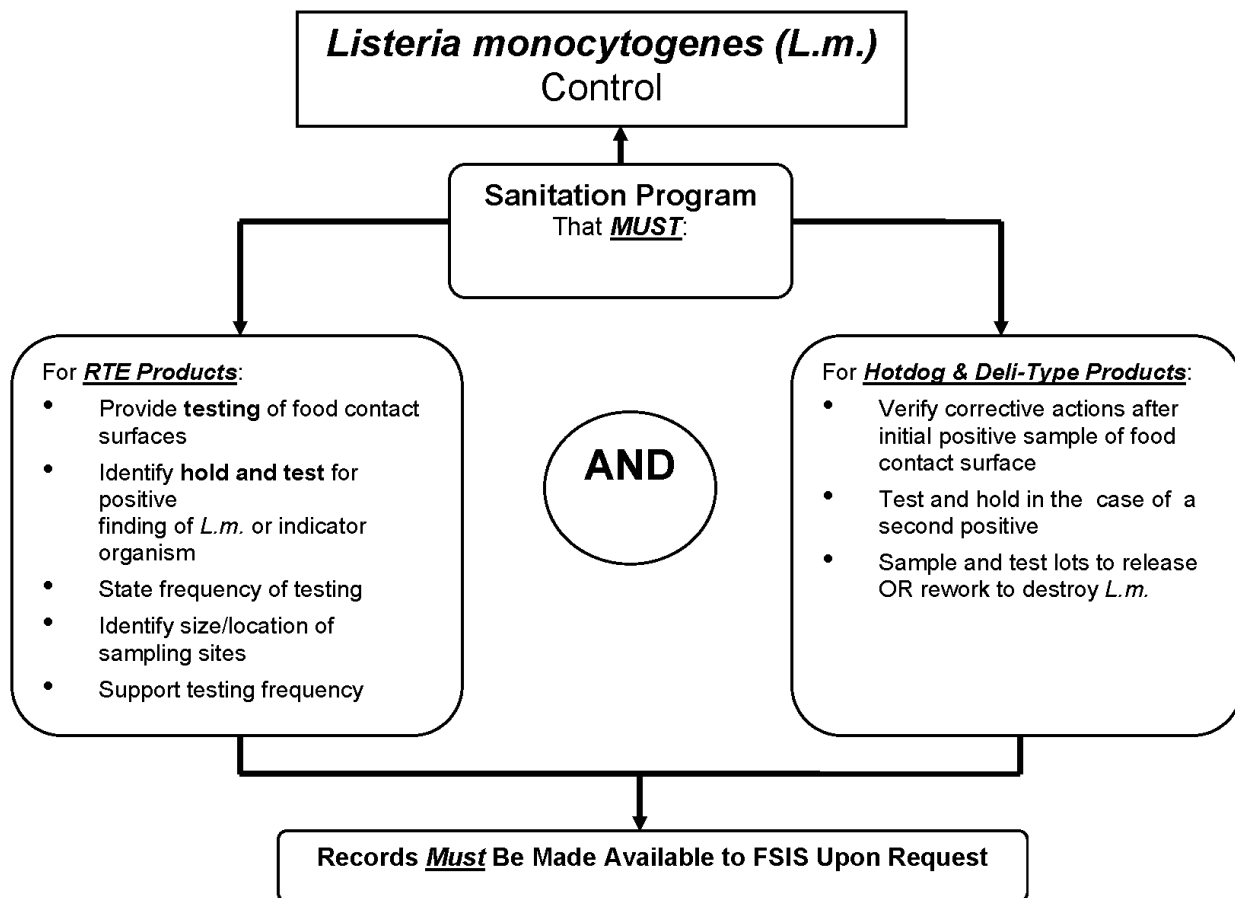
Sanitation only

Lm or indicator organism FCS testing

Sampling frequency based on establishment size or volume (large, small, very small) and whether or not the establishment produces deli meats and hotdogs.

RTE products processed under Alternative 3 are considered to be higher risk because the establishment is not applying either a post-lethality treatment or an antimicrobial agent or process. For this reason, the establishment must test FCS in post lethality environments to ensure they are sanitary and free of *Lm* or indicator organisms. The frequency, size, and location of FCS sites tested, support for the frequency, conditions for hold-and-test for positive samples must be identified.

Alternative 3



Alternative 3 Verification Questions

Does the establishment have on-going verification testing procedures designed to:

Have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program?

Test food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism?

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

Does the establishment have on-going verification testing procedures designed to:

- State the frequency with which testing will be done?
- Identify the size and location of the sites that will be sampled?
- Include an explanation of why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes*, or an indicator organism, is maintained?

The establishment MUST document the rational thought process it used in determining the frequency of FCS testing and why that frequency will ensure effective control of *Lm* or an indicator organism. Evidence such as scientific articles or prior history could be used. If you have an issue with the adequacy of the establishment's explanation, you should contact your FLS.

The frequency for testing FCS for *Lm* or an indicator organism is expected to be greater in establishments that produce deli and hot dog type RTE products under Alternative 3.

Remember there is a suggested sampling frequency table in the *Listeria* guidelines. Some establishments will use those guidelines for the frequency of testing and cite them as support.

Table 3.1 Minimum Routine Sampling Frequencies for Testing of Food Contact Surfaces (FCS) for Alternative 3.

Alternative	Daily Product Volume Range Food Contact Surface (FCS) Testing **	
		Minimum Frequency*
Alternative 3 Non-deli, non- hotdogs		1 time/month/line (monthly)
Alternative 3 Deli, hotdogs HACCP Size:		
Very Small	1-6,000	1 time/month/line (monthly)
Small	6,001 – 50,000	2 times/month/line (every 2 weeks)
Large	50,001->600,000	4 times/month/line (weekly)

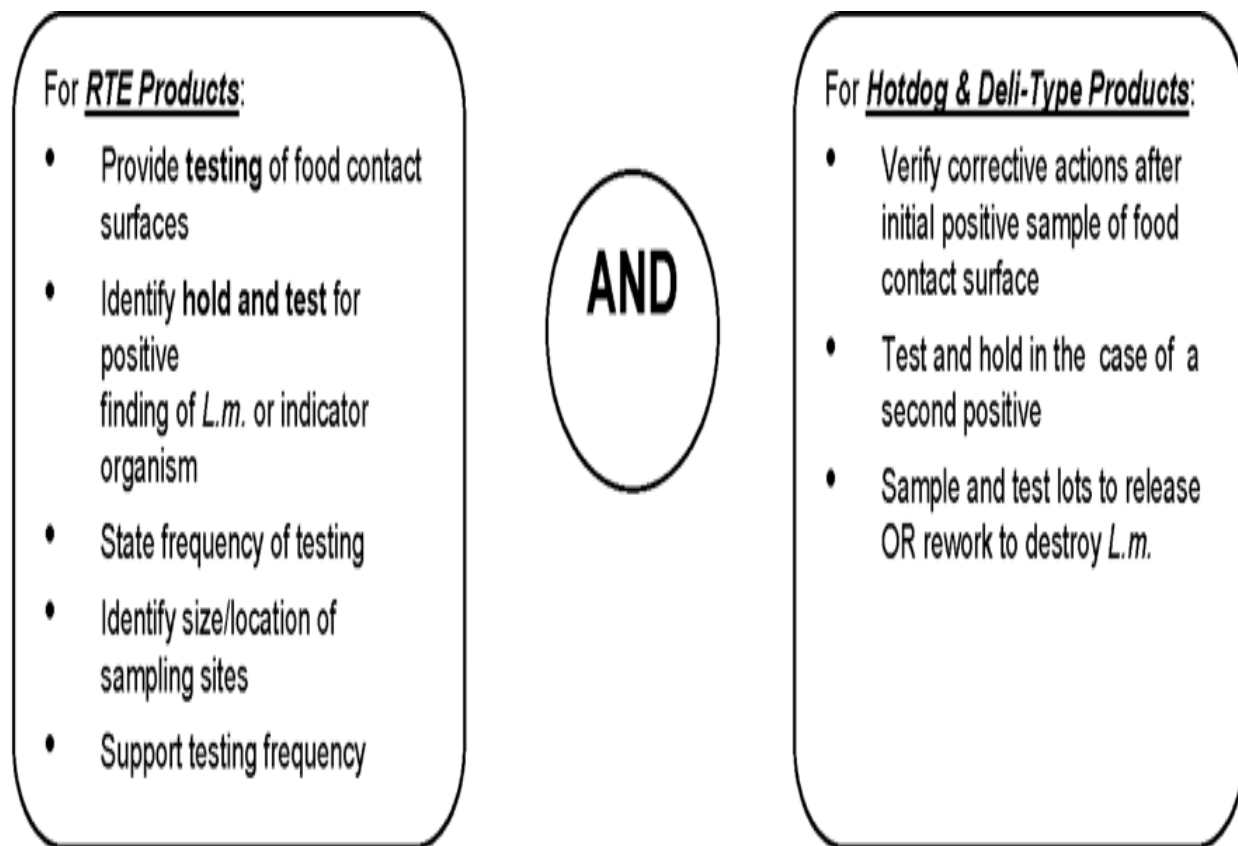
*At least 3-5 samples per production line should be sampled each time (every 6 months, quarterly, monthly, biweekly, or weekly).

**Establishments producing deli or hotdogs under Alt. 3 may decide to collect samples based on HACCP size or production volume.

Alternative 3 producing Deli & Hot Dog products:

The frequency for testing FCS for *Lm* or an indicator organism is expected to be greater in establishments that produce **deli and hot dog type RTE products under Alternative 3.**

○



- Has the establishment verified corrective action after a positive test for *Lm* or an indicator organism on a food contact surface and have they implemented follow-up testing?
- If follow-up testing resulted in a second positive test, did the establishment hold lots of product that may have become contaminated by contacting the food contact surface?

When the establishment obtains a second positive test for *Lm* or an indicator organism during its intensified FCS sampling (follow-up testing), the establishment **MUST** hold product lots that may have become contaminated by contact with the food contact surface until test results indicate the establishment has corrected the sanitation problem that led to the positive test results.

- Did the establishment sample and test product before it entered into commerce?
- Has the establishment documented the results of the testing?
- Did they destroy the product or rework the product using a process that has been validated to achieve at least a 5-log *Lm* reduction?

From the compliance guideline:

Alternative 3	Follow-up sampling	Intensified sampling	Hold and test required * (recommended after 3 rd positive)
Alternative 3 (deli or hotdog)	Follow-up sampling required	Intensified sampling	Hold and test required after 2 nd positive.

*Establishments in Alt. 2b and 3 (non-deli or hotdog producers) are **required** to identify when they will hold and test product. FSIS recommends that they do so after the 3rd consecutive

When the establishment elects to use Alternative 3 for its RTE products, it may incorporate its sanitation measures and testing protocol for controlling *Lm* in the post-lethality processing environment into the HACCP plan, SSOP, or another prerequisite program.

Review the HACCP plan, SSOP and/or prerequisite programs and the associated records to be familiar with the sanitation procedures and testing program that the establishment will employ to control *Lm*.

If the sanitation measures for controlling *Lm* and testing protocol are in a prerequisite program other than the SSOP, the establishment must include the program and the results produced by the program in the documentation that the establishment is required to maintain in accordance with §417.5.

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

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

Listeria Control Alternatives	
Alternative 1 Lowest risk and lowest level of FSIS Verification testing	The establishment uses a post-lethality treatment (PLT) to reduce or eliminate <i>Lm</i> in the product and an antimicrobial agent or process (AMAP) to limit or suppress growth of <i>Lm</i> in the product.
Alternative 2, Choice 1 Increased risk from Alternative 1 and increased level of FSIS Verification testing	The establishment uses a PLT to reduce or eliminate <i>Lm</i> in the product.
Alternative 2, Choice 2 Increased risk from Alternative 2, Choice 1 and increased level of FSIS Verification testing	The establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product.
Alternative 3 Highest risk and highest level of FSIS Verification testing	The establishment relies on sanitation alone to prevent <i>Lm</i> in the processing environment and on the product. There are separate requirements for deli meat and hot dogs under this alternative.

RTE Sampling

Unit Objectives

After completion of this module, the student will be able to:

- Describe the conditions for RTE product to be considered adulterated.
- Describe the steps for performing a RTE sampling task (6 steps).
- Describe what actions IPP take when a positive FSIS RTE sample result is identified.
- Describe the actions IPP take when establishment testing obtains a positive sample result.

FSIS sampling program is designed to verify:

- **Food safety systems are effective**
- **FSIS performance standards/regulations are met**

Pathogens of concern in RTE products that FSIS samples for:

- *Listeria monocytogenes (Lm)*-usually due to post-lethality contamination.
- *Salmonella*-usually indicates a breakdown in the lethality step.

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*.

Step 1 - Determine which product to sample and schedule in PHIS.

RTEPROD_RAND

- Randomly collect any RTE product.
- Includes post-lethality exposed products and those that are not.
- Rotate through different products.

RTEPROD_RISK

- Follow risk-based priority list.
- ONLY products that are post-lethality exposed.

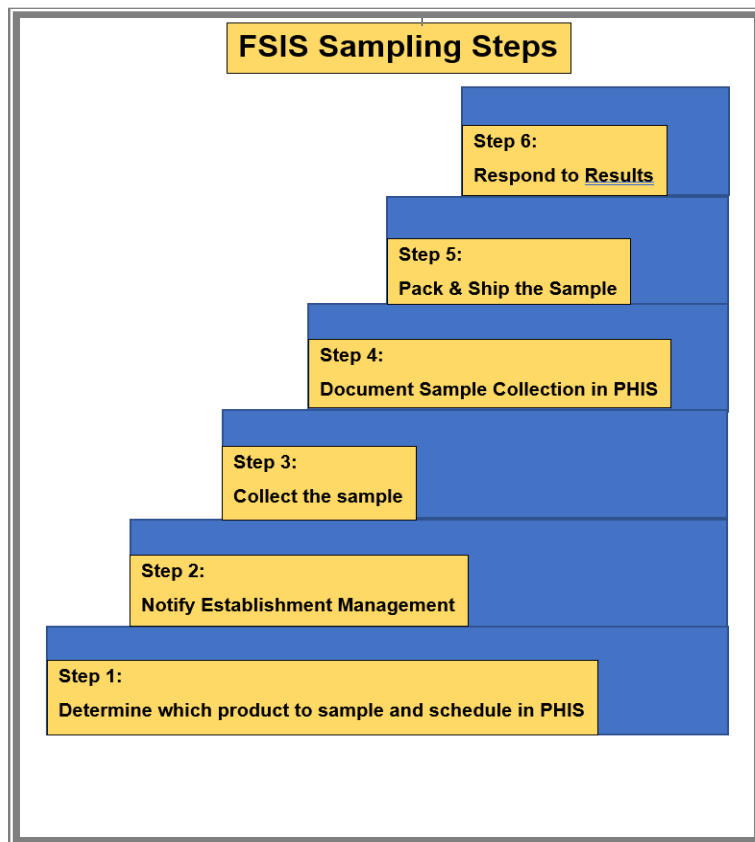
Step 2 - Notify Establishment Management

Step 3 -Collect the sample:

Step 4- Document Sample Collection in PHIS

Step 5- Pack & Ship the Sample

Step 6- Respond to Results



RTE Sampling Priority List

HACCP Processing Categories	Finished Product Categories	Production Volume Categories (by Product Groups)	Risk Level
Fully Cooked- Not Shelf Stable	RTE <u>fully-cooked</u> meat (PLE) ¹ / RTE fully-cooked poultry (PLE)	Other Fully Cooked Sliced Product	1
		Hot Dog Products	2
		Salad/Spread/Pate	3
		Diced/Shredded	4
		Meat + Nonmeat Components	5
		Sausage Products	6
		Patties/Nuggets	7
		Other Fully Cooked Not Sliced Product	8
Not Heat Treated- Shelf Stable/Heat Treated- Shelf Stable	RTE acidified/fermented meat (without cooking)-PLE/ RTE acidified/fermented poultry (without cooking)-PLE	RTE fermented meat sliced or not sliced)/ RTE fermented poultry (sliced or not sliced) (Acidified/Fermented Products) ²	9
	RTE dried meat (PLE)/ RTE dried poultry (PLE)	RTE dried meat (sliced or not sliced)/RTE dried poultry (sliced or not sliced) (Dried Products) ²	10
	RTE salt-cured meat (PLE)/ RTE salt cured poultry (PLE)	RTE salt-cured meat (sliced or not sliced)/ RTE salt-cured poultry (sliced or not sliced) (Salt-cured Products) ²	11
Product with Secondary Inhibitors – Not Shelf Stable	RTE salt-cured meat (PLE)/ RTE salt cured poultry (PLE)	RTE salt-cured meat (sliced or not sliced)/ RTE salt-cured poultry (sliced or not sliced) (Salt-cured Products) ²	11

¹PLE is defined as post-lethality exposed product. ² Product type to be used on Form 10,210-3.

Sample Management

Objectives

After completion of this module, the trainee will be able to

1. Describe the difference between directed samples and collector generated samples.
2. Schedule a directed sampling task.
3. State the purpose of the laboratory capacity reservation system.
4. Document a directed sampling task.
5. Cancel a scheduled sampling task from the Task Calendar.
6. Check laboratory results.
7. Print laboratory forms.
8. Describe the method of collecting a sample for establishments with no internet access.

References

FSIS Directive 13,000.2 Rev. 1 Performing Sampling Task in Official Establishments using the Public Health Information System 7-25-2014

FSIS Directive 10,800.1 Procedures for Residue Sampling, Testing and other responsibilities for the National Residue Program 7/12/2007

PHIS Users Guide on InsideFSIS Intranet PHIS page

Introduction

The Sample Management feature of PHIS streamlines scheduling, assigning, documentation, and tracking of FSIS's sampling tasks. IPP have the flexibility to schedule sample collection within the constraints of their particular assignment and the availability laboratory resources.

For instance, IPP at the establishment can either schedule the sample collection on the Task Calendar or cancel the sampling task when a sampling task is assigned to an establishment. When the sample collector places the lab sampling task on his/her task calendar, PHIS makes a laboratory reservation. The system generates a unique sample collection form number and bar code, which can be printed, and provides questions which the sample collector must answer as part of the sampling task.

Sampling Verification Programs and Sampling Tasks

FSIS administers three sampling verification programs.

- Microbiological sampling for food borne pathogens such as for *E. coli* O157:H7 on raw beef products, *Salmonella* sampling for raw products, and *Listeria Monocytogenes* and *Salmonella* on ready-to-eat (RTE) products.

- Carcass/tissue (kidney, liver, heart, or spleen) sampling for drug and chemical residues (antibiotics, pesticides, and heavy metals) to ensure that residue tolerance or action level established by FDA and EPA are not violated.
- Carcass/tissue sampling for pathology determinations (e.g., disease conditions, wholesomeness, etc.) to determine if there is a risk to humans handling or consuming the meat or poultry products.

Lab sampling tasks fall into two collection types.

Directed Sampling Tasks displayed on the **Establishment Task List** are based on the sampling verification programs for which the establishment is eligible. Eligibility for a specific sampling program is determined by information entered in the establishment's profile in PHIS such as the slaughter class, type of product produced or processed, and production volumes. One or more directed lab sampling tasks may be created by an authorized user (typically at the Headquarters or District level) and directed to specified establishments.

Directed sampling notification is received through alerts on the inspector homepage. MT43 sampling of raw ground beef and HC_CH_CARCO1- HACCP Verification Sampling for Young Chicken Carcasses are examples of directed sampling tasks. Residue testing in poultry carcasses, such as the NRP_YC- National Residue Program Sampling-Young Chickens, is also an example of directed sampling that will be displayed on the establishment task list.

Directed lab sampling tasks can also be created and distributed to an establishment based on a system-detected event such as a positive pathogen lab result. For example, MT44 sampling is a follow up sampling program in response to a MT43 positive *E. coli* O157:H7 test result.

Note: Scheduling the task, reserving lab capacity, and documenting the collection of *all* directed sample requests is done through the Task Calendar and *not* the sample management left navigation menu in PHIS.

Collector Generated Samples are **not** displayed on the Establishment Task List. For example, IPP assigned to livestock slaughter establishments may perform in-plant residue screening tests, such as the Kidney Inhibition Swab (KIS™) on suspect animals. In response to positive or indeterminate FSIS in-plant residue screening tests, the IPP may collect and submit confirmation samples to the lab for residue analysis.

In situations where IPP need to collect other types of samples (e.g., species substitution or a food borne illness outbreak) they are to contact their Frontline Supervisor (FLS) through their supervisory chain of command and request sample collection. IPP are to provide information to the FLS on the type of sample to be collected and a justification for the sample collection request. Upon approval of the sample collection, the IPP will add the sampling task to their Task Calendar and complete the sampling task.

Note: For *all* collector generated samples, the IPP will need to create a sampling task in PHIS by determining laboratory capacity, scheduling the collection date, and

documenting the collection of the sample. The mechanism for scheduling a sampling task and documenting collector generated samples varies in PHIS.

- The entry of in-plant **livestock residue** screening results (both negative and positive) and the scheduling and submission of confirmation samples in response to positive or indeterminate in-plant screening test results is done through the **Animal Disposition Reporting (ADR)** left navigation menu tab.
- The scheduling and submission of **livestock pathology** samples is done through the **ADR** left navigation menu tab.
- The scheduling and submission of **poultry pathology** samples is done through the **Sample Management** left navigation menu tab.
- The scheduling and submission of any **other approved collector generated** sample is done through the **Sample Management** left navigation menu tab.

PHIS Laboratory Capacity Reservation System

PHIS allows IPP to schedule sample collection tasks using the **PHIS Laboratory Capacity Reservation System**. The laboratory reservation system alerts the laboratory to expect the sample and ensures that FSIS laboratory resources will be available on the day the sample arrives. The requested collection date will be checked against the laboratory capacity and reservation module of PHIS. Confirmation will be provided indicating that there is available laboratory capacity on the requested collection date for the type of sample being collected. If capacity is not available, IPP are to select an alternate date. Once sample scheduling is completed, PHIS will display the address of the FSIS Laboratory that is scheduled to receive and analyze the sample.

IPP will document information about the collected sample and submit the sample form electronically through PHIS, ensuring that sample information is in the laboratory data systems when the lab analysis is complete. Sample results are reported to IPP through PHIS and are accessed through the IPP's Homepage.

These features as a whole will enhance the efficiency of all sampling resources, including IPP time in collecting samples, lab workload to analyze samples, and the effort needed to process and report results.

Remember

- Sampling tasks should be scheduled to the task calendar using a realistic collection date based on the plant's production schedule. This should be done as early as possible to ensure a capacity slot is available for the desired collection date. Once the sampling task has been moved from the task list to the calendar, a capacity slot is reserved to accommodate the scheduled sample. (See FSIS Directive 13,000.2 Rev. 1)
- Scheduled sampling tasks should be canceled or rescheduled as soon as IPP are aware they will not collect on a scheduled date so capacity slots can be released for others to use.
- Waiting to schedule sampling tasks in the last few days of the collection window may result in no capacity being available.

- Sampling for low and infrequent producers should be scheduled as far in advance as possible; IPP who encounter a 'no capacity available' issue should contact any laboratory to request a capacity slot be created. This may not be possible if the sampling is to occur late in the week and/or late in the sample collection window.

General Instructions for Performing Sampling Tasks in PHIS

The FSIS laboratory is completely dependent on IPP to properly collect, prepare, and ship the sample. The FSIS Sampling Form that accompanies each sample must be completely and accurately filled out. The IPP role in the sampling process is vital. The information entered on the form becomes part of a legal document. If mistakes are made during the collection of the sample or on the form, the lab will discard the sample.

IPP are to review all relevant directives and notices associated with each verification sampling program and follow the instructions in those documents before collecting a sample. Links to FSIS Directives and Notices are available through the PHIS Homepage, under the "My Dashboard" tab in the "Smart Links" menu box.

IPP are to refer to the PHIS User Guide and applicable Directives and Notices for detailed instructions on documenting FSIS sampling tasks using PHIS, including scheduling the sampling task, entering sample data, and printing sampling forms.

IPP must print a laboratory sample form upon completion of the sample collection task, sign the form, and place it in the sample box with the collected sample.

IPP are to refer to FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications, for instructions on packaging and sealing sample boxes to ensure the integrity of samples submitted to laboratories for analysis.

First shift samples should be shipped the same day they are collected or they will be discarded by the laboratory. First shift samples may be collected Monday through Friday. Samples collected on the second shift and shipped the next day will not be discarded. Second shift samples may be collected Monday through Friday.

Samples are mailed so they arrive at the FSIS lab the next day. Samples should not be held over the weekend if it is avoidable (not more than three days). If you hold the sample over the weekend, the sample must be frozen. (Friday to Monday) The current contract carrier will **deliver** on Saturdays, but not **pick-up** on a Saturday. With the newer expanded billable stamps, there is no need to designate Saturday delivery.

Note: There is no requirement that residue samples be frozen if shipped the same day. They should be frozen if held overnight and then shipped as soon as possible.

Ordering Sample Supplies

IPP should determine if adequate sampling supplies are on hand before collecting a sample. To ensure that the sample supplies are delivered to the correct location and in a timely manner, a physical address (no P.O. Box address) must be added as a "Laboratory Sample Supplies Address" in PHIS.

The Laboratory Sample Supplies Address field is under the "General" tab in the Establishment Profile page. The address must be a valid physical location and zip code to ensure delivery by FedEx.

To order supplies, after adding the sampling task to the calendar, right click on the sampling task. From the drop down list, select **Lab Sample Order supplies**. A pop-up window appears with two read only fields (project code and FSIS laboratory filling request) and one **Comments** field. IPP are to enter text in the **Comments** field for the request and click **Submit Request**. A confirmation message appears. IPP are to close the pop-up.

IPP may also submit requests for sampling supplies through Outlook:

FSIS - Sampling Supplies - Western Lab-

FSIS - Sampling Supplies - Midwestern Lab

FSIS - Sampling Supplies - Eastern Lab

In the Outlook message, provide the establishment name and number, IPP daytime phone number, project code for the scheduled sample, the scheduled date for sample collection, and the supplies needed.

Note: Requests for histopathology sample supplies must be sent to the Eastern Lab and KIS supply requests need to be sent to the Midwestern Lab. However, if the KIS requests are made through the sample task option, PHIS will send the request to the appropriate lab based on the project code.

Scheduling and Submitting a Directed Lab Sample

IPP must use the Establishment Task List and Task Calendar when scheduling or collecting a **directed sample**. For each lab sampling project, IPP will add the sampling tasks on their Task Calendar.

When scheduling a sampling task, IPP are to:

- Refer to the collection date range (sampling window) indicated in PHIS for the requested sample. Schedule the sampling task as soon as possible to ensure lab capacity. Also, if the sample can not be collected on that date, reschedule the sample so the lab can accommodate other samples.
- Use their knowledge of the establishment's production schedules to schedule and the collect the requested sample when the product is being produced.
- Ensure the establishment is given the opportunity to hold all product represented by the sample.
- Consider the priority of sampling tasks relative to the tasks already on their calendars and ensure that the most important tasks are completed by the end of the month.
- Ensure that sampling tasks are scheduled so that they can be completed within the time allowed for sample collection, as shown in PHIS.

To schedule a directed sampling task, IPP are to access the Establishment Task List, select the sampling task, and click the “Add” link adjacent to the Task Name to access the Assign Task pop-up window. In the pop-up window, IPP are to enter a sample collection date. The parcel pickup date (the date of sample pickup by the carrier) is generated when the sample collection date is entered and will default to the sample collection date. IPP change the parcel pickup date, if necessary, based on the availability of the carrier for sample pickup. IPP are to verify that there is laboratory capacity available for receipt of the sample for the parcel pickup date indicated. IPP click the “Save” button to schedule the sample and close the pop-up window. The sampling task will appear on the Task Calendar on the date scheduled.

To complete a sampling task, IPP are to refer to the PHIS User or Quick Reference Guide for detailed instructions on entering sample collection data. To assist them in their sampling task, IPP may choose to print a draft copy of the sampling form from PHIS for use as a reference during sample collection and to document product information to be recorded in PHIS. IPP are to enter the data requested in the data fields provided.

IPP will click on the **Additional information tab** and click on the **Take Questionnaire** link. IPP are to answer all the questions. If in doubt, IPP are to check the **Mark for Review** box in the upper right hand corner. IPP may research and answer the questions later. After IPP complete the questions, they are to click on **Next**. If IPP checked the **Mark for Review** box, these questions remain in a review status and IPP click on the **Save and Close**. If IPP choose **Save and Close**, the in progress Questionnaires are displayed from the **My Questionnaires** menu option. IPP may return to Lab Sampling with the **Lab Sampling** menu option or open the original requested questionnaire with **Requested Questionnaire** menu option. If IPP select **Next**, the Questionnaire is finalized and ready to be submitted. If IPP need to review a question again, they click **Back**. If not, IPP click **Submit**. If IPP click **Close**, the questionnaire is not submitted and IPP can review it later.

When sample collection data entry is completed, IPP are to click the “Submit to Lab” button, print a finalized form, apply the sample seal label (barcode identifier) to form, sign the form, and place it in the sample box. PHIS will display a message stating that the sample collection information has been successfully submitted.

1. Go to **Task Calendar** navigation menu
 - a. Go to Establishment Task List
 - b. Filter tasks by: Select **Lab Sampling** on the dropdown menu
 - c. Select the **establishment** from the Select Establishment task list window
 - d. Click **Add** to schedule a sample to your task calendar
 - e. Right click on the task added to your task calendar and select **Document**

- f. The **Collection and Parcel Pickup** dates will default to the date of the task. IPP change the Parcel Pickup date, if needed. Make certain the window shows available lab capacity.
- g. After scheduling the sample, collect the sample.
- h. After collecting the sample, right click on the task on the calendar and select **Document**. The Sample Collection window will open.
- i. Enter initial sample information and any additional information that is requested for completion.
- j. Click **Save and Continue**.
- k. After completion of sample information, if prompted, click **Additional Info** tab to complete a questionnaire.
- l. After completing each question, scroll to the bottom and click **Save** before advancing to the next question.
- m. After completion of all questions, click **Submit to Lab** button to transmit the information. The application will return a message stating the sample collection has been successfully submitted.
- n. Click **Print Form** at the top right of the page. Affix the sample ID seal in the designated space at the top center of the form.
- o. **Sign and date** the printed form. Place the signed and dated form in the shipping container with the sample.
- p. After the task has been scheduled and submitted, the task calendar will reflect the change under the “done” column on the task list.

Note: Two common mistakes that result in FSIS laboratory employees discarding samples are failing to sign the paper copy of the sampling form and failing to submit the sample information electronically through PHIS in a timely manner. IPP are to pay particular attention to avoid these common mistakes.

Rescheduling/Cancelling a Directed Sampling Task

In situations where a **scheduled** sampling task cannot be completed on the scheduled date or within the designated time frame (e.g., product is not being produced during the directed sample task's sampling window), the IPP must cancel and reschedule the sampling task if there is still time to collect the sample within the sampling window or completely cancel the sampling task from the task list. If IPP cannot collect the sample on the previously scheduled collection date, PHIS allows the collection date to be changed from the task on that date, once added to the task calendar. IPP are to right click on the task to be rescheduled and the

dropdown box opens. IPP are to select **Cancel/Reschedule** from the four available options: Information, Document, Cancel/Reschedule, and Order/Supplies. IPP are to click **Reschedule** this task as soon as they are aware that the sampling task needs to be rescheduled, and select a new Collection and Parcel Pickup Date and then click **Save**. The task shows up on the selected collection date on the Task Calendar.

Collecting Samples at establishments with no internet access

Method for IPP that collect samples at establishments that do not have internet access. PHIS has the ability to perform certain functions when the PHIS system is not actively communicating with the data server due to a lack of internet connectivity. Since some IPP perform sample collection, in establishments where internet connectivity is not available this capability allows IPP to perform part of the sample collection function in PHIS.

When operating without internet access, PHIS cannot interact with the FSIS Laboratory Capacity Reservation System or transmit sample collection information to FSIS laboratories. IPP are to schedule sampling tasks on their task calendar while connected to the internet. Before leaving the establishment with internet connectivity to perform the sample collection at the establishment without internet connectivity; IPP are to open the scheduled sampling task in PHIS, enter whatever information is available at the time about the sampling task, and print two copies of the sample form. IPP are to take both copies of the printed form with them to the establishment.

When they collect the appropriate sample(s) at the establishment, IPP are to document any remaining information by hand on both copies of the printed sample form. IPP are to sign one copy of the sample form and place that copy in the sample box. IPP are to close and seal the sample box with the sample and signed sample form inside before leaving the establishment where they collected the sample. IPP are to keep the second copy of the sample form with them as a record of the sample collection information to be recorded later in PHIS. Within 24 hours, IPP are to return to an establishment in their assignment with internet connectivity, log into PHIS, select the sampling task from the task calendar and document the sample information using the information recorded by hand on the printed copy of the sample form. IPP are to submit the sample information to the laboratory by clicking "Submit" upon completion of data entry for all required data fields in the Sample Collection page. This will also mark the sampling task as completed on the task calendar.

When IPP do not submit the sample information electronically within 24 hours of sample shipment, there is a risk that the FSIS laboratory will obtain results of the analysis before the electronic sample record has been created. When this happens, the laboratory will not be able to report the sample results electronically. In the rare event that FSIS laboratories are unable to report sample results electronically, they will report the results to the applicable district office by telephone or email. When this happens District Office personnel and the applicable Frontline Supervisor are to investigate why the electronic sample form was not submitted in a timely manner and initiate necessary action to prevent recurrence.

Reporting Sample Results

Positive results are communicated via Alerts in PHIS on the Inspector's Homepage. Sample history is posted in PHIS in the Establishment Homepage in the Laboratory Sampling panel.

Positive and negative sample results are also tracked and posted in the Laboratory Information Management System, (LIMS)-Direct. IPP may access (LIMS)-Direct on FSIS computers, via FSIS Applications, Internet-Intranet, LIMS Direct. LIMS-Direct is a service that provides sample status and analysis result information for samples submitted to FSIS laboratories. Data is updated every 15 minutes.

Information reported in LIMS-Direct includes:

- Collection Date
- Sample Form number
- LIMS Number
- Whether product is held, as specified in the sample form
- Status of analysis
- Result
- Last Update

Establishments may get individual sample results via e-mail if their e-mail addresses are entered into PHIS. The IIC should still inform the establishment of the results he or she obtains from LIMS-Direct or PHIS. Additionally, FSIS posts quarterly summaries of aggregate establishment set results on its website as an indicator of nationwide trends.

RAW BEEF PRODUCT SAMPLING

Objectives

To demonstrate mastery of this module, you will

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.

Introduction

Throughout the history of meat and poultry production, various pathogenic bacteria have caused food borne illness. FSIS works with other governmental agencies, industry, and

consumer groups to set policy and establish performance standards to reduce or eliminate pathogens from meat and poultry products.

CDC Estimates - The Centers for Disease Control and Prevention (CDC) estimates that there are approximately 175,905 domestically acquired foodborne illnesses associated with all Shiga toxin-producing *Escherichia coli* (STEC) annually. *E. coli* O157:H7 is the most well-known STEC and annually is responsible for approximately 63,153 (36%) of the domestically acquired foodborne STEC illnesses. The remainder of the illnesses associated with STEC (112,752 or 64%) are caused by non-O157 STEC. While many STEC serogroups have been associated with human illness, 70 to 80 percent of confirmed non-O157 STEC illnesses are caused by six STEC serogroups – O26, O45, O103, O111, O121, and O145. These illnesses can be equivalent in severity to those caused by *E. coli* O157:H7. Illnesses from non-O157 STEC serogroups have been associated with ground beef products. FSIS tests beef manufacturing trimming from cattle slaughtered on-site for six non-O157 STECs.

Hazard Analysis - *E. coli* O157:H7 is a food safety hazard that establishments need to consider in their hazard analysis if slaughtering, receiving, grinding, or otherwise processing raw beef products. Controls for *E. coli* O157:H7 should be adequate for non-O157 STEC. See Directive 10,010.2 Verification Activities for Shiga Toxin-Producing *Escherichia coli* (STEC) in Raw Beef Products for more information on verifying measures that an establishment may use to address STEC.

Positive Product is Adulterated - Non-intact raw beef products such as ground beef or mechanically tenderized beef, which are contaminated with *E. coli* O157:H7 or one of six non-O157 STECs (O26, O45, O145, O103, O111, and O121) are **adulterated**. Intact raw beef products contaminated with *E. coli* O157:H7 that are intended to be processed into non-intact products are also adulterated. Beef manufacturing trimmings are an example of an intact raw beef product that is intended to be used for non-intact product such as ground beef. Establishment records and HACCP documents such as the hazard analysis should identify the intended use of intact raw beef products. By sampling for STEC, we're verifying that establishment's adequately address STEC in raw non-intact products and product components (adequate in this context means STEC is below detectable levels). Salmonella sampling, on the other hand, is a measure of process control, and Salmonella is not considered an adulterant in raw product.

Purpose of Sampling - An objective of FSIS's verification sampling program is to test for *E. coli* O157:H7 (and for some products, six non-O157 STECs) and as a result, stimulate industry actions to reduce the presence of that pathogen in raw beef products.

FSIS microbiological sampling programs are part of **FSIS verification activities** to ensure the protection of public health. HACCP systems integrate science-based controls into food production processes. These controls must be combined with some means of verifying that meat and poultry establishments are achieving acceptable levels of food safety performance. Sampling programs are designed to verify that HACCP systems are effective in controlling harmful microorganisms in meat and/or poultry products. Establishments may also include a

microbiological sampling program in their HACCP system in order to verify that the system is performing as intended, that is, controlling, reducing or eliminating the identified food safety hazards.

FSIS also protects public health by keeping pace with changes, such as emerging pathogens, new products and processes, and new laboratory analyses methods. FSIS is continuously improving its sampling protocol and techniques, updating sampling and testing programs, and developing more rapid means of reporting results.

FSIS Directives

5000.1	Verifying an Establishment's Food Safety System
5000.2	Review of Establishment Data by Inspection Program Personnel
7355.1	Use of Sample Seals for Laboratory Samples and Other Applications
7700.1	Irradiation of Meat and Poultry Products
8080.1	Recall of Meat and Poultry Products
10,010.1	Sampling Verification Activities for Shiga Toxin-Producing <i>Escherichia coli</i> (STEC) in Raw Beef Products
10,010.2	Verification Activities for Shiga Toxin-Producing <i>Escherichia coli</i> (STEC) in Raw Beef Products
10,010.3	Traceback Methodology for <i>Escherichia Coli</i> (<i>E. Coli</i>) O157:H7 in Raw Ground Beef Products and Bench Trim
10,200.1	Accessing Laboratory Sample Information via LEARN (to be revised)
10,210.1	Unified Sampling Form
10,230.2	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses
13,000.2	Performing Sampling Tasks in Official Establishments Using the Public Health Information System

FSIS Notices

39-14	Clarification and Expansion of Sampling Eligibility Criteria for the Routine Beef Manufacturing Trimmings (MT60) and Bench Trim (MT55) Sampling Programs
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FSIS Policy - FSIS directives contain policy details specific to sampling projects and programs. Policy changes rapidly; amendments and new issuances are developed to keep you informed. You are responsible for properly selecting products and using appropriate sample collection techniques to ensure the integrity of samples received by the laboratories. You must review the updated resources *each* time you take a sample. You should review new issuances when they are issued.

The key policy related to raw beef sampling, **FSIS Directive 10,010.1 Rev. 4, Sampling Verification Activities for Shiga Toxin-Producing *Escherichia coli* in Raw Beef Products**, has been revised with instructions for collecting and submitting samples of raw beef products.

Terminology

Alternative Sampling and Lotting

When an establishment meets very specific criteria, FSIS may agree to alternative sampling or alternative lotting. Follow applicable instructions outlined in FSIS Directive 10,010.1.

Recall

A recall is an establishment's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA).

Product that is adulterated and has left the establishment's control may be subject to a recall. Contact the DO immediately if adulterated product has left the establishment's control. (see FSIS Directive 8080.1, "Recall of Meat and Poultry Products"). The recall would involve at least the sampled lot, but the scope of the recall could be expanded depending upon an establishment's control measures to limit potential contamination exposure. If the raw beef product, e.g., rework, was used as an ingredient in other raw product formulations, those secondary products could also be subject to recall.

Sample

A sample for raw products is a collection of product, such as ground beef or beef trimmings, that represents a larger amount of product (the sampled lot). A sample unit is an individual package or portion of product. It may take several sample units to make up one sample, depending upon the amount needed for the analysis.

Sampled lot

The sampled lot is the amount of product represented by the sample tested for *E. coli* O157:H7. The establishment defines the sampled lot. "Cleanup-to-cleanup" may be a part of the procedures that the establishment has in place to distinguish one portion of production from another portion of production. "Cleanup-to-cleanup" may be an effective means of preventing *E. coli* O157:H7 cross contamination between raw beef products during production. However, "cleanup-to-cleanup" without other supporting documentation **may not** be adequate to distinguish one portion of production from another (i.e., "cleanup-to-cleanup" is not a stand-

alone reason for distinguishing between segments of production because *E. coli* O157:H7 is source material contaminant).

Factors or conditions that may determine the sample lot include an establishment's:

- Use of a scientific, statistically based sampling program for *E. coli* O157:H7 to distinguish between segments of product;
- Sanitation Standard Operating Procedures (Sanitation SOPs) or any other prerequisite programs used to control the spread of *E. coli* O157:H7 cross-contamination between raw beef components during production;
- Use of processing interventions that limit or control *E. coli* O157:H7 contamination;
- Use of beef manufacturing trimmings and raw beef components or rework carried over from one production period to another production period; and
- Production of bench trim, i.e., small pieces of beef trimmings from raw intact steaks and roasts.

If multiple lots of raw ground beef product were produced from source materials from the same production lot of a single supplier, and some of this product was found positive for *E. coli* O157:H7, a scientific basis is necessary to justify why any other raw ground product produced at the grinder from the same source materials should not be considered adulterated. The use of source materials from multiple suppliers and establishment concerns related to potential recalls following a positive sample result are not a reason to not collect a sample.

General Instructions for STEC Sampling Projects

Establishment Interventions and CCPs

Collect the sample after the establishment has completed production of a lot and applied all antimicrobial treatments to the production lot.

If the establishment intends to test the product for *E. coli* O157:H7, non-O157 STEC or virulence markers before completing the pre-shipment review, you **do not** wait for the establishment to receive the test results before collecting and sending a sample to the FSIS laboratory.

Collect fresh and not frozen product for STEC sampling. The only exception is if the establishment has a CCP for freezing in its HACCP plan, and freezing is a process that achieves a reduction in STEC. In this case collect the sample after the freezing step.

Random Selection

All samples are selected **randomly** from the current day's production of the raw beef product requested. Use a method for randomly selecting the production lot. You must randomly select a day, shift, and time within the collection window start and end dates indicated in the PHIS establishment task list. In order for the sample to be representative of a lot, every attempt must be made to avoid taking a sample that is **biased**, or non-random. There should be an equal chance that sampling will occur during all shifts that the establishment operates. One of the best ways to ensure an unbiased sample is to randomly select a **time** to collect the sample. You can use a random number table or generator to determine the day and time. Record the time you collected the sample in PHIS in the additional information questionnaire. **All shifts and days are to be included in the random selection, including Fridays and night shift.**

Aseptic Sampling

Samples must be collected using aseptic sampling technique. An aseptic technique implies that you do not add any organisms to the sample when it is collected. You want to assure that the sample is not contaminated with extraneous microorganisms from the environment, hands, clothing, sample containers and sampling devices.

For raw beef products collected in their intact final package, such as ground beef in 1 lb. retail chubs, you are to clean and sanitize your hands before collecting the sample. For samples not in final packaging, such as beef manufacturing trimmings and bulk packaged ground beef products, you are to clean and sanitize your hands to the mid-forearm and put on sterile gloves before collecting the sample. The only items that should contact the external surface of the sterile glove on the sampling hand are the sample being collected and the sterile sampling equipment. You **must** put the samples collected from product packaged in institutional or bulk containers in the **sterile** Whirl-Pak® bags. Answer the questions on the additional information questionnaire in PHIS. Raw beef samples collected for *E. coli* O157:H7 sampling must be submitted to the laboratory in either the supplied sterile Whirl-Pak® bag or the establishment's final packaging, or else they will be discarded.

Sample Security and Shipping

You must safeguard the security of the samples when preparing, storing, packaging, and mailing the sample to the FSIS laboratory. Samples are to be sent to the laboratory the same day they are collected, or as soon as the overnight courier service is available.

Use the following guidelines:

- Samples collected before Federal Express pickup Monday through Friday should be held refrigerated until shipped that same day.
- Samples collected after Federal Express pickup Monday through Thursday should be held refrigerated overnight and shipped the next day.

- Samples collected during the weekend (after Federal Express pickup Friday through Sunday night) should be frozen and shipped on Monday. Note: If Monday is a holiday that Federal Express does not pick up samples, they may be held frozen until shipping on Tuesday.
- The only time a frozen sample is collected is when the establishment has a CCP for freezing. If the establishment has a CCP for freezing, the sample you collect is frozen and must be kept frozen.

Samples not meeting the above shipping criteria will be discarded upon receipt at the laboratory.

Steps in Sampling

There are 5 steps in product sampling.

1. Determine which product to sample
2. Notify establishment management
3. Collect the sample
4. Pack and mail the sample and form
5. React to the results

Step 1: Determine which Product to Sample

When directed sample request tasks are sent to the establishment task list they will be specific to the type of product to be collected. The project code and the raw beef product or category is specified in the task name, for example “MT43 – Risk-based *E. coli* O157:H7 Sampling of Raw Ground Beef or Veal Products” or “MT60 – *E. coli* O157:H7 Sampling of Beef Manufacturing Trimmings”. More information about the sampling project code can be found in FSIS Directive 10,210.1, including special collection information.

To assist you in determining which product to sample, you need to be familiar with the establishment’s processes and know how the finished product is labeled. Before collecting a sample, review the FSIS Notices and Directives covering that sample type or program.

Ensure that the PHIS Establishment Profile is accurate. Update the profile as necessary to ensure the establishment is subject to the correct sampling tasks. **An accurate Establishment Profile is critical** – FSIS uses the information in the PHIS profile to generate specific sampling tasks. Refer to specific instructions in the Directives for updating the establishment profile based on the types of products produced and intended use.

Sampling Project Codes

The routine sampling project codes for *E. coli* O157:H7 testing at domestic federal establishments are:

- **MT60** –Raw Beef Manufacturing Trimmings from cattle slaughtered onsite
(Analyzed for *E. coli* O157:H7, non-O157:H7 STEC, and *Salmonella*)
- **MT64** –Components other than Trim
(Analyzed for *E. coli* O157:H7 and *Salmonella*)
- **MT65** –Bench Trim, derived from cattle not slaughtered at the establishment
(Analyzed for *E. coli* O157:H7 and *Salmonella*)
- **MT43** – Routine Testing of Raw Ground Beef in Federal Establishments
(Analyzed for *E. coli* O157:H7 and *Salmonella*)
- **MT 60** - Beef Manufacturing Trimmings that are Sampled from Cattle Slaughtered at the Establishment

MT60 is the sampling program for **beef manufacturing trimmings** sampled for *E. coli* both O157:H7 and the other non-O157 STEC, and *Salmonella*. Beef manufacturing trimmings are trimmings produced from cattle (including veal) that are slaughtered onsite, that is, at the establishment where the MT60 sampling is occurring. Beef manufacturing trimmings includes trim of any size; or primal/subprimal cuts, like chucks, rounds, or shanks; or boneless beef of any size, in any packaging. The MT60 sampling project covers any trim that is used at the slaughter establishment for non-intact use, or is intended for raw non-intact use by other establishments.

The purpose of the MT60 beef manufacturing trimmings program is to assess the food safety controls the slaughter establishment has in place to address Shiga toxin-producing *Escherichia coli* (STEC) in the cattle it slaughters. MT60 test results reflect the effectiveness of the establishment's slaughter and dressing operations because the trim is from cattle slaughtered onsite.

In limited cases, beef manufacturing trimmings will be sampled at sister processing establishments that fabricate trim for their supplying sister slaughter establishments (FSIS Directive 10,010.1).

If the establishment commingles the beef trimmings with beef product processed at other establishments, collect the sample before the establishment commingles the product.

Randomly select only one type of trim to collect for each sample.

Do not collect samples of beef manufacturing trimmings from production lots that are going to be further processed into ready-to-eat products or from lots of commingled beef manufacturing trimmings produced at **different** establishments.

To determine the intended use of the products, review establishment records and HACCP documents such as flow charts, and hazard analyses. In cases where the establishment documents are unclear about the intended use, FSIS will sample the trimmings.

MT64 - Raw Ground Beef Components OTHER than Beef Manufacturing Trimmings that are Sampled

Raw ground beef components other than beef manufacturing trimmings eligible for FSIS sampling for *E. coli* O157:H7 and *Salmonella* under the MT64 program are intact or non-intact beef products intended for manufacturing into raw ground beef products. Components include raw beef esophagus (weasand) meat, head meat, cheek meat, hearts, beef from advanced meat recovery (AMR) systems, and low temperature rendered products such as lean finely textured beef (LFTB), partially defatted chopped beef (PDCB) and partially defatted beef fatty tissue (PDBFT) **that were produced from cattle slaughtered at the establishment.**

To determine the intended use of the products, review establishment records and HACCP documents. In cases where such documents are unclear about the intended use or consumer, or the establishment lacks control measures to ensure that the product is used as intended, handle the product as if it were for use in a ground beef product or other raw non-intact raw beef product.

When you receive a directed sampling request task for the MT4 sampling project code, you choose randomly among the products produced at the slaughter establishment. Over time, all eligible products the establishment produces will be selected.

If the establishment commingles components with beef product processed at other establishments, you need to collect the sample before the establishment commingles the product.

Do not collect samples of components from production lots that are going to be further processed into **ready-to-eat products** at that establishment or another official establishment. If any of the components listed above such as heart meat, cheek meat or head meat are sent to a retail store, these products should be sampled because the official establishment no longer has control over the intended use.

Ammoniated Beef Products - Some establishments inject gaseous ammonia into low temperature rendered (LTR) beef products such as partially defatted chopped beef (PDCB), lean finely textured beef (LFTB), and product known as boneless lean beef tissue (BLBT)) to raise the pH of the product rapidly. Ammoniated beef products are typically intended as a component of raw ground beef and beef patty products. These products are produced from beef trimmings. The beef trim is warmed to partially melt and loosen the fat portion from the lean portion. The warming allows the connective tissue to be removed and also the edible fat portion can be separated from the lean beef using centrifugation. The edible fat portion can be further processed. The partially rendered beef trimmings are ground into a slurry. The sinew (tendon) and connective tissue are removed from the lean tissue in a subsequent step by forcing the slurry through a “desinewer.” The lean beef slurry is then ammoniated with gaseous ammonia to rapidly raise the pH to produce the antimicrobial effect. The ammoniated lean beef portion is rapidly frozen on a drum freezer, broken into chips, and sprinkled with pelleted CO₂. Some processes then grind these chips and compress them into 60 lb. blocks using high hydrostatic pressure. The freezing and compressing steps typically provide an additional antimicrobial effect when combined with ammoniation. Scientific studies have

demonstrated that raising the pH of the product can reduce *E. coli* O157:H7 to an undetectable level in beef manufacturing trimmings.

When you receive a sampling request task for the MT64 sampling project code in establishments that produce ammoniated (pH enhanced) beef products, you are to sample the ammoniated product after it passes the final antimicrobial treatment. Ammoniated beef products that are produced at non-slaughter establishments are also eligible for MT64 sampling.

MT65 - Bench Trim or Beef Manufacturing Trimmings that are Sampled from Cattle NOT Slaughtered on-site at the Establishment

The purpose of the MT65 project is to verify the further processor's food safety procedures for STEC, for example, purchase specifications, or antimicrobial interventions. Generally, the same types of beef products are sampled under the MT65 sampling program as under the MT60 sampling program. However, MT65 samples are from products derived from cattle **not slaughtered** at the establishment.

The intended use is key - to determine it, review establishment records and HACCP documents. In cases where the establishment documents are unclear about the product's intended use, the bench trim will be considered for use in raw ground beef products and other non-intact raw beef products.

In addition, unlike the MT60 sampling program, if the establishment commingles beef trimmings from cattle it slaughtered with bench trim derived from cattle slaughtered at another establishment, those commingled beef trimmings **are** subject to sampling under the MT65 sampling program.

Do not collect samples of bench trim from production lots that are going to be given a full lethality treatment, e.g., further processed into **ready-to-eat (cooked) products** at the establishment or at another federal establishment.

MT43 - Raw Ground Beef Products that are Sampled

Raw ground beef products are subject to FSIS sampling for *E. coli* O157:H7 and *Salmonella* under the MT43 program. Raw ground beef products are described in the standards of identity for ground and chopped beef (9 CFR 319.15(a)), hamburger (9 CFR 319.15(b)), or beef patties (9 CFR 319.15(c)). They include:

- ground or chopped beef or veal;
- hamburger;
- beef or veal patties;
- beef or veal patty mix; and
- similar ground beef or veal products made with added seasonings or ingredients.

Sampled products may **contain** components such as beef derived from AMR systems, LFTB, or PDCB.

When an establishment produces multiple ground beef products and you receive subsequent sample request tasks for project code MT43 in PHIS, unless a specific product is requested, collect a sample from a different product than you submitted with the previous sampling task.

You **are** to collect samples from products that contain a mixture of ground beef and non-beef species (for example, beef and pork patty mix), **unless** the product is labeled in a manner to show that beef is not the predominant meat or poultry component. For example, “Beef Patty Mix, ground pork added” (ingredients: beef, water, pork, corn syrup and seasonings) would be subject to sampling because beef is the predominant species in the product. You are also to collect samples from products that contain seasonings.

Do not sample the ground beef product if the establishment only repacks intact packages and does not expose the product to the environment; for example, if the establishment removes product from bulk containers and breaks the bulk product it into consumer ready packages. Ground beef products intended to be further processed into **ready-to-eat products**, or products made with ground beef but subject to a different standard of identity than in §319.15(a)-(c), such as meatballs, meatloaf, beef sausage (§319.140), and fabricated steaks (§319.15(d)) **are not** subject to *E. coli* O157H:7 sampling.

Step 2: Notify Establishment Management

Establishment management must be notified before a sample of its raw beef product is taken. Inform the establishment that it is required to hold or maintain control of the sampled lot until negative results become available. Since the establishment must hold the lot, it needs sufficient time to make the necessary arrangements to do so. You need to give the establishment enough advance notice so the sampled lot may be held but not enough time for the establishment to alter the production process. Always identify the reason why you are taking the sample when you notify the establishment. Inform establishment management that it is responsible for supporting its basis for defining what product is represented by the sample.

You should discuss the notification and time frames with establishment management **prior** to any sample requests being received in order to have a notification protocol in place when a sample must be collected.

You need to be knowledgeable concerning the establishment’s production practices.

Give establishment management 1 day’s notice before you collect a sample if that’s enough time for the establishment to hold the sampled lot, or less than 1 day’s notice if it does not cause a hardship to the establishment. However, after becoming familiar with the establishment’s process, you may realize that 1 day’s notice before collecting a sample is not adequate time for the establishment to hold all of the product represented by the sample. You may provide 2 day’s notice, if necessary.

If the establishment requests more than 2 days’ notice prior to collection of the sample, consider the establishment product and process flow. The District Office or the Policy

Development Staff (PDS) should be contacted for guidance before allowing more than 2 days' notice.

Each time you collect samples tested for adulterants such as STECs, verify that the establishment is holding or controlling product. If an establishment does not hold or maintain control of product, Write an NR because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as required in 9 CFR 417.5(c). Also notify the District Office.

Step 3: Collect the Sample

Follow the general sampling instructions outlined in this handout. Randomly select a lot, day, shift and time for routine sampling. Collect a sample using aseptic technique from one completed production lot after all of the establishment's antimicrobial interventions. Collect the sample from one type of trim or component. Select the sample within the PHIS sampling window.

The N60 Sampling Method

The N60 method is used for sampling both beef manufacturing trimmings (MT60) and bench trim (MT65).

Before sampling, be sure you have the proper supplies. A plastic caddy, sharp boning knife, hook, sterile gloves and sterile sampling bag are needed for the N60 sampling procedure. It is critical that the knife used for sampling be kept sharp and properly steeled for collecting samples. Also available from the FSIS Western laboratory are disposable sampling surfaces, sanitizing solution, cut resistant mesh gloves, sampling templates and sanitizable clips which can be used to clip the wire at the top of the sampling bag to either the top of the combo bin or the edge of the sampling caddy during collection. The Whirl-Pak® sampling bags have a gusseted bottom (flat bottom) which allows the bags to stand without a rack or stand to hold them up. This allows you some assurance that the bag will be anchored in place while samples are cut and that the sampling bag will remain standing while sample pieces are placed in the bag.

You are to sanitize the caddy, knife, and hook before collecting the samples by using the establishment's sanitizing solution according to label instructions. If the establishment uses hot water only, then use hot water to sanitize sampling equipment.

Use sterile gloves and handle all sanitized surfaces so that they do not become contaminated. To use the mesh glove in an aseptic manner when collecting samples, you place the sterile glove over the mesh glove.

If a specific production lot is composed of greater than 5 containers, randomly select 5 containers for sampling. If the specific production is composed of fewer than 5 containers, use the table below.

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

Aseptically collect the appropriate number of pieces of beef trim. Use the sanitized hook to reposition and anchor a piece of meat at the top of the container. For larger pieces of meat, a curved boning knife and short boning hook may work better than the standard meat inspection hook and straight boning knife.

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). **You must make every effort to ensure that at least 60 thinly (approximately 1/8 inch thick) excised external surface tissue samples are included in the sample.** Using the sampling template to lightly score the surface in 2 parallel cuts approximately 1 inch apart and 3-4 inches long may facilitate obtaining the appropriately sized sample piece. The priority is to get the external surface of the carcass. Make sure that each sample slice contains some meat, that it isn't completely fat. Also, collect only one slice from each piece of trim.

For raw ground beef components, IPP are to use the Whirl-Pak® bag, but the fill line will not apply. When sample collection is completed, each bag will hold the equivalent of 325g of product. For beef manufacturing trimmings, each bag will hold 30 pieces. The laboratory will analyze the contents of one or two bags and hold a third bag as a reserve in case of a need to conduct additional analysis on positive samples. IPP are to use only the laboratory supplied Whirl-Pak® bags for submitting these samples. Do not use any other bag, for example a zip-top bag.

The 60 pieces that are 3 inches long by 1 inch wide and 1/8 inch thick should weigh approximately ¾ lb. (325g ± 10%). Place a total of 30 pieces in each of the first 2 bags for a total of 60 pieces.

In addition, you are to collect available smaller pieces of meat from the same specific production lot and place this product in the third Whirl-Pak® sample bag. You do not need to

cut or trim the pieces to any particular dimension or count the pieces. You can just grab smaller pieces. However, you need to collect pieces with as much external surface area as possible. Cut larger trim pieces so they fit in the bag. 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. Do not under- or over fill the bag.

Note: If an establishment produces both large pieces of trim and small pieces of trim, you are to sample only the product that can be sampled using the N60 sampling procedure.

Aseptic Grab Sampling

If the establishment only produces trim pieces that are too small to be sampled using the N60 sampling procedure, just collect three grab samples aseptically up to the fill line for each of the 3 Whirl-Pak® bags. If you are sampling larger components, such as hearts, you can collect one or more pieces to fill each of the 3 bags. Leave at least 2 inches of space at the top of each Whirl-Pak® bag to avoid overfill and leakage incidents. For component types that you can collect using a grab sample, such as AMR product or low temperature rendered products, you would collect 3 grab samples and fill up the fill lines of each of the 3 Whirl-Pak® bags.

Always place samples taken aseptically from bulk packaged raw ground beef components in sterile Whirl-Pak® bags provided by the laboratory, not ordinary zip-top bags.

Collecting Raw Ground Beef Products

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 with the sampling supplies. Collect the appropriate number of packaged products so that the sample equals two pounds. For example, 2 1-pound packages may be included in the larger, non-sterile bag. If product in final packaging is not available, aseptically collect a 2 lb. sample using the grab sampling method, fill 3 Whirl-Pak® bags to the fill-line. When an establishment produces multiple raw ground beef products, the IIC should oversee sampling procedures to ensure that a different product within the requested product type is sampled each time a sample request form is received.

Sampling Frequencies

Maximum monthly sampling task frequencies for routine sampling programs vary by plant size and production volume, per Figure 1 in Directive 10,010.1. You must collect a sample whenever a sample request task is received and product is available during the collection window start and end dates.

Analysis for Salmonella of all Beef Products Sampled for Shiga Toxin-Producing Escherichia Coli (STEC)

Raw beef samples that are analyzed for STEC will also be analyzed for *Salmonella*. This analysis is used to gather baseline data to determine the prevalence of *Salmonella* in ground

beef and trim for future sampling program policy use. IPP are to inform the establishment that all samples analyzed for STEC will also be analyzed for *Salmonella*. The establishment only has to hold and control lots until the results for STEC are received.

Collecting Supplier Information at the Time of Sample Collection

IPP are to record source material and supplier information **when they collect a sample** of ground beef product (MT43) or bench trim (MT65) or any follow-up sampling for these sampling programs (MT44, MT52, or MT53) to be submitted to the FSIS laboratory for *E. coli* O157:H7 testing. This will serve FSIS's goal to respond to FSIS positive results by identifying all affected product and all potential suppliers as quickly as possible to protect public health.

When ***the establishment produced the source materials in-house*** that were used in the production of the sampled lot, you are to obtain and record the following information.

- Establishment name and number,
- Lot numbers or slaughter dates,
- Production dates including slaughter production days if available,
- Name of the beef components used in the production of the sampled product (e.g., beef trimmings, subprimal cuts, beef hearts, veal trimming, weasand, head or cheek meat) or any information that identifies the material, such as product labeling if used, and
- Approximate amount of the beef component produced in each lot (in lbs.).

When the establishment uses ***source materials from another domestic establishment (outside source)*** to prepare the sampled lot, you are to obtain and record the following information.

- Establishment name and number that produced the source materials,
- Establishment phone number,
- Establishment point of contact (name, title, e-mail address, and fax number),
- Supplier lot numbers,
- Production dates,
- Name of the beef components used in the production of the sampled product, or any information from the label of the product that identifies the source material used, and
- Approximate amount of the beef component produced in each lot (in lbs.).

If the ***source materials are imported from a foreign establishment***, you will need to gather additional information (country of origin, foreign establishment number, shipping mark, I-house, and bar-coding or other information to aid in identifying the product).

You document source material and supplier information in a ***memorandum of interview (MOI)*** in PHIS. Provide a copy of the MOI to establishment management. You also make a note of any information that the establishment is unable to provide in the MOI. If the sample is reported as presumptive positive, notify management of the presumptive positive as soon as possible.

Also, when collecting for STEC record the sample source as:

- Veal;
- Beef; or
- Mixed (beef and veal, or beef or veal and other species).

This information will be recorded in PHIS when completing the sampling task.

Step 4: 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 (see Attachment 2 for discard reasons). Be sure the identification on the sample and the paperwork match, otherwise the lab will discard sample.

All samples received by the lab **without** a collection date are discarded.

The Sample Collection Data and Additional Information screens in PHIS for microbiological pathogen samples will have specific questions depending on the product requested. All requested data must be accurately recorded; otherwise the lab will discard the sample. For example, PHIS may ask for the date collected, the date sent to the lab, the product temperature, whether product was held by the establishment management, and whether the sample was collected in the final packaged form. There will be a question regarding with product is veal or beef. Other data requested may include the raw beef component sampled, the production volume, the shift, or other information needed for the type of sample submitted.

One or more individually identified samples may be submitted in a shipping container. Follow the instructions in FSIS Directive [7355.1](#), “Use of Sample Seals for Program Samples and Other Applications.” You may need to include additional cooling packages in the shipping container to keep the sample or samples cool during transportation. To submit multiple samples, you may request larger boxes from the laboratory identified by sending an e-mail message to their [e-mail addresses](#) on page 9 of this handout. If you include more than one sample in the shipping container, include one of the identifiers (bar code) for the other sample on the Container Seal, 7355-2A. This lets the lab know that there are multiple samples in the box. The labs will discard them if it is not clear which sample goes with which sample form.

Double-check and compare the address on the expanded billable stamp to make sure it is going to the lab indicated in PHIS and on the sample form. The lab will discard the sample if you mail it to the wrong lab.

The shipping containers you receive should have the top and bottom sealed by the lab with tamper-evident tape. You will **not** receive any tamper-evident tape to use. If the tape is cut or

missing, **do not** open the container. Follow the instructions in FSIS Directive 7355.1 (seal it with the Container Seal, 7355-2A, and ship it back to the lab of origin for processing; complete the seal by writing “seal broken” in the “Form No.” blank).

Pack the sample in this order.

1. Absorbent pad
2. Gel pack
3. Cardboard separator
4. Sample with paperwork (all in a zip-top bag)
4. Foam plug
5. Close the shipper with seal (7355-2A – Container Seal)

To ensure the product is maintained at refrigeration temperature, place the sample in a pre-chilled shipping container with an absorbent pad and frozen gel pack, even if the sample was previously refrigerated or frozen. A piece of cardboard goes on top of the gel pack to separate it from the sample. Put a small bar code sticker from Form 7355-2 at the top center of the sample form and put the form in a plastic bag. Put another small bar code sticker on each of the bagged sample units. Put the sample and form into the larger zip-top bag and affix the Identification Label (7355-2B) to the larger bag. Note that the 7355-2B is a **label** rather than a seal and is simply stuck on the bag. There is no need to fold over and seal the bag with the label. The zip-top bag, containing the bagged sample and the paperwork, is put into the shipper. Filler material is **not allowed** in the shipping container. This means that no newspaper or paper towels should be put inside the shipping container to take up empty space. The foam plug must be pushed down as far as possible to keep the sample from being tumbled inside the shipper. Put any extra unused bar codes into the box so that the lab can account for them, or put them on the Container Seal where they won't cover any written or printed information. Alternatively, if you keep a record of the sample, you can affix the extra bar code to your record. Close up the box and seal it.

For sample integrity, a Container Seal (FSIS Form 7355-2A) must be put on the shipping container in such a way that it cannot be opened without disturbing the seal.

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.

Double-check that the lab address in PHIS is the same as on the expanded billable stamp. If these are different, your sample will be discarded. If the lab listed is different from the one on the expanded billable stamp, e-mail the lab listed and request an expanded billable stamp from that lab. You should determine if you have a billable stamp for the correct lab when you **first** schedule the sample task, **not** when you are about to mail the sample.

Check the expiration date on the expanded billable stamp. Do not use it if it is expired.

On the expanded billable stamp, enter the establishment number, shipping date (day sample box picked up by carrier) and the establishment's phone number.

Step 5: 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. LIMS-Direct reports sample status and the results of the analyses..

Check LIMS-Direct each day after you submitted the sample to the FSIS laboratory. If the sample was discarded, notify the establishment immediately so it can release the product.

The first lab analysis is accomplished within two days of sample receipt. It is a screening test that identifies the possible presence of *E. coli* O157:H7 or one of the six non-O157 STEC. If the screening test is negative, *E. coli* O157:H7 is not present (or below detectable levels) in the sample tested. The negative results are posted in LIMS-Direct as "Acceptable". FSIS resumes normal sampling at that establishment.

Every FSIS verification sample that the laboratory confirms **positive for *E. coli* O157:H7** goes through three stages of analysis. If the screening test is positive, the sample is potentially positive for *E. coli* O157:H7 and additional testing is necessary to confirm the result. The laboratory reports the sample result in LIMS-Direct as a "Potential Positive". In the next stage, based on further analyses that reveal more evidence to suggest that *E. coli* O157:H7 may be present in the product, LIMS-Direct reports the sample result as "Presumptive Positive". Upon further analysis and conclusive evidence that *E. coli* O157:H7 is present in the sample, the result is reported as "Confirmed Positive". The confirmatory testing is usually accomplished within 3 to 4 days of the sample receipt at the FSIS laboratory, but can sometimes take longer.

Every FSIS verification sample that the laboratory confirms **positive for one or more non-O157 STEC serogroups** also goes through three stages of analysis. If the screening test is positive, the sample is potentially positive for one or more non-O157 STEC serogroups and additional testing is necessary to confirm the result. The laboratory reports the sample result in LIMS-Direct as a "Potential Positive". In the next stage, based on further analyses that reveal more evidence to suggest that one or more non-O157 STEC serogroups may be present in the product, LIMS-Direct reports the sample result as "Presumptive Positive". Upon further analysis and conclusive evidence that one or more non-O157 STEC serogroups is present in the sample, the result is reported in LIMS-Direct as "Confirmed Positive". The O group that was found to be positive will also be reported, for example O26 or O111. The confirmatory testing usually takes 3 to 4 days after the sample receipt at the FSIS laboratory, but can sometimes take longer.

Presumptive positive and positive sample results are e-mailed to establishments that have an e-mail address in the PHIS establishment profile. Negative results are not e-mailed to the establishment. **Even if the establishment receives sample result notifications by e-mail,**

it is still your responsibility to notify the establishment when sample results are posted on LIMS-Direct.

Note: Positive *Salmonella* results from raw ground beef samples submitted to the laboratory under project code MT43S will not have any immediate regulatory consequences. Therefore upon receiving negative *E. coli* O157:H7 results from the same sample (MT43) you are to notify the establishment that it may release any affected product on hold. If you receive the *Salmonella* results before the *E. coli* O157:H7 results, you should wait to notify the establishment until you receive the *E. coli* O157:H7 results.

FSIS Actions after a Positive FSIS or another Federal or State Entity Sample Result

FSIS Directive 10,010.2, Verification Activities for Shiga Toxin-Producing *E. coli* (STEC) in Raw Beef Products, provides instructions on the actions to take following a positive sample result.

FSIS Presumptive Positive Sample Result

The lab notifies the DO using BITES (Biological Information Transfer E-mail System) prior to posting the information in LIMS-Direct if the sample is presumptive positive for *E. coli* O157:H7 or one or more non-O157 serogroups, if applicable. Because the laboratory confirms most “presumptive positives”, the contact person in the DO where the establishment is located alerts the establishment if the sample is “presumptive positive.” This ensures that the establishment receives that important message when you are not available. The DO contact will also inform the establishment if the results are confirmed positive. Even though the establishment may already know about the presumptive positive or confirmed positive result, you are still required to notify the establishment of the presumptive positive and confirmed positive result.

Confirmed Positive Sample Result

When an FSIS laboratory or another Federal (Agricultural Marketing Service-AMS) or State entity confirms a sample is positive for *E. coli* O157:H7 or a non-O157 serogroup the DO accesses the System Tracking *E. coli* O157:H7 – Positive Suppliers (STEPS), and opens a case file for the incident. The DO enters all the supplier information you gathered into STEPS. The DO is also responsible for determining whether any of the supplying establishments were also **originating supplying slaughter establishments** that produced the source materials that were used in the raw beef product that tested positive for *E. coli* O157:H7. Follow-up samples are collected from originating supplying slaughter establishments.

With respect to supplying establishments that **are not** originating supplying slaughter establishments, the DO is to inform the IIC to collect supplier information on the source materials that went into the lot represented by the positive sample and forward the information to the DO.

Enforcement Actions Based on FSIS and Establishment Test Results

Before you can determine whether to document the positive result as a noncompliance, you need to gather information. You need to determine if the establishment has its own *E. coli* O157:H7 sampling program for its raw beef products or whether it tests for non-O157 STEC or virulence markers. If the raw beef product sample you submitted is positive for *E. coli* O157:H7 or one or more non-O157 STEC serogroups and the establishment tested the **same** product, check the establishment's test results to determine whether it also found the sampled product positive for *E. coli* O157:H7 or one or more non-O157 STEC serogroups.

If the establishment held the product or maintained control of the product pending its own test results, and FSIS **AND** the establishment found the product positive for *E. coli* O157:H7 or one or more non-O157 STEC serogroups, you **do not issue** a noncompliance record (NR). For example, if a sample of beef manufacturing trimmings tested positive for *E. coli* O26 and the establishment tested a sample from the same lot and found it positive for *E. coli* O157:H7 you would not issue a noncompliance record because they found the product positive for a Shiga-toxin producing *Escherichia coli* (STEC) organism. Even if the type of STEC positive did not match, you would still not issue an NR.

If the establishment has a documented procedure for diverting all product lots that are sampled by FSIS, you would issue an NR, unless the establishment also tested the product and found a positive. Verify that the product is diverted per the written program. The establishment must take corrective action per 9 CFR 417.3. If the establishment doesn't take CA, then issue an NR.

Issue an NR when FSIS finds product positive for *E. coli* O157:H7, but the establishment does not. Use a directed HACCP Verification task for the appropriate processing category, and cite §417.4(a) and §301.2 as the relevant regulations. Verify that the establishment has held on-site or maintained control of the affected product. When issuing the NR, review documentation to determine whether there have been previous NRs for positive product sampling, and if so consider whether it is appropriate to associate the NRs.

In addition, if the establishment has its own testing program, review its records to determine if the establishment has found multiple *E. coli* O157:H7 positive results which would be evidence of a systemic problem. Verify the implementation of the Sanitation SOP by following the instructions in FSIS Directive 5000.1 and 5000.4. Verify sanitary dressing procedures, if the positive result is from beef manufacturing trimming or other components produced at a slaughter establishment. If the establishment delays disposition of the positive product, you are to work with your FLS to determine how to work with the establishment to ensure timely disposal of the product.

Establishment management must account for all affected products by identifying them and their location. Establishments are expected to ship only wholesome unadulterated product. The establishment is responsible for determining what product it holds and what it determines to be affected product. (FSIS Directive 8080.1 contains more information related to affected product.) If the establishment does not control its product, then take a regulatory control action

(retain product if it is available or take a withholding action per §500.3(a) (1) if the establishment shipped the adulterated product into commerce). If any affected product has left the establishment and it is no longer under the establishment's control, notify the DO immediately. A recall may be recommended.

Continuing with that HACCP Verification task, determine whether or not the establishment implements corrective actions that meet the requirements described in §417.3. The establishment must take **corrective actions** that meet one of the following requirements.

- 417.3(a) if *E. coli* O157:H7 or STEC is addressed in the HACCP plan, or
- 417.3(b) if *E. coli* O157:H7 or STEC is not addressed in the HACCP plan, or if it is addressed in prerequisite programs, or
- 417.3(b) and 416.15 if *E. coli* O157:H7 or STEC is addressed in the Sanitation SOP.

The establishment may need to conduct a reassessment of its HACCP plan or reevaluate its Sanitation SOP or prerequisite programs to meet these requirements. In addition, the establishment should reassess (§417.4(a) (3)) because something in the process has changed. Issue an NR if the establishment fails to take the appropriate corrective actions.

In addition, you will conduct follow-up sampling, per instructions later in this module. You will verify that products that test positive for STEC receive appropriate disposition. Positive product may be treated with a lethality treatment to destroy the pathogen (cooking), rendered, or disposed of in a landfill.

If product disposition is to occur off-site, verify that the establishment maintains appropriate control of the product as explained in the next section.

Off-Site Disposition of E. coli O157:H7 or non-O157 Positive Product

Raw beef products confirmed positive for *E. coli* O157:H7 or a non-O157 serogroup 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. Establishments may also divert product that is presumptive positive, rather than wait for a confirmation. Presumptive positive product must be controlled just like confirmed positive product. Establishments may use their own controls (company seals) or move the product under FSIS control (using USDA seals or FSIS Form 7350-1, "Request and Notice of Shipment of MPI Sealed Meat/Poultry"). When the product is destined for a landfill or rendering operation, it moves under company controls, because FSIS representatives are not at those locations to remove USDA seals or follow up with FSIS Form 7350-1.

When the establishment moves presumptive positive or positive product off-site for disposition, verify the establishment that produced the positive product maintains appropriate control of the product at **all times**, including while it is in transit to the off-site location where the product will either be processed to destroy pathogens before entering commerce or be disposed of so it will not be used for human consumption.

When you perform a directed follow up HACCP Verification task verify that the establishment:

- Maintained records identifying the official establishment, renderer, or landfill operation that received positive product;
- Maintained control of product that was destined for a landfill operation or renderer while the product was in transit (through company seals);

Note: If an establishment ships adulterated product to a renderer or landfill operation, you are to verify the establishment denatures the product before the product leaves the establishment (9 CFR 314.3).

- Maintained control of product that was destined for an official establishment while the product was in transit (through company seals) or ensured that such product moved under FSIS control (under USDA seal or accompanied by FSIS Form 7350-1);

Note: An instructional “For Cooking Only” statement on the container label is not a sufficient control.

- Maintained records showing that every lot of product implicated by the positive test result received appropriate disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred; and

Note: Records of receipt at an official establishment, landfill operation, or renderer **are not** adequate to show that the product received appropriate disposition. Documentation (a record) 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. For example, a record of receipt and control until the product receives a lethality treatment. The record should include information necessary to identify the product, the number of pounds of raw beef product received and the number of pounds rendered or destroyed.

- Completed pre-shipment review for the positive product only after it has received the records described above for that particular product.

You cannot complete the HACCP Verification Task for the specific production until the establishment completes the corrective action and documentation requirements (417.3(a) or 417.3(b) and 416.15), which includes receiving documentation from the official establishment or landfill operation or renderer that demonstrates proper disposition/disposal of every lot implicated by the positive result and conducts pre-shipment review of the corrective actions.

Note: If the product is shipped to another official establishment for disposition (for example, cooking), IPP at that establishment are to verify that the receiving establishment adequately addresses the pathogen in the product as part of their ongoing verification duties.

Issue an NR if you find noncompliance while verifying the establishment's off-site product disposition corrective actions. Document the noncompliance under the appropriate task, depending on where STECs are addressed in the establishment's food safety system.

Verification Activities at an Establishment Receiving *E. coli* O157:H7 or non-O157 Positive Product

If you are the inspection program employee at the establishment that receives raw ground beef products, beef manufacturing trimmings, or other raw ground beef components, or raw beef patty components that tested positive for *E. coli* O157:H7, you have certain verification functions to perform to ensure the establishment adequately addresses the pathogen in the product.

When you perform a HACCP Verification task for such products, verify that the establishment:

- documents receipt of presumptive or confirmed positive product (as per §417.5),
- maintains control of the product, and
- addresses the receipt *E. coli* O157:H7 in its hazard analysis, flow chart, and HACCP plan (which includes an adequate lethality treatment to destroy the pathogen).

You are not required to be present at the establishment to verify the disposition of the raw beef product that is positive or presumptive positive for *E. coli* O157:H7 or one of the six non-O157 serogroups. You can verify that the product received proper disposition through records review.

Note: You are to verify that the establishment has supporting documentation validating the effectiveness of the lethality treatment during the Hazard Analysis Verification task.

Note: FSIS does not require establishments to re-test product for *E. coli* O157:H7 after the establishment subjects the product to a lethality treatment adequate to destroy the pathogen.

Document all noncompliance as per PHIS FSIS Directive 5000.1.

FSIS Verification Activities at Supplying Establishments when a Raw Beef Product at an Official Establishment or Retail Facility Tests Positive for *E. coli* O157:H7 or a non-O157 serogroup

When raw beef products are confirmed positive, FSIS will conduct verification activities at supplier establishments, including the originating supplying slaughter establishment that produced the source materials 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. If you are at the **supplying establishment**, remind the establishment that the notification is to ensure that the supplier knows that it **could be** the source of positive product. 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 (monitoring, verification, recordkeeping, and corrective actions) at all CCPs in the HACCP plan for source material production lots sent to the establishment or retail facility where the positive was found. If the establishment has its own *E. coli* O157:H7 sampling program for its raw beef products, IPP are to review establishment records to determine if it has found multiple positive results which would indicate there is a systemic problem. IPP are to verify the establishment's control of its sanitary dressing procedures during the beef slaughter Sanitary Dressing task per [FSIS Directive 6410.1](#). In addition, perform a Hazard Analysis Verification (HAV) task to review the HACCP system.

Multiple Follow-Up Sampling After an *E. coli* O157:H7 or non-O157 Positive Sample Result

Each time that an FSIS routine sample or another Federal or State entity's sample of raw ground beef product, ammoniated beef product, beef manufacturing trimmings, bench trim, or ground beef or raw beef patty components tests positive for *E. coli* O157:H7 or one or more non-O157 STEC serogroups, 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 *E. coli* O157:H7 **OR** when an originating slaughter establishment is the **sole supplier** or a **repeat** supplier of the source materials implicated in positive sample result. IPP will automatically receive sample requests through PHIS to sample product from the establishment that produced the positive raw beef product. In addition, IPP will automatically receive sample requests as a result of a positive follow-up test of raw ground products. All follow-up sampling at originating slaughter establishments is generated by PHIS and the Policy Analysis Staff (PAS) as outlined in the next section.

For low volume establishments, (establishments that produce less than 1000 pounds per day of the product to be sampled), **8** samples need to be collected instead of 16 samples.

The type of sample requested will be based on the type of raw beef product implicated in the positive test result. The sampling project code will identify the type of raw beef product to sample.

- **MT44** Follow-up sampling of raw ground beef product in response to a MT43 or Agricultural Marketing Service (AMS) positive result in raw
- **MT52** Follow-up sampling at suppliers of beef manufacturing trimmings or other components from originating slaughter suppliers, in response to a MT43, MT65, or AMS ground beef positive result

- MT53 Follow-up sampling of trim or other components at the establishment that produced product in response to a MT60, MT65, MT64, or AMS trim testing positive
- MT44T Follow-up sampling of raw ground beef, trim, or other component outside of projects MT44, MT53, and MT52 collected by IPP at Federally inspected establishment

Sampling from production lots produced after the positive result starts as soon as possible following receipt of the follow-up sample requests. You **DO NOT** wait for the establishment to complete the corrective actions taken in response to the positive result before conducting follow-up sampling.

If the establishment is not currently producing the type of raw ground beef component requested, you are to collect a sample of another component that is available. You are to sample beef manufacturing trimmings if the establishment is producing them. If the establishment is also not producing beef manufacturing trimmings, then you are to collect a sample of another type of raw ground beef component.

As soon as the establishment resumes production of the product(s) to be sampled, start your sample collection at the following daily and weekly frequencies. Collecting follow-up samples in a timely manner is of vital importance.

- Sample a maximum of 2 follow-up samples per shift per day, from different lots.
- At a minimum collect 3 samples per week.

You may submit more than one sample per shipping container if each sample is individually identified and the shipping container is large enough to hold more than one sample. Send the sample to the laboratory on the first available day the contract carrier picks up after collecting the sample.

While you are collecting follow-up samples for STEC testing, you may receive a **routine verification sample request form** for a raw beef product to be tested for *E. coli* O157:H7 and potentially non-O157 (for beef manufacturing trimmings). In this situation, continue to collect follow-up samples and make **follow-up sampling the priority**, rather than routine sampling. If your workload and the establishment's production practices allow it, collect the sample for routine testing within the allotted collection window. **Do not** collect a follow-up sample and a routine verification sample from the same product lot. If it is not possible for you to collect the routine sample, you should cancel the sample task and in the justification, state that you did not collect the routine sample because of follow-up sampling.

While you are collecting follow-up samples for *E. coli* O157:H7 and potentially non-O157 testing under one sampling project code, you may receive follow-up sample request forms for another project code or the same (repetitive) follow-up sampling project code. For example, you may be in the process of collecting the 16 follow-up samples under project code MT52 when the 3rd sample of this set tests positive. As a result of this positive sample result, you will

receive 16 follow-up samples for project code MT53. You are to collect the rest of the 16 follow-up samples from the MT52 project code as well as the 16 follow-up samples for the MT53 project code.

FSIS will continue to collect follow-up samples after a positive follow-up sample result until the FSIS laboratory finds no positive sample results in 16 or 8 **consecutive** follow-up samples. For example, if you receive forms to collect 16 follow-up samples under the MT53 project code, and the 3rd sample of this set tests positive, you will then receive 3 more follow-up sampling forms for MT53 sampling program. As a result of the positive sample result, you would collect the remaining 13 follow-up samples and the 3 new follow-up sampling forms for a total of 16 follow-up samples.

Follow-up Sampling at Supplying Establishments

FSIS has implemented a follow-up sample testing protocol for establishments that supply raw beef products to establishments that have had product test positive for *E. coli* O157:H7.

PHIS generates follow-up sampling tasks at supplier establishments. PHIS will send **16** follow-up sample request tasks if the originating slaughter establishment was the only supplier, or if an originating slaughter establishment is a repeat supplier for **each** source material used in the positive raw beef product. However, when a supplier is not the sole supplier or a repeat supplier, PHIS requests a **single** follow-up sample from the supplier for **each** source material used in the positive raw beef product.

The DO informs IPP of which type source materials the establishment supplied to the beef boning, cut-up, or grinder facility, so that IPP can sample that raw beef source material from the establishment's current production. If the originating supplying slaughter establishments produced more than one source material used by the boning, cut-up or grinding establishment, PHIS will generate sample request tasks, for each type of source material.

In combination slaughter/processing establishments, if FSIS or another Federal or State entity finds a raw ground beef product positive, and the establishment produced the source materials used to produce raw ground beef product that tested positive, PHIS generates MT53 sampling program request tasks. IPP are to collect either 8 or 16 samples, based on establishment production volume, of the type of source materials used in the positive raw ground beef product. IPP **are not** to collect follow-up samples of the ground beef product.

If ammoniated low-temperature-rendered (LTR) product was used as a component in raw ground beef products that tested positive for *E. coli* O157:H7, PHIS generates follow-up sample request tasks. IPP are to collect a sample of ammoniated beef trim at the establishment that produced the LTR product, even if that establishment is not an originating supplying slaughter establishment.

If a sample collected under follow-up sampling program tests positive, PHIS generates multiple follow-up sample requests.

Follow the sample collection instructions previously covered in this handout.

Establishment-Generated Sampling

Some establishments have their own sampling and testing programs for *E. coli* O157:H7, non-O157 STEC or virulence markers. Establishments are not **required** to sample and test their raw beef products or raw materials for *E. coli* O157:H7 or non-O157 STEC or virulence markers. What establishments are required to do is to conduct a hazard analysis and support the decisions they make in their hazard analysis. Sampling and testing is one way to support decision-making.

Establishments may address their sampling programs in the HACCP system, in either the HACCP plan, Sanitation SOP, or in a prerequisite or other supporting program. Even if these programs are not addressed in the HACCP system, establishments are still required to share records and analyses results with FSIS.

No establishment that produces raw ground beef products or beef manufacturing trimmings and raw ground beef and beef patty components **intended to be used in non-intact product** is exempt from FSIS verification testing for *E. coli* O157:H7, even when the establishment has its own robust testing program for *E. coli* O157:H7, non-O157 STEC or virulence markers.

Pre-shipment Review - FSIS has taken the consistent position that establishments can conduct pre-shipment review when the product is at locations other than at the producing establishment provided that the product does not leave the control of the producing establishment. Some establishments analyze samples for STEC while they are moving the product, but the product is still under the establishment's control

Review of Establishment Data - Based on the regulatory requirements of 9 CFR 417.2(a)(1)(2) and 9 CFR 417.5(a)(1), FSIS believes that the results of any testing that the establishment performs that may have an impact on the establishment's hazard analysis are subject to FSIS review and must be available to IPP upon request, including records from prerequisite programs. FSIS Directive 5000.2 states that, **on at least a weekly basis**, you must review the results of any testing and of any monitoring activities the establishment performed that may have an impact on the hazard analysis. There is a task in PHIS, "Review of Establishment Data" to document the performance of this review. Based on review of establishment records, if you have concerns about the design of testing, monitoring, or verification activities outside of a HACCP plan, or concerns about results from such activities, procedures, or prerequisite programs, contact the Policy Development Staff (PDS) or raise the concern through supervisory channels. When records show that the establishment tests beef trim and raw ground beef components for *E. coli* O157:H7, but **never** finds any positives, you are to contact the DO. In addition, when establishment testing records show **multiple** positive results for *E. coli* O157:H7, non-O157 or virulence markers that may be evidence of a systemic problem, you are to contact the DO. It may be determined that an EIAO needs to conduct a food safety assessment to assess such factors as what the test 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.

If the Establishment Rejects Product From Suppliers - An establishment may sample raw beef products for *E. coli* O157:H7, non-O157 STEC or virulence markers when they are received and hold the production lot pending the sample result. If the product is presumptive positive or positive for *E. coli* O157:H7 or non-O157, the establishment considers the product to be adulterated, does not accept the production lot, and returns the lot to the supplying establishment using FSIS Form 8140-1, "Notice of Receipt of Adulterated or Misbranded Product" under appropriate controls (e.g., company seals or FSIS seals). After the establishment notifies you that it has rejected the production lot, collect the supplier information. You need to notify the DO (9 CFR 320.7) and include the supplier information in your e-mail. The DO is to notify the IIC at the supplying establishment that rejected product is being returned and have IPP at the establishment conduct a HACCP Verification task on the affected lot of product.

Note: The Agency recognizes that it is probable that, despite the ongoing processing interventions for controlling *E. coli* O157:H7 and non-O157 STEC, some establishment samples of beef manufacturing trimmings and raw ground beef and beef patty components may test positive for *E. coli* O157:H7 or one or more of the six non-O157 STEC serogroups tested for by FSIS. These positives may be random events caused by normal process variation, or may have an identifiable, assignable cause that can be acted upon as part of corrective actions. Establishment verification testing should occur at a frequency to help determine the difference between acceptable process variation and assignable cause variation in the testing results associated with beef manufacturing trimmings and raw ground beef and beef patty components. Through this statistical analysis, the establishment will be able to justify whether corrective actions to address an assignable cause are appropriate and sensible.

If the Establishment Performs Only Screening Tests - If review of the establishment's *E. coli* O157:H7 and/or non-O157 sampling program reveals it is only performing screening tests and not further analyzing "potential positive" test results to determine whether *E. coli* O157:H7 or non-O157 is isolated from the product, e.g., presumptive positive or confirmed positive, you are to verify that the establishment appropriately addresses the product as if the product is positive for *E. coli* O157:H7 or non-O157. The establishment cannot perform a second screening test for *E. coli* O157:H7 or non-O157 on the product and find it negative. Performing additional screening tests does not negate the original positive screening test. A screening test is not a conclusive (specific) test for the pathogen.

If the establishment has a positive result from its own sampling program -

The establishment is not obligated to notify FSIS when it receives a presumptive positive or a positive sample result, but it **must take corrective actions** that meet the requirements of §417.3 **each time** a presumptive positive or a positive result is obtained. The establishment must also maintain appropriate control for any product that is presumptive positive or confirmed positive for *E. coli* O157:H7 or one of the six non-O157 STEC serogroups that is shipped to another establishment, or to a landfill or renderer for appropriate disposition.

FSIS Actions - When you are aware that there was a presumptive positive or positive result in establishment testing, you must:

- Conduct a HACCP Verification Task to verify the establishment's corrective actions (§417.3(a) or (b)), and
- Issue an NR **only** if the establishment fails to implement the corrective actions that meet the requirements of §417.3(a) or (b).

Note: *The HACCP Verification Task cannot be completed until pre-shipment review is completed, which includes the establishment's review of disposition documentation.*

Summary

Currently, several STEC serogroups – *E. coli* O157:H7 and six non-O157 STEC (O26, O111, O121, O45, O145, O103) are a public health concern associated with raw beef products. Therefore, FSIS is analyzing beef manufacturing trimmings, bench trim, other raw ground beef components and ground beef for *E. coli* O157:H7. FSIS is also currently analyzing beef manufacturing trimmings for six non-O157 STEC in addition to *E. coli* O157:H7.

If you are assigned to a beef establishment you may perform sampling for food safety concerns.

When an FSIS sample for a raw beef product is confirmed positive for *E. coli* O157:H7 or one or more of the six non-O157 STEC, and the establishment has not found the same product to be positive, issue an NR for HACCP noncompliance, verify the establishment's corrective actions, check appropriate decision-making documents, assist as needed in any recall, and conduct a HACCP Verification task on the specific production that tested positive. You cannot complete the task until the establishment has taken corrective actions and the product has received proper disposition (including completing a pre-shipment review). If the establishment maintained control of the product and sampled it, and both the establishment and FSIS samples were found positive for *E. coli* O157:H7 or a non-O157 STEC serogroups, you are NOT to issue a Noncompliance Record. You must verify that the establishment's corrective actions meet the requirements in §417.3.

If you find regulatory noncompliance, e.g., the establishment fails to take corrective action in accordance with §417.3, while performing the HACCP Verification Task, document it on an NR (as per FSIS Directive 5000.1). If you find that the establishment moved positive product without the necessary controls, or if you find that the establishment does not have records documenting proper disposition of the positive product moved off-site, contact your DO through supervisory channels.

As new technologies and methods of producing products are developed, and as new pathogens emerge that affect meat and poultry food safety, FSIS will adjust its efforts to continue being a public health agency. New or different microorganisms may be added to the

list of those for which the Agency currently tests. It will continue to be the responsibility of the in-plant inspection force to verify that establishments meet their food safety obligations.

Pathogen Reduction – *Salmonella* and *Campylobacter* Performance Standards Verification Testing

Objectives

To demonstrate mastery of Pathogen Reduction the trainee will:

1. Explain why *Salmonella* and *Campylobacter* testing is used.
2. State who will conduct *Salmonella* and *Campylobacter* testing.
3. List the species and types of product eligible for testing under the *Salmonella* and *Campylobacter* performance standards.
4. Describe how and when *Salmonella* and *Campylobacter* samples are taken.
5. Explain how FSIS uses the moving window approach when assessing process control.
6. Explain how to obtain completed *Salmonella* and *Campylobacter* results from LIMS-Direct and PHIS.
7. Recognize the description of the three process control categories.
8. Explain the Agency's actions when an establishment has failed a *Salmonella* performance standard for chicken and turkey carcasses, raw chicken parts, or not ready to eat comminuted poultry products.

References

1. FSIS Directive 7355.1, "Use of Sample Seals for Laboratory Samples and Other Applications".
2. FSIS Directive 10,210.5, "FSIS Sampling Data Reporting Through Laboratory Information Management System – Direct".
3. FSIS Directive 10,250.1, "*Salmonella* and *Campylobacter* Verification Program for Raw Meat and Poultry Products", and the DVD titled, "Sampling Raw Meat and Poultry for *Salmonella*". There are a list of supplemental documents containing information and instructions about the agency's sampling programs.
4. PHIS Directive 13,000.1, "Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)".
5. PHIS Directive 13,000.2, "Performing Sampling Tasks In Official Establishment Using the Public Health Information System".

6. PHIS Directive 5300.1, "Managing the Establishment Profile in the Public Health Information System (PHIS)".
7. Federal Register Notice, Vol. 77, No. 235, December 6, 2012 (Docket No. FSIS 2012-0007), "HACCP Plan Reassessment for Not-Ready-to-Eat Comminuted Poultry Products and Related Agency Verification Procedures".
8. Federal Register, Vol. 79, No. 108, June 5, 2014 (Docket No. FSIS-2012-0038), "Changes to *Salmonella* Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing *Escherichia coli* and *Salmonella*".
9. Federal Register Final Rule, Vol. 79, No. 162, August 21, 2014 (Docket No. FSIS-2011-0012), "Modernization of Poultry Slaughter".
10. Federal Register Notice, Vol. 80, No. 16, January 26, 2015 (Docket No. FSIS-2014-0023), "Changes to the *Salmonella* and *Campylobacter* Verification Testing Program: Proposed Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Related Agency Verification Procedures and Other Changes to Agency Sampling".
11. Federal Register Notice, Vol. 81, No. 28, February 11, 2016 (Docket No. FSIS-2014-0023), "New Performance Standards for *Salmonella* and *Campylobacter* in Not-Ready-to-Eat Comminuted Chicken and Turkey Products and Raw Chicken Parts and Changes to Related Agency Verification Procedures: Response to Comments and Announcements of Implementation Schedule".
12. Federal Register Notice, Vol. 83, No. 218, November 9, 2018 (Docket No. FSIS-2018-0043), "Changes to *Salmonella* and *Campylobacter* Verification Testing Program: Revised Categorization and Follow-up Sampling Procedures".
13. PHIS User Guide
14. "IPP Help" as a menu item under FSIS Applications; can access the following topics which contains all the pertinent information needed to collect samples under the different sampling project codes:
 - Raw Poultry Sampling Project Guidance
 - Follow-up Sampling *Salmonella*
 - Religious Exempt and Low Volume Poultry Carcass Sampling
 - Raw Pork Sampling Project Guidance
15. FSIS Notice 17-19, "Follow-up Sampling in Raw Poultry Establishments Not Meeting *Salmonella* Performance Standards".
16. FSIS Notice 21-19, "Actions to Take in Raw Poultry Establishments Exceeding *Salmonella* Performance Standards"

Introduction

FSIS established the *Salmonella* verification program in 1996 as part of the Pathogen Reduction, Hazard Analysis and Critical Control Point (PR/HACCP) Systems Final Rule. The PR/HACCP Final Rule established *Salmonella* performance standards that are used to verify process control in meat and poultry slaughter and processing establishments that produced certain classes of product (9 CFR 310.25(b)(1) and 381.94(b)(1), respectively). The performance standards were developed using national baseline studies conducted before the rule's implementation. Only the performance standards for livestock carcasses (9 CFR 310.25(b)) are still applicable. Actually, the Agency tests all raw beef samples collected under the routine and follow-up sampling programs for *E. coli* O157:H7, non-O157 STECs, and *Salmonella* as per FSIS Directive 10,010.1, Revision 4.

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*.

Since the PR/HACCP Rule, FSIS has conducted additional prevalence and risk assessments for pathogens in FSIS regulated products, as well as revising the performance standards to meet public health goals. In addition, the agency has published a number of Federal Register Notices (FRN).

- In 2014, FSIS published the Modernization of Poultry Slaughter Inspection, Final Rule (Federal Register Docket No. FSIS-2011-0012; August 21, 2014) to facilitate pathogen reduction in poultry products, improve the effectiveness of poultry slaughter inspection, make better use of Agency's resources, and remove unnecessary regulatory obstacle to innovation. In this publication, FSIS informed industry that it was removing the codified *Salmonella* pathogen reduction performance standards for poultry (9 CFR 381.94(b)).
- In January 2015, the Agency identified new *Salmonella* and *Campylobacter* performance standards for raw chicken parts and NRTE comminuted poultry products. (FRN Docket No. FSIS-2014-0023; January 26, 2015). FSIS also announced that it would use the results of routine sampling throughout the year, using a moving window approach, to assess whether the establishment's processes are effectively addressing pathogens on poultry carcasses and other products derived from these carcasses.
- In February 2016, FSIS published new performance standards for *Salmonella* and *Campylobacter* in not ready-to-eat (NRTE) comminuted chicken and turkey products, in addition to raw chicken parts (FRN Docket No. FSIS-2014-0023; February 11, 2016). The Agency also announced that it would begin assessing whether establishments meet the pathogen reduction performance standards for *Salmonella/Campylobacter* in raw chicken parts and NRTE comminuted chicken and turkey products. Furthermore, FSIS reassessed the minimum number of samples to assess process control for broiler carcass.

- In November 2018, FSIS is revising the categorization and follow-up sampling procedures in relation to the pathogen reduction performance standards. The establishment's category status will be based on FSIS results during the 52-week window and will no longer include follow-up sampling results as part of the moving window. In addition, the agency intends to use the revised categorization procedures for all establishments subject to a pathogen reduction performance standard for *Salmonella* or *Campylobacter*, including beef and pork establishments (in the future).

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. The *Salmonella* genus includes over 2,300 serotypes. There are several *Salmonella* serotypes commonly associated with human illness, including *Salmonella* Enteritidis and *Salmonella* Typhimurium. *Salmonella* bacteria are the most frequently reported cause of foodborne illness. According to the Centers for Disease Control and Prevention (CDC), salmonellosis causes an estimated 1.4 million cases of food borne illness and more than 400 deaths annually in the United States.

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 food borne illness, and *Campylobacter 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 (e.g., on-farm contamination can coat the exterior of the bird and remain attached to the skin). 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* can be transmitted to humans by eating foods contaminated with animal feces. The goal of the newly revised *Salmonella* and *Campylobacter* testing program is to protect the consumer from contaminated products by verifying that each establishment meets the new performance standards. Besides reporting individual *Salmonella* and *Campylobacter* sample results to establishments, FSIS posts nationwide *Salmonella* and *Campylobacter* data on its website on a quarterly basis.

In this module, we will focus our discussion on the *Salmonella* and *Campylobacter* testing program for poultry products.

***Salmonella* and *Campylobacter* Verification Testing – The Role of the Inspector**

The *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.

It is important for the IPP in establishments slaughtering or producing raw intact or raw non-intact chicken and turkey products to update the establishment's Public Health Information System (PHIS) profile information as per FSIS Directive 5300.1, Revision 1 (2016). The Agency has made changes to the product group options in the PHIS establishment profile to identify establishments that produce specific types of raw intact and non-intact chicken and turkey products.

Poultry Products Eligible for Sampling

IPP will collect the following poultry samples, using a moving window sampling approach, to be **analyzed for both *Salmonella* and *Campylobacter*** as described in Directive 10,250.1, and supplemental documents, as well as through the "IPP Help" menu under FSIS Application.

- Poultry carcasses
 - young chicken carcasses including broilers, fryers, roasters, and Cornish game hens, as described in 9CFR 381.170(a), and
 - young turkey carcasses
- NRTE ground and other comminuted poultry sampling program

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:

- (1) 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
- (2) mechanically separated (Mechanically Separated product group) – mechanically separated chicken or turkey, as defined in 9 CFR 381.173; or
- (3) 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). These products include:
 - 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); and
 - 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).

Note: These products include final (consumer-ready) products or intermediary product for further processing as NRTE product that are destined for sale as NRTE product for consumers.

Note: The Agency began collecting samples of young chickens carcasses produced under a *religious exemption* and not bearing the mark of inspection. In addition, FSIS will be testing for *Salmonella* and *Campylobacter* on young chicken/turkey carcasses, as well as poultry products, from establishments that produce less than 1,000 pounds per day. These samples are being collected under different sampling project codes.

As explained in the January 2015 and February 2016 Federal Register Notices (Docket Number FSIS-2014-0023), FSIS began assessing whether establishments meet the pathogen reduction performance standards for *Salmonella* and *Campylobacter* in raw chicken parts. Furthermore, the Agency announced its plans to begin sampling additional raw chicken parts to gain additional information in the prevalence and the microbial characteristics of *Salmonella* and *Campylobacter* in those products (refer to the list of supplemental documents associated with Directive 10,250.1 and “IPP Help” menu under FSIS Applications).

- Raw Chicken Parts Sampling Program: instructs IPP to collect raw chicken parts (finished product) to be analyzed for *Salmonella* and *Campylobacter*. Definitions are found in 9 CFR 381.170(b), Standards for kinds and classes, and for cuts of raw poultry. Eligible chicken parts for sample collection include:
 - Legs: whole legs (no backbone attached), drumsticks, thighs, and cut up or portioned leg meat (3/4 inch larger in at least one dimension),
 - Breasts: whole and half breasts (with or without ribs), boneless and skinless breasts, tenderloins and tenders, and cut up portioned breast meat (3/4 inch larger in at least one dimension), and
 - Wings: whole wings (with or without the wing tip), mixed wing sections, drumettes, mid-sections (flats), wing tips, and boneless wings

Note: Chicken half carcasses and quarter carcasses are not eligible for collection under this sampling program.

- Other Raw Chicken Parts Sampling Project (ORCPS): IPP will be collecting other raw chicken parts subject to sampling include hearts, whole or split gizzards, livers, necks, and quarter or half carcasses, together with both of those that are intact and those that are non-intact. These types of products will be analyzed for *Salmonella* and *Campylobacter*. 9 CFR 381.170(b) sets the requirements for specific cuts of poultry. This topic will not be discussed further in this module; refer to “IPP Help” menu under FSIS Applications – Raw Poultry Sampling Project Guidance for more information.

Circumstances in Which Sampling is not Warranted

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 a RTE product, FSIS will exclude the establishment from the *Salmonella* verification-testing program schedule, according to FSIS Directive 10,250.1 – Chapter VII.

For example, an establishment slaughters young chickens and produces NRTE ground chicken as one of its products. The establishment ships its entire ground chicken production to another establishment that uses it to make a RTE product. In this example, IPP would not sample the ground chicken. However, if other raw products were produced from the carcasses, then the chicken carcasses would still be eligible for *Salmonella* sampling.

If an establishment states that the intended use of all 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 in the establishment.

If an establishment claims to move all products from a particular product class to another federally inspected establishment for further processing into RTE products, IPP are to verify this by reviewing the establishment's HACCP plan and hazard analysis for the intended use of the products. In addition, IPP are to verify that the establishment has procedures incorporated in its food safety system that effect the movement of all products from that product class to another federally inspected establishment at which the product is further processed into RTE product.

If the establishment cannot produce sufficient documentation to demonstrate the assertion that the product is further processed into RTE product, then the product is still eligible for sampling under the verification-testing program.

If IPP verify that the product in question meets one of the exclusion criteria above, then IPP are to follow the additional instructions in FSIS Directive 10,250.1 – Chapter VII.

When an establishment produces more than 1 lot of NRTE poultry product class (for example, ground chicken) and ships the product to different establishments that further process the poultry into RTE product, but one of the establishments produces NRTE products, the IPP are to sample product under the *Salmonella* verification testing program. In this situation, the IPP is not to differentiate between the products going to the establishments producing the RTE products versus the products going to the establishments producing the NRTE product when taking the sample. In addition, IPP are to follow additional instructions described in FSIS Directive 10,250.1 – Chapter VII, Section III.

The Performance Standards

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

FSIS replaced its existing *Salmonella* sampling set-approach with a routine sampling approach for **ALL** FSIS-regulated products subject for *Salmonella* and *Campylobacter* verification

testing. This includes broiler and turkey carcasses, chicken parts, and NRTE comminuted poultry. *Salmonella* and *Campylobacter* performance standard verification samples are taken as part of a moving window and the results are used to determine if an establishment is meeting the performance standard on a continuous basis. When assessing process control under a moving window approach, FSIS intends to evaluate, over a certain period of time, a number of sequential results from a single establishment. Thus, given the fixed timeframe of one year (52 weeks) for which an establishment has been sampled, FSIS would assess the first moving window by evaluating the number of samples taken within the 52-week period. Subsequently, every week the 52-week period moves up one week adding a new week's testing result and removing the oldest week's results (refer to the "Moving Window for Analysis of Testing Results" diagram).

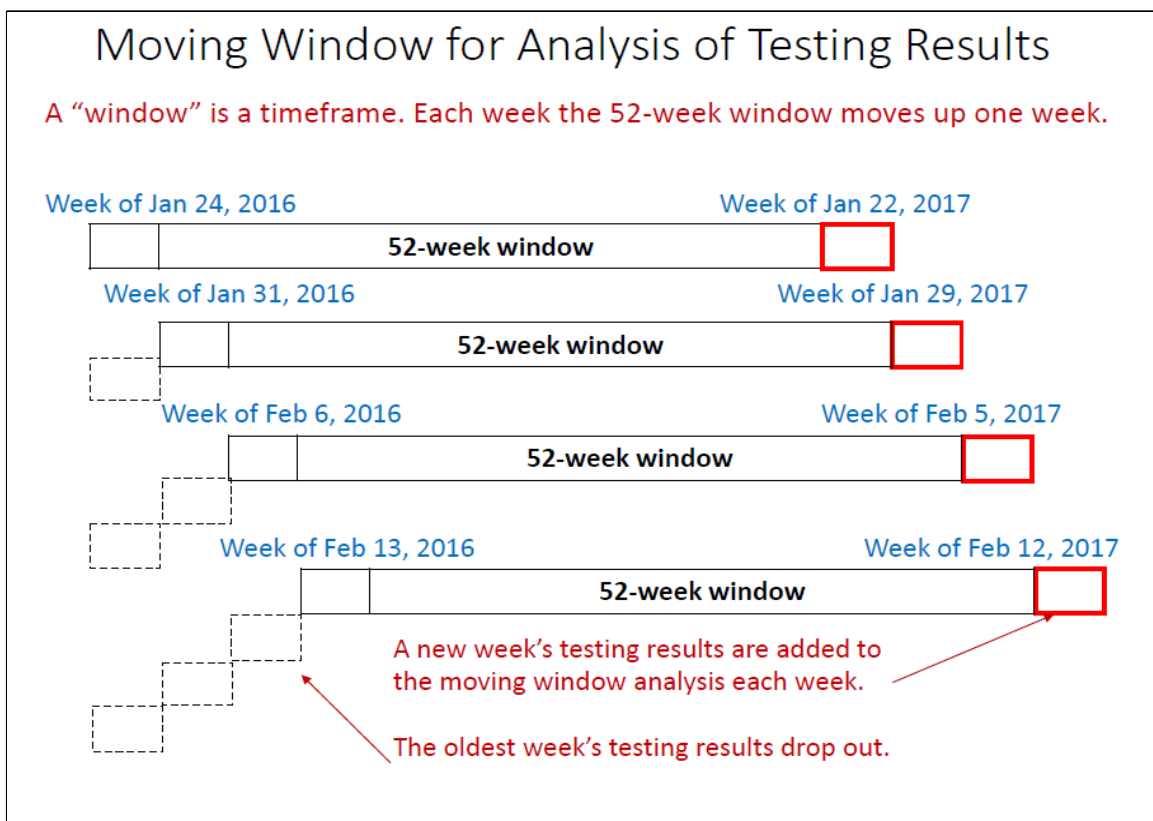


Diagram-shows how the moving window works

As an example, if an establishment has five *Salmonella* positives within 52 samples (one sample per week for a year), then the establishment passed the performance standard if the performance standard allows five positive samples among 52 samples. When the next sample is taken (week 53, in this example), the moving window would shift forward the fixed timeframe of one year (52 weeks); that is, the original week 1 (and the original first sample) is excluded, while the most recent week is included in the new 52-week moving window. This shifting is repeated with each new week and allows FSIS to continuously assess the process control of an establishment.

The chart below shows the maximum acceptable percent positive results or number of positives results allowed in the moving window before the establishment fails to meet the performance standard. In addition, FSIS will attempt to collect at least a minimum number of samples outlined in the chart below per year in order to assess process control in all establishments subject to the performance standards. A test is considered positive when any *Salmonella* or *Campylobacter* organisms are found.

***Salmonella/Campylobacter* Performance Standards for Poultry**

Product	Maximum Acceptable % Positive		Performance Standard		Minimum # of Samples to Assess Proc. Control	
	<i>Salmonella</i>	<i>Campylobacter</i>	<i>Salmonella</i>	<i>Campylobacter</i>	<i>Salmonella</i>	<i>Campylobacter</i>
Broiler Carcass ¹	9.8	15.7	5 of 51	8 of 51	11	10
Turkey Carcass ¹	7.1	5.4	4 of 56	3 of 56	14	19
Comminuted Chicken ²	25.0	1.9	13 of 52	1 of 52	10	52
Comminuted Turkey ²	13.5	1.9	7 of 52	1 of 52	10	52
Chicken Parts ³	15.4	7.7	8 of 52	4 of 52	10	13

¹ The maximum acceptable percent positive for *Salmonella* and *Campylobacter* under the performance standards for young chicken and turkey carcasses is published in the FRN Docket No. FSIS 2014-0023 (2015).

² New performance standards published in the FRN Docket No. FSIS-2014-0023 (2016) using the larger 325 g analytical portion.

³ New performance standards published in the FRN Docket No. FSIS-2014-0023 (2016) using the 4 lb. sample.

Note: The new *Salmonella* performance standards are to be applied to sample results in place of the performance standards for young chickens (as broilers) and ground chicken and ground turkey codified in 9 CFR 381.94(b).

For highest-volume establishments, FSIS expects to collect 52 samples within the 52-week moving window. In this case, to assess process control (at establishments producing products with performance standards measured in 52 samples), one need only to count the number of positives test results within the 52-week moving window. For example, the proposed performance standard for *Salmonella* in raw chicken parts is eight positives out of 52 samples. Assuming that 52 samples were collected from the establishment within a 52-week moving window, if the establishment has eight or fewer *Salmonella* positives within that 52-week timeframe, then it would pass the performance standard. If, on the other hand, the establishment has nine or more *Salmonella* positives within that same 52-week timeframe, then it would **fail** the performance standard.

To assess process control in establishments that FSIS samples less often than weekly (i.e., lower volume establishments), FSIS will assess establishment performance (as percent positive) based on the number of samples collected and positive results within the 52-week moving window. To illustrate this point, if a small establishment producing raw chicken parts is sampled fewer than 52 times in the 52-week moving window, only 26 times, for example, with three of those samples testing positive for *Salmonella*, 26 will be the denominator while three be the numerator. This gives the establishment a percent positive of 11.5 ($(3 \div 26) \times 100 = 11.5\%$). In this example, the resulting percent positive is less than 15.4, the acceptable percent positive for the performance standard for *Salmonella* in raw chicken parts. As such, the establishment would pass the performance standard.

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).

Sampling Procedure

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.

For example, if an establishment produces more than one product type (chicken carcasses, chicken parts, and NRTE comminuted chicken) that is eligible for sampling, then all of those products will be scheduled for sampling during the month.

If an establishment produces eligible product on more than one shift, IPP are to collect samples from different shifts for each sampling task so that all shifts are represented during routine sampling. IPP will collect a sample of product, using a random method, at an unannounced time for each sampling task, until enough samples have been taken and analyzed as part of the moving window. IPP are to collect samples in accordance with the step-by-step directions found in FSIS Directive 10,250.1 and supplemental documents, including applicable FSIS notices for all product classes including young chicken and turkey carcasses. Attachment 1 in this module gives an overview of the procedures for collecting samples as per FSIS Directive 10,250.1 (refer to the directive for detail instruction on how to collect the samples).

Note: “Random” refers to the time the samples are selected, not to when the sponging or rinsing is initiated or completed. Random sampling may include the use of random number tables, drawing cards, or using computer generated random numbers. For example, the time entered for collection is when the carcass is removed from the line and the date is the day the carcass is sponged or rinsed.

Salmonella and *Campylobacter* verification sampling is a **directed** sampling task. Taking into account risk factors including production volume and past establishment testing performance (i.e., positive *Salmonella* and *Campylobacter* test results), FSIS will establish the sampling frequency accordingly for a particular establishment. The Public Health Information System (PHIS) displays sampling tasks on the establishment task list for the sampling programs that apply to the establishment. The following are sampling project codes for the *Salmonella* sampling programs. Follow instructions outlined in the directive, supplemental documentations and guidelines.

- The **HC_CH_COM 01** (for chicken) and **HC_TU_COM01** (for turkey) sampling codes correspond to products in the “Ground Product” and “Other Comminuted” product groups by randomly selecting from available eligible raw ground and other comminuted (but not mechanically separated) products.
- The **HC_CH_CARC01** and **HC_TU_CARC01** sampling code corresponds to young chicken and turkey carcasses, respectively, to reflect the moving window approach.
- The **HC_CPT_LBW01** sampling code is used to collect samples at establishments producing chicken parts.

IPP document the completion of the sampling task in PHIS including completing the questionnaire. IPP schedule verification-sampling tasks following the instructions in FSIS Directive 13,000.1 and perform the sampling tasks following the instructions in FSIS Directive 13,000.2.

Sampling Method

The specific sampling methodologies for the product classes to be sampled are explained in detail in FSIS Directive 10,250.1, supplemental documents and applicable FSIS notices.

IPP collect samples using a carcass sponge swab, a whole bird rinse, or taking a specific amount of ground/comminuted product using the sampling technique as described in FSIS Directive 10,250.1, supplemental documents and guidelines, including published FSIS notices.

Turkey carcasses are sampled using a sponge sample technique. Sponge sampling of turkey carcasses uses two sponges, one that is analyzed for *Salmonella* and the other for *Campylobacter*. Sponge sample sites are to the left and right of the back and thigh as per instructions delineated in the directive.

Chicken carcasses are sampled using whole bird rinses; IPP are to collect 100 ml of rinsate.

Note: For poultry carcasses, at the post-chill sampling location, IPP are to determine a random time at which the carcass will reach the end of the drip line or the equivalent point in air-chill systems. IPP are to randomly select a poultry carcass from the post-chill area (after all interventions have taken place) and to allow drip time to prevent dilution of the sample.

Chicken parts are sampled by collecting approximately 120 ml of rinsate from 4 lbs. \pm 10% of the eligible raw chicken parts.

The amount of ground product collected (final package or aseptically when not in final package) by the IPP under the appropriate sampling project code is as follows:

- NRTE comminuted poultry products are sampled by collecting sufficient product to fill the two provided Whirl-Pak bags up to the fill-line indicated on each bag, following the instructions as described in the “IPP Help” menu (FSIS Applications) - Raw Poultry Sampling Project Guidance. The total weight of the two bags of samples should be approximately two pounds. This larger sample size will provide consistency as the Agency moves toward analyzing each sample for both pathogens.

In establishments that produce more than one type of product subject to testing, **all** eligible products produced will be scheduled for sampling during the month under routine sampling.

Additional Sampling Directions

The Inspector-in-Charge (IIC) at establishments subject to *Salmonella* and *Campylobacter* verification testing should ensure that adequate sampling supplies are available prior to the start of each sampling task.

IPP are to notify official establishment management just before collecting a routine *Salmonella* or *Campylobacter* sample.

IPP are to schedule the directed sampling tasks on the task calendar (refer to Sample Management Module, section “Scheduling and Submitting a Directed Lab Sample”) and collect a sample the day the product class is produced.

Once the IPP has scheduled the sampling task with the laboratory assignment, using the PHIS Laboratory Capacity Reservation System in the Task Calendar, then the IPP can proceed to collect the sample. The IPP may choose to print a draft copy of the “Sample Analysis Request” form to use as a reference during sample collection and to document product information (refer to Attachment 2 at the end of this module). Some information is already pre-printed in the Collection and Animal Information data fields of the sampling form, such as sample form ID, project code, and sample source.

Note: When entering information into PHIS for carcass-based *Salmonella* or *Campylobacter* sample collection (chicken whole bird rinses or turkey carcass swabs), IPP are to enter “N/A” (for Not Applicable) into all “Sample Management-Sample Collection” required data entry fields related to the producer name and address. Samples should not be frozen and should be kept secure at all times. Sample boxes should never be stored near heaters or areas exposed to excessive heat. Cool the shipping container the day before collecting the sample. The laboratory will discard rinse samples that arrive above 50°F or below 32°F. It is critical that refrigerated sample temperature is maintained during collection and shipment.

When a sample is collected, IPP are to enter the data requested in the data fields (as indicated above) on the sampling form, submit the sample form through PHIS, print and sign the form, pack and ship the sample as described in PHIS Directive 13,000.2 and the Sample Management module of this training. **Be careful** to send the sample to the appropriate laboratory as identified on the sample form; otherwise, it will be discarded. The lab analyzes the samples and the Office of Planning, Analysis and Risk Management (OPARM) tracks the data and results. IPP receive laboratory-testing results when they are posted in LIMS-Direct and in the establishment’s home page in PHIS for both pathogens. IPP receive an alert on the PHIS Inspector home page when an FSIS sample result is positive.

Defining Categories

If the sample under the routine *Salmonella* verification sampling meets the *Salmonella* and *Campylobacter* performance standards (i.e., the maximum acceptable percent positive allowed under the moving window approach), it passes. If the sample results in the moving window exceed the maximum percent positive allowed, the establishment has not met the performance standard.

FSIS uses categories in evaluating an establishment’s level of process control and for scheduling *Salmonella* and *Campylobacter* performance standard verification testing. For all products sampled under routine *Salmonella* verification sampling, FSIS has recently modified its process control category classification system as follows:

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.

Note: FSIS is not currently assessing the *Campylobacter* performance standards because is in the process of revising the performance standards in raw poultry products. The agency will not be taking any further action concerning to the sampling results until the new *Campylobacter* performance standards are in place.

Note: OPARM handles the data analysis and reporting; it also determines the official establishment category.

Agency's Actions

As per recently published instructions (FSIS Notices 18-18 and 32-18), when an establishment is assigned to Category 2 or 3, IPP are to do the following:

- 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 following instructions, as per published policy (Notice 18-18).
- 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 (Notice 32-18). 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))

FSIS will conduct follow-up samples and will only be scheduled for those raw poultry products subject to *Salmonella* performance standards (i.e., the number of positive samples within a specified timeframe exceeds the maximum acceptable for that product class); these aforementioned samples will be analyzed for both *Salmonella* and *Campylobacter*, where applicable (Notice 11-18).

IPP will receive a “New Follow-up Sampling Task” alert through the PHIS dashboard approximately 30 days after the Category 3 alert.

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)

Note: At this time, FSIS will not implement follow-up sampling in establishments that do not meet the *Campylobacter* performance standard in raw chicken parts or NRTE comminuted poultry products.

Specifically, either 16 or eight follow-up samples will be collected depending on the size and production volume of the establishment. IPP are to collect one follow-up sample per shift (when possible) as instructed in Notice 11-18. The Agency will analyze the follow-up sampling; FSIS will no longer include follow-up sampling results as part of the moving window when determining establishment category status.

IPP are to consider whether the overall pattern of inspection findings indicate a systemic problem with the establishment’s HACCP system, or whether the establishment is slaughtering and/or processing poultry under insanitary conditions. IPP are to bring such concerns to their FLS to evaluate the need to take further enforcement action.

SAMPLING RTE PRODUCT

Objectives

After completion of this module, the participant will be able to:

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. Describe why it is important to notify establishment management prior taking a sample.
 7. Identify how IPP obtain sample results.
 8. Describe what actions IPP take when a positive FSIS RTE sample result is identified.
 9. Describe the actions IPP take when establishment testing obtains a positive sample result.
 10. Explain the procedures in verifying corrective actions for a positive RTE sample.

Introduction

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 in RTE products are *Listeria monocytogenes* (*Lm*) and *Salmonella*. Therefore, RTE product samples are tested for both of these organisms by FSIS laboratories. *Salmonella* is generally associated with under-processing or cross-contamination post-processing while *Lm* is more often associated with cross-contamination post-processing. RTE product is adulterated if it contains *Lm*, *Salmonella*, or any pathogen known to cause illness including *E. coli* O157:H7, or if it comes into direct contact with a food contact surface contaminated with *Lm*.

Note that FSIS is continuously updating its sampling programs in order to keep pace with changes in policy. FSIS directives and notices for current sampling programs contain specific instructions to follow. **It is important to read recent issuances, so that when you are requested to collect a sample you have the latest information.** See Attachment 1 for a list of relevant FSIS Directives.

Definitions

Aseptic means, "free from pathogenic organisms." Aseptic technique implies that IPP do not add any organisms (pathogenic or not) to the sample when it is collected. It does not imply that the sample is aseptic. The purpose of aseptically collecting a sample is to prevent contaminating the sample or the surrounding product/product contact area. That is why it is important to aseptically collect a sample even when the sample is intact. IPP should wash and sanitize their hands before collecting an intact sample, but it is not necessary to sanitize the area and put on gloves. Good personal hygiene is essential anytime a sample is collected, whether intact or not.

Environmental samples are samples from surfaces that have:

- Indirect or potential contact with exposed RTE product in the RTE production area (mop handles, outer garments, etc., that may be handled by a person who may touch RTE product), or
- Non-contact surfaces in a RTE production area (e.g., floors, drains, walls, overhead structures).

Food contact surface is specific to the RTE verification testing program. 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). A food contact surface does not include items that may have indirect or potential contact with exposed RTE product.

Food contact surface samples are a collection of samples (e.g., swabs) from food contact surfaces that represent the conditions under which the sampled lot was processed. The samples are usually collected during the production shift, not pre-operational, but without disrupting production, such as during breaks and at the end of a shift.

Intact means product in the final packaged form (immediate container) in which it will be shipped. The lab receives the sample in the same immediate container as intended for the consumer.

Recall is an establishment's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). Product that is adulterated and has left the establishment's control may be subject to a recall. The recall would involve at least the sampled lot, but it could be expanded depending upon a review by the Recall Management Division (RMD) of all factors in the situation. FSIS Directive 8080.1 gives additional details on recalls.

RTE production area is one where exposed RTE products are stored, further processed, or packaged. This is the area from which food contact surface samples and environmental samples are taken and analyzed for *Lm* or indicator organisms.

Sample is a collection of product that represents a larger group of product (i.e., the sampled lot).

Sampled lot is the amount of product represented by the sample. For microbial issues, the actual (affected) product represented by the sample is usually interpreted as the product produced from clean-up to clean-up. Often, factors like the establishment's coding system, the pathogen of concern, the processing and packaging, the equipment, the establishment's sampling programs, the HACCP plan monitoring and verification activities, the SSOP records, etc., are considered when determining how much product is actually represented by the sample.

Short-weight or slack-filled containers meet the definition of an intact sample, but with less product (e.g., a liner from a bulk package which contains approximately 2-lb of product, folded down and sealed in the same manner that the bulk product is normally packed to prevent product contamination). A short-weight or slack-filled sample is one that has progressed

through all the production steps that the product normally goes through (not changed in any way that would affect the processing parameters). A short-weight or slack-filled sample may appear to the lab as a non-intact sample and may be discarded if PHIS information does not indicate it is short-weight or slack-filled.

Subsequent production is all product produced after the sampled lot. It is not usually part of the sampled lot, but it may or may not be affected product.

Sample Initiation

PHIS will display any RTE sampling tasks on the Task List based on the sampling programs for which the establishment is eligible. These PHIS generated requests are called “directed” sampling tasks. There are no “collector generated” sample requests for RTE product sampling. However, if IPP have concerns about the product or process they may follow their supervisory chain of command to request additional “directed” samples. IPP are to provide information on the type of sample to be collected and a justification for the sample collection request. If additional sampling is justified, the district office will contact DAIG to request that the tasks be generated through PHIS as a directed sample task. Once the additional directed sampling tasks appear on the establishment’s task list, IPP may then schedule them.

Steps in Sampling

There are 6 general steps in sampling RTE product.

- Determine which product to sample and schedule the sample
- Notify establishment management
- Collect the sample
- Document the Sample
- Pack and ship the sample and form
- Respond to the results

Step 1: Determine which product to sample and schedule the sample

IPP collect RTE product samples under the following project codes:

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 from the highest risk level, according to the table below.

HACCP Processing Categories	Finished Product Categories	Production Volume Categories (by Product Groups)	Risk Level
Fully Cooked-Not Shelf Stable	RTE fully-cooked meat (PLE) ¹ / RTE fully-cooked poultry (PLE)	Other Fully Cooked Sliced Product	1
		Hot Dog Products	2
		Salad/Spread/Pate	3
		Diced/Shredded	4
		Meat + Nonmeat Components	5
		Sausage Products	6
		Patties/Nuggets	7
		Other Fully Cooked Not Sliced Product	8
Not Heat Treated-Shelf Stable/Heat Treated-Shelf Stable	RTE acidified/fermented meat (without cooking)-PLE/ RTE acidified/fermented poultry (without cooking)-PLE	RTE fermented meat (sliced or not sliced)/ RTE fermented poultry (sliced or not sliced) (Acidified/Fermented Products) ²	9
	RTE dried meat (PLE)/ RTE dried poultry (PLE)	RTE dried meat (sliced or not sliced)/RTE dried poultry (sliced or not sliced) (Dried Products) ²	10
	RTE salt-cured meat (PLE)/ RTE salt cured poultry (PLE)	RTE salt-cured meat (sliced or not sliced)/ RTE salt-cured poultry (sliced or not sliced) (Salt-cured Products) ²	11
Product with Secondary Inhibitors – Not Shelf Stable	RTE salt-cured meat (PLE)/ RTE salt cured poultry (PLE)	RTE salt-cured meat (sliced or not sliced)/ RTE salt-cured poultry (sliced or not sliced) (Salt-cured Products) ²	11

¹ Post-lethality exposed product.

² Product type to be used on Form 10,210-3.

Exceptions: Do not collect samples of oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats that are Ready-to-Eat (RTE) because there is no validated test method for detecting *Lm* in these products.

FSIS will sample popped pork skins, pork rinds, dried soup bases, concentrated (high salt content) soup mixes, and pickled pig's feet under both programs. FSIS will collect samples of RTE products that are shipped hot from the establishment.

When IPP receive an RTEPROD_RAND or RTEPROD_RISK request in PHIS, they are to schedule an RTE product sample within the sampling window timeframes given. IPP are to randomly select a day, shift, and time within the sample window timeframe. There should be an equal chance that sampling will occur during any shift where eligible product is produced. IPP should not wait until the end of the sampling window to schedule the sample. Scheduling the sample at the beginning of the sampling window will allow more time to ensure that a sample is available during that timeframe.

Step 2: Notify Establishment Management

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

When notifying the establishment that FSIS will collect a sample, IPP are to confirm that the establishment will be producing post-lethality exposed RTE product (RTEPROD_RISK) or RTE product (RTEPROD_RAND) on the day sampling is scheduled. In addition, IPP are to confirm that the establishment is planning to implement its documented routine production, Sanitation SOP, and food-safety practices on the day the sample is scheduled.

IPP are to generally provide a one day advance notice if that is sufficient for the establishment to hold the sampled lot but not to change practices. IPP may provide more advance notice if the establishment can support that more time is necessary because of the innate characteristics of the process. IPP should inform the establishment that, if it changes routine practices without justification for doing so, FSIS may provide it with less than a one day notice if that is sufficient to hold the sampled lot. If IPP have questions about an establishment's basis for requesting more notice, they are to submit them through askFSIS.

IPP should inform the establishment that, if it intends to modify its documented routine production, sanitation, or food-safety practices before the sampling, it should inform IPP as soon as possible so that sampling can be rescheduled. If the establishment continues to change routine practices and cannot support the changes, less than one day advance notice may be provided, or an FSA may be scheduled at the establishment.

NOTE: Justifiable reasons for changing practices may include limiting the lot size to facilitate holding the product, changes in customer orders, or documented changes to Sanitation SOPs or HACCP plans.

IPP should inform the establishment that it is responsible for supporting its basis for defining the product represented by the sample (i.e., the sampled lot); and inform the establishment that it is required to hold or control the sampled lot until negative results are received. IPP will verify that the establishment is holding or controlling the product represented by the sampled lot (the product produced from clean-up to clean-up) and record the information in PHIS. Immediately contact the DO if the establishment does not hold or maintain control the sampled lot.

Step 3: Collect 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 two-pound sample of product in an **intact package**. Collecting products in the intact package will help to ensure that the product does not become contaminated with *Lm* from the environment during the sample collection process. If packages weigh less than two pounds, IPP are to collect enough packages to bring the total to a minimum of two pounds.

IPP are to collect the product at least three hours after the start of production (if possible), to allow *Lm* to work its way out of the equipment. If the establishment's production lot is typically less than three hours, IPP may collect the samples during the production shift. IPP are to vary the shifts in which they collect samples, if possible.

If the establishment produces reworked product, IPP are to sample the product as part of the production lot, as long as IPP provide the establishment with adequate notice to hold the sample. Rework is the process of re-cooking, reprocessing, or repackaging the product. FSIS considers any process that removes the product from the package and exposes it to the environment as rework.

If the finished product contains meat or poultry and non-meat or non-poultry ingredients, IPP are to follow the instructions below.

- If the meat or poultry and non-meat or poultry ingredients are commingled (in contact) in the final package (e.g., a salad with meat or poultry mixed in), IPP are to collect a two-pound sample of the complete product (including the meat or poultry and nonmeat or poultry component).
- If the meat and nonmeat ingredients are not commingled (not in contact) in the final package (e.g., an entree with separate compartments for meat or poultry and vegetables), then IPP are to collect a two-pound sample of the meat or poultry component in the final package.

IPP are to submit the samples to the laboratory for microbiological analysis in **intact** packages. The laboratory does not supply sterile bags or gloves for sampling because IPP are not to have direct contact with the exposed, unpackaged RTE product. This is because *Listeria* may be present in the environment and could be transferred to the product if exposed RTE product is collected.

If an intact product or product container is too large, heavy, or costly to ship to the laboratory, IPP can ask the establishment to slack-fill or short-weight a product for a 2-pound sample and send it in the usual establishment packaging such as the container liner.

If the slack-filled or intact package is an unsealed bag, IPP are to tie it off (e.g., twist tie or rubber band) so smaller particles (e.g., shredded meat pieces) do not spill into the shipping container. IPP are to place the slack-filled package in a secondary bag. The laboratory will discard the sample if it contains spilled or leaking products. When IPP document the sampling task in PHIS, under the "Additional Info" tab, they are to click "yes" to the question "Is this sample short-weighted/slack-filled?" to ensure that the sample is not discarded as a non-intact sample by the laboratory.

IPP are not to use any laboratory-supplied bag as the primary wrap for the sample. Laboratory supplied bags provided by the laboratory are for secondary containment only because they are not sterile. The laboratory-supplied bag protects the box in case the primary container leaks.

If IPP cannot collect an intact short-weighted or slack-filled sample, and the establishment is not producing any other type of RTE product that the IPP could collect, IPP are to contact the designated laboratory to discuss other options for collecting the sample.

NOTE: Examples of inappropriate samples for short-weight or slack-filled samples include a sample that would have to be cut to fit inside the shipping container, and samples that are packed in a waxed box without a liner bag that is too large to fit inside a laboratory shipping box.

When a sample cannot be collected on the date originally scheduled, inspectors should follow instructions specific to rescheduling lab sampling tasks in PHIS. When sample collection cannot be rescheduled for any date within the requested time frame, IPP should cancel the sample request within PHIS and provide a justification as to why the sampling could not be performed.

Intervention Considerations

If the establishment treats the product with an intervention (e.g., HPP), either at the establishment or at another establishment, IPP are to review documentation the establishment keeps as part of its HACCP program to determine the purpose of the treatment.

If the HPP is applied as a *Listeria* intervention, and the establishment has supporting documentation demonstrating that the treatment achieves at least a 1-log reduction of *Lm*, IPP are to collect the sample after the treatment is applied. If the product is not returned to the producing establishment after the HPP treatment, IPP are to sample another product, if possible. The product, in this case, would be subject to sampling at the HPP facility if records show that the treatment was applied as a *Listeria* intervention. If the establishment is not producing any other RTE product at the time the sampling is scheduled, IPP are to cancel the task and enter into PHIS “all interventions have not been applied at this establishment.”

NOTE: If the establishment’s validation supports that the HPP treatment achieves at least a 5-log reduction of *Lm*, the product is not considered post-lethality exposed and would only be sampled under the RTEPROD_RAND project code.

If the treatment is applied to extend the shelf life of the product, and the establishment does not have supporting documentation describing the treatment as a *Listeria* intervention, then IPP are to collect the product before the treatment. The product would not be subject to sampling at the HPP facility, as long as it has records on file supporting that the treatment was applied to extend the shelf life.

Altered Practices

On the day of sample collection, if IPP find that the establishment has altered its documented routine production, sanitation, or food-safety practices, and the establishment cannot provide a supportable rationale, IPP are not to perform sampling and are to reschedule if possible.

IPP are to issue an NR under the following circumstances:

- If IPP find that the establishment has made changes in its food safety systems (e.g., temporarily changing its supplier of RTE product on the day the sample is collected) and does not have documents supporting the appropriateness of the change, IPP are to issue an NR. The NR would be issued because the establishment did not consider the changes in its hazard analysis in accordance with 9 CFR 417.2(a) (1), or did not support the changes to its hazard analysis as in 9 CFR 417.5(a) (1).
- Likewise, if IPP find that the establishment has made changes in its sanitation practices (e.g., temporarily increasing the use of sanitizer only on the day the sampling is scheduled) and did not revise its Sanitation SOP to reflect these changes, IPP are to issue an NR under 9 CFR 416.14.

NOTE: If an establishment decides to limit its product lot size solely to facilitate holding the product during sampling, it would not be considered to have significantly altered its production practices, as long as IPP can collect samples that accurately represent routine production. If IPP have questions about whether an establishment is altering routine production, sanitation, or food-safety practices, they can submit them through askFSIS.

At the next weekly meeting, IPP are to discuss the altered food safety practices with the establishment. Inform the establishment that if it continues to change its practices, FSIS may collect more samples and may give less than 1 day notice (if less time is enough to hold the sampled lot) or schedule a “for-cause” FSA.

Step 4: Document the Sample in PHIS

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 must answer the questionnaire in PHIS before submitting the sample. The questionnaire includes:

1. Selection of the appropriate RTE product type.
2. Amount of pounds represented in the sample. This is based on what the establishment declared the sample lot to be.
3. Is the product post lethality exposed? If yes then the IPP must answer 3a, which asks for the Alternative the product was processed under. If no then PHIS will forward to question 4.
4. Identify the production line the sample was taken from. If the establishment has only one line mark N/A.
5. Enter the time the collection was made in military format.
6. Enter the contact person for the establishment.
7. Enter the contact phone number for the contact.
8. Answer yes or no, whether establishment management was notified of this sample collection.

9. Indicate if the sample was short weighted or slack filled. This will prevent the laboratory from discarding the sample because it is not in the final retail package.
10. Answer where the sampled lot is being held or controlled.

When IPP are certain that the correct information has been entered in PHIS, they must submit both the questionnaire and the Sample Analysis Request Form electronically to the laboratory. Then IPP 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 the sample will be discarded.

Step 5: Pack and Ship the Sample and Form

Identify the sample and paperwork, and place them into the bag provided by the lab.

Double check and compare the address on the FedEx expanded billable stamp to make sure it is going to the lab indicated in PHIS and on the Sample Analysis Request Form. The lab will discard the sample if shipped to the wrong lab. Also be sure to check the expiration date on the expanded billable stamp. Do not use an expired expanded billable stamp.

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. Place one of the small bar code stickers from the 7 part sample seal set (7355-2A/B) on the sample package, and another on the Sample Analysis Request Form. Put the Sample Analysis Request Form in a plastic bag or sleeve to protect it. Put the sample and the form into a zip-lock bag, and attach the Identification Label, 7355-2B, to the zip-lock bag so that the bar code is readable.

Pack the sample. Samples should be shipped in FSIS-furnished containers, unless special arrangements are made with the lab. Pack one sample per pre-chilled shipping container to avoid confusion. Multiple samples can be sent in one container, as long as each sample is accompanied by its sample form and there are no concerns over maintaining product temperature. In cases where multiple product packages are necessary for a single sample, all of them must be shipped in the same shipment container. 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)

NOTE: The shipping containers should have the top and bottom sealed by the lab with tamper-evident tape. IPP will **not** receive any tamper-evident tape to use. If the tape is cut or missing, **do not** open the container. Follow the instructions in FSIS Directive 7355.1 (seal it with the Container Seal, 7355-2A, and ship it back to the lab of origin for processing; complete the seal by writing “seal broken” in the “Form No.” blank).

The absorbent pad is placed in the bottom of the shipping container. Its purpose is to absorb any fluid that may leak into the box in order to maintain the integrity of the shipping container for future use. A frozen freeze pack must be added for product that was stored refrigerated or frozen. The cardboard separator goes on top of the freeze pack to separate the freeze pack from the sample. The bagged sample is then put into the shipper. Do not use filler material in the shipping container. Any unused bar code sticker needs to go into the shipper with the sample. This insures that it won't accidentally get used on another sample, and allows the lab to account for all 7 parts of the seal/label. Alternatively, the unused bar code may be retained with the file record of sample collection. The foam plug must be pushed down as far as possible to keep the sample from being tumbled inside the shipper.

An FSIS Laboratory Sample Container Seal (FSIS Form 7355-2A) must be put on the shipping container in such a way that it cannot be opened without disturbing the seal.

Ship the sample. IPP are to ship samples Monday through Friday so that they arrive at the laboratory overnight. IPP are not to ship samples on Saturdays or on the day before a Federal holiday, or as directed by a user notice via e-mail.

Step 6: Respond to Results

IPP will access LIMS-Direct to track sample receipt and for detailed information on FSIS sample results or discards. LIMS stands for Laboratory Information Management System. LIMS-Direct is a program that reports FSIS lab sample results directly from LIMS. It will provide close to real-time sample data electronically to FSIS program personnel, Federal, and State establishments (via email), and State officials, if FSIS laboratories conduct testing for States. LIMS-Direct will be updated every 15 minutes and display sample data history longer than the last 90 days of data. If, in limited cases, LIMS does not receive an electronic record from the Public Health Information System (PHIS) because of technical reasons, sample results will still be available in LIMS-Direct.

When IPP go to the LIMS-Direct address, several options are available.

1. Single Sample Results – search using the form number.
2. Single Establishment Results – search using the establishment number to obtain all the results in the database for that establishment.
3. Results for All Establishments in a Circuit – search by entering the circuit number.
4. Results for State Inspection Sample – search using the state code.
5. Samples Not Analyzed for All Establishments in a Circuit – search using the circuit number.
6. More Reports – search for more types of reports that are available.

Option 3 is particularly useful if it is a patrol assignment, since one can see the status of the samples of all the establishments at one time.

Once the analyses are complete, the results are posted in the results column.

IPP should provide sample result information to establishment management even if the establishment receives e-mail notifications automatically.

Sampling Project Positive Results

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. In addition, IPP are to consider the following:

- If FSIS finds the product positive, and the establishment tested the product under its documented sampling programs, IPP are to check the establishment's *Salmonella* or *Lm* testing results to determine whether the establishment also found the sampled product to be positive for *Salmonella* or *Lm*.
- IPP are to determine whether the establishment held the product or maintained control of the product pending its own test results.
- If IPP find that the establishment did not hold or maintain control of the product, they are to issue an NR. The NR would be warranted because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as set out in 9 CFR417.5(c).

Generally, if FSIS finds the product positive for *Salmonella* or *Lm*, IPP are to issue an NR (cite 9 CFR 417.4(a)). However, if the establishment also found the product to be positive for *Salmonella* or *Lm* and held the product, IPP are not to issue an NR. They are to verify that the establishment performs the appropriate corrective actions, using a directed HACCP Verification Task.

Establishment Sampling Program Positive 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 properly disposing of the sampled product lot.

An establishment may or may not conduct environmental sampling, other than on food contact surfaces, under its HACCP plan or Sanitation SOPs or other prerequisite program. If the

establishment is conducting such sampling, and positive results are received, IPP are to verify that the establishment takes the appropriate action as outlined in the program under which the establishment did the sampling. If the establishment is conducting such sampling but is not addressing the sampling under HACCP or Sanitation SOPs or other prerequisite programs, and IPP find that such sampling is resulting in repetitive positive results, IPP are to notify the district office through supervisory channels.

Verifying Corrective Actions

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. Although the regulations do not require establishments to specifically control for *Salmonella* in post-lethality exposed RTE products, as stated previously, FSIS considers RTE products to be adulterated if products or food contact surfaces test positive for *Salmonella* or other pathogens. Therefore, establishments are required to take corrective actions in response to positive results and to reassess their HACCP plan. FSIS will perform an IVT/FSA for *Salmonella*, as described in FSIS Directive 10,300.1.

In addition, if FSIS develops a verification plan in response to an establishment's proffered corrective actions and preventive measures when enforcement is deferred following the issuance of a Notice of Intended Enforcement (NOIE), or a suspension is held in abeyance, IPP are to verify that the establishment implements its corrective actions, and that the corrective actions are effective.

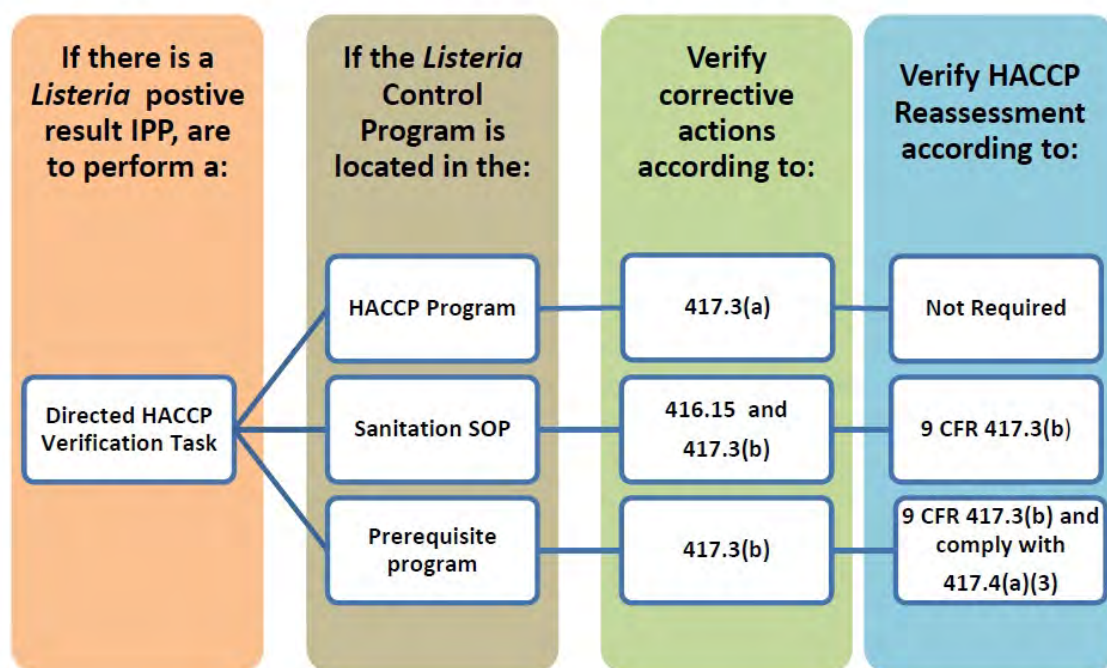
IPP are to verify that the establishment reassessed its HACCP plan as follows:

- If *Lm* control is addressed as a CCP in the HACCP plan (e.g., PLT), the establishment must meet the requirements of 9 CFR 417.3(a), which requires that corrective action be taken but does not require reassessment of the HACCP plan.
- If *Lm* is addressed in the Sanitation SOP, then the establishment must implement corrective actions in accordance with 9 CFR 417.3(b), which includes reassessment of the HACCP plan. In addition, it must implement the corrective action requirements for the Sanitation SOP in 9 CFR 416.15, which includes appropriate re-evaluation or modification of the Sanitation SOP.

- If *Lm* is addressed in a prerequisite program (e.g., *Listeria* Control Program) that is used to support the decision that *Lm* is not a hazard reasonably likely to occur in the product, then the establishment must implement the corrective actions in 9 CFR 417.3(b) and comply with 417.4(a)(3). These regulations state that when there is a change in the process (e.g., a positive result) that could impact the hazard analysis, a reassessment must be performed.

The establishment is required under 9 CFR 417.4 (a)(3)(ii) to make a record of the reassessment and document the reasons for any changes that it made to its HACCP plan based on the reassessment, or, if it did not make any changes, to document the reasons that it did not.

Steps for Verifying an Establishment's Corrective Actions



Verifying Product Disposition

The establishment may reprocess or dispose of adulterated product. If the establishment reprocesses the product, IPP are to verify that it used a process that achieves adequate lethality of pathogens. FSIS considers a process that has been validated to achieve a 5-log reduction of *Lm* sufficient for reworking contaminated product.

In addition, establishments may use Appendix A and Appendix B of the final rule, "Performance Standards for the Production of Certain Meat and Poultry Products," FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks, and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, or other supportable processes to reprocess *Lm*-positive product.

NOTE: Appendix A and B, the FSIS Guidance on Safe Cooking of Non-intact Meat Chops, Roasts, and Steaks, and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, are designed to achieve reductions in *Salmonella*. Establishments are not expected to validate that these processes also achieve reductions in *Lm* because *Salmonella* is considered an indicator of lethality for *Lm*.

If the establishment chooses to dispose of the product, it may do so either on-site or off-site. If the product is disposed of on-site, IPP are to verify that the establishment maintained records showing that the positive product received the proper disposition.

If the establishment transports positive product to another site for appropriate disposition, IPP are to verify that the establishment has met all corrective action requirements by verifying that the establishment:

- Maintained records identifying the official establishment, renderer, or landfill operation that received positive product;
- Maintained control of product that was destined for a landfill operation or renderer while the product was in transit (e.g., through company seals);
- Maintained control of product that was destined for an official establishment while the product was in transit (e.g., through company seals) or ensured that such product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);
- Maintained records showing that positive product received the proper disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred; and
- Completed pre-shipment review for the positive product only after it has received the records described above for that particular product.

If an establishment ships adulterated product to a renderer or landfill operation, IPP are to verify the establishment denatures the product before the product leaves the establishment (9 CFR 314). In situations where the establishment has not properly moved or disposed of the product, IPP are to notify their DO through supervisory channels.

If IPP find that there is noncompliance with the corrective action requirements for product disposal, they are to document the noncompliance in accordance with FSIS PHIS Directive 5000.1.

Labeling

Objectives

After completing this module, the student will be able to:

1. Define the following terms:
 - Immediate container
 - Label
 - Principal display panel
 - Generic labeling
 - Sketch labeling
 - Shipping container
2. Identify the eight mandatory features of an immediate container label.
3. Describe the regulatory requirements for each of the mandatory features.
4. Identify the mandatory features that must be shown on shipping containers.
5. Identify the two types of labeling approvals granted by the Labeling and Program Delivery Staff (LPDS).
6. Identify the product name labeling requirements for raw meat and poultry products that contain added solutions.
7. Identify the product name and cooking instruction labeling requirements for mechanically tenderized raw beef products.
8. Describe the recordkeeping requirements for labels.
9. Identify the requirements for transferring labels.
10. Describe how to perform the General Labeling inspection task.
11. Given an example label, verify that the labeling regulatory requirements are met.

Regulatory Authority

Containers or packages of inspected and passed meat and poultry products must bear a label or other labeling when shipped from official establishments. The Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA) give FSIS authority to maintain a labeling approval program. Before a label or other labeling can be applied to Federal and State inspected meat and poultry products, it must comply with labeling requirements. In certain cases, labels must be sketch approved by the Labeling and Program Delivery Staff (LPDS) prior to use, however only some types of labels must be submitted to LPDS for approval.

The prior approval program benefits both consumers and the regulated industry. Consumers receive products that have informative labeling that is not false or misleading. Unfair competitive advantages are prevented because all establishments

under State and Federal inspection must comply with the same label requirements and standards.

Labeling means all labels and other written, printed, or graphic matter (1) upon any product or any of its containers or wrappers, or (2) accompanying the product. Official marks and other markings are considered labeling. Certain labeling, such as labels bearing no special statement or claims, is given generic approval, and may be used by the establishment without FSIS authorization. Other types of labeling, such as labels for temporary approval and labels bearing certain special statements or claims must be submitted to LPDS for review and approval. Some labeling after sketch approval can be modified and the establishment can treat them as generic labels. The establishment is fully accountable for the content and production of all labeling, whether generically approved or submitted to FSIS for review and approval.

Mandatory information must be prominently shown on labels attached to immediate containers. This information must accurately describe the enclosed product.

When IPPs perform the General Labeling inspection task, they will verify that the label is approved, contains the mandatory information, and accurately reflects the product. This module will familiarize IPPs with labeling regulatory requirements that official establishments must meet.

Labeling Regulatory Requirements

Labeling regulatory requirements for meat products appear in Part 317—Labeling, Marking Devices, and Containers. Labeling regulatory requirements for poultry products appear in Part 381—Poultry Products Inspection Regulations, Subpart N—Labeling and Containers. This segment of the module will specifically address the requirements in Subpart A of Part 317 of the regulations. The section of the poultry inspection regulations that references the same or similar requirements is identified in brackets at the end of pertinent paragraphs.

§317.1—Labels required; supervision by program employee.

*§317.1(a)—When, in an official establishment, any inspected and passed product is placed in any receptacle or covering constituting an **immediate container**, there shall be affixed to such container a **label** as described in §317.2 [§381.115]*

§301.2 identifies an **immediate container** as the receptacle or other covering in which any product is directly contained or wholly or partially enclosed.

Products, such as whole or half carcasses or carcass parts, bearing the required, legible marks of inspection may be removed from the official establishment without further restriction. Once an official establishment places any inspected and passed product into any receptacle (carton, box, etc.) or covering (wrapper, plastic bag, etc.) constituting an immediate container, a *label* that complies with the regulations, must be affixed to it prior to it leaving the establishment.

Some coverings or immediate containers do not have to have a label affixed to them. These exceptions are identified in §317.1(a)(1) through (6). For example, properly marked products enclosed in uncolored, transparent coverings, such as cellophane, do not have to be labeled if the markings are clearly legible through the covering. The coverings cannot have any printed or graphic material on them.

Note: §301.2 identifies a **shipping container** as the outside container (box, bag barrel, crate or other receptacle) containing or wholly or partly enclosing any product packed in one or more immediate containers. In some cases, the shipping container becomes the immediate container (e.g., when product units are bulk packed and not individually wrapped and labeled) and must then bear a label with all the required features.

*§317.1(b)—Folders and similar coverings made of paper or similar materials, whether or not they completely enclose the product, and which bear any written, printed, or graphic matter, shall bear **all features** required on a label for an immediate container.*

Paper, or similar covering, that has any written, printed, or graphic material must bear all the mandatory features required on an immediate container label. This is true even if the covering only partly encases product.

§317.1(c)—No covering or other container which bears or is to bear a label shall be filled, in whole or in part, except with product which has been inspected and passed in compliance with the regulations in this subchapter, which is not adulterated, and which is strictly in accordance with the statements on the label. No such container shall be filled, in whole or in part, and no label shall be affixed thereto, except under supervision of a Program employee. [§381.136]

Only inspected and passed product that meets all regulatory requirements, is unadulterated, and has an accurate label may be packaged. Packaging and labeling operations can only be performed under the supervision of an IPP. Under the supervision of the IPP only means that he or she is on duty. The IPP **does not** need to **continually oversee** the filling and labeling of packages or containers.

§317.2—Labels: definition; required features.

Label Definition

§317.2(a)—A **label** within the meaning of this part shall mean a display of any printing, lithographing, embossing, stickers, seals, or other written, printed, or graphic matter upon the **immediate container** (not including package liners) of any product.

Placement of Mandatory Label Information

§317.2(b)—Any word, statement, or other information required by this part to appear on the label must be prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. [§381.116(a)]

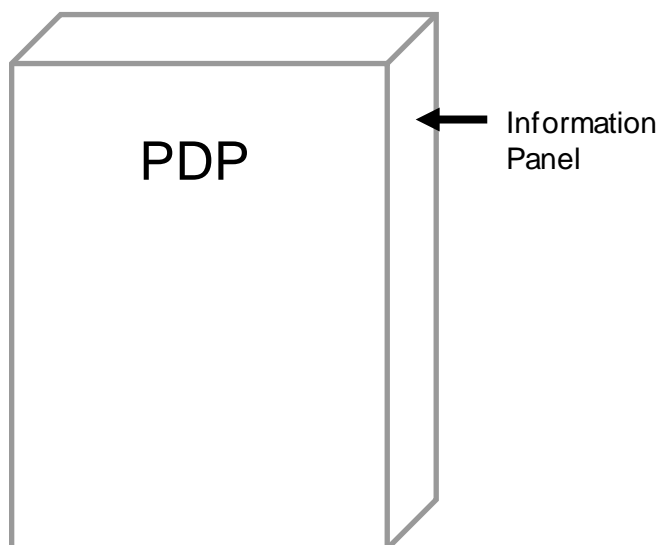
All mandatory information must appear on the label's **principal display panel**, except as otherwise permitted in 9 CFR 317.2 and 9 CFR 381.116. Except for products exported to foreign countries or distributed solely to Puerto Rico, the required information **must be** printed in the **English** language.

§317.2(d)—The **principal display panel** shall be the part of the label that is most likely to be displayed, presented, shown, or examined under customary conditions of display for sale...The principal display shall be large enough to accommodate all of the **mandatory label information** required to be placed thereon...with clarity and conspicuousness and without obscuring of such information by designs or vignettes or crowding. [§381.116(b)]

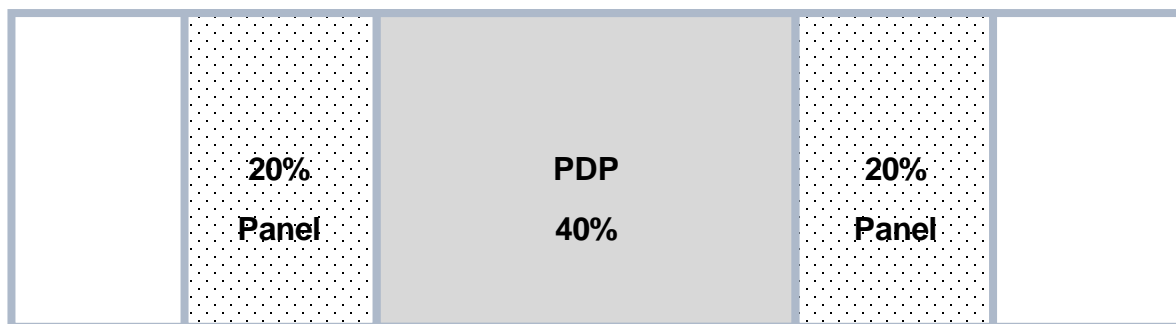
Principal display panels have specific size requirements to accommodate the mandatory information (features). The size requirements for the principal display panel for the various shapes of containers or packages are identified in §317.2(d)(1) through (3) and 381.116(b)(1) through (3).

Additional panels where certain mandatory label information may be shown in lieu of showing it on the principal display panel are identified in 9 CFR 317.2 and 9 CFR 381.116. For example, the ingredients statement, signature line, and/or nutritional facts may be placed together to form the information panel. Certain mandatory features may also be displayed on the front riser panel of a frozen food cartons and the 20% panel of a cylindrical container.

Information Panel

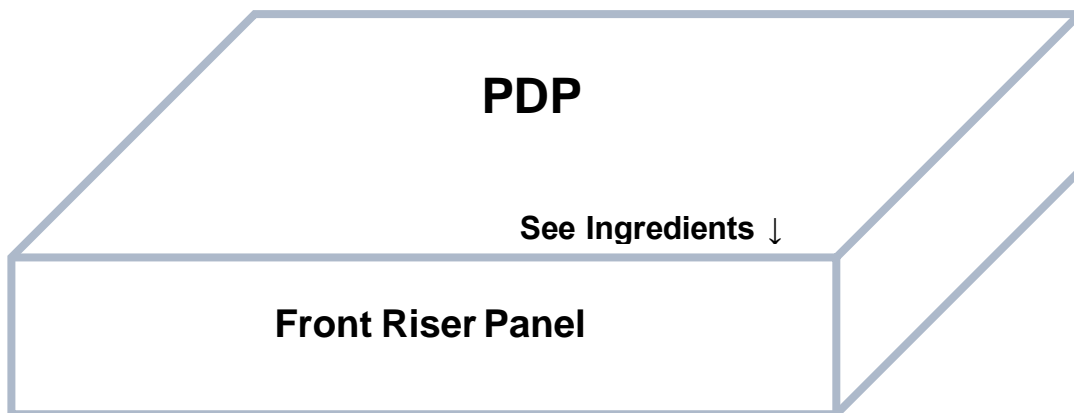


20% Panel on a Cylindrical Container



Either to the left or right of the PDP

Front Riser Panel



Mandatory Features of a Label

Up to eight features may be required on an **immediate container** label. The eight mandatory features are identified in the table in Attachment 1.

- **Name of the Product**

§317.2(c)(1)—The name of the product, which in the case of a product which purports to be or is represented as a product which a definition and standard of identity or composition is prescribed in part 319...shall be the name of the food specified in the standard, and in the case of any other product shall be the common or usual name of the food, if any there be, and if there is none, a truthful descriptive designation as prescribe in paragraph (e) of this section... [§381.117(a)]

Fresh pork sausage (§319.141), Italian sausage (§319.145) and frankfurters (319.180(a)) are examples of products that have standards of identity we have covered in this course. Ground beef is another meat product that has a standard of identity (§319.15(a)). Pork Shoulder and Beef Rib Eye Steak are common and usual names. "Sloppy Joe" is a fanciful name and must be qualified with the descriptive name "barbecue sauce with (species)".

Product names must be prominently shown on the principal display panel.

Validated Cooking Instructions would address:

- A cooking method, (e.g., grill or bake)
- That these products need to be cooked to a specified minimum internal temperature,
- Whether these products need to be held for a specified time at that temperature or higher before consumption, i.e., dwell time or rest time, to ensure that potential pathogens are destroyed throughout the product, and
- A statement that the internal temperature should be measured by a thermometer.

Cooking Instruction Example:

For Food Safety and Quality Follow These Cooking Instructions:

Gas Grill:

1) Heat gas grill on Medium-High.

2) Cook for 6 minutes to an internal temperature of 145°F as measured with a food thermometer. Flip steak over at least twice during cooking.

3) After removing from the gas grill, for safety, allow meat to rest at or above 145° F internal temperature for at least three minutes before serving.

Note: Cooking instructions may not be the same as these; however, the instructions should provide the preparer with clear instructions to get to the necessary end point temperature.

To assist industry develop validated cooking instructions the FSIS published the **FSIS Compliance Guideline for Validating Cooking Instructions for Mechanically Tenderized Beef Products**. The guideline is available on the internet.

- **Ingredients Statement (if needed)**

§317.2(c)(2)—If a product is fabricated from two or more ingredients, the word "ingredients" followed by a list of ingredients as prescribed in paragraph (f) of this section...

[§381.118(a)]

The word “ingredients” must be spelled out, never abbreviated. The ingredients must be listed by their common and usual name in descending order of predominance according to the amounts used in the product’s preparation. There are a few exceptions.

Spices (e.g., mustard, pepper, etc.) and flavorings (e.g., oleoresin of black pepper, garlic oil, etc.) as defined in §317.2(f)(i) may be listed as “spice” or “flavoring” as appropriate in the ingredients statement. For instance, spices, spice extractives, essential oils, oleoresins, onion powder, garlic powder, celery powder, onion juice, and garlic juice may be listed as flavorings but flavorings (e.g., oleoresins, essential oils, etc.) cannot be listed as spices in the ingredients statement.

Ingredients present in individual amounts of 2% or less may be listed in other than descending order of predominance if:

- Such ingredients are listed by their common or usual name at the end of the ingredients statement; *and*
- Such ingredients are preceded by a quantifying statement such as "contains ____ percent of ____," or "less than ____ percent of ____." The blank before the word "percent" shall be filled with a threshold level of 2% (or less, as appropriate, e.g., 1.5%, 1%, or 0.5%). No ingredient subject to the quantifying statement may be present in an amount greater than the stated threshold. Such ingredients may be adjusted in the formulation without changing the label if the adjusted amount complies with §318.7(c)(4) or §381.147(f)(4) and does not exceed the stated threshold level.

The ingredient statement must be located on either the principal display panel, information panel, 20% panel of a cylindrical container, or the front riser panel of a frozen food carton.

Note: For some products, an ingredients statement can be substituted with a “Cured with statement.” The label states “Cured with water, salt, sodium phosphate.....” The meat is left out and just includes all the other ingredients. We see this with bacon, corned beef, ham, and other cured products.

- *Signature Line*

§317.2(c)(3)—*The name and place of business of the manufacturer, packer, or distributor for whom the product is prepared, as prescribed in paragraph (g) of this section...*
[§381.122]

The name and place of business of the product’s manufacturer, packer, or distributor is known as the signature line. The place of business shall be shown on the label by city, state, and zip code when the business is listed in a telephone or city directory; and if not listed in such a directory, the place of business shall also show the street address. **The signature line must be located on either the principal display panel, information panel, 20% panel of a cylindrical container, or the front riser panel of a frozen food carton.** When the product is prepared by one company and distributed by a different company, phrases like “prepared for...” or “distributed by” must precede the name and business address.

- **Net weight statement (if needed).**

§317.2(c)(4)—*An accurate statement of the net quantity of contents as prescribed in paragraph (h) of this section...*[§381.121(a)]

As stated in §317.2(h)(1) through (5), the net weight statement must:

- **Appear on the principal display panel** in a conspicuous and easily legible boldface print or type in distinct contrast to other material on the container.
- Not be false or misleading and shall express an accurate statement of the quantity of contents exclusive of wrappers and packing materials. The term "Net Weight" or "Net Wt." refers to contents in terms of weight. "Net Content" refers to fluid measure.
- Appear in the lower 30 percent portion of the principal display panel, unless otherwise exempt in the regulations. §317.2(h)(3)
- Be expressed in terms of Avoirdupois weight (US system) or liquid measure. Per §317.2(h)(4), a $\frac{3}{4}$ pound retail package would be labeled “Net Wt. 12 oz.”. Retail packages containing one pound and less than four pounds are required to declare the net weight statement in *both* pounds and ounces (dual declaration), for example, “Net Wt. 24 oz (1 lb. 8 oz).” per §317.2(h)(5).

The net weight statement has a size and a spacing requirement as specified in §317.2(h)(6) through (8). §317.2(h)(9) identifies several exemptions from the requirements for the net weight statement. A net weight statement is not required for bulk containers or wholesale (non-retail/consumer size) product, such as combo bins of product for further processing. However, if a net weight statement *is* on the bulk container it must be on the principal display panel and accurately represent net quantity of contents. Individual catch weight or random weight items are not required to have a net weight statement. However, the shipping container for these products must bear a net weight statement [317.2(h)(9)(i)]. Sliced shingle packaged bacon in rectangular containers is exempt from the placement and dual declaration requirements.

Note: Net weight may also appear in grams (g) on the label. Declaring net weight in grams does not remove other net weight requirements, and an optional net weight expressed in grams may not interfere with other net weight requirements.

- **Inspection Legend and Establishment Number**

§317.2(c)(5)—An official inspection legend and...the number of the official establishment...[§381.123(a)(b)]

Labels on all products shall show an official inspection legend as illustrated in §312.2, §352.7, or §381.96 of the regulations. The inspection legend shall be in the exact form and arrangement as shown in the examples. It may be of any size, provided it is sufficient, and any color as long as it is conspicuous and readily legible. The proportions of letter size and boldness must be as illustrated in the regulations. **The legend must be located on the principal display panel or on the 20% panel of a cylindrical container.**

As stated in §317.2(i), the establishment number may be located inside or outside of the inspection legend. The establishment number may be located anywhere on the exterior of the container or its labeling; for example, it may be located on the end of a can if it is prominent, legible, and accompanied by the prefix “Est”. The establishment number may be located off the exterior of the container when there is a statement identifying the location of the number; for example, "Est. No. on clip" is printed on a bag containing product.

- **Handling Statement (if needed)**

§317.2(k)—Packaged products which require any special handling to maintain their wholesome condition shall have prominently displayed on the principal display panel of the label the statement: [§381.125(a)]

- *Keep Refrigerated.*
- *Keep Frozen.*

- *Perishable Keep Refrigerated.*
- Previously handled frozen for your protection. Refreeze or Keep Refrigerated.

Note: Except for canned perishable products (e.g., canned hams), there are no type or print size specifications for the handling statement.

- Safe handling instructions (if needed)

§317.2(l)—Safe handling instructions shall be provided for: all meat and meat products...that do not meet the requirements contained in §318.17, or that have not undergone other processing that would render them ready-to-eat; and all comminuted meat patties not heat processed in a manner that conforms to the time and temperature combinations in the Table for Permitted Heat-Processing Temperature/Time Combinations for Fully Cooked Patties in §318.23 [§381.125(b)].

As described in §317.2(l)(1), the instructions are required to be prominently and conspicuously displayed on products (described above) destined for household consumers, hotels, restaurants, and institutions (HRI). Lettering must be no smaller than 1/16 inch, set off by a border, all in one color on a single-color contrasting background. The heading, “Safe Handling Instructions,” must be in larger print than the rationale statement and the safe handling statements. The rationale statement identified in §317.2(l)(2) must be immediately after the heading and before the safe handling statements. The specific safe handling statements that must appear as part of the product’s labeling are identified in §317.2(l)(3). Each statement must have the graphical illustration beside it.

Product that will be further processed at another official establishment is exempt from the safe handling requirements.

The safe handling instructions may be located anywhere on the outside of an immediate container.

- **Nutrition Facts Panel (unless an exemption applies)**

§317.300—(a) Nutrition labeling must be provided for all meat and meat food products intended for human consumption and offered for sale, except single-ingredient, raw meat products that are not ground or chopped meat products described in §317.301 and are not major cuts of single-ingredient, raw meat products identified in §317.344, unless the product is exempted under §317.400. Nutrition labeling must be provided for the major cuts of single-ingredient, raw meat products identified in §317.344, either in accordance with the provisions of §317.309 for nutrition labels, or in accordance with the provisions of §317.345 for point-of-purchase materials, except as exempted under §317.400. For all other products

for which nutrition labeling is required, including ground, or chopped meat products described in §317.301, nutrition labeling must be provided in accordance with the provisions of §317.309; except as exempted under §317.400.

FSIS requires nutrition labeling of the top 40 major cuts of single-ingredient, raw meat, and poultry products (as defined in §317.344 and §381.444). This nutrition labeling must be on labels or at point-of-purchase, unless an exemption applies, however, the small business exemption specifically is not applicable to these cuts. FSIS also requires nutrition labels on all ground or chopped meat and poultry products as defined in §317.301 and §381.401 respectively, with or without added seasonings, unless an exemption applies. In addition, when a ground or chopped product does not meet the regulatory criteria to be labeled "low fat" (317.362(b)), a lean percentage statement may be included on the label or in labeling as long as a statement of the fat percentage that meets the specified criteria also is displayed on the label or in labeling when in compliance with §317.362(f) or §381.462(f). Note: Ground and chopped product does not include products such as sausage, meatballs, beef patties. The "ground/chopped" products only includes products named "ground beef," "hamburger," "ground pork," "ground chicken," "ground turkey," "chopped beef," etc.

The format of the nutrition panel shall be in accordance with §317 Subpart B. These regulations also prescribe the standard serving size, which nutrients are mandatory to list, and which are voluntary to list. Additionally, the other nutritional information regulations specify requirements to be met before any nutritional claims, such as "light," may be made on the label. [§381 Subpart Y or 381.409]

Nutrition labeling information may be shown on the principal display panel, on the information panel, or anywhere on the immediate container. There are exceptions for gift packs or when packaging does not allow for sufficient space (§317.302 or §381.402).

Establishments may voluntarily provide nutrition labeling for single ingredient, raw meat and poultry products that are not one of the top 40 major cuts and are encouraged to do so.

The regulations in §317.302 exempt products produced by small businesses, provided that the labels for these products bear no nutrition claims or nutrition information. There are two criteria for exemption, 1) less than 500 employees AND 2) less than 100,000 pounds of a specific product formula/nutrition profile per year. When calculating the total pounds of a formula, both retail and custom exempt with all pack sizes are included. For example, an establishment has a ground beef 70/30 formula. This formula is sold in bulk, as patties, in various retail sized packages, under various brand names, for HRI, some retail exempt, and some as custom exempt. All of this ground beef 70/30 is counted together for the total pounds per year. Each specific product formula/nutrition profile will need to be evaluated for the small business exemption and both criteria need to be met for that product labeling

to be exempt from bearing the nutrition facts panel. It is possible for popular products manufactured in quantities larger than 100,000 pounds per year to be exempt but other products with production lower than 100,000 pounds per year to be exempt even though they are manufactured in the same establishment.

The establishment has the responsibility to determine whether a product is exempted from the nutrition labeling requirements. The IPP should ensure that all products, except those identified by the establishment as exempted, carry the "Nutrition Facts" panel on the label. Guidelines for enforcing nutrition labeling of meat and poultry products can be found in FSIS Directives 7130.1 and 7221.1.

Date of Packing/Processing

Two types of product dating may be shown on a product label. "Closed Dating" and "Open Dating."

Packing codes are a type of closed dating which enable the tracking of product in interstate commerce. These codes consist of a series of letters and/or numbers applied by manufacturers to identify the date and time of production. They enable manufacturers to rotate their stock and locate their products in the event of a recall. The codes are not meant for the consumer to interpret as a best or peak quality date.

A calendar date applied to a food product by the manufacturer or retailer is a type of open dating. The calendar date provides consumers with information on the estimated period of time for which the product will be of best quality and to help the store determine how long to display the product for sale. For meat, poultry, and egg products under the jurisdiction of the Food Safety and Inspection Service (FSIS), dates may be voluntarily applied provided they are labeled in a manner that is truthful and not misleading and in compliance with FSIS regulations. If calendar dating is used, the requirements of §317.8(b)(32) and 381.129(c)(1)(2) must be met. The calendar date must express both the month and day of the month. In the case of shelf-stable and frozen products, the year must also be displayed. Additionally, immediately adjacent to the date must be a phrase explaining the meaning of that date such as "Packing", "Sell By", "Use Before" or "Best if Used By."

Mandatory Features for Shipping Containers

Shipping containers must bear the following mandatory features:

- Inspection legend [316.13(a)] and establishment number [317.2(i)]
- Handling statement (if needed) [317.2(k)]
- Net weight statement (if needed) [317.2(h)(9)(i)]

The establishment number may be located outside the inspection legend or elsewhere on the exterior of the container or its labeling if shown in a prominent and legible manner in a size sufficient to ensure easy visibility and recognition and accompanied by the prefix "EST."

Note: The shipping container must bear a *net weight* statement per 381.121(a) and the following statements: "*Tare weight* of consumer package ____ oz." (weighed to nearest 1/8 ounce or less), and the "Net wt." to be marked on consumer packages prior to display and sale" when **retail random weight poultry products** without the *net weight* statement are in the shipping container.

§412.1—Labeling approval.

§412.1(a)---No final label may be used on any product unless the label has been submitted for approval to the FSIS Labeling and Program Delivery Staff, accompanied by FSIS Form 7234-1, Application for Approval of Labels, Marking, and Devices, and approved by such staff, except for generically approved labels authorized for use in §412.2. The management of the official establishment or establishment certified under a foreign inspection system, in accordance with parts 327 and 381, subpart T, must maintain a copy of all labels used, in accordance with parts 320 and 381, subpart Q, of this chapter. Such records must be made available to any duly authorized representative of the Secretary upon request.

No final labeling shall be used on any product unless the sketch labeling of such final labeling has been submitted for approval to FSIS except for generically approved labels authorized for use in 9 CFR 412.2. A sketch label is a printer's proof or the equivalent which clearly shows all labeling features, including the size, and location.

FSIS requires the submission of labeling applications for the following four categories:

1. Labels for products produced under religious exemption (9 CFR 412.1(c)(1))
2. Labels for products for export with labeling deviations other than foreign language on the label or net weight in accordance with the usage of the country to which the product is exported (9 CFR 412.1(c)(2))
3. Labels with special statements and claims (9 CFR 412.1(c)(3))
4. Labels for temporary approval (9 CFR 412.1(c)(4)). Under certain conditions, LPDS may grant a temporary approval for the use of a final label that may be deficient in some particular for up to 180 calendar days

Any label that was previously approved as a sketch by FSIS qualifies to be used without any further approval.

"Special statements and claims" are claims, logos, trademarks, and other symbols on labels that are not defined in the Federal meat and poultry products inspection regulations or the

Food Standards and Labeling Policy Book, (except for “natural” and negative claims (e.g., “gluten free”)), health claims, ingredient and processing method claims (e.g., high-pressure processing), structure-function claims, claims regarding the raising of animals, organic claims, and instructional or disclaimer statements concerning pathogens (e.g., “for cooking only” or “not tested for E. coli O157:H7”). Examples of logos and symbols include graphic representations of hearts and geographic landmarks. Special statements and claims do not include allergen statements (e.g., “contains soy”) applied in accordance with the Food Allergen Labeling and Consumer Protection Act.

A parent company for a corporation may submit only one labeling application for a product produced in other establishments that are owned by the corporation. Establishments must maintain records to support the use of labeling on meat and poultry products. These records must be available to IPPs upon request. A company that has multiple establishments may keep the labeling file at corporate headquarters.

When LPDS approves a label or other labeling as a sketch, the label application is electronically stamped in the Label Submission and Approval System (LSAS) to indicate approval. The sketch may be modified by LPDS prior to approval to meet a labeling requirement. This sketch label will be stamped with “approved as modified”. Once a label has been approved, approved as modified, or returned in LSAS; the submitter is notified via email. If the establishment submitted a paper copy of the label to LPDS, this paper copy is scanned into LSAS for review, and a hard copy is printed out and mailed back to the submitted once the label has been evaluated in LSAS.

The requirements for generically approved labels are covered in §412.2. IPP do not generically approve labels. Establishments do not generically approve labels. Generically approved labels are approved by FSIS provided that the label meets the criteria listed in §412.2(b). “Approved by FSIS” refers to compliance with the FSIS 9 CFR regulations, it does not mean that the labels have been submitted to Labeling and Program Delivery Staff (LPDS).

All labels that do not fit into one of the four categories (above) described in §412.1, except for egg product labels and exotic species labels, are eligible for generic approval. Some labels eligible for generic approval based on the regulations include labeling for:

- Geographic claims such as “German Brand Made in the US” in compliance with §317.8(b)(1).
- Allergen statements (e.g., “contains soy”) applied in accordance with the Food Allergen Labeling and Consumer Protection Act (FDA).
- Labels that bear claims and statements that are defined in FSIS regulations or the Food Standards and Labeling Policy Book (*except for natural and negative claims*).

The responsibility of ensuring that generic labeling complies with regulatory requirements rests

with the establishment. The establishment is responsible for creating the generic labeling record and is required to keep a copy of all generic labeling and related information in its files. A corporate headquarters may create and maintain the labeling files for their associated establishments. When labeling records are needed, the IPP may request the labeling records from the assigned establishment. The labeling records are required to be made available to the requesting IPP within 24 hours (FSIS Directive 7221.1).

There is no specific format for a generic labeling record, however, it is required to include all information in FSIS Form 7234-1 that would be provided to LPDS as if they were submitting for sketch approval. Some establishments choose to use the FSIS 7234-1 form since they are familiar with the form and it is a reminder of what information is needed in the labeling record, but they could provide all required information in another format. The labeling record should also include the final printed labeling that will be used on the finished packaged product and any supporting information that may be needed to verify that labeling is truthful and not misleading. Some companies choose to number their generic approvals to track them internally, but there is no FSIS requirement to do so.

Note: The establishment's product formulations and other proprietary information should not be in IPP files or in the IPP possession except when he or she is performing an inspection task related to the product's formulation.

§317.8—False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

§317.8(a)—No product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling. No product shall be wholly or partly enclosed in any wrapper, packaging, or other container that is so made, formed, or filled as to be misleading. [§381.129(a)(b)]

The product or its packaging material may not bear any false or misleading label, marking, or labeling. No written or graphic material on the product label or in its marking or labeling may convey a false impression or give a false indication of contents. A product's packaging material color, design or kind may not be misleading. Product that bears false or misleading marking or labeling is misbranded.

§317.24—Packaging materials.

§317.24(a)—Edible products may not be packaged in a container which is composed in whole or in part of any poisonous or deleterious substances which may render the contents adulterated or injurious to health. All packaging materials must be safe for their intended use within the

meaning of section 409 of the Federal Food, Drug, and Cosmetic Act, as amended (FFDCA). [§381.144(a)]

Part 442—Quantity of Contents Labeling and Procedures and Requirements for Accurate Weights.

§442.1—This part prescribes the procedures to be followed for determining net weight compliance and prescribe the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with 9 CFR 317.2(c)(4), 317.2(h), and 381.121.

NFSCP PHIS Task

Performing the General Labeling Task

Inspection program personnel perform this task to verify general labeling regulatory requirements and determine if the label accurately reflects the finished product.

- **General Labeling Requirements**

Verifying that the general labeling requirements involves:

- *observing the application of the label or labeling,*
- *selecting labels and labeling for review, and*
- *reviewing the establishment's labeling records*

When IPP observe the packaging and labeling operations, they ensure that immediate containers of meat and poultry products have a label attached to them and that shipping containers bear the required information.

When IPP select and review the label/labeling applied to the container or package, they determine if:

- *the label contains the mandatory features and other required information such as a qualifying statement or descriptive designation, and*
- *any printing or colors on the label and packaging material gives a false impression or does not meet specific formatting criteria*

Product is misbranded if its label is missing a required feature, qualifying statement, or descriptive designation or is anyway false or misleading.

When IPP review the establishment's labeling file, they determine if the:

- *label is on file and either met the generic approval requirements or was sketch approved by LPDS,*

- label required sketch approval by LPDS and if so, the sketch is attached to the final label,
- label is being used beyond the expiration date if it has been granted a temporary approval by LPDS, and
- product's formulation (if applicable) and processing procedures are attached to or accompany the label/labeling.

If IPP find noncompliance, they issue an NR and take the appropriate action necessary to ensure misbranded product does not enter commerce.

- **Label Accurately Reflects the Product**

Determining that the label accurately reflects the finished product involves reviewing the product's formulation record and observing its actual preparation and, in some cases, performing formula calculations.

When IPP perform this task, they should select one or more batches of product at formulation and verify ingredient amounts comply with the formula on file and that no undeclared ingredients are added or declared ingredients are omitted.

The verification may involve:

- observing pre-weighed ingredients for proper identification and weights, or
- observing establishment employees weighing ingredients or
- actually, weighing pre-weighed ingredients to determine if the weight on the container is accurate.

An ingredient added at a different level than indicated in the product formula could affect the ingredient order of predominance on the label. The product is misbranded if a declared ingredient is omitted, an ingredient is added but not declared on the label, or the ingredient order of predominance is not accurate. Depending on the type of undeclared ingredient (e.g., an allergen) that is added to the product, it may be either adulterated or misbranded or both.

The regulations and many product standards of identity allow the establishment to add various ingredients to the formulae of certain meat and poultry products.

Some meat and poultry components used in the formulation may have regulatory limits. Some nonmeat ingredients have a specified maximum amount or percentage allowed in the product. These nonmeat ingredients are called **restricted** ingredients. The establishment **MAY** add the component or ingredient in any amount up to its permitted limit.

If the product is formulated with a meat or poultry component with a regulatory limit or with a restricted ingredient, the IPP should select one or more batches of product during

formulation. They should determine the amount or percentage of the meat or poultry component and/or the amount one or more restricted ingredients used in the formula. The IPP verifies that the:

- percentage of meat or poultry component meets the regulatory limit,
- restricted ingredient is allowed in the product, and
- the amount of the restricted ingredient added to the product does not exceed the regulatory limit.

Verifying meat and poultry components or restricted ingredients are in compliance with regulatory limits usually requires the IPP to perform a formula calculation.

When meat or poultry components or restricted ingredients are added at levels in excess of their maximum regulatory limit, they become **economic adulterants**.

If IPP find noncompliance, they issue an NR and take the appropriate action necessary to ensure adulterated or misbranded product does not enter commerce.

Attachment 1: FSIS Directive 7221.1 Table 1 Required Label Features

Feature	Reference	Location	Applies to
Product Name	9 CFR 317.2(c)(1) or 381.117	Principal display panel	All products
Inspection Legend and Establishment Number*	9 CFR 317.2(c)(5) or 381.123	Principal display panel, or 20% panel of a cylindrical container	All products
Handling Statement (e.g., "Keep Frozen")	9 CFR 317.2(k) or 381.125(a)	Principal display panel	Products requiring special handling to maintain wholesomeness
Net Weight Statement	9 CFR 317.2(h) or 381.121	Principal display panel	Product sold at retail, unless the net weight is applied at retail
Ingredients Statement**	9 CFR 317.2(f) or 381.118	Principal display panel, Information panel, 20% panel of a cylindrical container, or Front riser panel of a frozen food carton	Products with multiple ingredients
Name and Place of Business of the Manufacturer, Packer, or Distributor	9 CFR 317.2(g) or 381.122	Principal display panel, Information panel, 20% panel of a cylindrical container, or Front riser panel of a frozen food carton	All products
Nutrition Facts Panel	by 9 CFR 317.300 or 381.400	Principal display panel or Information panel	Products not exempted by 9 CFR 317.400 or 381.500
Safe Handling Instructions	9 CFR 317.2(l) or 381.125(b)	Anywhere on the immediate container	Products with a not-ready-to-eat meat or poultry component

***NOTE:** As stated in §317.2(i), the establishment number may be located inside or outside of the inspection legend. The establishment number may be located anywhere on the exterior of the container or its labeling; for example, it may be located on the end of a can if it is prominent, legible, and accompanied by the prefix "Est". The establishment number may be located off the exterior of the container when there is a statement identifying the location of the number; for example, "Est. No. on clip" is printed on a bag containing product.

****NOTE:** All ingredients used in the product must be listed in the ingredients statement. Product is considered adulterated if an allergen is not listed in the ingredients statement. IPP are to contact their supervisor for guidance if at any time they have reason to believe that product failing to declare one of the “big 8” allergens [wheat, crustacean shellfish (e.g., crab, lobster, shrimp), eggs, fish, peanuts, milk, tree nuts (e.g., almonds, pecans, walnuts), and soybeans] or other ingredients of public health concern has entered commerce. FSIS ingredient and allergen compliance guidelines are available online.

Net Weight Verification Task

Introduction

Meat and poultry establishments must assure that the net weight statement on a label is not false or misleading and expresses an **accurate** statement of the quantity of contents. Since absolute accuracy is virtually impossible, FSIS net weight regulations allow “reasonable” variations from labeled weight.

Section 9 CFR 442.1 prescribes the procedures to be followed for determining net weight compliance and prescribes the reasonable variations from the declared net weight on the labels of immediate containers of products in accordance with 9 CFR 317.2(c)(4), 317.2(h) and 381.121.

FSIS uses the **NIST Handbook 44** and the **NIST Handbook 133** standards as the basis for verifying net weights. FSIS has incorporated, by reference, the appropriate NIST standards in the Federal meat and poultry inspection regulations. Note: The specific sections of NIST Handbook 133 identified in 9 CFR 442.2(b) are **Not** to be utilized when verifying FSIS product net weights as they are not incorporated by reference.

Terminology

Net weight -The weight of the packaged product remaining after the deduction for **tare** weight. It is the weight of the nutritious content in the container suitable for food.

Drained weight -The weight of the solids in the container when packed in non-nutritious media.

Tare weight -The weight of the container, box, wrapper, or other packaging material. It is always excluded from gross weight when determining the actual net weight.

Labeled weight - The net weight declared on the label.

Inspection lot - A collection of identically labeled packages or containers from the same production shift available for inspection at one time. The IPP determines the inspection lot. The inspection lot passes or fails as a result of net weight testing.

Standard weight packages - Packages or containers that contain a predetermined amount of product and have identical net weight declarations, e.g., the full net weight statement is pre-printed on labeling, such as, Net Wt. 12 oz.

Random weight packages - Packages or containers that contain a varying amount of product and will not have identical net weight declarations, e.g., each package is weighed, and the specific net weight is written into a printed open net weight statement, such as, Net Wt.

_____LBS, another example is when a scale generates an individual price/weight sticker to

Task Name	9 CFR References	FSIS Issuance References	Inspection Personnel Verification Activities
Labeling - Net Weights	9 CFR §442.1, §442.2, §442.3, §442.4, §442.5	NIST Handbook 133 NIST Handbook 44 * FSIS inspectors are to use these handbooks as the definitive references for determinations of net weight compliance. Sections identified in §442.2(b) of NIST HB133 should Not be used.	Select an appropriate retail- sized product and 1. Verify net weight regulatory requirements by reviewing establishment records and conducting net weight/drained weight, scale calibration, or tare weight checks. 2. Follow the QC program requirements after evaluating the program to ensure that following the program results in compliance with net weight regulatory requirements.

apply
to
the

package.

Net Weight Lot Inspection Verification Task

When IPP verify net weight compliance, they are to:

- Determine the inspection lot,
- Verify the scale regulatory requirements,
- Randomly collect a tare sample and determine the average tare weight,
- Randomly select sample units (packages or containers) from the inspection lot and weigh them,
- Determine the MAV, individual package errors, and total package error,
- Apply the decision criteria to determine net weight compliance, and
- Take appropriate action based on net weight testing results.

Directive 7000.1, *Verification of Non-Food Safety Consumer Protection Regulatory Requirements*, identifies the regulations, references, and verification activities for performing the Net Weight task.

Prior to performing a net weight verification activity, IPP should review the requirements in *NIST Handbook 44* and then will verify net weight following the procedures in *NIST Handbook 133*. IPP must ensure the scales are of sufficient size, solidly supported, level and accurate. The scales are to be certified by the state's or local government's weights and measures authority or from a registered or licensed individual at least once per calendar year. The valid certification is to be displayed on or near the scale.

Steps to Determine Net Weight

1. Determine the number of containers or packages in the inspection lot.

IPP should define which packages are to be tested as well as determine the size of the inspection lot. An *inspection lot* is defined as a collection of identically labeled packages or containers from the same production shift available for inspection at one time. Enforcement action can only be taken on the packages contained in the lot that has been defined.

Example: The inspection lot consists of 260 Standard Weight packages of beef ribeye steaks labeled with a net quantity of 16 oz. (1 lb.) from company lot ABC packaged on 1/2/2019.

NOTE: Lots may be made up of either standard or random weight packages. “**Standard packages**” are those with identical net content declarations such as containers of soda in 2 L bottles and 2.26 kg (5 lb.) packages of flour. “**Random packages**” are those with differing or no fixed pattern of weight, such as packages of meat, poultry, fish, or cheese.

2. Refer to second column of Table 2-2 Sampling Plans for Category B from NIST Handbook 133.

Table 2-2. Sampling Plans for Category B

(for Use in USDA-Inspected Meat and Poultry Plants Only)

1	2	3	4
Inspection Lot Size	Sample Size	Initial Tare Sample Size	Number of Packages Allowed to Exceed the MAVs in Table 2-9
250 or Fewer	10	2	0
251 or More	30	5	0

There are sampling plans that are used when inspecting packages:” Category A” and “Category B”. IPP should use “Category B” sampling plans only to test meat and poultry products that are subject to USDA/FSIS regulatory requirements at the point-of-pack locations.

IPP should use “Category A” sampling plan for all other packages. See Table 2-2 for Sampling Plans for Category B.

3. Record the inspection data.

All information collected should be recorded on an inspection form. There is no regulation or policy stating that there is a specific type of form that should be utilized to document the inspection data. However, there are two forms in the NIST Handbook 133, E2 and E3, or a personalized form that could be used. It may be more practical to write the information in a notebook vs a form. See **Attachment 2**.

IPP must become familiar with the required information needed to officially determine if net weight is in compliance. There are minimum requirements for the information that should be collected to verify net weight compliance. Each state may alter the forms slightly as long as the minimum NIST criteria are met. The IPP should attach any additional notes, worksheets, etc. as needed.

NOTE: When using the NIST form it would not be necessary to convert to dimensionless units in Boxes 15, 16, 17, & 18 if the weights are being verified in pounds. If you compare the FSIS form to the NIST form, the dimensionless units conversion and the information from blocks 20-24 have been deleted since they are not necessary.

Example: Alterations such as adding instructions is an acceptable amendment to the NIST forms or deleting the dimensionless unit’s conversion and the information from blocks 20-24, since they are not necessary.

4. Select the random sample.

Testing a “sample” of packages from a lot instead of every package in a shipment is efficient, but the test results have a “sampling variability” that must be corrected before determining if the lot passes or fails.

A randomly selected sample is necessary to ensure statistical validity and reliable data. This is accomplished by using random numbers to determine which packages are chosen for inspection. Improper collection of sample packages can lead to bias and unreliable results. Appendix B of NIST Handbook 133 provides Random Number Tables and describes various ways to use the tables to randomly select packages within the inspection lot.

5. Randomly collect a tare sample and determine the average tare weight.

- See Column 3 of NIST Handbook 133 Table 2-2 Sampling Plan for Category B to determine the Initial Tare Sample Size based on the Inspection Lot Size
- If available, unused dry packaging may be used to determine the tare weight
- When packages are opened to determine the tare weight, use the first 2 (or 5) randomly selected packages of the Inspection Lot in order that they were selected to determine the dry tare weight.

- Weigh each set of packaging materials in the tare sample
- Add the weights together
- Divide the total tare weight by the sets of packaging material in the tare sample

NOTE: When the average tare weight is exactly half of a scale division, round the value up to the next scale division (e.g. If the scale units are 1 gram and tare 1=19 g and tare 2=20 g, round the 19.5 g average up to 20g). Additional rounding examples are in **Attachment 1** at the end of the module.

6. Determine:

Nominal Gross Weight: Add the Average Tare Weight (as determined in step 5 above) to the labeled weight to determine the Nominal Gross Weight. Make sure you use the same units of measure for both values and that matches the units of measure of the scale being used.
 $(\text{average tare weight} + \text{labeled weight}) = \text{nominal gross weight}$

Package error: The difference between the gross weight (the weight of each individual sample package that includes the food product and the packaging weight) and the nominal gross weight.

$(\text{gross weight of the sample} - \text{nominal gross weight}) = \text{package error}$

-/+ Package error: When the nominal gross weight weighs more than the gross weight the sample package weighs more than what the label declares and is recorded as a positive (+) package error under the + column. When the nominal gross weight weighs less than the gross weight the sample package weighs more than what the label declares and is recorded as a negative (-) package error under the – column.

If desired, the package error may be expressed as “plus” or “minus” dimensionless unit by dividing the package error by the scale graduation. This method eliminates leading zeros and the units of measure and results in whole numbers.

Example - if the scale division (unit of measure) is 0.001 lb. and the package error is +0.038 lb., $+0.038 \text{ lb.} \div 0.001 \text{ lb.} = + 38$ (which could be recorded in the plus column). If a different package error is -0.003 lb., it would be recorded as “3” in the negative column, and so on (See Table 1 below).

Total Package Error: The sum of all the individual package errors.

-	+
1.	38
2.	12
3.	8
4.	4
5. 3	
6. 2	
7.	12
8. 3	
9.	4
10. 1	
Total: 9	Total: 78
Total Package Error: +69	

Table 1: *Maximum Allowable Variation (MAV)*: The maximum amount the actual net weight of an individual package or container may be under its labeled weight. It represents the maximum underweight or short weight a package can be and still be considered “reasonable” under good manufacturing processes. The MAV is provided in NIST Handbook 133 Table 2-9.

Table 2-9. U.S. Department of Agriculture, Meat and Poultry Groups and Lower Limits for Individual Packages (Maximum Allowable Variations)

Definition of Group and Labeled Quantity		Lower Limit for Individual Weights (MAVs)
Homogenous Fluid When Filled (e.g., baby food or containers of lard)	All Other Products	
Less than 85 g or 3 oz		10% of labeled quantity
85 g or more to 453 g 3 oz or more to 16 oz		7.1 g 0.016 lb. (0.25 oz)
More than 453 g More than 16 oz	85 g or more to 198 g 3 oz to 7 oz	14.2 g 0.031 lb. (0.5 oz)
	More than 198 g to 1.36 kg 7 oz to 48 oz	28.3 g 0.062 lb. (1 oz)
	More than 1.36 kg to 4.53 kg More than 48 oz to 160 oz	42.5 g 0.094 lb. (1.5 oz)
	More than 4.53 kg More than 160 oz	1 % of labeled quantity

NOTE: To determine the lower limit for an individual weight (MAV) from Table 2-9, the IPP must first know whether not the product is a homogenous fluid when filled or not, and the labeled weight. Beef gravy is a homogenous fluid when filled; beef burritos are not a fluid when packaged. The lower limit for an 8-ounce beef burrito is 1.0 oz. The lower limit for 20 lb. box ground beef patties would be $[.01 (1\%) \times 20 \text{ lb.}] = 0.2 \text{ lb.}$

7. Apply the decision criteria to determine net weight compliance.

Decision criteria: The rules for determining whether the inspection lot complies with the net weight requirements. The net weight test results must meet **BOTH** criteria.

- The total package error (sum of the individual package errors) is equal to or greater than zero; **AND**
- No individual minus package error can exceed the MAV.

Example: You perform the net weight task for an inspection lot of 250, 7.5 oz. (213 g) bowls of pasta in meat sauce. The scale divisions are 0.1 grams. You determine the MAV is -28.3 grams or -283 (converted to dimensionless units). Table 1 (example shown above) lists the individual package errors and total package error and shows a total package error of +69. None of the values in the negative (-) column exceed the MAV. The inspected lot passes the net weight test because the total package error is zero or positive, and no individual minus package error exceeds the MAV.

8. Take appropriate action based on net weight testing results.

9 CFR 442.5 specifies that a lot tested in an official establishment and found not to comply with net weight requirements **may** be reprocessed and **must** be reweighed and remarked. A lot tested outside an official establishment **must** be reweighed and remarked with a proper weight statement.

Using the Calculation Aid

Access the Calculation Aid as follows: Start Menu > FSIS Applications > Calculation Aid > Select Net Weights

Attachment 1:

Tare Rounding Examples

Tare Weights	Scale Graduation	Average Tare Weight	Rounded Tare Value
0.14 & 0.17 lb.	0.01 lb.	0.155 lb.	0.16 lb.
5/32 & 8/32 oz	1/32 oz	6.5/32 oz	7/32 oz
0.20 & 0.25 lb.	0.05 lb.	0.225 lb.	0.25 lb.
5.06 & 5.15 g	0.01 g	5.105 g	5.11 g

ATTACHMENT 2:

NET WEIGHT WORKSHEET					
DATE	ESTABLISHMENT NO.	SCALE DIVISION	AVERAGE TARE WT.	GROUP NO.	MAV (Lower Limit)
LOT SIZE	SAMPLE SIZE	PRODUCT AND CONTAINER CODE:			LABELED WEIGHT

STANDARD WEIGHTS (10 or 30 sample size)		
UNIT	+	-
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		
TOTAL + 'S AND -'S (10 weights)		
TOTAL ERROR + 'S AND -'S (10 wts.)		
11		
12		
13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
26		
27		
28		
29		
30		
TOTAL + 'S AND -'S (30 weights)		
TOTAL ERROR + 'S AND -'S (30 wts.)		

CATCH WEIGHTS (10 or 30 sample size)				
UNIT	LABEL WEIGHT	ACTUAL WEIGHT	+	-
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
TOTAL + 'S AND -'S (10 weights)				
TOTAL ERROR + 'S AND -'S (10 weights)				
11				
12				
13				
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25				
26				
27				
28				
29				
30				
TOTAL + 'S AND -'S (30 weights)				
TOTAL ERROR + 'S AND -'S (30 weights)				

PASS / FAIL DECISION CRITERIA

MAV CRITERIA: Is any single minus (-) unit greater than the MAV?	TOTAL ERROR CRITERIA: Is the total error equal to or greater than zero
<input type="checkbox"/> YES - Lot Fails <input type="checkbox"/> NO - Check Total Error	<input type="checkbox"/> YES - Lot is Acceptable <input type="checkbox"/> NO - Lot Fails

FSIS FORM 7240-1 (7/91)

REPLACES FSIS FORM 7240-1 (3/86), WHICH IS OBSOLETE.

[illegible]