



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

# **Inspection Methods**

## **Student Study Guide**

**2 of 2**

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## Table of Contents

01 Course Information and Introduction.....	7
02 Statutes (Acts).....	16
03 Rules of Practice .....	18
04 Regulatory Process Overview .....	22
05 Food Safety Systems Fundamentals.....	24
06 Food Microbiology & Specified Risk Materials (SRM).....	27
07 Sanitation Performance Standards (SPS).....	37
08 Sanitation Standard Operating Procedures (SSOP).....	45
09 Sanitation Scenarios .....	58
10 Noncompliance.....	59
11 HACCP Processing Categories and Fish Inspection.....	68
12 HACCP 7 Principles.....	76
13 HACCP Regulatory Process .....	80
14 Hazard Analysis Verification (HAV) Task .....	84
15 HACCP Verification Task .....	97
16 Slaughter Food Safety Standard.....	141
17 <i>Salmonella</i> and <i>Campylobacter</i> Testing.....	145
18 Raw Beef Sampling .....	154
19 Hazard Analysis Verification (HAV) and Raw Beef Sampling Scenario.....	162
20 Sampling Requirements to Demonstrate Slaughter Process Control .....	168
21 Humane Handling (Livestock) and Good Commercial Practices (Poultry).....	173
22 Sanitary Dressing.....	182
23 Review Establishment Data Task .....	186
24 Ready-to-Eat and Shelf Stable Products Process Familiarization .....	192
25 Lethality and Stabilization.....	194
26 Food Ingredients of Public Health Concern.....	198
27 RTE-SS Hazards and Controls Workshop.....	209
28 Ready-to-Eat Sanitation .....	212
29 <i>Listeria monocytogenes</i> Regulations.....	216
30 RTE Sampling .....	230
31 HACCP System and Recall Verification .....	234
32 Export Certification .....	250
33 Food Defense.....	254
34 Non-Food Safety Consumer Protection .....	258
PHIS Introduction to the Public Health Information System (PHIS).....	262
PHIS 1 – Establishment Profile.....	266
PHIS 2 – Task List / Task Calendar.....	270
PHIS 3 – Inspection Documentation, NRs, MOI, Notes, Meeting Agenda.....	274
PHIS 4 – Sample Management.....	282
PHIS 5 – Animal Disposition Reporting .....	285
Workshops.....	286
PHIS Simulations.....	298
Case Study Scenarios.....	314
Food Safety Regulations Job Aid.....	327
Acronyms .....	328
Note-taking Pages .....	332



## 21 Humane Handling Verification for Livestock and Good Commercial Practices for Poultry

### Objectives:

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

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

The two approved methods of slaughter are:

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

## Livestock Humane Handling Verification Task

In livestock slaughter establishments, you will verify compliance with the Humane Handling regulations by performing the Livestock Humane Handling Verification task. This task must be performed **once per shift**, every shift animals are slaughtered or on-site.

## Recording Time in HATS (Humane Activities Tracking System)

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

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

At many very small establishments, the total amount of inspection time spent on HATS procedures, including observations at antemortem inspection, may only total .25 hour (or less). Therefore, IPP should record .25 hour per day in a different HATS category each slaughter day. **Note:** Ante-Mortem Inspection **must still be performed** when animals are presented for slaughter, even if you do not record HATS time.

## 9 HATS Categories

I. **Inclement Weather:** Some things to look for include:

- Animals slipping or falling because of wet floors.
- Livestock overheated because of a lack of proper shade or because of a lack of water for cooling.
- Disabled livestock not in a covered pen protected from the elements.

II. **Truck Unloading:** Some things to look for include:

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

III. **Water and Feed Availability:** Some things to look for include:

- Water not accessible to livestock in holding pens.
- Feed not provided to livestock held for longer than 24 hours.
- Feed provided not appropriate for species and age.

**Note:** If animal appears exhausted and/or dehydrated refer to the **Twenty-Eight Hour Law**. The Animal and Plant Health Inspection Service (APHIS) Twenty-Eight Hour Law requires transporters to stop at least every 28 hours to provide animals with food, water, and rest, and those who do not are in violation of this law. Consult with your supervisor if you have concerns about the condition of the animals being delivered.

**IV. Ante-mortem Inspection:** Some things to look for include:

- Livestock being injured because of handling practices.
- Livestock being moved faster than a normal walking speed.

**V. Suspect and Disabled:** Some things to look for include:

- Conscious animals being dragged.
- Disabled animals not separated from normal ambulatory animals.
- US Suspect and disabled livestock are not provided or placed in a covered pen.

**VI. Electric Prod/Alternative Object Use:** Some things to look for include:

- Livestock being excessively prodded resulting in overexcitement or injury.
- Livestock being driven with sharp objects or other means which cause pain or injury.

**VII. Slips and Falls:** Some things to look for include:

- Livestock slip and fall due to inadequate footing or improper handling practices (typically observed during movement of animals *after* ante-mortem inspection).
- Livestock slip and fall because of lack of slip-resistant flooring.

**VIII. Stunning Effectiveness:** Some things to look for include:

- Livestock not rendered unconscious with a single application of the stunning methodology.
- Use of secondary entrances with potential for injury (or actual injury) of livestock.

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

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

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

regain sensibility on the bleed rail.

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

1. Chemical (carbon dioxide - CO<sub>2</sub>)
2. Mechanical (captive bolt)
3. Mechanical (gunshot)
4. Electrical (electrical current)

Some signs of a properly stunned animal (but not limited to):

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

IX. **Conscious Animals on the Rail:** Some things to look for include:

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

### **Ritual Slaughter (HMSA - Humane Methods of Slaughter Act)**

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

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

### **Odd-Hour Verification Visits**

The IIC, in conjunction with the FLS and DVMS, determines how frequently IPP need to perform odd-hour inspection to observe the livestock facilities and handling practices. These visits are unannounced and outside of operating hours.

## Robust Systematic Approach

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

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

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

## Enforcement

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

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

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

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

## Non-egregious Noncompliances

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

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

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

- If the noncompliance is the result of facility deficiencies, disrepair, or equipment breakdown, but is not immediately causing injury or distress to livestock, attach a U.S. Retained / Rejected tag to the noncompliant equipment/pen/etc. Noncompliance examples include holes in pen floors or fences that can trap/injure an animal's legs or feet.
- If the noncompliance is the result of establishment employee actions in the handling or movement of livestock and animals are being injured or treated inhumanely, attach the tag either at a point specific to the location and nature of the violation or to the alleyways leading to the stunning area. Noncompliance examples include animals driven faster than a normal walking speed or animals slipping and falling because of slick floors.

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

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

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

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

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

### **Egregious Noncompliances**

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

If you observe a noncompliance that you believe is egregious, your next set of actions will depend on whether or not you are the IIC. **If you are the IIC, place a U.S. Retained/Rejected tag at the appropriate place and inform establishment managers that you are communicating** with the FLS, District Office and DVMS to discuss the incident and recommend that a suspension without notification is imposed in accordance with 9 CFR 500.3(b).

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

**NOTE: Regardless of whether or not you are the IIC, your very first step—even before applying a tag—is to stop the activity that is causing harm to animals.**

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

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

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

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

## **Poultry Good Commercial Practices (GCP) Verification Activities**

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

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

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

If the poultry are stunned prior to bleeding, check the stunning equipment to ensure it is functioning properly. Poultry that have been effectively stunned will have an arched neck and tucked-in wings posture.

Check in the bleeding area to determine if the bleeding equipment is functioning properly. One way that you might be alerted to problems with the bleeding equipment is if the line inspectors report an increased number or clusters of cadavers at inspection stations or increased numbers of bruised wings or legs.

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

## **Enforcement**

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

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

## **Poultry Mistreatment MOIs**

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

## **DVMS - District Veterinary Medical Specialist**

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

## 22 Sanitary Dressing

### Objectives:

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

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

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

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

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

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

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

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

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

Each establishment must design their own procedures. Effective sanitary dressing and process control procedures, coupled with effective decontamination and antimicrobial intervention treatments, are needed to prevent the creation of insanitary conditions. Establishments that fail to control these procedures and treatments create the potential for carcass contamination in their food safety systems. Establishments may elect to maintain written sanitary dressing and process control procedures as part of their HACCP Plan, Sanitation SOP, Good Manufacturing Practices (GMP), or other prerequisite programs. If the sanitary dressing procedures are used to support decisions made in the hazard analysis in accordance with 9 CFR 417.5(a)(1), establishments must maintain records addressing the

sanitary dressing and process control program. The records must demonstrate that the program is effective and thus decisions made in the hazard analysis can be supported on an on-going basis. Establishments have flexibility on how they demonstrate effective sanitary dressing and maintain records.

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

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

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

FSIS has questions about the establishment's ability to support the food safety system as the hazard analysis anticipates, unless the establishment has: documentation that supports that the food safety system at slaughter, including sanitary dressing procedures coupled with all

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

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

## 23 Review of Establishment Data Task

### Objectives:

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

### What Data do IPP Review and Why?

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

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

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

## Records Subject to the Review Establishment Data Task

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

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

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

FSIS Directive 5000.2 specifies that IPP have access to any type of record maintained by the establishment if the record relates to the establishment maintaining its food safety system. Establishments must decide what type and frequency of testing is necessary to support the decisions made in its hazard analysis. Thus, the establishment decides which testing programs are necessary to ensure food safety and which testing programs are unrelated to food safety. **However, the establishment would have to explain to IPP why certain test records are not related to food safety and do not impact the hazard analysis.** If IPP learn of a testing program and have questions about whether records of that testing program should be included in the Review Establishment Data task, they should seek guidance from their supervisors and ask FSIS.

**NOTE:** The Review Establishment Data task targets records of monitoring and testing results that bear on food safety, not product quality concerns. Certain regulatory product quality concerns would be verified through non-food safety, other consumer protection (OCP) tasks instead of the Review Establishment Data task.

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

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

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

## Performing the PHIS Review Establishment Data Task

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

### Gathering Information

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

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

## **Assessing Information**

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

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

## **Documenting the Review Establishment Testing Data Task**

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

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

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

Once IPP have conducted the Review Establishment Data task, discussed any concerns with plant management, and included the items above in the MOI, they are to indicate within PHIS that the inspection task has been completed.

### **Refusal of Access to Records**

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

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

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

## 24 Ready-to-Eat and Shelf-Stable Products Process Familiarization

### Objectives

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

**Fully-Cooked, Not Shelf-Stable.** This category applies to establishments that further process products by using primarily a full lethality heat process step (e.g., cooking) to achieve food safety. The finished products are not shelf-stable and must be frozen or refrigerated for food safety purposes. The products must be labeled “Keep Refrigerated or Frozen” These products also **meet the definition of Ready-to-Eat (RTE)** as defined in 9 CFR 430.1.

**RTE (Ready-to-Eat)** product is a meat or poultry product that is **in a form that is edible without additional preparation** to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear safe handling instructions or other labeling that directs that the product must be cooked or otherwise treated for safety and can include frozen meat and poultry products.

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

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

**Not Heat-Treated, Shelf-Stable.** This category applies to establishments that further process by curing, drying, or fermenting to achieve food safety. The finished products are shelf-stable and not required to be frozen or refrigerated for food safety purposes.

Cooking is a very important step, because it is here that any pathogens (e.g., *Salmonella*) that may be in the product will be eliminated and the numbers of spoilage bacteria will be lowered to an acceptable level. This is called a **lethality** treatment. The cooling process is also known as **stabilization**.

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

### **Dried Whole Muscle Meat Products**

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

### **Dry and Semi-Dry Sausages**

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

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

## 25 Lethality and Stabilization

### Objectives:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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



## 26 Food Ingredients of Public Health Concern

### Objectives:

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

### Introduction

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

### Food Allergies

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

The FDA has identified eight foods (“Big 8”) and any ingredients that contain protein derived from these eight foods as major food allergens. The foods that account for approximately 90% of food allergies are:

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

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

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

### **Food Intolerances**

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

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

**Sulfites** are added ingredients used as to preserve food and prevent browning of processed fruits, vegetables, and shellfish. People with sulfite intolerance can experience chest tightness, hives, stomach cramps, diarrhea, breathing problems, and an increased risk of having asthma symptoms for sensitive people with asthma.

**FD&C Yellow No. 5**, a color additive also known as tartrazine, is used in a variety of food products. Tartrazine can cause symptoms similar to an allergic reaction (i.e., hives and swelling) in intolerant consumers.

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

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

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

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

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

## Establishment Responsibilities

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

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

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

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

Avoiding cross-contact between products containing a food allergen and those that do not is critically important. Cross-contact could result from inadequate control or inappropriate use of ingredients of public health concern.

**Situations that may allow for cross-contact to occur include the establishment failing to:**

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

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

- Declare ingredients listed in the product formula on the product label by common or usual name.
- Change labels when changing over from one product formulation to another.
- Review the labels on incoming non-meat/non-poultry ingredient mixes at receiving for changes.
- Discard obsolete labels after a change in product formulation.
- Review newly printed labels to ensure accuracy.
- Control labels for products with similar appearance but different ingredients to ensure application of the correct label (e.g., storing mixed bundles of labels for similar products with different ingredient formulas which could lead to a mix-up of labels).
- Maintain adequate production controls over a product that contains an allergenic ingredient and is intended for rework, allowing it to be reworked into a product not labeled to contain that ingredient.

- Declare an allergen that was indirectly added to the product. An example would be an establishment that is producing product on a food contact surface sprayed with a non-stick coating (a release agent intended to prevent product from adhering to the food contact surface) containing soy lecithin and is not properly declaring the soy lecithin on its finished product label. Note that substances used as release agents on surfaces, including grills, loaf pans, cutters, or other hard surfaces, are generally considered to be processing aids and are not required to be declared in the ingredients statement on the meat or poultry product label. However, if a particular release agent contains a known allergen, such as soy lecithin, official establishments must list the allergenic ingredient in the ingredients statement on the product label. Many cooking sprays (e.g., PAM®) used as release agents will contain soy lecithin as an emulsifier. Some may contain other allergenic ingredients as well.

## **Label Declarations**

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

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

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

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

## **Factual Labeling Statements**

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

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

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

### **Factual Labeling Statement Example:**

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

## **Inspection Program Personnel Responsibilities**

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

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

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

### **"Big 8" Formulation Verification Task**

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

IPP assigned to establishments that produce products in any of the HACCP processing categories other than slaughter must determine whether the establishment produces any products that may contain any of the "Big 8" food allergens. Review the preventive and control measures developed by the establishment to verify that such measures are being effectively implemented and product label ingredients are consistent with product formulation records.

Depending on its processes and decisions made in its hazard analysis, an establishment's preventive and control measures to control allergens may be in its HACCP plan, Sanitation SOPs, or a prerequisite program.

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

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

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

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

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

Performing the task involves:

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

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

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

### **Documenting Noncompliance with the "Big 8" Formulation Verification Task**

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

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

**NOTE:** If IPP identify concerns when performing the "Big 8" Formulation Verification task and believe a directed HAV task should be performed, they are to discuss those concerns with their supervisor.

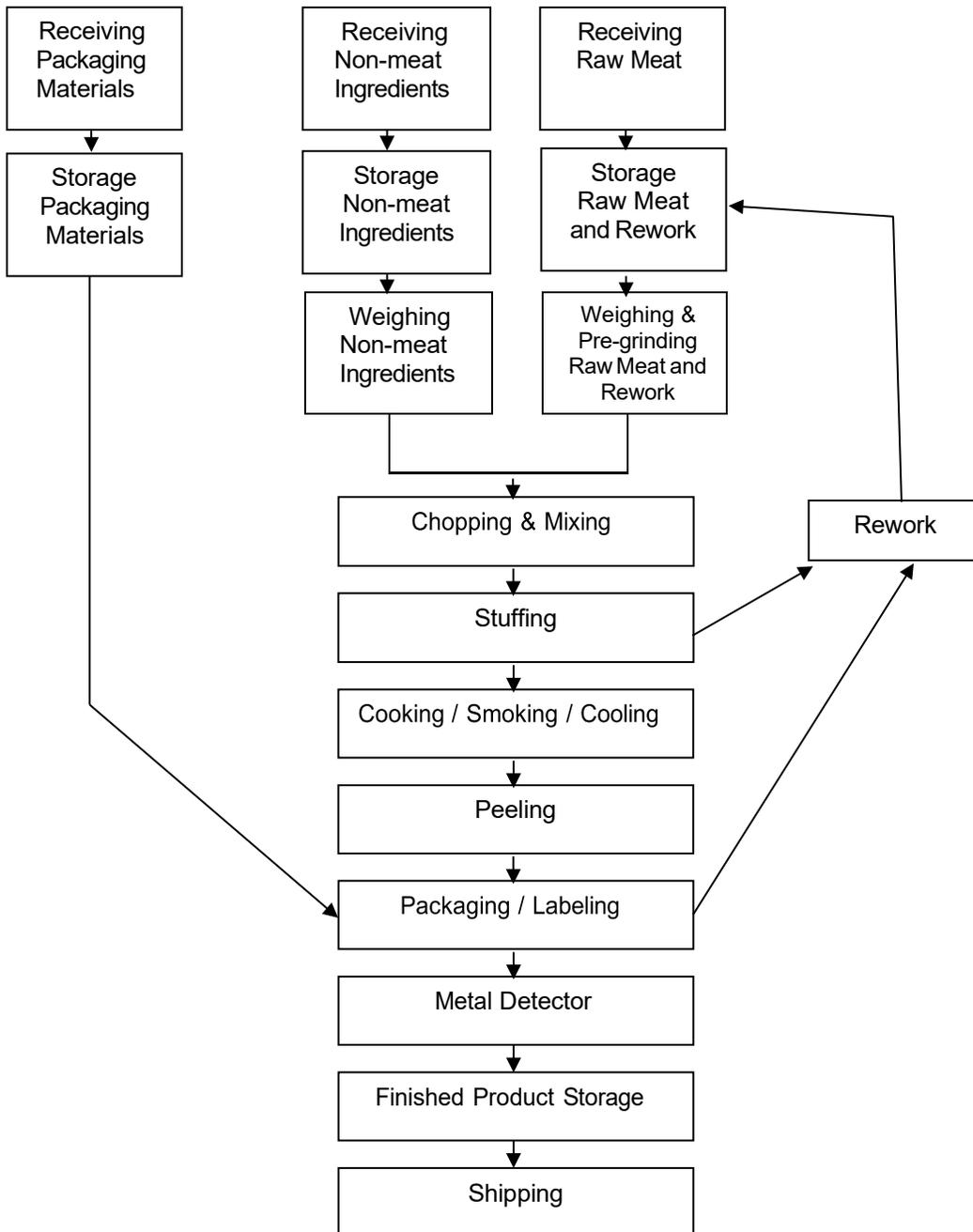
## **Documenting Noncompliance for Other Undeclared Ingredients**

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

### **Other Actions**

IPP may need to take regulatory control of product at the official establishment as necessary to prevent the product from entering commerce. IPP should always contact the FLS for guidance any time they have reason to believe any product bearing labels that fail to declare one of the “Big 8” food allergens or any other ingredient of public health concern has entered commerce. An immediate withholding action on the process may be necessary and a product recall may be requested by the Recall Management and Technical Analysis Division (RMTAD). Refer to FSIS Directive 8080.1 for more information on recalls.

**27 RTE-SS Hazards and Controls Workshop**  
**Hotdog Flow Diagram**



No returned product accepted.  
 (Training Example Only)

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

(Training Example Only)

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

### Hotdog HACCP Plan (Training Example Only)

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

## 28 Ready-to-Eat (RTE) Sanitation

### Objectives

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

**Ready-to-eat product** - As per 9 CFR 430.1 definitions, a meat or poultry product that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes. RTE product is not required to bear safe-handling instructions (as required for non-RTE products by 9 CFR 317.2(i) and 381.125(b) or other labeling that directs that the product must be cooked or otherwise treated for safety and can include frozen meat and poultry products.

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

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

**Cross-contamination** - The transfer of bacteria, possibly including pathogenic bacteria, to the exposed RTE product after the lethality treatment. These bacteria can come from the environment, from the employees, or from the equipment. They can be transferred directly, such as when an exposed RTE product is placed on a tabletop that has bacteria on it. Often, they are transferred indirectly, such as when a pallet placed on the floor in a raw area is subsequently used in the RTE area, or when an employee handles a pallet and then touches exposed product.

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

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

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

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

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

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

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

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

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

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

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

## 29 *Listeria monocytogenes* (*Lm*) Regulations

### Objectives

1. Identify reasons *Listeria monocytogenes* (*Lm*) is a public health threat for ready-to eat (RTE) meat and poultry products.
2. Verify compliance with the regulations in 9 CFR 430 by following instructions in FSIS Directive 10,240.4 “*Listeria* Rule Verification Activities.”

### Introduction

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

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

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

*Lm* may cross-contaminate RTE product exposed to the post-lethality environment due to inadequate sanitary practices. Dust, movement of personnel, and equipment associated with construction projects (e.g., air handling system repairs, removal of walls, repairs to plumbing systems) create opportunities for *Lm* to cross-contaminate post-lethality exposed product. An establishment may need to implement additional sanitation practices and containment procedures for any construction projects in or around processing areas where post-lethality exposed products are handled and packaged.

FSIS considers *Lm* to be a significant foodborne pathogen of great potential public health concern that must be controlled by establishments producing post-lethality exposed RTE products. FSIS has developed regulatory requirements specifically for controlling *Lm* in post-lethality exposed RTE products. In addition, the agency has developed *Lm* sampling programs as part of its public health strategy for protecting consumers against *Lm*.

### **Listeria Rule**

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

### **Definitions**

9 CFR 430.1 provides several definitions that are specific to ready-to-eat (RTE) products. Two RTE product definitions are ***deli products*** and ***hotdog products***. A deli product is an RTE meat or poultry product that is typically sliced, either in an official establishment or after distribution, and assembled in a sandwich for consumption. A hotdog product is an RTE meat or poultry frank, frankfurter, or wiener product with a standard of identity defined in 9 CFR 319.180 and 319.181. A risk assessment performed jointly by FSIS and the FDA indicated that on a per serving basis, deli meats and hotdogs (not reheated) posed the greatest risk of illness and death from *Lm*.

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

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

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

The following three terms are associated with the three *Listeria* control alternatives used to control or prevent *Lm* in an RTE product in the post-lethality environment:

- **Post-lethality treatment (PLT)** - an additional lethality treatment, following the initial lethality treatment, applied to the final product or sealed package of product to reduce or eliminate the risk of *Lm* contamination during post-lethality exposure. Examples of post-lethality treatments include steam pasteurization, hot water pasteurization, radiant heating, and high-pressure processing (HPP). Some antimicrobial agents may also function as post-lethality treatments.
- **Antimicrobial agent** - a substance in or added to an RTE product that suppresses or limits growth of *Lm* in the product throughout the shelf life of the product. Examples of antimicrobial agents used in RTE products are sodium lactate, potassium lactate, and sodium diacetate. FSIS Directive 7120.1 identifies additional antimicrobial agents approved for use in the production of RTE meat and poultry products.
- **Antimicrobial process** - an operation (e.g., freezing) applied to an RTE product that suppresses or limits the growth of *Lm* in the product throughout the shelf life of the product. Drying and fermenting are operations that may be applied to a product to make it RTE and subsequently suppress or limit the growth of *Lm*.

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

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

### **Establishment Responsibilities**

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

### **Sampling Program**

Under §430.4(b)(2)(iii)(A) and (3)(i)(A), establishments that produce post-lethality exposed RTE products are required to provide for FCS testing in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or indicator organism.

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

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

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

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

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

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

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

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

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

## Alternative 1 Compliance Example

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

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

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

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

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

## Alternative 2 Compliance

**Example 1:** An establishment's product line includes chicken salad and ham salad in hermetically seals containers under Alternative 2, Choice 1. The cooked, sealed containers are batch loaded into cylinders and the cylinders are loaded into a chamber, to undergo High Pressure Processing (HPP) as a post-lethality treatment. You are reviewing the establishment's hazard analysis and HACCP plan for these products to verify compliance with the requirements for Alternative 2, Choice 1 as specified in 9 CFR 430. In its hazard analysis, the establishment concluded that *Lm* was a hazard reasonably likely to occur (RLTO) in the post-lethality processing environment. The establishment identified the HPP as a post-lethality treatment and included it in its HACCP plan as a CCP. The critical limit for HPP is time at a specific pressure level. In reviewing supporting documents for the CCP, you determine there are other critical parameters associated with this type of treatment, including product temperature before high pressure processing and water fill level of the pressure chamber. You request additional

documentation supporting that the establishment achieves these additional critical parameters. The establishment provides documents that show the product temperature is consistently 40°F or less at the packaging step and that the pressure chamber water level is monitored to ensure that the required level of pressure can consistently be achieved in the high pressure process. You conclude that the establishment is in compliance with 9 CFR 430.4(b)(2).

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

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

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

### **Alternative 3 Compliance**

**Example 1:** You are verifying that the establishment is meeting 9 CFR 430 and Alternative 3 requirements. You review the establishment's hazard analysis for fully cooked, not shelf stable breakfast type products (e.g., bacon, sausage patties, sausage links, etc.). You verify that the cooking and chilling steps have been identified as CCPs in the hazard analysis and were incorporated into a HACCP plan. *Lm* was considered a potential hazard NRLTO at the packaging step because the establishment has implemented sanitary measures to control *Lm* in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is NRLTO in the post-lethality environment. You review the establishment's

SSOP program and records. You verify that the establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. the establishment has also identified the conditions under which it will implement hold-and-test procedures following a positive test of a food contact surface for *Listeria* spp., the size and location of the sample sites, and frequency of testing. The establishment provided a thought process documenting why the testing frequency selected is sufficient to ensure that effective control of *Lm* is maintained. Based upon your review, you determine that the establishment is in compliance with 9 CFR 430.4(b)(3).

**Example 2:** You are verifying that the establishment is meeting the requirements of 9 CFR 430 and Alternative 3. You review the establishment's hazard analysis for fully cooked, not shelf stable deli and hotdog type products (e.g., franks, sliced ham, sliced bologna, sliced roast beef, sliced turkey breast, etc.). You verify that the cooking and chilling steps were identified as CCPs in the hazard analysis and incorporated into a HACCP plan. The establishment considered *Lm* a food safety hazard NRLTO at the packaging step because of *Listeria* control measures in its SSOP intended to prevent *Lm* from occurring in the post-lethality processing environment. You request the supporting documentation for the decision that *Lm* is NRLTO in the post-lethality environment. You review the establishment's SSOP and records and verify that the establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Listeria* spp. The establishment has identified the conditions under which it will implement hold-and-test procedures following a positive test of a food-contact surface for *Listeria* spp., the size and location of the sample sites, and the testing frequency. It also provided a thought process documenting why the testing frequency selected is sufficient to ensure that effective control of *Lm* is maintained.

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

## VERIFYING COMPLIANCE

### Gather Information

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

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

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

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

that the surfaces are sanitary and free of *Lm* or of an indicator organism?

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

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

1. Effectively implemented corrective actions (with respect to sanitation after an initial positive result on a food contact surface in the post-lethality processing environment) by follow-up testing that includes targeted testing of the specific site on the food contact surface area and other sites as necessary to ensure effectiveness of the corrective actions.
2. Holds product lots that may have become contaminated by contact with the food contact surface when the establishment obtains a second positive test for *Lm* or an indicator organism during follow-up testing until the problem is corrected as indicated by negative follow-up test results.
3. Sample and test product lots for *Lm* or an indicator organism using a sampling method and frequency that will provide a level of statistical confidence that ensures that each lot is not adulterated with *Lm*.
4. Documents testing results.
5. Reworks held product using a process that is destructive to *Lm*.

### **Assess Information**

To answer these questions, IPP should:

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

## Determine Compliance

IPP must determine regulatory compliance after all available information pertaining to the *Listeria* Control Alternative selected has been gathered and assessed. There is no noncompliance if the establishment has met all regulatory requirements. If the establishment has not met all regulatory requirements, the noncompliance should be documented on an NR under the appropriate PHIS task as described in FSIS Directive 5000.1, citing the appropriate sections of §430.4(b), §417 for HACCP and prerequisite programs, and/or §416 for sanitation. IPP should verify that the establishment has taken effective corrective and preventive actions to bring itself into compliance with 9 CFR 430. Such actions may include a reassessment of the HACCP plan and the establishment's choice of another alternative.

### Alternative 1 Noncompliance Examples:

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

### Alternative 2 Noncompliance Examples

1. The establishment is testing food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism but does not have a post-lethality treatment to reduce or eliminate *Lm* included in a HACCP plan OR an antimicrobial agent or process to suppress or limit the growth of *Lm* incorporated into a HACCP plan, SSOP, or a prerequisite program. Cite §430.4(b)(2), 417.2, 417.5(a)(1) & (2)
2. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 only addresses the testing of non-food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *Lm* or of an indicator organism. Cite §430.4(b)(2), 416, 417.5(a)(1) & (2)
3. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the conditions under which or at what point hold-and-test

procedures following a positive test of a food-contact surface for *Lm* or an indicator organism will be initiated. Cite §430.4(b)(2), 417.5(a)(1) & (2)

4. The written sanitation procedures the establishment is using to meet the requirements of Choice 2 do not identify the size of the sites to be sampled or explain why the testing frequency selected is sufficient to ensure that effective control of *Lm* or an indicator organism is maintained. Cite §430.4(b)(2), 417.5(a)(1) & (2)

### **Alternative 3 Noncompliance Examples**

1. The establishment does not have sanitation measures incorporated in its HACCP, Sanitation SOP, or other prerequisite program. Cite §430.4(b)(3), 417.5(a)(1) & (2)
2. An establishment that produces deli and hotdog products does not conduct follow-up testing of target sites on the FCS area that is the most likely source of contamination after an initial positive test for *Lm*, or its indicator organisms, to verify the effectiveness of its sanitation corrective actions. Cite §430.4(b)(3), 417.5(a)(1) & (2)
3. An establishment that produces deli and hotdog products does not hold-and-test lots of product for *Lm*, or an indicator organism, that may have become contaminated by contact with the food contact surface when it obtains a second positive test for *Lm*, or an indicator organism, during its follow-up testing. Cite §430.4(b)(3), 417.5(a)(1) & (2)

### **Documentation and Enforcement**

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

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

**ATTACHMENT 1: CONTROL REQUIREMENTS for *Listeria MONOCYTOGENES***

Requirements	→ 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 Antimicrobial agent or Process	Choice 1: Post-lethality Treatment	Choice 2: Antimicrobial Agent or Process	Sanitation and Testing Program	Deli or hot-dog product
<b>Validate effectiveness of post-lethality treatment (PLT).</b> 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			
<b>Document effectiveness of antimicrobial agent or process:</b> Must be included as part of the establishment's HACCP, Sanitation SOP, or Pre-requisite Program and should demonstrate no more than 2-logs growth of <i>Lm</i> over the estimated shelf life.	X		X			
<b>Sanitation Program Requirements</b>			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
<b>Additional Sanitation Program Requirements</b>			X		X	X
Effective after 1 <sup>st</sup> 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 <sup>nd</sup> 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
<b>Establishments in all three alternatives</b> must maintain sanitation in accordance with 9 CFR 416.	X		X	X	X	X

## ***Listeria monocytogenes* Regulations: Workshop**

1. Establishments are required to comply with section 9 CFR 430.4 (Control of *Listeria monocytogenes*) if they produce:
  - a. Ready-to-eat products processed and sold in impermeable packaging.
  - b. Not ready-to-eat products with secondary inhibitors.
  - c. Ready-to eat products.
  - d. Ready-to-eat products exposed to the environment after the lethality step.
  
2. Fill in the blanks with one of the following:
  - a) Alternative 1
  - b) Alternative 2, Choice 1
  - c) Alternative 2, Choice 2
  - d) Alternative 3

\_\_\_\_\_ Use of only a post-lethality treatment (which may be the antimicrobial agent or process) that reduces or eliminates microorganisms on the product.

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

\_\_\_\_\_ Sanitation measures only, in the HACCP plan, SSOP, or prerequisite program, including testing of food contact surfaces to verify the effectiveness of the sanitation procedures.

\_\_\_\_\_ Use of an antimicrobial agent or process that suppresses or limits the growth of *L. monocytogenes*, along with a sanitation program addressing the testing of food contact surfaces to verify the effectiveness of the sanitation procedures.

3. An establishment MUST implement hold-and-test procedures when a positive result for an indicator organism is found on a food-contact surface during follow-up testing (second consecutive food contact surface positive for *L. monocytogenes*) if the establishment is producing:

- a. RTE products exposed to the environment after the lethality treatment using Alternative 1, 2, or 3.
- b. Non-deli and hotdog type RTE products exposed to the environment after the lethality treatment using Alternative 3.
- c. Deli and hotdog type RTE products exposed to the environment after the lethality treatment using Alternative 3.
- d. Deli and hotdog type RTE products exposed to the environment after the lethality treatment using Alternative 2, Choice 2

4. An establishment MUST identify the conditions under which it will implement hold-and-test procedures after a positive result for an indicator organism is found on a food-contact surface if the establishment is producing:

- a. Non-deli and hotdog type or deli or hotdog type RTE products exposed to the environment after the lethality treatment using either Alternative 2 (Choice 2) or Alternative 3.
- b. Deli and hotdog type RTE products exposed to the environment after the lethality treatment using either Alternatives 1, 2, or 3.
- c. Deli and hotdog type RTE products exposed to the environment after the lethality treatment using Alternative 1 or Alternative 2, Choice 1.
- d. Non-deli and hotdog type RTE products exposed to the environment after the lethality treatment using Alternative 2, Choice 1

## 30 Sampling Ready-to-Eat (RTE) Product

### Objectives:

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

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

The pathogens of public health concern are *Listeria monocytogenes* and *Salmonella*

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

RTE product is adulterated if it:

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

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

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

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

There are **6 general steps** in sampling RTE product:

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

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

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

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

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

For both RTEPROD\_RAND and RTEPROD\_RISK samples, IPP are to collect a one-pound sample of product in an **intact package**.

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

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

Pack the sample in this order:

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

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

Establishments under Alternative 2 Choice 2 and Alternative 3 are required to conduct sampling of food contact surfaces. Establishments may also choose to conduct sampling of product. If an establishment's product or food contact surface test result is positive for *Lm*, IPP **should not** issue an NR unless the establishment failed to hold the affected product and did not implement corrective actions, which includes proper disposition of the sampled product lot.

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

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

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

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

[https://www.fsis.usda.gov/sites/default/files/media\\_file/2020-08/10240.4.pdf](https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/10240.4.pdf)

[https://www.fsis.usda.gov/sites/default/files/media\\_file/2022-03/10240.3.pdf](https://www.fsis.usda.gov/sites/default/files/media_file/2022-03/10240.3.pdf)

## 31 HACCP System and Recall Verification

### Objectives

1. Explain the regulatory thought process, define its four components, and identify key aspects of each component.
2. Understand four essential questions to consider in determining when to document a failure to meet HACCP regulatory requirements.
3. Use the regulatory thought process to determine if a food safety system is inadequate.
4. Identify three types of enforcement actions taken when a noncompliance determination is made.
5. Identify two scenarios when a HACCP verification plan is necessary.
6. Verify that establishments maintain written recall procedures per 9 CFR 418.3 requirements.

### Introduction

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

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

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

### HACCP Regulatory Process

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

- **Inspection Methodology**
  - Performing HACCP inspection tasks
  - Verifying specific HACCP regulatory requirements by performing the HACCP inspection task

- **Decision-making (GAD)**
  - **Gathering** information, making observations, reviewing documentation, **assessing** the gathered information, arriving at a supportable compliance **determination**
- **Documentation**
  - Entering HACCP inspection task results (observations and determinations) in PHIS
  - Documenting noncompliance on a Noncompliance Record (NR)
  - Associating noncompliance from the same cause
- **Enforcement**
  - Following the Rules of Practice (ROP)
  - Providing the establishment with due process

### **FSIS Responsibilities**

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

### **Inspection Methodology**

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

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

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

### **Decision-Making (GAD)**

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

- Reviewing hazard analyses, HACCP plans, prerequisite programs, supporting documentation, and ongoing monitoring records, HACCP plans, SSOPs, prerequisite programs, and other supporting programs or procedures.
- Observing establishment employees performing or implementing HACCP, SSOP, or prerequisite program or other supporting program procedures, and occasionally taking measurements as specified in HACCP system documents.

After reviewing the gathered information, IPP are to assess the significance and meaning of information gathered by:

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

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

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

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

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

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

### **HACCP System Compliance**

The purpose of the HACCP verification task is more than to just identify isolated instances of noncompliance. IPP must also consider what their positive, negative, or inconclusive findings indicate about the overall effectiveness of the establishment’s HACCP system. It is important that each piece of information be considered in the context of the HACCP system and the potential for product adulteration. The following questions will help IPP to consider the significance of each finding for the HACCP system:

- **Is this information part of a pattern or trend?** For example, is the establishment missing a measurement for a prerequisite program an isolated incident or has the establishment regularly failed to implement its prerequisite programs?
- **Is there other information to indicate that the HACCP system is working or is not working?** For example, if an establishment's prerequisite program specifies product will be received with supplier certificates of analysis (COA) and periodically tested but the establishment failed to receive a COA for a particular product, how did they respond on whether or not to use the product?
- **Does the information seem to agree with the other available information about the food safety system?** For example, an establishment uses a prerequisite program to prevent a hazard in incoming products, and the records appear to show that a particular hazard is being prevented. However, the establishment's testing of finished product for the particular hazard finds positive results.
- **Do these results support each other or is there an apparent contradiction?** For example, an establishment that uses a prerequisite program to prevent *E. coli* O157:H7 in incoming beef has COAs and verification test results on incoming trim that indicate the hazard is not reasonably likely to occur, but the establishment gets a positive test result on a finished product lot. The finished product test result calls into question the effectiveness of the prerequisite program as means of supporting the decision that *E. coli* O157:H7 is not reasonably likely to occur.

### **Inadequate HACCP System Determination**

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

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

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

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

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

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

If an establishment did not implement all or some of its HACCP plan or did not meet regulatory requirements, IPP would be unable to determine whether or not the establishment was producing unadulterated product in compliance with 9 CFR Part 417. For example, the HACCP

system is inadequate if an establishment does not maintain any records associated with its HACCP plan, does not monitor critical limits at any CCP, or did not reassess or modify its HACCP plan when necessary.

## **2. Was adulterated product produced or shipped?**

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

## **3. Is there a trend in establishment noncompliance?**

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

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

### **Action to Take If an Inadequate System Exists**

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

## **DOCUMENTATION**

### **Completing a Noncompliance Record**

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

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

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

## Enforcement Rules of Practice

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

1. **Regulatory Control Action** - The retention of product, rejection of equipment or facilities, slowing or stopping of lines, or refusal to allow the processing of specifically identified product.
2. **Withholding Action** - The refusal to allow the marks of inspection to be applied to products. A withholding action may affect all product in the establishment or product produced by a particular process.
3. **Suspension** - An interruption in the assignment of program employees to all or part of an establishment.

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

## Regulatory Control Actions

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

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

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

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

Examples of common regulatory control actions related to slaughter include stopping a line or retaining a carcass as a result of a slaughter food safety standard finding.

## **Withholding Actions Without Prior Notice**

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

## **Withholding and Suspension Actions With Prior Notification**

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

### **District Office Notification**

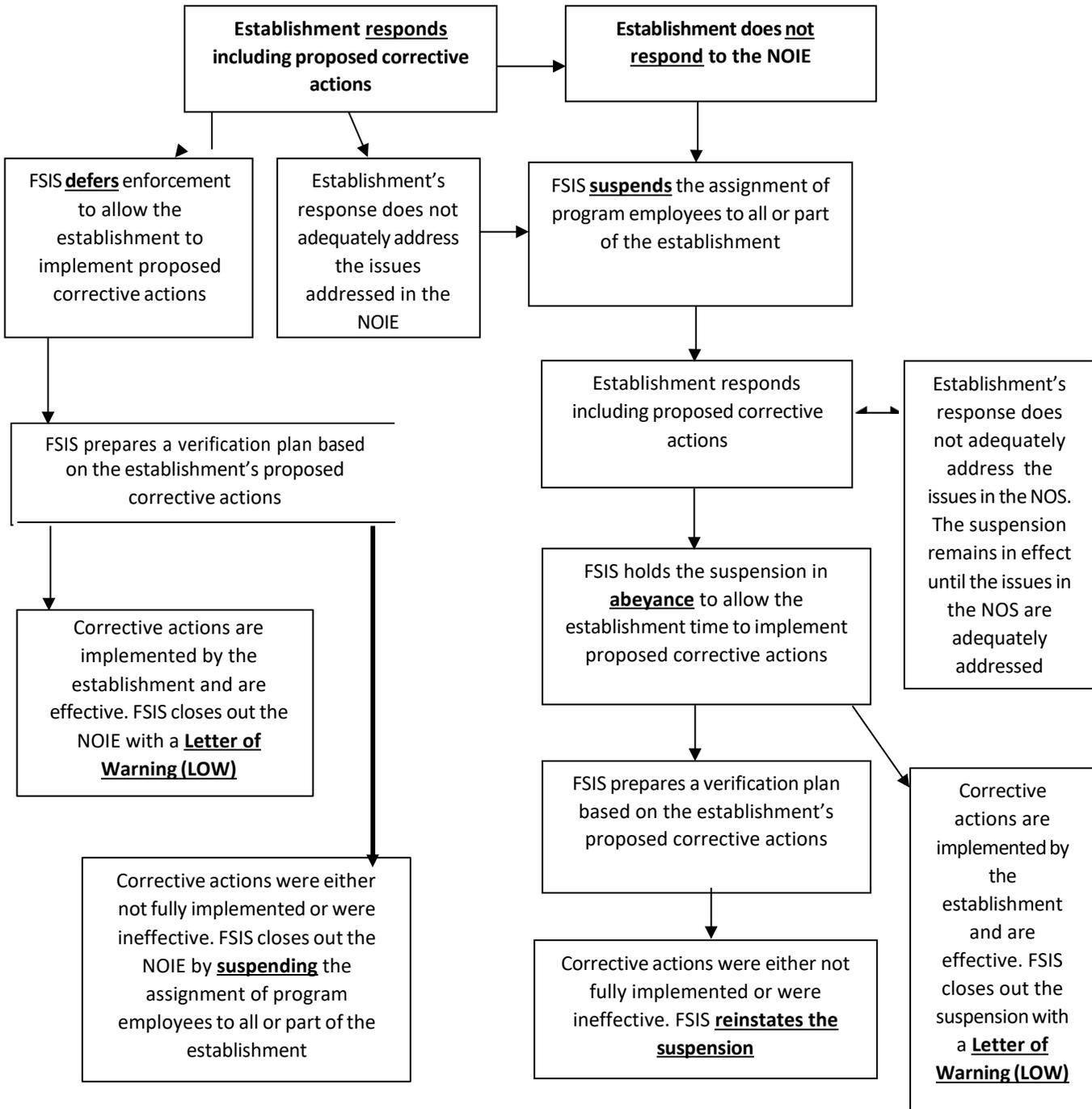
After determining that an inadequate HACCP system may exist, IPP should notify the District Office and request that a Notice of Intended Enforcement (NOIE) be issued to the establishment. The DO will provide direction about any further actions that may need to be taken. The DO may assign an EIAO to evaluate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

### **District Office Determines Enforcement Action**

After evaluating all of the facts of the case, the District Office will determine the appropriate enforcement action based upon the ROP.

# Notice of Intended Enforcement Action

Establishment has 3 business days to respond



## Verification Plan

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

A Verification Plan:

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

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

## RECALLS

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

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

### Establishment Recall Requirements

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

1. Notify the local FSIS DO within 24 hours of learning or determining that an adulterated or misbranded meat or poultry product received by or originating from the official establishment has entered commerce (9 CFR 418.2). The 24-hour period begins once an establishment believes that a product in commerce is adulterated or misbranded under the FMIA or PPIA (e.g., final results of a laboratory analysis show that raw ground beef contains *E. coli* O157:H7 or product contains an allergen that is not declared on the product label).
2. Prepare and maintain written procedures for the recall of all meat and poultry products produced and shipped by the establishment (9 CFR 418.3).

3. Prepare written recall procedures as required by 9 CFR 418.3 before being granted Federal inspection (9 CFR 304.3(a) and 381.22(a)).

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

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

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

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

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

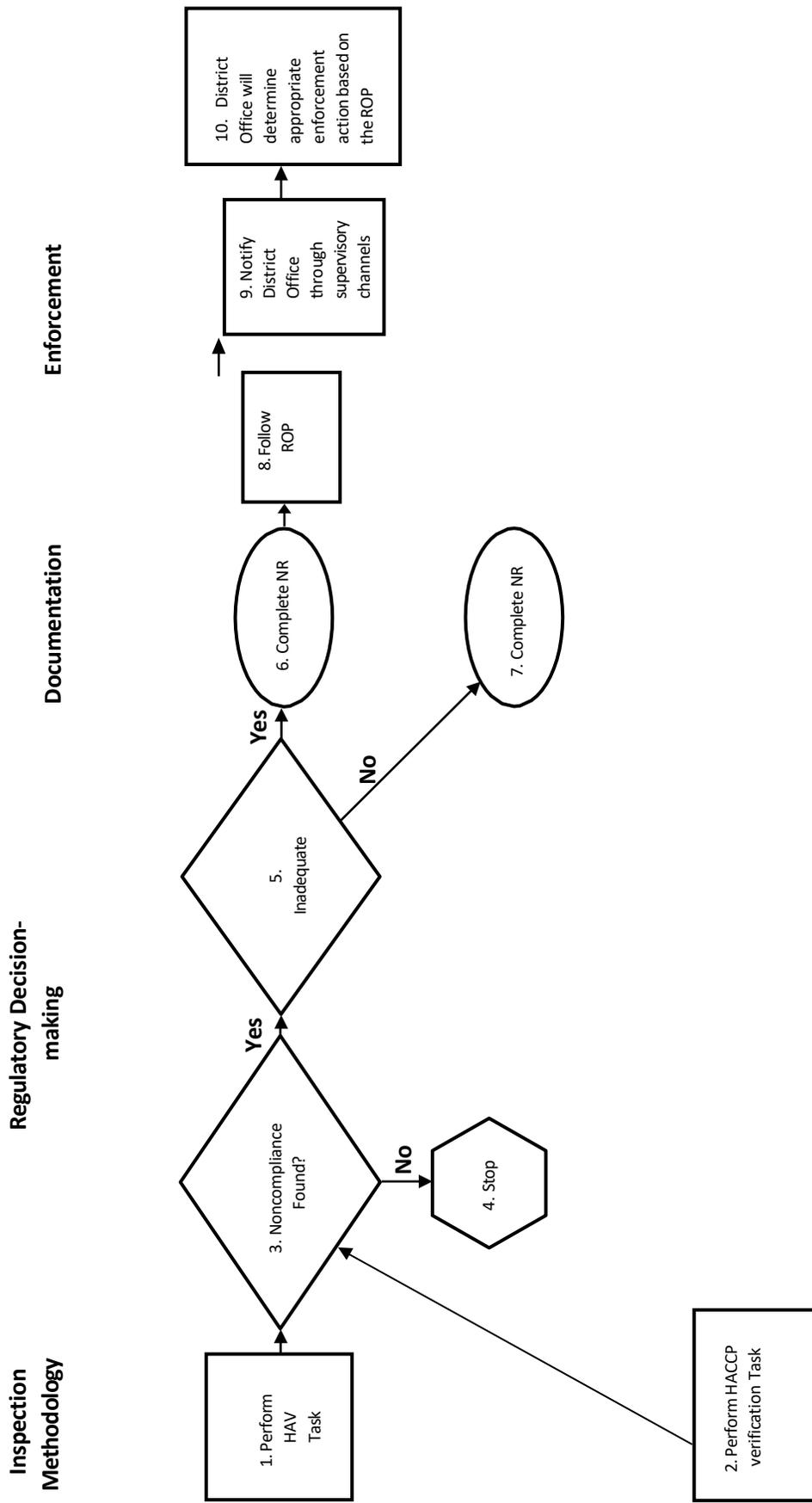
**The establishment is expected to perform a voluntary recall of any unsafe product in commerce.** If the establishment does not voluntarily recall product, the DO will coordinate actions to detain or seize affected product.

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

### **FSIS Verification**

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

# HACCP Regulatory Process



## HACCP Systems and Recall Verification: Workshop

Refer to the module and to FSIS Directive 5000.1 to complete the following questions.

1. You are the IIC at a small establishment that produces frozen spaghetti and tomato sauce with meat entrees and frozen non-amenable spaghetti entrees made with a lobster cheese sauce. You are performing Pre-Operational Sanitation Review and Observation Task.
  - a. What are the regulation sections you are to use when verifying regulatory compliance?

You observe various product contact surfaces in the formulation area. You see that some of the blending equipment appears to have product residue from the previous day's production. You inspect the interior surfaces of the blenders and find residue. You see what appears to be cheese sauce residue in several areas, and you see what appears to be tomato sauce residue in several other areas. You check the production records from the previous day and determine that the establishment produced lobster cheese spaghetti in the morning and tomato sauce with meat spaghetti in the afternoon. The label of the spaghetti containing meat does not list any lobster or milk ingredients.

- b. Are the conditions you observed creating an insanitary condition?
    - c. Could the conditions you observed lead to contaminated product?
    - d. Is there a food safety hazard associated with the contamination you observed? Why or why not?
  - e. You take official control of the blenders by placing a U.S. Rejected tag on them. What regulations give you the authority to take this action?

f. What statutes give you the authority to take this action? Explain in your own words the reasoning behind this authority.

g. What actions would you take next?

You review the HACCP plan and hazard analysis. The establishment found that food allergens were potential food safety hazards but determined that they were not likely to occur in this process because the establishment has a food allergen control program which prevents the hazard.

h. Which corrective action regulation would apply in this situation?

As part of a Directed Fully Cooked but Not Shelf Stable HACCP Verification Task, you review the establishment's food allergen control program. You find that the establishment lists several daily in-plant checks and verification activities and the associated documentation that will be kept. You request recent records, and your review reveals that the food allergen control program verification activities are not being done at the frequency listed in the program. Records are also not available for some of the days.

i. Could this indicate an inadequate system? Why or why not?

j. How would you document what you have found? What regulations would you use?

k. What actions would you take next?

2. While performing a Fully Cooked Not Shelf Stable HACCP verification task in a ready-to-eat product operation to verify the HACCP regulatory requirements, you review the establishment's HACCP plan. During this review, you determine that the establishment has not identified a CCP to control *Lm* in the post-processing environment. You also observe that the establishment has documented a recent reassessment of its HACCP plan. You do not see the establishment's *Lm* testing program referenced in the HACCP plan.

You request from plant management the establishment's hazard analysis and verify that the establishment identified *Lm* as a food safety hazard NRLTO. After reviewing the HACCP plan and hazards analysis, you ask management what event triggered the reassessment. The operations manager states that the reassessment was performed in response to a positive *Lm* result from finished RTE ham lunchmeat. When questioned about the *Lm* sampling program, the operations manager states that *Lm* testing is performed as a verification requirement at the request of a customer. You ask management to provide the results of their microbiological testing of the finished ham lunchmeat, which the establishment provides to you. You determine that the most recent sample analyzed was found to be positive for *Lm*.

You request information about corrective actions taken and are shown an unforeseen hazard log that documents that the establishment segregated and held affected ham product. The establishment also has records to show that it performed a review to determine the acceptability of affected product and took corrective actions to ensure that no product injurious to health entered commerce by denaturing and disposing of the adulterated product. Documentation that the product was denatured and disposed of in a landfill is provided. The unforeseen hazard log further shows that a reassessment was performed, and the establishment determined that *Lm* was a hazard not reasonably likely to occur in the ham lunchmeat process. The basis for this decision is documented as: "It is the only positive ever received. We apply a full lethality treatment and apply our Sanitation Standard Operating Procedures daily. The application of our Sanitation Standard Operating Procedures daily should continue to be sufficient in the future. This result is a fluke. No changes to the HACCP plan are necessary at this point."

When you ask for support for the decision that the hazard is still not reasonably likely to occur, the establishment manager says, "The result was a fluke and we documented that on the corrective action log." Based on this information, you determine that no alterations were made to the hazard analysis or the HACCP plan as a result of the *Lm* positive sample. You are also able to verify that all other HACCP requirements, including pre-shipment review, were met as part of the Fully Cooked Not Shelf Stable HACCP Verification Task for this specific product.

- a. Has the establishment supported its decision about the results of the reassessment? Why or why not?
- b. What are the 4 questions you would seek answers to as you gather information to determine whether or not to document this as a noncompliance, and what conclusion would you make?  
**NOTE:** Remember the 4 questions from the HACCP Regulatory Process presentation. If the system is working, you may not document some noncompliance.
- c. What regulations need to be considered?
- d. Is there a noncompliance? Why or why not?
- e. If you determine that noncompliance should be documented, what regulations would you cite?
- f. What are the questions you would seek answers to as you gather information to determine whether or not there is an adequate HACCP system?
- g. Based on your determinations, is the establishment's HACCP system inadequate? Why or why not?
- h. If you determine that you would document an NR, please complete **only** blocks 6, 8, 9, and 10 on the next page.

The request for this information is voluntary. It is needed to monitor defects found in this inspection system. It is used by FSIS to determine whether establishments are in compliance. 9 CFR 301 and 9 CFR 381. FORM APPROVED OMB No. 0583-0089. OMB DISCLOSURE STATEMENT: Public reporting burden for this collection of information is estimated to average 7 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, DC 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget.

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE <b>NONCOMPLIANCE RECORD</b>		TYPE OF NONCOMPLIANCE <input type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection	
1. DATE	2. RECORD NO.	3. ESTABLISHMENT NO.	
4. TO (Name and Title)		5. PERSONNEL NOTIFIED	
6. RELEVANT REGULATIONS		6a. ASSOCIATED NR(s)	
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING		7a. NAME OF CCP(S) or PREREQUISITE PROGRAM DOCUMENTATION	
8. INSPECTION TASK	9. VERIFICATION ACTIVITY <input type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION  9b. RETAIN/REJECT TAGS		
10. DESCRIPTION OF NONCOMPLIANCE			
11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE			
<i>You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR</i>			
12. PLANT MANAGEMENT RESPONSE:			
<b>This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.</b>			
13. SIGNATURE OF PLANT MANAGEMENT		14. DATE	
15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE		16. DATE	

## 32 Export Certification

### Objectives:

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

### Resources:

FSIS Export Library - <https://www.fsis.usda.gov/inspection/import-export/import-export-library>  
[Directive 9000.1](#) – Export Certification  
[Directive 12,600.1](#) – Voluntary and Other Reimbursable Inspection Services  
[Directive 13,000.5](#) – Public Health Information System Export Certification  
[Notice 09-23](#) – Seven-Digit Export Stamp, Enhanced Digital Signature, Plain Paper Printing, and Statements Module for Use With the Export Module of the Public Health Information System - Phase Eight

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

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

memorandum of interview (MOI) detailing your discussions and whether your concerns were addressed adequately. Give a copy of the completed MOI to the exporter and file a copy in the inspection file.

### **Means of stamping**

The USDA export stamp is an accountable item that must be held under control. The stamp is applied to the container. Establishments may also use computer-generated stickers. Stickers must be the exact size and impression as the export stamp, must be printed with authorization, must be based on assigned export number, and the establishment must identify number of stickers produced prior to applying. They must give all unused stickers to the inspector upon completion. Establishments may also perform direct inkjet printing of the export mark to the carton or container. You are to verify that the inkjet mark is equal in size and an exact impression of the FSIS rubber export stamp. They should also not be printed on the cartons or containers until authorized by you, should only be applied in the quantity needed for application to the consignment, and the establishment should notify you in advance of the quantity of cartons or containers to be printed. Applying the export mark to the cartons or to the containers should be done under the supervision of a designated plant employee.

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

### **Pre-stamping**

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

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

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

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

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

If the certificate is lost, IPP are not to issue a replacement certificate unless the exporter provides a letter of assurance to the CO stating the certificate will be returned if found. The replacement certificate only restates the information contained on the original certificate or if the country of destination has changed. The exporter may split or consolidate a shipment with stamped pallet or conveyance. The Remarks section for a replacement certificate must contain the statement as follows: "This certificate replaces certificate number \_\_\_\_ (insert original certificate number(s) dated \_\_\_\_ (insert date(s) of the original certificate(s)). The export mark covered by the certificate shows certificate number \_\_\_\_ (insert original certificate number)."

## **Export Verification/Quality System Acceptance (EV/QSA)**

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

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

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

## 33 Food Defense

### OBJECTIVES

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

### FOOD DEFENSE TERMINOLOGY

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

**Food Security** – Ensuring all people at all times have both physical and economic access to enough food for an active, healthy life. Food security includes both physical and economic access to food that meets people's dietary needs and food preferences. Therefore, the concept of food security certainly includes but encompasses much more than the idea of food defense.

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

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

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

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

## **FOOD DEFENSE VULNERABILITIES AND FOOD DEFENSE PRACTICES**

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

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

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

## FOOD DEFENSE IN FSIS-REGULATED ESTABLISHMENTS

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

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

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

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

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

## NATIONAL TERRORISM ADVISORY SYSTEM

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

## PERFORMING FOOD DEFENSE TASKS IN PHIS

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

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

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

## SUMMARY

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

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

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

Report any suspicious activities in establishments to your District Manager through supervisory channels or call the **FSIS 24-hour emergency hotline** at **1-866-395-9761**.

## 34 Non-Food Safety Consumer Protection (NFSCP)

### Objectives:

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

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

### Statutes

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

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

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

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

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

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

### **Labeling & Standards of Identity**

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

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

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

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

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

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

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

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

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

## Verification Methodology for Non-Food Safety Tasks

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

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

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

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

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

## **PHIS - Introduction to the Public Health Information System**

**Objective:** Understand how PHIS enhances inspection and protects public health The Food Safety and Inspection Service (FSIS) is the public health regulatory agency responsible for ensuring that domestic and imported meat, poultry, and processed egg products are safe, wholesome, and properly labeled. FSIS has made significant advances in the inspection process and is constantly evolving to enhance our ability to protect public health. Looking back, certain milestones may come to mind. In 1906, Congress passed the Federal Meat Inspection Act. In 1996, FSIS finalized the “Pathogen Reduction: Hazard Analysis Critical Control Point (HACCP) Systems” rule. In 2011, FSIS implemented the Public Health Information System (PHIS) to support a data-driven approach to FSIS inspection, auditing, and scheduling.

### **PHIS Introduction**

PHIS is a user-friendly, web-based application that replaces several legacy systems and automates many processes. It allows FSIS to obtain and quickly analyze more data about domestic and international food safety systems producing FSIS regulated products. It also enables the Agency to better identify food safety risks before they result in outbreaks or recalls. The Predictive Analytics component supports a data driven approach to inspection and sampling by automatically searching data to identify trends and notifying FSIS personnel about potential public health threats.

PHIS generates specific tasks and adjusts task frequencies based on public health risk factors. IPP, supervisors, and analysts access real time data for early recognition of food safety system deficiencies and trends. Data is used to quickly and effectively respond to prevent product adulteration, recalls, and outbreaks. The quality of the analysis and the response however depends on the quality of the data in the system. It is critical that IPP enter data that is complete and accurate.

PHIS was developed in response to an Office of the Inspector General (OIG) recommendation that FSIS develop an integrated data infrastructure to support a comprehensive, timely and reliable data driven inspection system. PHIS enables FSIS to utilize real time data to inform all aspects of its business process (e.g., domestic inspection, import inspection, and export activities).

PHIS replaced several legacy systems, facilitating maintenance and analysis of the composited data. Work efficiency and effectiveness continues to improve since FSIS personnel with different roles (e.g., inspectors, managers, analysts, policy developers) can readily access and utilize inspection and sampling data. Agency resources are better utilized since tasks are prioritized.

There are four functional areas within PHIS:

- **Domestic Inspection**
- **Exports Certification**
- **Imports**
- **Predictive Analytics**

This course covers Domestic Inspection and Export Certification. Imports are covered in a separate training course.

PHIS is role-based. There are many different roles and permissions based on duties, job description and job series. Each user role sees a unique navigation menu. For example, CSIs can access the establishment profile, task calendar, inspection verification data, animal disposition, and export certification menus for their assignments.

Establishment profile data drives many important PHIS functions. Therefore, IPP must routinely update and ensure the accuracy of the profile data. The profile includes critical information about the establishments' operations, product types, product volumes, and HACCP system.

This information allows FSIS to tailor inspection, sampling, or other activities based on establishment factors. Sample requests are electronically routed to inspectors based on establishment profile information. If profile data is inaccurate or missing, IPP could receive sample requests for products that the establishment no longer produces.

A "task list" is generated for each establishment based on profile data. The Task List identifies task priorities and frequencies. IPP consider the task priorities, time constraints, and their knowledge of establishment operations to schedule tasks on their task calendar.

In addition to routine tasks, "directed" tasks may be added to the task list. PHIS generates some directed tasks in response to sample results. Sampling tasks specify a time frame during which IPP are to schedule and collect the requested sample. IPP can add directed tasks to document a noncompliance found when not performing a routine task. PHIS also allows directed tasks to be initiated at various Agency levels and targeted to subsets of establishments in response to public health findings or other information. The system tracks completion of tasks and can alert supervisors when tasks are performed.

PHIS contains links to applicable guidance material (e.g., Directives, Notices). The guidance is based on the establishment profile and the specific inspection task. Linking to only the applicable guidance reduces time spent searching for and reviewing information that may not be helpful or pertinent.

In PHIS, IPP document the specific regulations verified and the findings of compliance or noncompliance for each regulation. If a noncompliance is found, it is documented on an NR along with other applicable information such as product type, lot number, retain or reject tags used, and/or the applicable CCP verified for some tasks. The system also facilitates documenting meeting minutes in a memorandum of interview (MOI). Inspectors can create notes in PHIS that can be used to communicate with other inspectors or included as agenda topics for meetings.

### **Predictive Analytics**

Predictive analytics integrates data from various sources such as Centers for Disease Control and Prevention (CDC), PulseNet, the Agricultural Research Service VetNet, and the National Antimicrobial Resistance Monitoring System (NARMS) and stores the collected data in the FSIS Data Warehouse. Algorithms perform real time data analysis. When anomalies are identified, PHIS sends alerts to the appropriate user homepages or email addresses. Users may subscribe to alerts that are of interest.

Predictive analytics also uses algorithms to automate scheduling in response to certain events. The system generates appropriate follow-up tasks in response to sampling results. For performing and scheduling directed tasks, IPP should follow guidance in FSIS Directive 13,000.1.

Predictive analytics incorporates decision criteria to schedule Food Safety Assessments and identifies when an establishment should reassess their hazard analysis. Analysts can also conduct spontaneous data analyses from multiple data sources to identify trends and anomalies.

## PHIS 1 – Establishment Profile

### Objectives

1. Describe the Establishment Profile in PHIS and why it is important to maintain the accuracy of information.
2. Describe when and how to perform the Update Establishment Profile task in PHIS.
3. Describe what to discuss and do at the weekly meeting related to the profile.

### References

1. [FSIS Directive 5300.1](#), *Managing the Establishment Profile in the Public Health Information System (PHIS)*
2. PHIS Quick Reference Guide

### Background

The Establishment Profile (EP) is a series of web pages in PHIS that Inspection Program Personnel (IPP) use to enter data about official establishments and other facilities where FSIS provides inspection services. The profile includes information on the products produced, the processes performed, the equipment employed, the HACCP systems that the establishment has put in place, and other general information.

PHIS uses the establishment profile information to assign routine inspection tasks, to create tailored inspection tasks, to generate FSIS sample requests, and to manage inspection assignments. Therefore, it is critical to make sure that the profile is accurate and reflects what the establishment is actually producing and the food safety system it is using to ensure that its products are safe.

For new establishments, the District Office enters information in PHIS to populate parts of the profile and IPP complete the remainder and verify the accuracy of information on an ongoing basis. For existing establishments, IPP maintain and verify accuracy of information on an ongoing basis. During the process of granting inspection, the Grant Curator (GC) is to assign an establishment number and enter information regarding the application for grant of inspection or inspection services. A Frontline Supervisor (FLS), EIAO, or other designated personnel will visit the applicant's establishment and report the information gathered at the establishment which will be used to complete parts of the establishment profile. After the grant process is complete, the assigned inspector-in-charge (IIC) is responsible for keeping the information in the establishment profile up-to-date and accurate as part of their in-plant duties.

The EP information is essential to the Agency's goal of protecting public health because FSIS uses the establishment profile information for generating inspection tasks, determining eligibility for sampling programs, for automated reporting and for ad hoc data analysis. When an establishment begins production of a new product, there is a significant change in product volume, an establishment address changes or there is a jurisdiction change, IPP are to update the establishment profile as soon as the change occurs to ensure the appropriate inspection

tasks are being generated. Other changes, not directly related to task scheduling and sampling eligibility, can be completed during the next routine monthly Update Establishment Profile task.

**The following profile features aid in the determination of task scheduling and sampling eligibility and are critical to keep updated and accurate:**

- 1. HACCP Processing Category**
- 2. Product Volume Information**
- 3. Jurisdiction**
- 4. Sampling Supplies Address**

Other Establishment Profile information of critical importance includes:

- Grants and Approvals
- Operating Status
- Inspection Activities
- Shifts
- Slaughter
- Products produced

**Grants** include all information related to the Application for Federal Inspection (AFI) and Application for Voluntary Reimbursable Services (AVRS). **Operating Status** is the overall status of the establishment (not just of a particular grant) and is “active” or “inactive”. When Operating Status is “inactive”, no inspection tasks are allocated to the establishment, so it is critical to recognize and correct an “inactive” status as soon as possible. An **Inspection Activity** is one of the following: meat slaughter, meat processing, poultry slaughter, poultry processing, egg product, or imported product. Inaccurate inspection activities indicate that EP information needs changing and as a result the proper tasks may not show up in the establishment task list. **Shift** information is critical to ensure that all shifts receive the appropriate inspection tasks and coverage. Operating Status, Inspection Activities, Grants and Shifts cannot be modified by IPP as it is “Read Only.” However, it is very important that this information is corrected as soon as possible, so IPP should examine it right away. Contact the DO through supervisory channels if it is incorrect.

**Slaughter** includes the slaughter system, inspection system, number of slaughter lines, number of slaughter lines operating simultaneously, maximum line speed, and staffing. **HACCP Processing Categories** are critical because the tasks for each category will only be assigned if reflected in the profile. It is important that **Inspection Tasks** assigned to the establishment’s inspection task list are applicable and no tasks are missing. The **Products** and **Production Volume Information** has an impact on sampling projects and sampling frequencies. The **Jurisdiction** information identifies the government organization that performs inspection of food products at the establishment. The **Sampling Supplies Address** is critical since lab sampling supplies cannot be delivered to the establishment if this information is missing or not accurate. This information can be entered or edited by IPP.

**Performing the Update Profile Task**

PHIS will display the routine update profile task on the establishment task list monthly.

- IPP are to perform the routine Update Establishment Profile inspection task monthly by updating the information in the establishment profile with any new information and reviewing the establishment task list. IPP are also to focus on verifying the accuracy of a specific area of the establishment profile each month according to the following schedule:

<b>Table: Establishment Profile Update Schedule</b>	
<u>Month</u>	<u>Profile Information Focus Area</u>
January	<b>Establishment Contacts</b>
February	<b>HACCP Systems Information</b> for Raw-Intact product categories
March	<b>HACCP Systems Information</b> for Raw-Non-Intact product categories
April	<b>HACCP Systems Information</b> for Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, and Heat Treated Shelf Stable product categories
May	<b>HACCP Systems Information</b> for Fully Cooked–Not Shelf Stable, Product with Secondary Inhibitors–Not Shelf Stable, and Heat Treated but Not Fully Cooked–Not Shelf Stable product categories
June	<b>General Profile Information</b>
July	<b>Product Information</b> for Raw-Intact product categories
August	<b>Product Information</b> for Raw-Non-Intact product categories
September	<b>Product Information</b> for Thermally Processed-Commercially Sterile, Not Heat Treated-Shelf Stable, and Heat Treated Shelf Stable product categories
October	<b>Product Information</b> for Fully Cooked–Not Shelf Stable, Product with Secondary Inhibitors–Not Shelf Stable, and Heat Treated but Not Fully Cooked–Not Shelf Stable product categories
November	<b>Slaughter Information</b>
December	<b>General Profile Information</b>

- IPP are to also perform the Update Establishment Profile task if they become aware while performing other inspection tasks, or through communication with a management official, that the establishment is producing **a new product**. A directed task may be used for this purpose if the routine task has already been performed for that month. IPP perform the update profile task by reviewing and updating the information in the establishment profile. The EP link on the left navigation menu contains the sub-links needed to access the various establishment profile pages. IPP can only edit profile information for establishments in their inspection assignments.

- IPP provide a copy of the EP report to establishment management during the next weekly meeting upon entering a new assignment, or following a change to an existing assignment. Management will have an opportunity to affirm or correct any of the profile information in PHIS. When management responds with a correction, IPP are to change their response only after seeing establishment records or other data that is needed to support the basis for the correction. IPP are to resolve any issues or discrepancies regarding profile information before they document the task as completed in PHIS.
- To generate the Establishment Profile Report, IPP are to:
  - Select the establishment under the **Establishment Profile** tab on the left navigation menu;
  - Scroll down to the bottom of the page and find the **Reports** tab; and
  - Click on **Reports**, then select **Establishment Profile Report**. This will generate the report that can then be saved or printed.

**Note:** Refer to the PHIS user guide or the PHIS Help Button for step-by-step information.

When performing the **Update Establishment Profile** task, IPP are to gather information from a management official at the establishment or facility and complete or update information as needed. The following parts of the EP will be accessed in making updates:

- Establishment Contacts
- General
- Establishment Task List
- HACCP Systems Information (meat and poultry establishments only)
- Slaughter Information (meat and poultry establishments only)
- Product Information (meat and poultry establishments only)
- Production Volume Information (meat and poultry establishments only)
- Profile Questionnaires

**Note:** Information concerning Grants and Approvals (Read only), Profile Summary, Operating Schedule, Facilities, Equipment (Thermal Processing), and Training can also be accessed.

## PHIS 2 – Task List / Task Calendar

### Objectives

1. Identify the FSIS directive that provides instructions to IPP for scheduling inspection task in PHIS.
2. Define the following terms: Task Library, Establishment Task List, Task Calendar, Routine Task, Directed Task.
3. Describe how the task list is created for an establishment and how to navigate the features of the task list.
4. Identify situations that require IPP to schedule and perform directed tasks and how to schedule a directed task.
5. Identify the two sections of the PHIS tasks calendar page and how to navigate the features of the page and filter for the inspector and the establishment.
6. Describe the principles that IPP follow when scheduling and performing inspection tasks.
7. Describe the steps that IPP need to perform the first time they log in to PHIS each day.

PHIS, which stands for Public Health Information System, is a web-based application used by FSIS to generate specific tasks for inspection personnel to schedule tasks to perform based on public health risk factors.

The PHIS Task Library is a component of PHIS that lists **all** the different kinds of routine inspection tasks that may be performed by IPP. It also provides a description of each task. The Office of Policy and Program Development staff members maintain the tasks in the task library. Each task is given a priority level and an expected frequency to be performed in a one-month period. The Task Library will also display inspector guidance, mandatory regulations cited, other regulatory concerns, and the specific data to be recorded each time IPP perform the task.

The Task Calendar page is divided into two sections, the Establishment Task List and the Establishment Task Calendar. The Establishment Task List displays all the tasks which are assigned to the establishment based on the information in the establishment profile. In other words, the establishment task list is the source of routine inspection tasks added on the Task Calendar and performed by IPP assigned to that establishment. The Establishment Task Calendar displays all the scheduled, in-process, completed, and not performed task for the establishment. It provides IPP with the flexibility to schedule tasks on days that work best for their assignments.

There are two types of tasks: Routine tasks and Directed tasks.

- **Routine tasks** are inspection verification activities conducted on a routine, on-going or planned basis under normal conditions. Routine tasks are allocated based on the information in the establishment's profile, e.g., HACCP processing category and products.

- **Directed tasks** are those that do not occur on a routine basis under normal circumstances. These tasks are performed on an as needed basis. Sampling tasks and export certification tasks are considered to be directed tasks because they do not occur on a routine basis. Directed tasks may be initiated in several ways: Positive pathogen result, FSIS headquarters personnel, supervision, and conditions observed in the establishment.

When scheduling tasks, inspection personnel should use the frequency and priority level of each task. They should also utilize their knowledge of the establishment, travel times between inspection assignments, allocate the tasks over the entire month, avoid predictable patterns, and do not schedule too many tasks. If IPP determine that they will not be able to complete all high priority tasks or all directed tasks by the applicable end dates, they are to discuss the situation with their immediate supervisor as soon as possible. The supervisor will be able to advise IPP on how to best arrange the necessary tasks or may be able to spread the necessary work to other IPP.

At the beginning of each work week, IPP should ask establishment management what operations will be conducted and what products will be produced during the week. Based on the information provided by the establishment, IPP may need move, or remove and reschedule inspection tasks. If all of the work cannot be performed on a given day due to the addition of directed tasks, sampling tasks or export certification requests, IPP should adjust the Task Calendar by moving tasks to another day. IPP assigned to the same establishment are expected to coordinate work efforts. This may require reassigning and completing tasks on the Task Calendar that **have not been started** and tasks that have been started (in-progress) but **not completed** from each another. **Note:** An inspector cannot assign a task (work) to another inspector, but an inspector can claim a task (work) assigned to or originally scheduled by another inspector. The ideal situation or overall goal is that IPP complete all routine tasks for the month. In this case, the number of completed tasks would equal the number of planned tasks by the end of the month.

The ideal situation or overall goal is that IPP complete all the routine tasks for the month (*i.e., the number of completed tasks matches the number of expected or planned tasks at the end of the month*). Even though IPP have scheduled all of the expected tasks, there are going to be times when they cannot perform all of them by the end of the month. Those tasks that are still on the Task Calendar that have not been started by the end of the month are marked as “not performed”. IPP must select the appropriate “justification” for not performing the task from a dropdown list in PHIS. Thus, at the end of the month, IPP account for all the expected instances of a task that were on the establishment’s Task List in one way or another.

PHIS maintain information about IPP in-plant assignments. The information available to the IPP is limited to his/her work assignments. However, IPP often cover assignments other than their permanent assignment. The most obvious example is relief inspectors, but other IPP will temporarily cover an assignment that is not their assignment. To access and interact with PHIS while temporarily covering another employee’s inspection duties, IPP must be designated as covering that assignment in PHIS. The temporary coverage does not disrupt the permanent assignment structure but allows IPP to enter information into the system for the coverage assignment. A coverage assignment can be set up within PHIS on a long-term basis and only used when needed, or it can be set up only when the coverage occurs.

**PHIS Daily Activities to Ensure Tasks are Scheduled and Performed when Logging into PHIS for the First Time during the Work day, IPP should (in this order):**

1. Review any new alerts on the dashboard of the homepage. The alerts:
  - Are generated automatically based on data entered into the system and events that occur in the establishment
  - Provide IPP with urgent or critical information
  - May direct IPP to perform additional inspection tasks or take other action
  
2. Review each establishment's Task List to find any new directed tasks. Directed inspection tasks:
  - Are generated automatically based on data entered into the system
  - May be generated by supervision, the District Office, or Headquarters
  
3. Review each establishment's task list to find any new sampling tasks.
  
4. If the establishment exports product, determine if there are any new export requests.
  
5. Review the task calendar to see what inspection tasks are already scheduled for the week or month.
  
6. Add any new directed inspection tasks/sampling tasks/export requests to the Task Calendar.

IPP are to consider the priorities of the new tasks relative to the tasks already scheduled on the calendar to ensure that they still complete the most important tasks by the end of the month. For sampling tasks, they need to plan to ensure they can collect the sample during the designated time period.

7. Adjust the Task Calendar, if the work cannot all be performed on a given day due the addition of directed inspection tasks/sampling tasks/export requests.
  
8. Review any open NRs to determine if they can verify that the establishment has brought itself back into compliance while performing inspection tasks.

	Status in PHIS	Definition
Inspection Task	<b>Not Open</b> Task Color Blue on the calendar	<ul style="list-style-type: none"> <li>Task has been added to inspector's task calendar</li> <li>Verification component option has NOT been selected in PHIS</li> </ul>
	<b>Open</b> (in-progress) Task Color Yellow on the calendar	<ul style="list-style-type: none"> <li>Verification component option has been selected in PHIS</li> <li>IPP have begun to enter results</li> </ul>

	Status in PHIS	Definition
Inspection Task	<b>Completed</b> Task Color Green on the calendar	<ul style="list-style-type: none"> <li><b>All</b> verification has been performed and <b>all</b> results have been entered for the task</li> <li>If an NR was issued, the NR's status has been updated to "completed"</li> <li>"Inspection completed" box has been marked on "the inspection results" page for the task</li> </ul>
	<b>Not Performed</b> Task Color Red on the calendar "if scheduled"	<ul style="list-style-type: none"> <li>IPP has NOT started the task before its end date (usually the last workday of the month)</li> </ul>

## PHIS 3 - Inspection Documentation, NRs, MOIs, Inspector Notes, Meeting Agenda

**Objective:** Understand how to:

1. Navigate the Inspection Results page
2. Record the result of an inspection task
3. Document the regulations verified
4. Create an inspection note
5. Document an NR
6. Document an MOI
7. Create a meeting agenda

### Documenting Inspection Task Results in PHIS

FSIS uses the results of inspection tasks and information about establishment operations to guide policy development and target Agency resources to those activities that will best protect public health. To assist with these types of decisions, the **Public Health Information System** (PHIS) is designed to capture information about inspection tasks such as:

1. Which regulatory requirements IPP verified, and whether they observed compliance or noncompliance;
2. How IPP verified the regulatory requirements (i.e., recordkeeping, review and observation, or both).

IPP use PHIS to document the results of their inspection tasks. After IPP perform an inspection task, they are to open the “**Inspection Results**” page for the specific inspection task, select applicable “tabs”, and record their results in PHIS. They are to make the appropriate entries regarding the task and their findings of regulatory compliance or noncompliance by checking appropriate boxes, making appropriate selections from lists, or typing in text. PHIS will allow inspection tasks to extend over more than one day. Thus, IPP may enter partial results on one day and then continue/finish performing the task by entering the remaining results on another day.

The primary method of accessing the Inspection Results page is through the Task Calendar. Other pathways are also available in PHIS for accessing the Inspection Results page. For example, IPP can also access the Inspection Results page using the Inspection Verification left navigation menu. The results of *all* inspection tasks are documented on the **Inspection Results** page.

### Completing the Noncompliance Record (NR, FSIS Form 5400-4) in PHIS

When IPP determine that the establishment has not met one or more regulatory requirements, they check the “**Regulatory Noncompliance**” box at the bottom of the “Regulations” tab of the Inspection Results page, and then click “Save” in PHIS. Checking the “Regulatory Noncompliance” box enables the “Create/Edit NR button” on the bottom of the Inspection Results page. Much of the information that appears in the sections/blocks on the printed NR is automatically added by PHIS. Some blocks on the printed NR are completed with information entered by the IPP. For instance, the IPP must provide a complete, clear, and concise description of each noncompliance.

## The Role of Inspection Notes

The “Notes” tool enables IPP to document observations, trends, and other issues that relate to establishment operations that should be brought to the attention the establishment. Notes can also be used as memory joggers for IPP to follow-up on a particular observation or issue. For example, IPP should document and discuss less-than-perfect sanitary conditions or execution of establishment procedures and programs with establishment management that at the time do not represent noncompliance but could lead to noncompliance. Inspection notes are maintained within the system in 10 categories: facilities, equipment, sanitation, processing, safety, FSA, food defense, export, support and records.

There are **several advantages** to entering specific observations into PHIS using the Inspection Notes feature. For instance, entering notes into PHIS can facilitate communication between:

1. IPP in the same assignment;
2. Relief IPP and the assigned IPP;
3. IPP and their supervisors, and
4. IPP and other parts of the FSIS chain of command.

The Inspection Notes tool allows IPP in the same assignment and relief IPP to review findings, issues, or concerns previously observed. By having access to such information, they are better equipped to identify developing problems. They can act to prevent issues that could affect public health. For example, while performing inspection verification tasks, assigned IPP can continue to focus attention on a particular finding, trend, or issue and if necessary, continue to document the establishment’s inability or unwillingness to address or correct the issue before it leads to noncompliance.

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**Note:** The use of inspection notes is not intended to replace documentation of noncompliance on NRs. All regulatory noncompliance should be documented on an NR.  
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## PHIS Features IPP Use to Document Meetings between IPP and Establishment Management

PHIS has several time-saving features that IPP use to document the mandatory meetings that they have with establishment management. These features enable IPP to work efficiently. First, there is a Meeting Agenda tool for recording the topics to be discussed at the meeting. Secondly, there is an inspection notes tool to record IPP concerns that do not rise to the level of noncompliance but still need to be discussed with establishment management. The Inspection Notes can be easily transferred to the Meeting Agenda. Lastly, the Memorandum of Interview (MOI) tool creates the official record of the discussion between IPP and establishment management at each meeting.

### Entrance Meetings

Upon rotation into an assignment, or when IPP are newly assigned to an establishment, they are to review the establishment’s history, which is reflected in the **establishment’s homepage in PHIS**. They are to consult with their immediate supervisor if they have questions or concerns about the establishment’s history.

After IPP familiarize themselves with establishment’s history, HACCP plans, and programs, they are to conduct an **entrance meeting (e.g., the first weekly meeting)** with the establishment

management. At this meeting, IPP should inquire about the specific operations of the establishment and seek to answer any questions that came up during their review of the establishment's history or programs. IPP are to ask establishment management about the location of the applicable records and the protocol for FSIS personnel to access and review the records. Establishments are required to provide access to records needed by IPP to perform their duties. However, IPP must review the necessary records in the location specified by establishment management. IPP are not to maintain any copies of the establishment's written programs or data from such programs in the inspection office. Likewise, IPP are to ask about any previously agreed upon notification (e.g., when IPP need to inform the establishment they will be collecting a sample) when Agency sampling is performed at the establishment. IPP need to know this information so that an establishment can properly control sampled product pending FSIS test results.

**IPP take notes at the entrance meeting and document the notes in a MOI in PHIS and provide a copy of the MOI to the establishment.**

### **Awareness Meetings**

When new regulations, policies, performance standards, compliance guidelines, or product sampling protocols are published in a Federal Register Notice, FSIS provides information, guidance and instructions to IPP for verifying the new policy or implementing the new performance standards or implementing the new sampling protocol through either a FSIS Directive or FSIS Notice. The Directive or Notice often directs IPP to conduct an awareness meeting with establishment management upon receipt of notice or directive. The Notice or Directive identifies specific information that IPP are to share with establishment management at the meeting. **IPP take notes at the awareness meeting and document the notes in a MOI in PHIS and provide a copy of the MOI to the establishment.**

### **Weekly Meetings and Agenda Items**

As set out in FSIS Directive 5000.1, IPP are to have weekly meetings with establishment management. IPP are to use the tools in PHIS to record inspection notes, create meeting agendas, document MOIs, and record the performance of weekly meeting tasks. The performance of the weekly meeting **AND** other meetings is documented in PHIS under the "Meeting with Establishment Management" task.

The purpose of the weekly meeting is to provide an opportunity for IPP to address matters that affect the establishment's on-going compliance with FSIS requirements. The discussion of issues during the weekly meeting is not intended to replace documentation of noncompliance on an NR. Moreover, the fact that an issue is not discussed at the weekly meeting does not mean that the issue could not become the subject of an NR.

Meetings should benefit both IPP and the establishment. For instance, it is important that IPP discuss topics pertinent to the establishment's food safety system that could affect public health. IPP are not precluded from asking establishments about any subject of regulatory concern, e.g., recalls, allergen control, etc. Establishment management may wish to share information regarding their operations, such as facility improvements and changes to their food safety systems, or express concerns at the meetings.

A wide variety of topics can be discussed at the meetings, including individual noncompliances, developing trends of noncompliance, and findings by IPP that do not represent regulatory noncompliance but that need to be brought to the attention of the establishment. For example,

discussion of information from external sources, such as customer or consumer complaints, can provide information to alert establishment management about a safety risk or about other information that is relevant to the establishment's food safety system.

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**Note:** FSIS Directive 5000.1 **requires** IPP to discuss developing trends in noncompliance at the weekly meetings and document the discussion of noncompliance trends and the associated NRs in an MOI. IPP are to discuss any identified associations between current and past noncompliances, and describe to establishment management why the associated NRs indicate a trend of noncompliance. It is recommended that IPP explain that continued noncompliance may result in further enforcement actions, to help the establishment understand the consequences of continued noncompliance.

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FSIS Directive 5010.1 provides a **general list** of food safety related topics that IPP **may** consider discussing with the establishment during weekly meetings. Given the range of the issues confronting FSIS-regulated establishments, it may be difficult to discuss all of the topics that either FSIS or the establishment wishes to address during any one weekly meeting. Similarly, IPP should not use the list of topics in FSIS Directive 5010.1 like check list nor should they attempt to discuss all topics listed during a given period of time. The topics in the directive should be discussed as they arise. The list below is not all-inclusive. Possible topics for discussion listed in FSIS Directive 5010.1 include:

1. In-plant observations, e.g., individual NRs, less than perfect conditions that may, if not addressed, become noncompliances, and humane handling/poultry good commercial practices issues;
2. Issues and information that the establishment wishes to share;
3. Agency issuances, e.g., FSIS Notices and Directives and askFSIS questions;
4. Information regarding FSIS sampling;
5. Information related to the establishment's food safety system, e.g., changes to prerequisite programs used to support food safety decisions;
6. Information from external sources, e.g., consumer complaints and recalls; and
7. Any inspection related activities occurring outside of approved hours of operation.

On a periodic basis, about once a month as scheduled using the PHIS "Update Establishment Profile" task, IPP are to ask establishment management at the weekly meeting whether it has made any changes in the production process or other changes that could affect the safety of the product. If IPP learn that establishment management has made a change in its process, based on the nature of the change, IPP are to perform the appropriate verification activities outlined in FSIS Directives 5000.1 and 5000.6. If IPP are unsure how to proceed, they are to contact their supervisor for guidance.

Before the weekly meeting with the establishment, IPP may use the **Meeting Agenda tool** in PHIS to create an outline of the topics to be discussed. The topics discussed at the weekly meeting are dependent upon the events or conditions that occur in the establishment each week. The meeting agenda may be printed and distributed to IPP who will attend the meeting. IPP are to share a copy of the meeting agenda with establishment management when requested. PHIS will enable IPP to link the meeting agenda to an MOI to create an establishment meeting MOI.

When an establishment has multiple inspection shifts and/or multiple assigned IPP, it is the Inspector-in-Charge's (IIC) duty and responsibility to conduct and document weekly meetings. The IIC:

- Ensures that regulatory concerns that arise on all shifts are discussed at the weekly meetings;
- May delegate conducting the meeting to IPP;
- May include IPP (CSIs or FIs) in the meeting with establishment management;
- Signs all documentation, and
- Ensures that all IPP on all establishment shifts are made aware of regulatory concerns that are discussed at weekly meetings.

When the IIC designates an FSIS employee to conduct the weekly meeting, it **does not** mean that IIC never conducts the weekly meeting or attends the weekly meeting. Depending upon the events occurring (e.g., a product recall, positive pathogen result, humane handling issues or an inadequate HACCP system) or conditions observed (e.g., trends in noncompliance) in the establishment, it may be appropriate for the IIC, or even the FLS, to conduct the weekly meeting or at least be in attendance to assist and support IPP.

**As set out in FSIS Directive 5000.1, IPP are to take notes at the weekly meetings and are to document the notes in a MOI in PHIS. IPP are to provide establishment management with a copy of the MOI.**

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**Note:** If IPP do not conduct a weekly meeting, they are to document this fact and the reason why in an MOI. For example, if establishment management chooses not to attend the weekly meeting, IPP are to document this in an MOI. If IPP cannot conduct the meeting due to the performance of higher priority tasks, such as sampling, IPP are to document this in an MOI.

### **For Cause Meetings**

As needed, IPP can schedule a meeting with establishment management to discuss urgent issues such as a positive pathogen result, recall, outbreak, or inhumane handling incident. **IPP take notes at the meeting, document in a MOI in PHIS, and provide a copy of the MOI to the establishment.**

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### **Memorandum of Interview (MOIs)**

FSIS Directives 5000.1 and 5010.1 and several notices instruct IPP to meet with establishment management and document the outcome of the meeting in an MOI. **An MOI is used to record and convey discussions with establishment or facility management.** The MOI is the written summary of an interview. It should not be a verbatim recitation of the interview, nor does it necessarily have to be written in the same order as the interview was conducted. Instead, it includes the date of the meeting, who was at the meeting, and captures and summarizes critical, relevant information including the specific topics discussed and answers to any questions asked during the meeting.

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**Note:** IPP are not to use the MOI as a means to document daily conversations with establishment employees.

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IPP can create and document the following MOIs in PHIS:

- Establishment Meeting
- Standard
- Domestic Food Defense
- Import Food Defense

An MOI is a very important inspection tool for IPP because it documents the fact that IPP maintain open lines of communication with official establishments. For instance, after the weekly meeting, IPP are to prepare either an establishment meeting MOI or a standard MOI in PHIS to document the agenda items covered in the meeting and document any establishment responses. IPP are to document any discussion of noncompliance trends and NR associations at the weekly meeting in the MOI. Open NRs and NRs under appeal may be linked to an establishment meeting MOI or a standard MOI in PHIS.

An MOI can **also** document a variety of other issues including, but not limited to the:

- Discussion of a new inspection policy transmitted through a FSIS notice (e.g., a directed awareness meeting);
- Performance of records review in accordance with FSIS Directive 5000.2, and
- Performance of specific verification activities (e.g., supplier tracking information and humane handling) as deemed necessary by FSIS.

If establishment management provides no response to issues/concerns, this fact should be recorded in the MOI.

IPP are to maintain a copy of the MOI in the official government file and **must** provide a copy of the MOI to the establishment. When the MOI is provided to the establishment or facility, it is designated as “finalized” in PHIS.

MOIs can be used to track the establishment’s history of responding to issues/conditions in the establishment that are not noncompliance but can lead to noncompliance if conditions worsen or if the establishment doesn’t act upon the information the IPP has given the establishment, e.g., less than perfect execution of prerequisite program. If the situation has been documented in a MOI on numerous occasions, it would be hard for the establishment to say it didn’t know the issue/condition could lead to noncompliance when it finally results in noncompliance documented on an NR.

If an establishment objects to any part of the MOI, IPP are to document the objection at the end of, or as an attachment to, the MOI. If the establishment’s objection is in writing, IPP are to attach the written objection to the MOI. When the establishment’s written objection is transmitted electronically, e.g., e-mail or other file format, IPP can upload the file in PHIS and save the document as an attachment to the MOI record. IPP provide a copy of the amended MOI to the establishment. MOIs can be reviewed by the Frontline Supervisor.

## ***Tips for Writing MOIs***

- Write the MOI as soon as possible after conducting the meeting. “Cold notes” are difficult to understand.
- Document who attended the meeting, the topics that were discussed, and what was said at the meeting. Document only the facts and not any opinions.
- Use quotations only when directly quoting a person.  
Example: Mr. Adams said, “I told Ms. Popadoupolis, the Food Safety Manager, that the SSOP and HACCP records need to be available to the second shift inspector.” Ms. Popadoupolis said she would take care of it.”
- Paraphrasing is generally a safer way of relating what someone said since it is difficult to capture the verbatim account when a person is speaking quickly.
- When paraphrasing, use words like “said” and “stated” to maintain a neutral tone.  
Example: “Mr. Adams stated that Mr. Wallace, the Maintenance Manager, is waiting for a quote to repair a large section of epoxy flooring outside the smokehouses and rack wash area.”
- Do not use “claimed” as a synonym for “said” because this verb has an undertone of blame and mistrust.  
Example: “Mr. Wilson claimed he was not present during pre-operational sanitation inspection.” (This sounds as though we do not believe him.)
- When discussing several people of the same gender, restate the name to prevent confusion.  
Example: “Mr. Irvine said that he told his Quality Assurance Manager that not making the SSOP and HACCP records available to the second shift inspector was a violation of the USDA regulations and that he will develop a method of making them available.” (Who will develop a method of making the records available? Mr. Irvine or the Quality Assurance Manager?)
- Use the first person for your observations.  
Example: “I asked Mr. Irvine to tell me which office he contacted within the FSIS.”
- Use the third person to relate information about the interviewee.  
Example: “Ms. Jones said she was the acting HACCP Coordinator of the establishment during the Food Safety Assessment.”

## **Creating Inspection Notes**

The PHIS inspection notes feature is designed to be helpful to IPP in several ways: First, inspection notes help foster communication between IPP assigned to the establishment across days and shifts. Secondly, they provide a way to capture inspection findings that do not rise to the level of noncompliance but still need to be discussed with establishment management. Lastly, PHIS provides a mechanism for easily transferring these notes into a meeting agenda for the weekly meeting and MOIs.

## **Creating a Meeting Agenda**

FSIS Directive 5000.1 requires IPP to conduct entrance meeting and weekly meetings with establishment management. Some FSIS Notices require IPP to conduct an awareness meeting with establishment. Conditions in the establishment and some inspection findings may require IPP to have non-routine meeting with establishment management, e.g., a positive pathogen or positive residue sample result, humane handling issues, or a recall. These are often referred to as for cause meetings. A wide variety of topics can be discussed at the meetings, including individual noncompliances, developing trends of noncompliance, and findings by IPP that do not represent regulatory noncompliance but need to be brought to the attention of the establishment. IPP can use the meeting agenda tool in PHIS to create an agenda for the meeting.

The PHIS agenda feature lets IPP select inspector notes and import those notes into a meeting agenda. This allows IPP to include appropriate entries from the PHIS inspector notes feature into a draft agenda in preparation for the weekly meeting. Some inspector notes may be memory joggers for the IPP or just to convey information to IPP assigned to the same establishment that may not need to be a discussion item at the weekly meeting with the establishment. When there are no inspection notes that need to be discussed at the weekly meeting, IPP will use the Agenda tab to add discussion topics to the meeting agenda.

Inspection notes are placed in the agenda “as is” and may need some editing and additions such as introduction and conclusion text before completing the meeting agenda.

IPP may add additional topics to the agenda that they did not enter in as inspector notes that they feel need to be discussed at the weekly meeting. If the IPP feels that a particular noncompliance on an open NR needs to be discussed with establishment management at the weekly meeting, IPP should associate the open NR with the Meeting Agenda.

### **Conduct the Meeting**

Now that the IPP has created the establishment meeting Agenda, he or she would log off PHIS and conduct the meeting. IPP use the Agenda to assist in the organization and focus of the meeting. IPP **are required** to take notes and document the outcome of the meetings they have with establishment management. An MOI is used to record and convey IPP discussions with establishment or facility management.

### **Creating an Establishment Meeting MOI from the Agenda**

After the meeting, IPP document the outcome of the meeting on the MOI. IPP should include the establishment’s response to regulatory and non-regulatory concerns discussed at the meeting.

## PHIS 4 - Sample Management

### Objectives

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.

### General Instructions:

- IPP review relevant FSIS Directives and Notices applicable to the sampling program before collecting the sample.
- IPP utilize the PHIS Quick Reference and Users Guides for detailed instructions on the sample management feature of PHIS.
- IPP answer the sample questionnaire, submit it, then print the lab sample form, sign it and place it in sample box.
- IPP follow the instructions in FSIS Directive 7355.1 for packaging, sealing sample boxes, and maintaining the integrity of samples submitted to the lab.

### References:

[FSIS Directive 13,000.2](#), *Performing Sampling Tasks in Official Establishments using the Public Health Information System*

[FSIS Directive 10,800.1](#), *Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products*

[FSIS Directive 10,800.2](#), *Residue Sampling and Testing under the National Residue Program*

**PHIS Users Guide** on USDA Intranet webpage

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.

## 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:

1. Directed Sampling task
2. Collector Generated sample

**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. 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. 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 *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.

## **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.

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).
- 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.

## **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.

## PHIS 5 - Animal Disposition Reporting (ADR)

**Objective:** Perform the following functions in PHIS:

- Specify weight reporting frequencies
- Record No Kill periods
- Enter livestock inspection results
- Record custom slaughter data
- Enter poultry inspection results
- Print condemnation certificates

### References

PHIS Users Guide – USDA Intranet

FSIS Directive 6100.1, *Ante-Mortem Livestock Inspection*

FSIS Directive 6100.2, *Post-Mortem Livestock Inspection*

FSIS Directive 6100.3, *Ante-Mortem and Post-Mortem Poultry Inspection*

FSIS Directive 6170.1, *Ratite Ante-Mortem and Post-Mortem Inspection*

FSIS Directive 10,800.1, *Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products*

### Animal Disposition Reporting

Inspection findings by Inspection Program Personnel (IPP) during ante-mortem and post-mortem inspection that identify diseased animals or carcasses, must be reported in PHIS in Animal Disposition Reporting. The IPP is responsible for collecting, storing, and reporting information on the disposition of livestock and poultry presented for slaughter at all official Federal and Talmadge-Aiken establishments. Within PHIS, IPP are authorized to create and edit several types of animal disposition data within the system.

Daily dispositions for livestock slaughter establishments are entered on a per shift basis. If there are two slaughter shifts, then data will be entered for both shifts. Daily dispositions for poultry slaughter establishments are entered on a per lot basis. The establishment is responsible for designating the lots.

Disposition data is associated with the actual day of slaughter, not the date that the information is entered into PHIS. Whenever possible, ADR data should be entered at the end of shift. In PHIS, only the post-mortem carcass dispositions made by the PHV (carcasses railed out to the PHV) are entered into PHIS. The individual entries will have the retain tag number, and there is a free text narrative box to record additional information.

Condemnation certificates can be automatically generated by PHIS for both AM and PM condemnations. These certificates can be printed out and signed.

Animal Disposition will be the portal for collecting data on in-plant residue screening test results (KIS™) and for requesting laboratory confirmation of presumptive positive test results. Each residue screening test result will be individually associated with the AM or PM disposition decision for that carcass. Additionally, ADR will be the portal for collecting the number of Brucellosis and Tuberculosis samples taken, along with BSE sample information.

## **Workshop #1 – Poultry Slaughter/Processing Establishment, SPS, SSOP, and HACCP**

**Please read the following scenario and answer the questions at the end within the table boxes.**

**Please review the HACCP plan and the records that are associated with this scenario.**

**Background:** K. Nugget, a Consumer Safety Inspector (CSI), is assigned to a poultry establishment that slaughters and further processes young chickens during a single operating shift, Monday through Friday, from 0700 to 1530 hours. The establishment has 2 evisceration lines, produces raw intact and raw non-intact products, and occasionally exports poultry products.

**Scenario:** At 1000 hours, on March 1, 2023, CSI Nugget was leaving the shipping dock after completing export certifications and noticed a foul odor in the hallway outside the processing department. The CSI determined the odor originated from empty, damaged, inedible containers that were being stored in the hallway to be discarded due to their unacceptable condition. CSI Nugget performed an Operational SSOP Review and Observation verification task as she walked through the further processing department on her way to the slaughter department. In the processing department, she observed the establishment monitoring operational sanitation activities. Quality Assurance (QA) personnel were applying yellow caution tape around an area below a leak in the processing room ceiling. The leak was located between two processing lines in a potential product zone.

CSI Nugget proceeded to the slaughter floor to continue to observe operational sanitation throughout the establishment.

At 1230 hours, CSI Nugget decided to review the establishment's SSOP program and records for the leak that was observed earlier in the further processing department. (Note that these SSOP records are not required to be available until the start of the same shift on the following day). The establishment's SSOP records had two entries related to the leaking

ceiling. An entry at 0900 hours which stated that an employee observed a leak and notified QA and maintenance personnel. The area was roped off by QA. There was another entry on the SSOP record at 1030 hours that the area was released because maintenance fixed the leak, and the ceiling was no longer leaking.

Before CSI Nugget headed back to the processing room, decided to review the Zero Tolerance CCP records for the current day since she had not noticed any establishment personnel performing the Zero Tolerance CCP monitoring. CSI Nugget found the clipboard with the CCP monitoring record, but it was blank.

CSI Nugget decided to follow-up on the conditions in the processing room. When she arrived, she noticed that the caution tape had been removed from the area that was previously segregated. Now, there were five metal combo bins with poultry thighs and wings in that area. The CSI observed that there was a large blue plastic tarp partially covering three of the five bins. The other two combo bins were completely uncovered. There was an accumulation of clear liquid on the plastic tarp that was slowly running into one of the three combo bins that were partially covered. The CSI investigated further and noticed that the ceiling above the metal combo bins was slowly leaking liquid into the uncovered combo bins.

CSI Nugget headed to the QA office and reviewed the HACCP plan. The HACCP plan specified that the slaughter Zero Tolerance CCP will be monitored each production hour on each line. CSI Nugget informed the QA Supervisor that there were no monitoring results for CCP 1 documented on the HACCP records for the entire day. The QA Supervisor checked into the matter and informed CSI Nugget that the checks had been performed by the QA Technician but due to her monitoring the work on the ceiling leak she had forgotten to document the results of her monitoring checks.

**HACCP Plan (excerpt) CCP 1**

Poultry Slaughter HACCP Plan					
Process Step	CCP Number	CCP Description	Critical Limits	Monitoring Procedures	Verification Procedures
Zero tolerance Examination (carcass)	1 – Biological (Pathogens in fecal material)	No visible contamination	No visible fecal material  If a deviation from the critical limit occurs, corrective actions shall meet all requirements of 9 CFR 417.3 and be documented on the Zero Tolerance Monitoring form.	Designee will examine 10 randomly selected carcasses each production hour per shift, per line.  Document findings on Zero Tolerance Monitoring Form.	Once per week a supervisor observes the designee performing the monitoring.  A supervisor will conduct records review daily.

**Establishment’s Zero Tolerance Monitoring Record for March 1, 2023**

Zero Tolerance Monitoring Form (CCP1)					
Date	No fecal material identified on 10 carcass sample = 0	Performed by	Time	Corrective Actions and/or Comments	Verification Procedures
3/1/2023					

### Establishment's SSOP Monitoring Record for March 1, 2023

SSOP Monitoring Record – Further Processing (Monitor Implementation 4 times daily)				
Date	Time	Performed by	Processing Room	Corrective Actions and Preventive Measures
3/1/23	0800	MJ	Acceptable	
3/1/23	0900	MJ	Unacceptable - employee observed leak and notified QA and maintenance personnel.	No product was involved. Maintenance is working on the leak and area is sectioned off.
3/1/23	1030	MJ	Acceptable	Maintenance fixed the leak. The ceiling is no longer leaking. Area released.  Blue plastic tarps will be placed over the product combo bins until the corrective actions are complete. A QA Tech will monitor the area twice per shift, per day for the next three days.

**Questions:**

<p><b>Q1</b> - Please explain why the establishment is not in compliance with FSIS regulations. Include the regulatory citation.</p>		<p><b>Q2</b> - If you were the CSI in this establishment, what are the actions you would take? (i.e., List the actions you should take as a CSI in relation to each noncompliance you identify in this scenario).</p>
<p><b>Noncompliance Description</b></p>	<p><b>Regulation(s) not met</b></p>	<p><b>Your Actions for This Noncompliance</b></p>
<p>HACCP Noncompliance</p>	<p>HACCP Regulation</p>	
<p>SSOP Noncompliance</p>	<p>SSOP Regulation</p>	
<p>SPS Noncompliance</p>	<p>SPS Regulation</p>	

## Workshop #2 – Livestock Establishment NR

*After completing the workshop, the participants will be able to:*

- 1. Determine the required data that needs to be included in an NR.*
- 2. Determine the situations that require associating NRs.*

**Please read the scenario, review the NR, and answer the questions at the end.**

### **Livestock Establishment Scenario**

**Background:** CSI Naomi Thompson is assigned to Veal on Wheels, a small veal slaughter and processing facility. The establishment slaughters approximately fifty veal calves a day on one shift, five days a week. They use a bed dress system (cradle) during slaughter operations. Incorporated into the HACCP system to address *E. coli* O157:H7 and non-O157:H7 STEC are two critical control points including zero tolerance and a lactic acid intervention.

**Scenario:** On June 1, 2022, at approximately 0910 hours, CSI Thompson performed a scheduled Slaughter HACCP verification task on the slaughter floor and noticed that the establishment is hanging both hindquarters of each carcass on one rail trolley hook prior to the final wash and antimicrobial intervention steps. Since the establishment does not split the veal carcasses, they usually use a gambrel to separate the hindquarters for adequate washing and antimicrobial coverage. By using the one trolley hook this caused both hindquarters of each carcass to be touching. Upon observing the inside of the hindquarters of three carcasses she identified that they were not receiving any lactic acid coverage. The plant employee pushed these three carcasses into the cooler. She notified the slaughter foreman, Mr. James Drayer, of the noncompliance.

The critical limit for the antimicrobial intervention CCP includes a 2% lactic acid concentration applied to the entire carcass so that complete coverage is achieved. CSI Thompson observed the establishment perform a titration to verify the appropriate concentration prior to starting operations. Note: Titration is a standard method of chemical analysis which can be used to determine the concentration of a known reactant. CSI Thompson also noted that the establishment used a small garden type sprayer to apply the lactic acid. She determined that solution was mixed to the correct concentration and the garden sprayer was an acceptable means of applying the solution.

Since the ten veal carcasses already hanging in the cooler were observed to be hanging from one hook in the same manner and the inside of the hindquarters appeared completely dry, CSI Thompson told Mr. Drayer she is taking a regulatory control action by applying U.S. Retained tag B19042869 to the carcass cooler door. She notified Mr. Drayer that the one tag encompassed all thirteen carcasses. It included the carcasses she observed on the slaughter floor and the ones slaughtered earlier that morning because of the deviation from a critical limit.

CSI Thompson reviewed PHIS and determined NR KIH4527923981N was documented May 10, 2022, for failing to detect a deviation from the critical limit at the zero tolerance CCP. She associates the two NRs because they indicate a problem with establishment employees assigned to monitor CCPs.

**Resources:**

[FSIS Directive 5000.1, Verifying an Establishments Food Safety System](#)

[9 CFR Part 417](#)

**CSI Thompson's Noncompliance Record**

U.S. Department of Agriculture FOOD SAFETY AND INSPECTION SERVICE <b>NONCOMPLIANCE RECORD</b>		TYPE OF NONCOMPLIANCE <input checked="" type="checkbox"/> Food Safety <input type="checkbox"/> Other Consumer Protection
1. DATE 06/01/2022	2. RECORD NO. KNL1612111329N	3. ESTABLISHMENT NO. M8383
4. TO (Name and Title) Mr. Scott Snook, Plant Manager		5. PERSONNEL NOTIFIED Mr. James Drayer, Slaughter Foreman
6. RELEVANT REGULATIONS 9 CFR 417.2(c)(4)		6a. ASSOCIATED NR(s) KIH4527923981N
7. TITLES OF HACCP OR SSOP PLAN or OTHER SUPPORTING DOCUMENTATION PROGRAM Veal Slaughter		7a. NAME OF CCP(S) or PREREQUISITE Lactic Acid
8. INSPECTION TASK Slaughter HACCP	9. VERIFICATION ACTIVITY <input type="checkbox"/> Review & Observation <input type="checkbox"/> Recordkeeping <input checked="" type="checkbox"/> Both 9a. AFFECTED PRODUCT INFORMATION: 13 Whole Veal Carcasses 9b. RETAIN/REJECT TAGS: B19042869	

10. DESCRIPTION OF NONCOMPLIANCE

On June 1, 2022, at approximately 0910 hours, while performing the Slaughter HACCP verification task, I noticed that the establishment was hanging both hindquarters of each veal carcass on one hook prior to the final wash and antimicrobial intervention steps. The critical limit for the antimicrobial intervention CCP includes a 2% lactic acid concentration applied to the entire carcass so that complete coverage is achieved. I observed the establishment perform a titration to verify the concentration prior to starting operations. Upon observing the inside of the hindquarters of each carcass were not receiving any lactic acid coverage, I notified the slaughter foreman, Mr. James Drayer, of the noncompliance. A review of PHIS showed a similar NR documented on May 10, 2022, in NR KIH4527923981N, for a different CCP. The preventative measures and further planned actions of retraining employees on correct HACCP monitoring procedures have been ineffective in preventing noncompliance recurrence.

11. SIGNATURE OF INSPECTION PROGRAM EMPLOYEE

*You are hereby advised of your right to appeal this decision as delineated by 306.5 and/or 381.35 of 9 CFR*

12. PLANT MANAGEMENT RESPONSE:

**This document serves as written notification that your failure to comply with regulatory requirement(s) could result in additional regulatory or administrative action.**

13. SIGNATURE OF PLANT MANAGEMENT  
14. DATE

15. VERIFICATION SIGNATURE OF INSPECTION PROGRAM EMPLOYEE  
16. DATE



### **Workshop #3 – Poultry Establishment: Sampling and Process Control**

**Please read the following scenario and answer the questions at the end.**

**Background:** Establishment Ink, LLC is a large poultry slaughter and processing establishment (P-0000) located in Salt, Alabama. Their slaughter and processing operations are conducted by way of a first shift (0530 to 1400 hours) and second shift (1400 to 2030 hours), with a cleanup operation after both shifts have been completed. Establishment Ink has two Meyn Maestro slaughter lines that run at a maximum speed of 140 birds per minute. Establishment Ink slaughters and processes approximately 268,000 young chickens a day. The further processing operations consist of a Cut-up Department, Debone Department, and Mechanically Deboned Meat (MDM) Department. The MDM Department produces NRTE ground chicken that is shipped to their sister plant where it is used to produce raw chicken patties. This product is eligible for *Salmonella/Campylobacter* testing. Both shifts have a staffing level of 8 Food Inspectors (4 inspectors per line), 2 Consumer Safety Inspectors, 1 Supervisory Consumer Safety Inspector, and a Public Health Veterinarian.

**Scenario:** It's Tuesday, April 5, 2022. CSI Red opens PHIS and observes in the establishment task list that he needs to verify the establishment's generic *E. coli* testing procedures and results to see if they are maintaining process control for microbial contamination. He knows that Establishment P-IK has chosen generic *E. coli* as their indicator organism to demonstrate whether or not they are maintaining process control and that this program is addressed in their SSOP plan, so he schedules a routine Operational SSOP Review and Observation task in PHIS.

He goes to the QA office and reviews the SSOP program which contains the procedures for collecting and testing for generic *E. coli*. The program states that the establishment will perform testing via a carcass rinse using an approved AOAC method. The procedures state that the establishment will aseptically collect 1 carcass rinse sample per 22,000 carcasses, but a minimum of one sample during each week of operation. The sample will then be maintained under refrigerated conditions and analyzed the same day in the establishment's onsite laboratory.

He next inquires about the next time a sample would be taken for *E. coli* sampling. The QA supervisor informs him that one of his technicians was about to take a sample in the next few minutes. He goes along with the QA technician to the post chill location where the sample will be taken. He observes her prepping the sampling table and using aseptic technique by washing her hands, etc. The technician decides to do a swab sample using a carcass from the chiller belt. CSI Red was confused, because the program read that the sampling was supposed to entail a whole bird rinse. He saw nothing about a swab sampling nor support for it.

He observes the technician follow through on procedures of a swab sampling but not a bird rinse as per the establishment's written program. Once completed, he follows the QA technician to the lab and watches her place the sample in the freezer. She states that it is the end of the day and she needs to make an appointment and will analyze it in the morning. In the meantime, CSI Red asks to review the Statistical Process Control chart for data that has been plotted for the last 10 days. When he reviews the chart, he notices that 4 of those 10 days had results that were markedly below the normal (average) control line in the chart. This was very odd to CSI Red, because he knows that 2 sanitation NRs and 3 fecal zero tolerance NRs were written during this ten day period.

**Resources:**

[9 CFR 381.65\(g\) & \(h\)](#)

[9 CFR 416.15\(b\)](#)

[9 CFR 417.3\(b\)](#)

[FSIS Directive 5000.1 - Verifying an Establishment's Food Safety System](#)

[FSIS Directive 6420.5 - Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with feces and Enteric Pathogens](#)

**Question:**

Please list the issues that you noticed in the above scenario that you have concerns about (critique the actions, results, or the procedure that was performed by the establishment employee).

## PHIS Simulations

There are 16 training simulations that will familiarize you with navigating and using the Public Health Information System (PHIS) to document various inspection tasks. The instructor will introduce each simulation and then provide time for you to review the simulation on your own in the FSIS Training Site. Please follow the instructions in the simulation and click on the various buttons and targets to complete each simulation. Depending on the strength of your internet connection, the simulation may load slowly.

Link to PHIS Simulations in the FSIS Training Site:

<https://fsistraining.fsis.usda.gov/course/view.php?id=46>

### References:

[FSIS Directive 13,000.1 - Scheduling In-Plant Inspection Tasks in the Public Health Information System \(PHIS\)](#)

[FSIS Directive 13,000.2 - Performing Sampling Tasks in Official Establishments Using the Public Health Information System](#)

## 1 - PHIS Navigation

This lesson introduces the PHIS navigation process.

Objective: Upon completing this lesson, you will be able to describe how to navigate through PHIS features and pages

- Log into PHIS
- Homepage
- My Dashboard tab – Alerts, My Tasks, Inspection Results, Smart Links
- My Establishments tab – My Establishments, Non-Compliance Record, FSA
- My Inspections and Samples tab – Inspection Agenda, Inspection Note, Lab Sample Collection
- Left Navigation Menu

## 2 - SPS Verification Task

This lesson introduces the SPS Verification Task – compliance scenario.

Objective: Upon completing this lesson, you will be able to describe how to complete the SPS verification task in PHIS.

- Schedule the SPS Verification Task from the Task List to the Task Calendar
- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Create an Inspection Note

### 3 – Pre-Operational SSOP Review and Observation Task

This lesson introduces the Pre-Operational Sanitation Standard Operating Procedures (SSOP) Review and Observation Task – Noncompliance scenario.

Objectives: Upon completing this lesson, you will be able to: 1) Describe how to document noncompliances in PHIS, and 2) Describe how to complete the Pre-Operational SSOP review & observation task in PHIS.

- Schedule Pre-Op SSOP Review and Observation Task from the Task List to the Task Calendar
- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified, check Regulatory Non-Compliance box
- Create/Edit NR
- Add Noncompliance, check noncompliant regulation(s), type Noncompliance Description
- Print NR, view NR, edit NR, Finalize NR
- Verify Corrective Actions, Complete NR
- Complete the task

#### **4 - Operational SSOP Review and Observation Task**

This lesson introduces the Operational Sanitation Standard Operating Procedures (SSOP) Review and Observation Task – Compliance scenario.

Objectives: Upon completing this lesson, you will be able to describe how to complete the operational SSOP review & observation task in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Complete the task

## 5 - HACCP Verification Task

This lesson introduces the HACCP Verification Task scenario.

Objective: Upon completing this lesson, you will be able to describe how to complete the HACCP Verification task in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Complete task

## **6 - Poultry Zero Tolerance Verification Task**

This lesson introduces the Poultry Zero Tolerance Task – Compliance scenario.

Objective: Upon completing this lesson, you will be able to describe how to complete the Poultry Zero Tolerance Verification task in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Complete task

## 7 - Livestock Zero Tolerance Task

This lesson introduces the Livestock Zero Tolerance Task – Noncompliance scenario.

Objectives: Upon completing this lesson, you will be able to: 1) Describe how to complete the Livestock Zero Tolerance Verification task in PHIS and 2) Describe how to document noncompliances in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Create/Edit NR
- Add Noncompliance, check noncompliant regulation(s), type Noncompliance Description
- Print NR, view NR, edit NR, Finalize NR
- Verify Corrective Actions, Complete NR
- Complete task

## **8 - Scheduling and Submitting a *Salmonella/Campylobacter* Poultry Parts Sample**

This lesson introduces the scheduling and submitting of a *Salmonella/Campylobacter* poultry parts sample in PHIS.

Objectives: Upon completing this lesson, you will be able to: 1) Describe how to create a lab sampling task in PHIS and 2) Describe how to submit a lab sample in PHIS.

- Filter Task List by Establishment
- Filter Task by Lab Sampling
- Add the Sampling for Chicken Parts – Legs, Breasts, and Wings Task.
- Select the Collection Date and View Laboratory Capacity
- Document the task
- Select Sample
- Complete Sample Collection Data
- Take Questionnaire and Submit
- Print Form
- Submit to Lab

## 9 - Creating Inspection Notes, Meeting Agendas, and MOIs

This lesson introduces how to create inspection notes, agendas, and Memorandum of Interviews (MOIs) in PHIS.

Objectives: Upon completing this lesson, you will be able to describe how to create inspection notes, agendas, and MOIs in PHIS.

- Select Establishment
- Inspection Notes
  - Create Note
  - Select Category
  - Enter Text
- Meeting Agendas
  - Create Agenda
  - Select Meeting Date, Time, Subject, and Attendees
  - Comment List
  - NR
- MOI
  - Meeting Agendas
  - MOI - Meeting
  - Agenda Text Box
  - NR
  - Review
  - Finalize
  - Print

## 10 - Livestock Humane Handling Task

This lesson introduces the livestock humane handling task.

Objective: Upon completing this lesson, you will be able to describe how to complete a livestock humane handling task in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- HATS Tab (Humane Activities Tracking System)
  - Select HATS categories verified
  - Enter Duration (minutes/hours) in 15-minute intervals
- Regulations Tab – Check mandatory regulations and any other regulations verified
- Complete task

## 11 - Establishment Profile – Add a HACCP Plan

This lesson introduces the PHIS Establishment Profile navigation process.

Objectives: Upon completing this lesson, you will be able to add a new HACCP plan to an establishment's profile

Step 1: Click Establishment Profile

Step 2: Click Open on the establishment row

Step 3: Click on the **HACCP Tab** for the establishment

Step 4: Click on the HACCP Plans Tab

Step 5: Click on Add a HACCP Plan above the grid

Step 6: Click the Signature date and select the date on the calendar

Step 7: Click on Plan Name and enter the name of the plan

Step 8: Click on the Processing Categories box for the product type

Step 9: Click on Add

Step 10: The HACCP Plan has been added to grid, click Exit Profile

## 12 - Establishment Profile – Updating Production Volume

This lesson introduces the PHIS Establishment Profile navigation process.

Objective: Upon completing this lesson, you will be able to explain the steps CSIs take to update an establishment's production volume.

Step 1: Click Establishment Profile

Step 2: Click Open on the establishment row

Step 3: Click on the **Products Tab** for the establishment

Step 4: Click Open for the Raw-Intact/Raw-Intact Chicken/Chicken/Poultry (Leg, Breast, Wings ONLY)

Step 5: Click Edit

Step 6: Click the Drop down arrow for the Average Daily Volume. Select 50,001-250,000.

Click Update

Step 7: Click Save HACCP Volumes. The HACCP Volumes have been updated in the grid.

### 13 - Establishment Profile – Updating and Adding an Establishment Contact

This lesson will introduce you to the procedure to update and add an Establishment Contact.

Objective: Upon completing this lesson, you will be able to explain the steps CSIs use to update and add an establishment contact.

Step 1: Click Establishment Profile

Step 2: Click Open on the establishment row

Step 3: Click on the **Facility Tab** for the establishment

Step 4: Click on the Contacts Tab

Step 5: Click on Open on the contact's row to be updated

Step 6: Click inside the First Name box, enter the replacement first name

Step 7: Click inside the Last Name box, enter the replacement last name

Step 8: Click inside the Email Address box, enter the replacement email address

Step 9: Click Save

Step 10: The establishment contact has been edited, to Add a new establishment contact, Click

Add a New Contact

Step 11: Click inside the box for Responsibilities and select from the drop-down menu

Step 12: Click inside the First Name box, enter the first name

Step 13: Click inside the Last Name box, enter the last name

Step 14: Click inside the Phone Number box, enter the phone number

Step 15: Click inside the Email Address box, enter the email address

Step 16: Click Yes or No if the person is a Primary Contact

Step 17: Click Yes or No if the person is an After-Hours Contact

Step 18: Click Yes or No if the person should receive NR Notification

Step 19: Click Yes or No if the person is a Billing Contact

Step 20: Click Add button

Step 21: The new contact has been added to grid

## 14 – Hazard Analysis Verification (HAV) Task

This lesson introduces the HAV task.

Objective: Upon completing this lesson, you will be able to describe how to complete an HAV task and document a noncompliance in PHIS.

- Document the task
- Inspection Results
- Activity Tab – Select verification activity (review and observation, record keeping, both)
- Regulations Tab – Check mandatory regulations and any other regulations verified
  - Check Regulatory Non-Compliance box
  - Create/Edit NR
  - Noncompliances Tab , Add noncompliance
    - Check Regulation(s) Found Noncompliant
    - Type Noncompliance Description, complete the rest of fields
    - Save, view draft, check Noncompliance Finalized box, print
    - Check NR completed box after you have verified establishment is back in compliance
- Take Questionnaire
- Complete task

## 15 – Animal Disposition Reporting - Poultry

This lesson introduces the Animal Disposition Reporting (ADR) section in PHIS.

Objective: Upon completing this lesson, you will be able to describe how to record a no kill period in the ADR section and describe how to enter poultry slaughter and disposition data in o the ADR section.

- Click on Animal Disposition on the left navigation menu
  
- Select No Kill Period
  - Select Establishment name, click on Add No Inspected Slaughter Period
  
  - Enter Start and End dates, select Reason Code, save
  
- Select Establishment Reporting to enter slaughter data
  - Select Establishment name, date, click on Add Slaughter Record
  
  - Enter Sub-Class, Lot Number, Head Count, and weights
  
  - Enter head counts, weights, and Post-mortem Carcass Condemnation Details
  
  - Repeat steps for each Sub-Class and Lot
  
  - Print the condemnation certificate for each lot

## 16 – Animal Disposition Reporting - Livestock

This lesson introduces the Animal Disposition Reporting (ADR) section in PHIS.

Objective: Upon completing this lesson, you will be able to describe how to report the weight reporting frequency in the ADR section and describe how to enter livestock slaughter and disposition data into the ADR section.

- Click on Animal Disposition on the left navigation menu
- Select Weight Reporting Frequency
  - Select Establishment name then Slaughter Frequency
- Select Establishment Reporting to enter slaughter data
  - Select Establishment name, date, click on Add Slaughter Record
  - Enter Sub-Class, Head Count, and weights
  - Enter head counts, weights, and Post-mortem Carcass Condemnation Details
    - Option to use Add Multiple Disposition Records
  - Edit Disposition Record as needed
  - Print the condemnation certificate

## **Case Studies: Scenario-Based Learning**

Use the information below to navigate through case-study scenarios and apply what you've learned during the Inspection Methods training. If you get stuck or identify a topic you need to revisit further, make a note and continue on with the scenario. You can note the slide number (upper right corner, e.g., **L-1**) for reference.

Don't worry if you make a mistake – you will have multiple opportunities to try if you don't get it right the first time. You can select “Back” to try again. After you complete the scenario, the trainers will review key points and answer any questions you noted.

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**Note:** In each scenario, you can choose any task first. Prior to completing the scenario, you will complete all the tasks.

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### **1) Livestock Slaughter/Processing Scenario**

- a. Part I – Familiarize yourself with the establishment
- b. Part II – Complete Livestock Zero Tolerance, Operational SSOP Review and Observation, and SPS Verification tasks

### **2) Poultry Slaughter/Processing Scenario**

- a. Part I – Familiarize yourself with the establishment & complete Pre-Op SSOP task
- b. Part II – Complete Poultry Zero Tolerance and Slaughter HACCP tasks

### **3) Ready-to-eat (RTE) Heat Treated Shelf Stable Scenario (optional, not covered in class)**

- a. Part I – Familiarize yourself with the establishment & update establishment profile
- b. Part II – Complete SPS Verification, Heat Treated Shelf Stable HACCP, and Operational SSOP Record Review tasks

## **#1 - Livestock Slaughter/Processing Scenario**

**L-3** Background: Congratulations! You are a new CSI assigned to a very small livestock slaughter and processing establishment, M8765. It's your first day on the job, and you want to familiarize yourself with the establishment.

### ***A. Livestock Scenario Part I – Familiarize***

**L-4** Review the establishment profile. Notes:

**L-7/9** Review establishment programs (HACCP, Sanitation SOPs, Prerequisite programs). Notes:

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#### **Questions to consider:**

Which SSOP regulations correspond to which parts of the Sanitation SOPs?

What are some examples of this establishment's Prerequisite Programs?

What are the CCPs at this establishment?

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**L-8** Match the Sanitation SOP regulations to the corresponding Sanitation SOP. Notes:

**L-12** Review FSIS Directive 5000.1 for information on conducting an Entrance Meeting.

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#### **Questions to consider:**

What types of content would you include in an entrance meeting?

After conducting an entrance meeting, how will you document the meeting?

After documenting the meeting, what will you share with the establishment?

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**L-13** Type the topics you plan to discuss at the entrance meeting. Notes:

**L-16** Review the example MOI. Notes:

**L-17/18** Review your PHIS Task list. Review FSIS Directive 13,000.1.

---

**Question to consider:**

How would you prioritize scheduling tasks in PHIS?

---

**B. Livestock Scenario Part II – Complete 3 inspection tasks**

**L-20** Choose which task to complete first: Livestock Zero Tolerance, Operational SSOP Review and Observation, or SPS Verification.

---

**Note:** you can choose any task first. Prior to completing the scenario, you will complete all three tasks.

---

**Livestock Zero Tolerance task**

**L-21** Review FSIS Directive 6420.2 for information on how to conduct a Livestock Zero Tolerance task.

---

**Questions to consider:**

What substance(s) must livestock carcasses be free of on the Zero Tolerance task?

What are examples of supportable descriptions of fecal and ingesta in each species?

How will you determine what number of carcasses to examine on Zero Tolerance?

What will you do if you identify fecal or ingesta on Zero Tolerance?

What do you expect the establishment to do if they fail Zero Tolerance?

What regulations will you use to document Zero Tolerance noncompliance?

What should your Zero Tolerance NR include to be supportable?

What task should you schedule in response to a Zero Tolerance noncompliance, and why?

---

**L-23** Match the feces descriptions by species. Notes:

**L-25** Conduct the Zero Tolerance task. What are your observations? Notes:

**L-30** Identify the W's in the Livestock Zero Tolerance NR. Notes:

**L-33** Match corrective actions from Zero Tolerance failure to regulations. Notes:

### **Operational SSOP Review and Observation task**

**L-39** Review FSIS Directive 5000.1 for information on how to conduct an Operational Sanitation SOP Review and Observation task.

---

#### **Questions to consider:**

What is the difference between SPS Verification and SSOP tasks?

What are you observing when you conduct an Operational SSOP Review and Observation task?

What action would you take if you observe product or food contact surface contamination?

What do you expect the establishment to do if product or food contact surfaces become contaminated?

What should your SSOP NRs include to be supportable?

When must an establishment have their SSOP records completed?

---

**L-42** Conduct the Operational SSOP Review and Observation task. What actions do you take? Notes:

**L-47/48** Document an SSOP NR. Review the example SSOP NR. Notes:

## **SPS Verification task**

**L-35** Review FSIS Directive 5000.1 for information on how to conduct a SPS Verification task.

---

### **Questions to consider:**

What is the difference between SPS Verification and SSOP tasks?

What types of facilities are you observing to verify which SPS regulations?

---

**L-37** Match the regulations to the SPS picture. Notes:

Once you have completed the Livestock ZT, Operational SSOP Review and Observation, and SPS Verification tasks, you have completed this scenario. Add any additional notes or questions below.

Notes:

## **#2 - Poultry Slaughter/Processing Scenario**

**P-3** Background: You are a CSI assigned to a large chicken slaughter establishment, P1357. The establishment slaughters Monday through Saturday. Finished products include whole birds and poultry parts. You're at the establishment bright and early this morning, because you are going to conduct a Pre-Operational SSOP Review and Observation task.

### ***A. Poultry Scenario Part I – Familiarize***

**P-4** Review FSIS Directive 5000.4 for information on how to conduct the Pre-Op task.

---

#### **Questions to consider:**

What type of verification activities will you use when conducting a Pre-Op SSOP Review and Observation task?

How much equipment should you inspect?

What equipment should you inspect?

What will you take with you when you conduct Pre-Op?

---

**P-5** Review the establishment's Sanitation SOP program. Notes:

**P-11** Review recent NRs. Do you notice any trends? How will you apply this information to Pre-Op? Notes:

**P-12** Choose which equipment you will bring to conduct Pre-Op. Notes:

**P-14/15** Make Pre-Op observations. What do you see? What will you do? Notes:

**P-16** Review the establishment's Pre-Op records. Compare their findings to yours. Notes:

**P-21** After your Pre-Op observations, consider how your observations will be documented. Review FSIS Directive 5000.1 on how to associate noncompliance.

---

**Questions to consider:**

Why is it important to associate NRs?

What should you include in the narrative of an NR when documenting an association?

---

**P-24** Review an example NR documenting your Pre-Op observations. Notes:

**P-26** Review FSIS Directive 10,250.2 for information on actions you should take when an establishment is assigned to Category 3 for *Salmonella* positive results.

---

**Questions to consider:**

Where can you go to learn more about conducting poultry follow-up sampling?

When should you schedule and conduct poultry follow-up sampling?

---

**P-32** Which topics will you discuss at the weekly meeting? Notes:

**P-33** Review the MOI documented from your weekly meeting. Notes:

**P-34** Review FSIS Directive 5010.1 for information on other topics you may consider discussing at weekly meetings.

## **B. Poultry Scenario Part II – Complete 2 inspection tasks**

**P-35** Choose which task to complete first: Poultry Zero Tolerance or Slaughter HACCP.

---

**Note:** you can choose any task first. Prior to completing the scenario, you will complete all three tasks.

---

### **Poultry Zero Tolerance task**

**P-36** Review Directive 6420.5 for information on how to conduct the Poultry Zero Tolerance task.

---

#### **Questions to consider:**

How do you determine how often to conduct a Poultry Zero Tolerance task?

Where do you conduct the Poultry Zero Tolerance task?

How many carcasses will you inspect during the Poultry Zero Tolerance task?

What procedures will you follow to conduct the Poultry Zero Tolerance task?

What contaminants are you looking for during your Poultry Zero Tolerance task? Which finding will result in noncompliance? What regulations would you cite?

---

**P-42** You perform your Zero Tolerance inspection and identify ingesta on a carcass. What should you do? Notes:

## **Slaughter HACCP Verification task**

**P-45** Review the Slaughter HACCP plan. Review FSIS Directive 5000.1 for information on how to conduct a HACCP task.

---

### **Questions to consider:**

What CCPs will you verify regulatory requirements for?

What Prerequisite programs will you verify regulatory requirements for?

What regulations are you verifying when conducting HACCP tasks?

What are examples of compliance with the HACCP regulatory requirements? With CCP monitoring? Verification? Recordkeeping? Corrective Actions?

---

**P-59** Match the recordkeeping regulation to the HACCP regulatory requirements. Notes:

**P-61** Review the establishment's prerequisite programs. Notes:

**P-62** Review the establishment's prerequisite program records. Notes:

**P-66** Review the establishment's corrective actions record. Notes:

Once you have completed the Poultry Zero Tolerance and Slaughter HACCP tasks, you have completed the scenario. Add any additional notes or questions below.

Notes:

### **#3 - Ready-to-eat (RTE) Heat-Treated Shelf-Stable Scenario**

**R-3** Background: You are a CSI at Establishment M/P 1234, Riverton Foods. You've just come back from two weeks of annual leave, and you are excited to be back at work! Previously, you and the establishment agreed upon having your weekly meeting every Monday at 10am. You decide to get prepared for the weekly meeting. To catch up on what has happened since you are gone, you decide to see if the Coverage CSI placed any information in the Inspection Notes in PHIS.

#### **A. RTE Scenario Part I – Familiarize**

**R-4** Review the inspector notes. Notes:

**R-7** Review FSIS Directive 5300.1 for information on updating the establishment profile.

---

#### **Questions to consider:**

How do you know what to review for accuracy in the PHIS profile each month?

After you conduct the update establishment profile task, what do you need to provide the establishment?

---

**R-10** Review the labels for the new jerky products. What do you note about the ingredients? Notes:

**R-12** Review the establishment's HACCP system. Notes:

**R-13** Match the HACCP regulations to the corresponding part of the HACCP plan. Notes:

#### **B. RTE Scenario Part II – Complete 3 inspection tasks**

**R-15** Choose which task to complete first: Heat Treated Shelf Stable HACCP, Operational SSOP Record Review, or SPS Verification.

---

**Note:** you can choose any task first. Prior to completing the scenario, you will complete all three tasks.

---

## **SPS Verification task**

**R-51** Review FSIS Directive 5000.1 for information on verifying SPS regulatory requirements.

---

### **Questions to consider:**

What are some examples of SPS noncompliance?

What should you do if you observe SPS noncompliance?

What regulations would you cite in SPS noncompliance reports?

What actions should you take after documenting a noncompliance in PHIS?

---

**R-52** Match the SPS regulation with the SPS findings. Notes:

**R-53** Conduct SPS observations. What do you observe? What will you do next? Notes:

**R-18/19** Document a SPS noncompliance report. Compare your NR to the example. Notes:

## **Heat Treated Shelf Stable HACCP task**

**R-23** Review your Inspection Methods student notebook for information on the steps to conduct a HACCP verification task.

**R-24** Match the steps used to conduct a HACCP verification task. Notes:

**R-25** Review FSIS Directive 5000.1 for information on what activities you could conduct to verify compliance with HACCP regulatory requirements.

---

### **Questions to consider:**

What activities could you perform to verify HACCP regulatory requirements (monitoring, verification, recordkeeping, corrective actions)?

What regulations will you be verifying when conducting the HACCP verification task?

What are examples of noncompliance with HACCP regulatory requirements?

---

**R-29/33** Review the establishment's HACCP records for compliance. Notes:

**R-35** Review FSIS Directive 5000.1 for information on how to verify regulatory requirements associated with prerequisite programs.

---

### **Questions to consider:**

What activities will you use to verify regulatory requirements with Prerequisite programs?

What regulations will you verify?

How can you verify that pre-shipment review is being conducted per regulation? What regulatory requirement is associated with this activity?

---

**R-36** Review the establishment's Prerequisite programs. Notes:

**R-37** Review the establishment's Prerequisite program records. What do you determine? Notes:

## **Operational SSOP Record Review task**

**R-43** Review Directive 5000.1 for information on how to conduct an Operational SSOP Record Review task.

---

### **Questions to consider:**

What actions should you take to conduct an Operational SSOP Record Review task?

What are examples of noncompliance with SSOP recordkeeping regulatory requirements?

What regulations are you verifying when conducting an Operational SSOP Record Review task?

What are establishments required to take when product or food contact surfaces become adulterated?

---

**R-44** Review the establishment's Sanitation SOPs. Notes:

**R-45** Review the establishment's Sanitation SOP records. Notes:

Once you have completed the Heat Treated Shelf Stable HACCP, Operational SSOP Record Review and SPS Verification tasks, you have completed the scenario. Add any additional notes or questions below.

Notes:



## Additional Resources

### Acronym Listing

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

FCS	Food Contact Surface
FDA	Food and Drug Administration
FDIB	Foodborne Disease Investigation Branch
FFDCA	Federal Food, Drug, and Cosmetic Act
FI	Food Inspector
FIFRA	Federal Insecticide Fungicide and Rodenticide Act
FLS	Frontline Supervisor
FMIA	Federal Meat Inspection Act
FNS	Food and Nutrition Service
FO	Field Operations
FOIA	Freedom of Information Act
FPS	Finished Product Standard
FR	Federal Register
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
GAD	Gather Assess Determine
GMP	Good Manufacturing Practice
GRAS	Generally Recognized as Safe
HA	Hazard Analysis
HACCP	Hazard Analysis and Critical Control Point
HATS	Humane Activities Tracking System
HAV	Hazard Analysis Verification
HCG	Hazards Control Guide
HEP	High Event Period (with regard to STECs)
HH	Humane Handling
HIMP	HACCP-based Inspection Models Project
HMSA	Humane Methods of Slaughter Act
HPP	High Pressure Processing
HRI	Hotels, Restaurants, and Institutions
HUS	Hemolytic Uremic Syndrome
ICMSF	International Commission on the Microbiological Specification for Foods
IIC	Inspector in Charge
IKE	Interactive Knowledge Exchange
IPP	Inspection Program Personnel
IVT	Intensified Verification Testing
KIS	Kidney Inhibition Swab
LIMS	Laboratory Information Management System Direct
Lm	<i>Listeria monocytogenes</i>
LOG	Letter of Guarantee
LOI	Letter of Information
LOW	Letter of Warning
LPDS	Labeling and Program Delivery Staff
LTD	Less Than Daily
MOI	Memorandum of Interview
MOU	Memorandum of Understanding
MPCM	Microbial Pathogen Computer Modeling
MPN	Most Probable Number
MPR	Moisture Protein Ratio

NACMCF National Advisory Committee on the Microbiological Criteria for Foods  
 NACMPI National Advisory Committee on Meat and Poultry Inspection  
 NFCS Non Food Contact Surface  
 NFSCP Non-Food Safety Consumer Protection  
 NIST National Institute of Standards and Technology  
 NOIE Notice of Intended Enforcement  
 NOL No Objection Letter  
 NOS Notice of Suspension  
 NPDW National Primary Drinking Water  
 NR Noncompliance Record  
 NRLTO Not Reasonably Likely to Occur  
 NRTE Not Ready to Eat  
 OCP Other Consumer Protection  
 OFO Office of Field Operations  
 OIG Office of Inspector General  
 OM Office of Management  
 OEED Office of Employee Experience and Development  
 OPACE Office of Public Affairs and Consumer Education  
 OPARM Office of Planning, Analysis, and Risk Management  
 OIEA Office of Investigation, Enforcement, and Audit  
 OPHS Office of Public Health Science  
 OPPD Office of Policy and Program Development  
 OSHA Occupational Safety and Health Administration/Act  
 PDS Policy Development Staff  
 PFGE Pulsed Field Gel Electrophoresis  
 PHV Public Health Veterinarian  
 PHIS Public Health Information System  
 PLE Post Lethality Exposed  
 PLT Post Lethality Treatment  
 PM Postmortem Inspection  
 PMP Pathogen Modeling Program  
 PMP Pest Management Program  
 PPIA Poultry Products Inspection Act  
 PPM Parts Per Million  
 PR Pathogen Reduction  
 PRP Pre-Requisite Program  
 QA Quality Assurance  
 QC Quality Control  
 QRG Quick Reference Guide  
 RCA Regulatory Control Action  
 RD Regional Director (OIEA)  
 REC Recall Effectiveness Check  
 RMIS Risk Management and Innovation Staff  
 RLm Risk Based *Listeria monocytogenes* Testing  
 RLTO Reasonably Likely to Occur  
 RMA Resource Management Analyst  
 RMS Resource Management Specialist  
 RMTAD Recall Management and Technical Analysis Division

ROP Rules of Practice  
RTE Ready to Eat  
RTE/SS Ready to Eat/Shelf Stable  
SCSI Supervisory Consumer Safety Inspector  
SEIAO Supervisory Enforcement Investigations and Analysis Officer  
SIP *Salmonella* Initiative Program  
SOP Standard Operating Procedures  
SPC Statistical Process Control or Standard Plate Count  
SPHV Supervisory Public Health Veterinarian  
SPS Sanitation Performance Standards  
SRM Specified Risk Materials  
SSOP Sanitation Standard Operating Procedures  
STEC Shiga toxin-producing *E. coli*  
STEPS System Tracking *E. coli* Positive Suppliers  
SVMO Supervisory Veterinary Medical Officer  
TA Talmadge-Aiken Act  
TCOE Training as a Condition of Employment  
TDT Thermal Death Time  
TPC Total Plate Count  
TSP Trisodium Phosphate  
TT Time Temperature  
USC United States Code  
USDA United States Department of Agriculture  
vCJD Variant Creutzfeldt-Jakob disease  
VMO Veterinary Medical Officer  
VP Verification Plan

**Handwritten Note-taking Pages 1 of 10**

**Handwritten Note-taking Pages 2 of 10**

**Handwritten Note-taking Pages 3 of 10**

**Handwritten Note-taking Pages 4 of 10**

**Handwritten Note-taking Pages 5 of 10**

**Handwritten Note-taking Pages 6 of 10**

**Handwritten Note-taking Pages 7 of 10**



**Handwritten Note-taking Pages 9 of 10**

**Handwritten Note-taking Pages 10 of 10**