

## SAMPLING RTE PRODUCT

### Objectives

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

1. Identify the pathogens of concern associated with sampling of ready-to-eat (RTE) product.
2. Describe the conditions for RTE product to be considered adulterated.
3. Define the following terms:
  - a. Food contact surface
  - b. Intact package
  - c. Sampled lot
4. Describe the steps for performing a RTE sampling task.
5. Explain the difference between the RTEPROD\_RAND and the RTEPROD\_RISK sampling project codes.
6. 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.

## Introduction

FSIS's microbiological testing program is designed to verify that the establishment's food safety system is effective and that FSIS performance standards and regulations are met. FSIS tests RTE products for pathogens because of the potential public health impact of a breakdown in the establishment's food safety system. The pathogens of public health concern in RTE products are *Listeria monocytogenes (Lm)* and *Salmonella*. Therefore, RTE product samples are tested for both of these organisms by FSIS laboratories. *Salmonella* is generally associated with under-processing or cross-contamination post-processing while *Lm* is more often associated with cross-contamination post-processing. RTE product is adulterated if it contains *Lm*, *Salmonella*, or any pathogen known to cause illness including *E. coli* O157:H7, or if it comes into direct contact with a food contact surface contaminated with *Lm*.

Note that FSIS is continuously updating its sampling programs in order to keep pace with changes in policy. FSIS directives and notices for current sampling programs contain specific instructions to follow. **It is important to read recent issuances, so that when you are requested to collect a sample you have the latest information.** See Attachment 1 for a list of relevant FSIS Directives.

## Definitions

**Aseptic** means, "free from pathogenic organisms." Aseptic technique implies that IPP do not add any organisms (pathogenic or not) to the sample when it is collected. It does not imply that the sample is aseptic. The purpose of aseptically collecting a sample is to prevent contaminating the sample or the surrounding product/product contact area. That is why it is important to aseptically collect a sample even when the sample is intact. IPP should wash and sanitize their hands before collecting an intact sample, but it is not necessary to sanitize the area and put on gloves. Good personal hygiene is essential anytime a sample is collected, whether intact or not.

**Environmental samples** are samples from surfaces that have:

- Indirect or potential contact with exposed RTE product in the RTE production area (mop handles, outer garments, etc., that may be handled by a person who may touch RTE product), or
- Non-contact surfaces in a RTE production area (e.g., floors, drains, walls, overhead structures).

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

food contact surface does not include items that may have indirect or potential contact with exposed RTE product.

**Food contact surface samples** are a collection of samples (e.g., swabs) from food contact surfaces that represent the conditions under which the sampled lot was processed. The samples are usually collected during the production shift, not pre-operational, but without disrupting production, such as during breaks and at the end of a shift.

**Intact** means product in the final packaged form (immediate container) in which it will be shipped. The lab receives the sample in the same immediate container as intended for the consumer.

**Recall** is an establishment's voluntary removal of distributed meat or poultry products from commerce when there is reason to believe that such products are adulterated or misbranded under the provisions of the Federal Meat Inspection Act (FMIA) or the Poultry Products Inspection Act (PPIA). Product that is adulterated and has left the establishment's control may be subject to a recall. The recall would involve at least the sampled lot, but it could be expanded depending upon a review by the Recall Management Division (RMD) of all factors in the situation. FSIS Directive 8080.1 gives additional details on recalls.

**RTE production area** is one where exposed RTE products are stored, further processed, or packaged. This is the area from which food contact surface samples and environmental samples are taken and analyzed for *Lm* or indicator organisms.

**Sample** is a collection of product that represents a larger group of product (i.e., the sampled lot).

**Sampled lot** is the amount of product represented by the sample. For microbial issues, the actual (affected) product represented by the sample is usually interpreted as the product produced from clean-up to clean-up. Often, factors like the establishment's coding system, the pathogen of concern, the processing and packaging, the equipment, the establishment's sampling programs, the HACCP plan monitoring and verification activities, the SSOP records, etc., are considered when determining how much product is actually represented by the sample.

**Short-weight or slack-filled** containers meet the definition of an intact sample, but with less product (e.g., a liner from a bulk package which contains approximately 2-lb of product, folded down and sealed in the same manner that the bulk product is normally packed to prevent product contamination). A short-weight or slack-filled sample is one that has progressed through all the production steps that the product normally goes through (not changed in any way that would affect the processing parameters). A short-weight or slack-filled

sample may appear to the lab as a non-intact sample and may be discarded if PHIS information does not indicate it is short-weight or slack-filled.

**Subsequent production** is all product produced after the sampled lot. It is not usually part of the sampled lot, but it may or may not be affected product.

## Sample Initiation

PHIS will display any RTE sampling tasks on the Task List based on the sampling programs for which the establishment is eligible. These PHIS generated requests are called “directed” sampling tasks. There are no “collector generated” sample requests for RTE product sampling. However, if IPP have concerns about the product or process they may follow their supervisory chain of command to request additional “directed” samples. IPP are to provide information on the type of sample to be collected and a justification for the sample collection request. If additional sampling is justified, the district office will contact DAIG to request that the tasks be generated through PHIS as a directed sample task. Once the additional directed sampling tasks appear on the establishment’s task list, IPP may then schedule them.

## Steps in Sampling

There are 6 general steps in sampling RTE product.

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

### Step 1: Determine which product to sample and schedule the sample

IPP collect RTE product samples under the following project codes:

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

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

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

<sup>1</sup> Post-lethality exposed product.

<sup>2</sup> Product type to be used on Form 10,210-3.

**Exceptions:** Do not collect samples of oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats that are Ready-to-Eat (RTE) because there is no validated test method for detecting *Lm* in these products.

FSIS will sample popped pork skins, pork rinds, dried soup bases, concentrated (high salt content) soup mixes, and pickled pig's feet under both programs. FSIS will collect samples of RTE products that are shipped hot from the establishment.

When IPP receive an RTEPROD\_RAND or RTEPROD\_RISK request in PHIS, they are to schedule an RTE product sample within the sampling window timeframes given. IPP are to randomly select a day, shift, and time within the sample window timeframe. There should be an equal chance that sampling will occur during any shift where eligible product is produced. IPP should not wait until the end of the sampling window to schedule the sample. Scheduling the sample at the beginning of the sampling window will allow more time to ensure that a sample is available during that timeframe.

## **Step 2: Notify Establishment Management**

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

When notifying the establishment that FSIS will collect a sample, IPP are to confirm that the establishment will be producing post-lethality exposed RTE product (RTEPROD\_RISK) or RTE product (RTEPROD\_RAND) on the day sampling is scheduled. In addition, IPP are to confirm that the establishment is planning to implement its documented routine production, Sanitation SOP, and food-safety practices on the day the sample is scheduled.

IPP are to generally provide a one day advance notice if that is sufficient for the establishment to hold the sampled lot but not to change practices. IPP may provide more advance notice if the establishment can support that more time is necessary because of the innate characteristics of the process. IPP should inform the establishment that, if it changes routine practices without justification for doing so, FSIS may provide it with less than a one day notice if that is sufficient to hold the sampled lot. If IPP have questions about an establishment's basis for requesting more notice, they are to submit them through askFSIS.

IPP should inform the establishment that, if it intends to modify its documented routine production, sanitation, or food-safety practices before the sampling, it should inform IPP as soon as possible so that sampling can be rescheduled. If the establishment continues to change routine practices and cannot support the changes, less than one day advance notice may be provided, or an FSA may be scheduled at the establishment.

NOTE: Justifiable reasons for changing practices may include limiting the lot size to facilitate holding the product, changes in customer orders, or documented changes to Sanitation SOPs or HACCP plans.

IPP should inform the establishment that it is responsible for supporting its basis for defining the product represented by the sample (i.e., the sampled lot); and inform the establishment that it is required to hold or control the sampled lot until negative results are received. IPP will verify that the establishment is holding or controlling the product represented by the sampled lot (the product produced from clean-up to clean-up) and record the information in PHIS. Immediately contact the DO if the establishment does not hold or maintain control the sampled lot.

## **Step 3: Collect the Sample**

IPP will collect the sample from the current day's production after the establishment has applied all interventions except any microbiological testing

intervention. If the establishment intends to test the product for *Lm* or *Salmonella*, IPP are not to wait for the establishment to receive the test results.

For both RTEPROD\_RAND and RTEPROD\_RISK samples, IPP are to collect a two-pound sample of product in an **intact package**. Collecting products in the intact package will help to ensure that the product does not become contaminated with *Lm* from the environment during the sample collection process. If packages weigh less than two pounds, IPP are to collect enough packages to bring the total to a minimum of two pounds.

IPP are to collect the product at least three hours after the start of production (if possible), to allow *Lm* to work its way out of the equipment. If the establishment's production lot is typically less than three hours, IPP may collect the samples during the production shift. IPP are to vary the shifts in which they collect samples, if possible.

If the establishment produces reworked product, IPP are to sample the product as part of the production lot, as long as IPP provide the establishment with adequate notice to hold the sample. Rework is the process of re-cooking, reprocessing, or repackaging the product. FSIS considers any process that removes the product from the package and exposes it to the environment as rework.

If the finished product contains meat or poultry and non-meat or non-poultry ingredients, IPP are to follow the instructions below.

- If the meat or poultry and non-meat or poultry ingredients are commingled (in contact) in the final package (e.g., a salad with meat or poultry mixed in), IPP are to collect a two-pound sample of the complete product (including the meat or poultry and nonmeat or poultry component).
- If the meat and nonmeat ingredients are not commingled (not in contact) in the final package (e.g., an entree with separate compartments for meat or poultry and vegetables), then IPP are to collect a two-pound sample of the meat or poultry component in the final package.

IPP are to submit the samples to the laboratory for microbiological analysis in **intact** packages. The laboratory does not supply sterile bags or gloves for sampling because IPP are not to have direct contact with the exposed, unpackaged RTE product. This is because *Listeria* may be present in the environment and could be transferred to the product if exposed RTE product is collected.

If an intact product or product container is too large, heavy, or costly to ship to the laboratory, IPP can ask the establishment to slack-fill or short-weight a

product for a 2-pound sample and send it in the usual establishment packaging such as the container liner.

If the slack-filled or intact package is an unsealed bag, IPP are to tie it off (e.g., twist tie or rubber band) so smaller particles (e.g., shredded meat pieces) do not spill into the shipping container. IPP are to place the slack-filled package in a secondary bag. The laboratory will discard the sample if it contains spilled or leaking products. When IPP document the sampling task in PHIS, under the “Additional Info” tab, they are to click “yes” to the question “Is this sample short-weighted/slack-filled?” to ensure that the sample is not discarded as a non-intact sample by the laboratory.

IPP are not to use any laboratory-supplied bag as the primary wrap for the sample. Laboratory supplied bags provided by the laboratory are for secondary containment only because they are not sterile. The laboratory-supplied bag protects the box in case the primary container leaks.

If IPP cannot collect an intact short-weighted or slack-filled sample, and the establishment is not producing any other type of RTE product that the IPP could collect, IPP are to contact the designated laboratory to discuss other options for collecting the sample.

NOTE: Examples of inappropriate samples for short-weight or slack-filled samples include a sample that would have to be cut to fit inside the shipping container, and samples that are packed in a waxed box without a liner bag that is too large to fit inside a laboratory shipping box.

When a sample cannot be collected on the date originally scheduled, inspectors should follow instructions specific to rescheduling lab sampling tasks in PHIS. When sample collection cannot be rescheduled for any date within the requested time frame, IPP should cancel the sample request within PHIS and provide a justification as to why the sampling could not be performed.

### Intervention Considerations

If the establishment treats the product with an intervention (e.g., HPP), either at the establishment or at another establishment, IPP are to review documentation the establishment keeps as part of its HACCP program to determine the purpose of the treatment.

If the HPP is applied as a *Listeria* intervention, and the establishment has supporting documentation demonstrating that the treatment achieves at least a 1-log reduction of *Lm*, IPP are to collect the sample after the treatment is applied. If the product is not returned to the producing establishment after the HPP treatment, IPP are to sample another product, if possible. The product, in this case, would be subject to sampling at the HPP facility if records show that the

treatment was applied as a *Listeria* intervention. If the establishment is not producing any other RTE product at the time the sampling is scheduled, IPP are to cancel the task and enter into PHIS “all interventions have not been applied at this establishment.”

NOTE: If the establishment’s validation supports that the HPP treatment achieves at least a 5-log reduction of *Lm*, the product is not considered post-lethality exposed and would only be sampled under the RTEPROD\_RAND project code.

If the treatment is applied to extend the shelf life of the product, and the establishment does not have supporting documentation describing the treatment as a *Listeria* intervention, then IPP are to collect the product before the treatment. The product would not be subject to sampling at the HPP facility, as long as it has records on file supporting that the treatment was applied to extend the shelf life.

### Altered Practices

On the day of sample collection, if IPP find that the establishment has altered its documented routine production, sanitation, or food-safety practices, and the establishment cannot provide a supportable rationale, IPP are not to perform sampling and are to reschedule if possible.

IPP are to issue an NR under the following circumstances:

- If IPP find that the establishment has made changes in its food safety systems (e.g., temporarily changing its supplier of RTE product on the day the sample is collected) and does not have documents supporting the appropriateness of the change, IPP are to issue an NR. The NR would be issued because the establishment did not consider the changes in its hazard analysis in accordance with 9 CFR 417.2(a) (1), or did not support the changes to its hazard analysis as in 9 CFR 417.5(a) (1).
- Likewise, if IPP find that the establishment has made changes in its sanitation practices (e.g., temporarily increasing the use of sanitizer only on the day the sampling is scheduled) and did not revise its Sanitation SOP to reflect these changes, IPP are to issue an NR under 9 CFR 416.14.

NOTE: If an establishment decides to limit its product lot size solely to facilitate holding the product during sampling, it would not be considered to have significantly altered its production practices, as long as IPP can collect samples that accurately represent routine production. If IPP have questions about whether an establishment is altering routine production, sanitation, or food-safety practices, they can submit them through askFSIS.

At the next weekly meeting, IPP are to discuss the altered food safety practices with the establishment. Inform the establishment that if it continues to change its practices, FSIS may collect more samples and may give less than 1 day notice (if less time is enough to hold the sampled lot) or schedule a “for-cause” FSA.

#### **Step 4: Document the Sample in PHIS**

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

IPP must answer the questionnaire in PHIS before submitting the sample. The questionnaire includes:

1. Selection of the appropriate RTE product type.
2. Amount of pounds represented in the sample. This is based on what the establishment declared the sample lot to be.
3. Is the product post lethality exposed? If yes then the IPP must answer 3a, which asks for the Alternative the product was processed under. If no then PHIS will forward to question 4.
4. Identify the production line the sample was taken from. If the establishment has only one line mark N/A.
5. Enter the time the collection was made in military format.
6. Enter the contact person for the establishment.
7. Enter the contact phone number for the contact.
8. Answer yes or no, whether establishment management was notified of this sample collection.
9. Indicate if the sample was short weighted or slack filled. This will prevent the laboratory from discarding the sample because it is not in the final retail package.
10. Answer where the sampled lot is being held or controlled.

When IPP are certain that the correct information has been entered in PHIS, they must submit both the questionnaire and the Sample Analysis Request Form electronically to the laboratory. Then IPP will print and sign the form and include it with the sample in the sample shipment container. If the lab receives a sample with missing or incomplete paperwork the sample will be discarded.

#### **Step 5: Pack and Ship the Sample and Form**

**Identify the sample and paperwork, and place them into the bag provided by the lab.** Double check and compare the address on the FedEx expanded billable stamp to make sure it is going to the lab indicated in PHIS and on the Sample Analysis Request Form. The lab will discard the sample if shipped to the wrong lab. Also be sure to check the expiration date on the expanded billable stamp. Do not use an expired expanded billable stamp.

IPP are to safeguard the integrity of samples during submission according to FSIS Directive 7355.1, Use of Sample Seals for Laboratory Samples and Other Applications. Place one of the small bar code stickers from the 7 part sample seal set (7355-2A/B) on the sample package, and another on the Sample Analysis Request Form. Put the Sample Analysis Request Form in a plastic bag or sleeve to protect it. Put the sample and the form into a zip-lock bag, and attach the Identification Label, 7355-2B, to the zip-lock bag so that the bar code is readable.

**Pack the sample.** Samples should be shipped in FSIS-furnished containers, unless special arrangements are made with the lab. Pack one sample per pre-chilled shipping container to avoid confusion. Multiple samples can be sent in one container, as long as each sample is accompanied by its sample form and there are no concerns over maintaining product temperature. In cases where multiple product packages are necessary for a single sample, all of them must be shipped in the same shipment container. Pack the sample in this order.

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

**NOTE:** The shipping containers should have the top and bottom sealed by the lab with tamper-evident tape. IPP will **not** receive any tamper-evident tape to use. If the tape is cut or missing, **do not** open the container. Follow the instructions in FSIS Directive 7355.1 (seal it with the Container Seal, 7355-2A, and ship it back to the lab of origin for processing; complete the seal by writing “seal broken” in the “Form No.” blank).

The absorbent pad is placed in the bottom of the shipping container. Its purpose is to absorb any fluid that may leak into the box in order to maintain the integrity of the shipping container for future use. A frozen freeze pack must be added for product that was stored refrigerated or frozen. The cardboard separator goes on top of the freeze pack to separate the freeze pack from the sample. The bagged sample is then put into the shipper. Do not use filler material in the shipping container. Any unused bar code sticker needs to go into the shipper with the sample. This insures that it won't accidentally get used on another sample, and allows the lab to account for all 7 parts of the seal/label. Alternatively, the unused bar code may be retained with the file record of sample collection. The foam plug must be pushed down as far as possible to keep the sample from being tumbled inside the shipper.

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

**Ship the sample.** IPP are to ship samples Monday through Friday so that they arrive at the laboratory overnight. IPP are not to ship samples on Saturdays or on the day before a Federal holiday, or as directed by a user notice via e-mail.

### **Step 6: Respond to Results**

IPP will access LIMS-Direct to track sample receipt and for detailed information on FSIS sample results or discards. LIMS stands for Laboratory Information Management System. LIMS-Direct is a program that reports FSIS lab sample results directly from LIMS. It will provide close to real-time sample data electronically to FSIS program personnel, Federal, and State establishments (via email), and State officials, if FSIS laboratories conduct testing for States. LIMS-Direct will be updated every 15 minutes and display sample data history longer than the last 90 days of data. If, in limited cases, LIMS does not receive an electronic record from the Public Health Information System (PHIS) because of technical reasons, sample results will still be available in LIMS-Direct.

When IPP go to the LIMS-Direct address, several options are available.

1. Single Sample Results – search using the form number.
2. Single Establishment Results – search using the establishment number to obtain all the results in the database for that establishment.
3. Results for All Establishments in a Circuit – search by entering the circuit number.
4. Results for State Inspection Sample – search using the state code.
5. Samples Not Analyzed for All Establishments in a Circuit – search using the circuit number.
6. More Reports – search for more types of reports that are available.

Option 3 is particularly useful if it is a patrol assignment, since one can see the status of the samples of all the establishments at one time.

Once the analyses are complete, the results are posted in the results column.

IPP should provide sample result information to establishment management even if the establishment receives e-mail notifications automatically.

### **Sampling Project Positive Results**

If any RTE product sample collected by IPP under the RTEPROD\_RAND or RTEPROD\_RISK sampling projects tests positive for *Lm* or *Salmonella*, product in the sampled lot is adulterated.

IPP are to follow the instructions in FSIS PHIS Directive 5000.1 when taking enforcement actions in response to positive sampling results. In addition, IPP are to consider the following:

- If FSIS finds the product positive, and the establishment tested the product under its documented sampling programs, IPP are to check the establishment's *Salmonella* or *Lm* testing results to determine whether the establishment also found the sampled product to be positive for *Salmonella* or *Lm*.
- IPP are to determine whether the establishment held the product or maintained control of the product pending its own test results.
- If IPP find that the establishment did not hold or maintain control of the product, they are to issue an NR. The NR would be warranted because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as set out in 9 CFR417.5(c).

Generally, if FSIS finds the product positive for *Salmonella* or *Lm*, IPP are to issue an NR (cite 9 CFR 417.4(a)). However, if the establishment also found the product to be positive for *Salmonella* or *Lm* and held the product, IPP are not to issue an NR. They are to verify that the establishment performs the appropriate corrective actions, using a directed HACCP Verification Task.

## **Establishment Sampling Program Positive Results**

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

An establishment may or may not conduct environmental sampling, other than on food contact surfaces, under its HACCP plan or Sanitation SOPs or other prerequisite program. If the establishment is conducting such sampling, and positive results are received, IPP are to verify that the establishment takes the appropriate action as outlined in the program under which the establishment did the sampling. If the establishment is conducting such sampling but is not addressing the sampling under HACCP or Sanitation SOPs or other prerequisite programs, and IPP find that such sampling is resulting in repetitive positive results, IPP are to notify the district office through supervisory channels.

## Verifying Corrective Actions

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

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

When performing a directed HACCP Verification Task in response to a *Salmonella* positive result, IPP are to verify that the establishment took the appropriate corrective actions according to 9 CFR 417.3(a) or (b), or 9 CFR 416.15. Although the regulations do not require establishments to specifically control for *Salmonella* in post-lethality exposed RTE products, as stated previously, FSIS considers RTE products to be adulterated if products or food contact surfaces test positive for *Salmonella* or other pathogens. Therefore, establishments are required to take corrective actions in response to positive results and to reassess their HACCP plan. FSIS will perform an IVT/FSA for *Salmonella*, as described in FSIS Directive 10,300.1.

In addition, if FSIS develops a verification plan in response to an establishment's proffered corrective actions and preventive measures when enforcement is deferred following the issuance of a Notice of Intended Enforcement (NOIE), or a suspension is held in abeyance, IPP are to verify that the establishment implements its corrective actions, and that the corrective actions are effective.

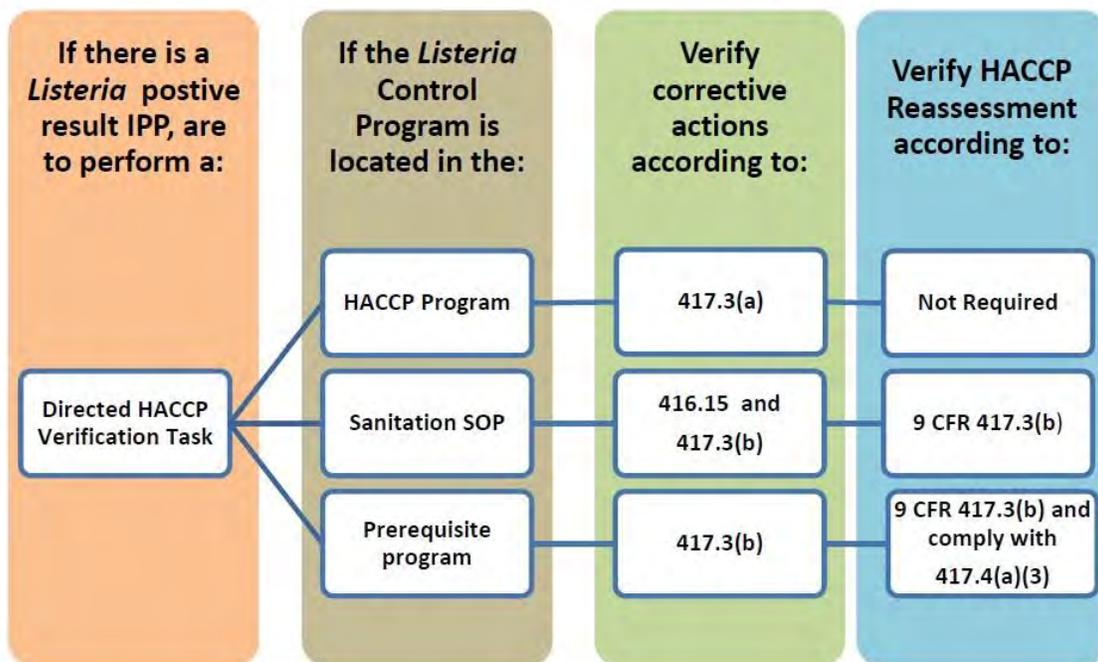
IPP are to verify that the establishment reassessed its HACCP plan as follows:

- If *Lm* control is addressed as a CCP in the HACCP plan (e.g., PLT), the establishment must meet the requirements of 9 CFR 417.3(a), which requires that corrective action be taken but does not require reassessment of the HACCP plan.
- If *Lm* is addressed in the Sanitation SOP, then the establishment must implement corrective actions in accordance with 9 CFR 417.3(b), which includes reassessment of the HACCP plan. In addition, it must implement the corrective action requirements for the Sanitation SOP in 9 CFR 416.15, which includes appropriate re-evaluation or modification of the Sanitation SOP.

- If *Lm* is addressed in a prerequisite program (e.g., *Listeria* Control Program) that is used to support the decision that *Lm* is not a hazard reasonably likely to occur in the product, then the establishment must implement the corrective actions in 9 CFR 417.3(b) and comply with 417.4(a)(3). These regulations state that when there is a change in the process (e.g., a positive result) that could impact the hazard analysis, a reassessment must be performed.

The establishment is required under 9 CFR 417.4 (a)(3)(ii) to make a record of the reassessment and document the reasons for any changes that it made to its HACCP plan based on the reassessment, or, if it did not make any changes, to document the reasons that it did not.

### Steps for Verifying an Establishment's Corrective Actions



### Verifying Product Disposition

The establishment may reprocess or dispose of adulterated product. If the establishment reprocesses the product, IPP are to verify that it used a process that achieves adequate lethality of pathogens. FSIS considers a process that has been validated to achieve a 5-log reduction of *Lm* sufficient for reworking contaminated product.

In addition, establishments may use Appendix A and Appendix B of the final rule, "Performance Standards for the Production of Certain Meat and Poultry

Products,” FSIS Guidance on Safe Cooking of Non-Intact Meat Chops, Roasts, and Steaks, and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, or other supportable processes to reprocess *Lm*-positive product.

NOTE: Appendix A and B, the FSIS Guidance on Safe Cooking of Non-intact Meat Chops, Roasts, and Steaks, and the Time-Temperature Tables for Cooking Ready-to-Eat Poultry Products, are designed to achieve reductions in *Salmonella*. Establishments are not expected to validate that these processes also achieve reductions in *Lm* because *Salmonella* is considered an indicator of lethality for *Lm*.

If the establishment chooses to dispose of the product, it may do so either on-site or off-site. If the product is disposed of on-site, IPP are to verify that the establishment maintained records showing that the positive product received the proper disposition.

If the establishment transports positive product to another site for appropriate disposition, IPP are to verify that the establishment has met all corrective action requirements by verifying that the establishment:

- Maintained records identifying the official establishment, renderer, or landfill operation that received positive product;
- Maintained control of product that was destined for a landfill operation or renderer while the product was in transit (e.g., through company seals);
- Maintained control of product that was destined for an official establishment while the product was in transit (e.g., through company seals) or ensured that such product moved under FSIS control (e.g., under USDA seal or accompanied by FSIS Form 7350-1);
- Maintained records showing that positive product received the proper disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred; and
- Completed pre-shipment review for the positive product only after it has received the records described above for that particular product.

If an establishment ships adulterated product to a renderer or landfill operation, IPP are to verify the establishment denatures the product before the product leaves the establishment (9 CFR 314). In situations where the establishment has not properly moved or disposed of the product, IPP are to notify their DO through supervisory channels.

If IPP find that there is noncompliance with the corrective action requirements for product disposal, they are to document the noncompliance in accordance with FSIS PHIS Directive 5000.1.

## IVT Sampling Program

EIAOs trained in the IVT methodology will 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) under the following sampling project codes.

1. **IVTCONT** - the testing of surfaces that have direct contact with RTE product in the RTE production area, e.g., conveyor belts, cooler storage racks, luggers, slicers, peelers, loaders, table tops. This would also include brine that comes in contact with product (e.g., product is chilled in a permeable container).
2. **IVTPROD** – the testing of intact product samples collected concurrently with food and environmental contact surface swabs throughout the selected production shift.
3. **IVTENV** - testing of environmental (non-food contact) surfaces in the RTE production areas, e.g., floors, drains, walls, air-vents, overhead structures. This would include brine that does not contact product directly (e.g., product is chilled in an impermeable container).

IVTs are scheduled by the district office within 30 days and completed within 90 days of receiving notification of a positive sample result. IVTs may also be scheduled due to repetitive occurrences of noncompliance in the establishment’s *Lm* control program, including sanitation issues. IVTs are performed in response to *Salmonella* positives as well.

## RLm Sampling Program

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. The RLm testing program consists of the following sampling project codes:

1. **RLMCONT** – the routine risk-based testing of surfaces that have direct contact with RTE product in the RTE production area, e.g., conveyor belts, cooler storage racks, luggers, slicers, peelers, loaders, table tops. This would also include brine that comes in contact with product (e.g., product is chilled in permeable container).

2. **RLMENVC** – the routine risk-based testing of environmental (non-food contact) surfaces in the RTE production areas, e.g., floors, drains, walls, air-vents, overhead structures. Samples are composited in the lab testing protocol.

3. **RLMPRODC** – the routine risk-based testing of intact product samples collected concurrently with food and environmental contact surface swabs throughout the selected production shift. Samples are composited in the lab testing protocol.

4. **RLMENVR** – the routine risk-based testing of brine used for chilling RTE product and the product does not come in contact with the brine (e.g., product is chilled in an impermeable container).

RLm sample collection does not take precedence over the other sampling programs.

## **RLm Sampling Program Results**

IPP may be instructed to document noncompliance at the completion of an FSA conducted by an EIAO. IPP issues the NR on the determinations of the EIAO's FSA which may include positive sample results from the RTE RLm or IVT sampling program. IPP are to issue an NR under the appropriate HACCP Verification task citing 9 CFR 417.4(a) and 301.2 or 381.1 for positive product or food contact surface results. If the determination of the EIAO's FSA is to document a noncompliance related to the design or execution of environmental sampling, the CSI is to issue an NR under the SPS Verification task and cite 9 CFR 416.4(b).

## Workshop - Sampling RTE Product

1. \_\_\_\_\_ is a verification activity for RTE products.
  - a. Enforcement
  - b. Sampling
  - c. Recall
  - d. Documentation
  
2. You are assigned to an establishment that produces a variety of ready-to-eat (RTE) products including those that are shelf-stable. You receive a directed sample request for a RTE product (project code RTEPROD\_RISK). Which of the following would you choose based on the risk level?
  - a. RTE deli-meats that are cooked in an impervious bag and shipped from the establishment without being removed from the impervious bag
  - b. RTE deli-meats that are sliced in the federal establishment
  - c. Any RTE product as long as it is randomly selected
  - d. RTE fermented products
  
3. Fill in the blank. When you get a directed sample request for RTE product, you should \_\_\_\_\_ collect a sample.
  
4. FSIS sampling is done to
  - a. Verify that FSIS performance standards and regulations are met.
  - b. Validate HACCP plans and compare results to establishment analyses.
  - c. Generate public support.
  - d. Monitor in-plant activities.
  
5. RTE sliced ham is analyzed for: (Circle all that apply)
  - a. *E. coli* O157:H7.
  - b. *Salmonella*.
  - c. *L. monocytogenes*.
  - d. *Staphylococcus enterotoxin*.

6. When an establishment has a sanitation program that includes sampling RTE product as part of the HACCP plan, you do not have to collect RTE samples.
- True
  - False
7. When an establishment has a sanitation program that includes sampling RTE product as part of the HACCP plan, and they receive a positive for *L. monocytogenes*, what actions would we expect them to do? (Circle all that apply)
- Hold the affected product
  - Implement corrective actions per §417.3(a)
  - Make appropriate disposition of the sampled product
  - Notify the IIC
8. When an establishment has a sanitation program that includes sampling RTE product contact surfaces as part of the SSOP program, and they receive a positive for *L. monocytogenes*, what actions would we expect them to do? (Circle all that apply)
- Hold the affected product
  - Implement corrective actions per §417.3 & 416.15
  - Make appropriate disposition of the affected product
  - Notify the IIC
9. Under what circumstance might the DO schedule Intensified Verification Testing (IVT)? What would be the purpose?
10. When should a RTE product sample be sent to the lab for a *L. monocytogenes* directed sample?
- The day before the “use by” date
  - Just prior to packaging
  - The first day pickup for shipment is available after sample collection
  - As soon as the lot is assembled

11. Establishment management must be notified of pending sample collection
- When you receive the analysis result.
  - After pre-shipment review has been completed.
  - Enough in advance to allow the establishment to hold the product, but not soon enough to allow it to alter the process.
  - Because of the Freedom of Information Act (FOIA).
12. If a sample is too large for the shipping container, you
- Have the establishment use a different package to enclose the product.
  - Contact the FSIS lab for a larger shipping container.
  - Select a different product produced under the same HACCP plan.
  - Contact the DO.
13. An establishment produces fully cooked, not shelf stable ham. This product is produced using Alternative 2, Choice 1. The establishment performs a post-lethality treatment on the hams immediately following packaging. As a verification activity for the post-lethality treatment, it samples the hams for *Lm*, and holds product pending results. This morning, the establishment received a positive result for *Lm* from one of its samples. Based on the information presented so far, answer the following questions.
- Which corrective action regulation would apply in this situation?
  - What would you verify in this case? List all that apply.
  - Would you issue an NR?
  - Would FSIS request a recall?

Continuing with the above situation, while you are reviewing the establishment's corrective action documentation, you observe "The product represented by the sample will be relabeled as not fully cooked. The future production of these products will be as heat-treated, not fully cooked. The HACCP plan will be reassessed and modified to change the cooking temperature. The label will be changed to include cooking instructions."

e. What would you do next?

## ATTACHMENT 1

### Resources

Currently, there are several directives and notices associated with microbial sampling of RTE products. IPP should review the pertinent directives prior to obtaining a sample. The review should consist of checking to see if the directive is the current version. The FSIS website lists those directives that have been published most recently.

Number	Title
5000.1	Verifying an Establishment's Food Safety System
7355.1	Use of Sample Seals for Laboratory Samples and Other Applications
8080.1	Recall of Meat and Poultry Products
10,200.1	Accessing Laboratory Sample Information via LEARN (to be revised for LIMS-Direct)
10,210.1	Unified Sampling Form
10,230.2	Procedures for Collecting and Submitting Domestic Samples for Microbiological Analyses
10,240.4	Verification Procedures for Consumer Safety Inspectors for the <i>Listeria monocytogenes</i> ( <i>Lm</i> ) Regulation and <i>Lm</i> Sampling Programs
10,240.5	Enforcement, Investigations, and Analysis Officer (EIAO) Assessment of Compliance with the <i>Listeria monocytogenes</i> ( <i>LM</i> ) Regulation and Introduction of Phase 2 of the <i>LM</i> Risk-based Verification Testing Program
10,300.1	Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for <i>Listeria Monocytogenes</i>
13,000.1	Scheduling In-Plant Inspection Tasks in the Public Health Information System
13,000.2	Performing Sampling Tasks in Official Establishments Using PHIS

**ATTACHMENT 2 RTEPROD\_RISK and RTEPROD\_RAND Sampling Instructions**

<b>Project Codes</b>	<b>RTEPROD_RISK – Risk Based Verification Testing of Only Post-lethality Exposed RTE Meat and Poultry Products</b>	<b>RTEPROD_RAND– Random Verification Sampling of RTE Meat and Poultry Products</b>
SAMPLE COLLECTOR	IPP in establishments that produce post-lethality exposed RTE product.	IPP in establishments that produce all RTE products, regardless of whether the product is post-lethality exposed or not.
PRODUCT TO SAMPLE	IPP are to select the highest-risk post-lethality exposed RTE product produced at the time of collection using the Product Sampling Priority List (Page 4). When assigning product categories, IPP are to use the RTE Product Group Flowchart Resource 2.	IPP are to randomly select a product produced at the time of collection. IPP are to make every effort to sample all the RTE products produced at the establishment by rotating through the products.
ANALYZED FOR	<i>Listeria monocytogenes and Salmonella</i>	
SPECIAL COLLECTION INSTRUCTIONS	IPP are to submit a two-pound sample of product in an intact package. FSIS is not collecting samples of oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats because there is no validated method for testing these products for Lm. FSIS will continue to sample popped pork skins, pork rinds, dried soup bases, concentrated (high salt content) soup mixes, and pickled pig's feet under both RTE project codes. FSIS will collect samples of RTE products that are shipped hot from the establishment. In addition, IPP are not to collect product labeled "For Further Processing," in which the product is expected to receive a lethality treatment at another federally inspected establishment.	
SCHEDULING INSTRUCTIONS	IPP are to randomly select a day, shift, and time within the sample window timeframe. IPP are to collect samples from all shifts the establishment operates. There should be an equal chance that sampling will occur during any particular shift.	
ESTABLISHMENT NOTIFICATION	IPP are to notify the establishment before collecting samples. IPP are to provide enough time for the establishment to hold the sampled lot but not enough time to alter its process.	
SPECIAL SHIPPING INSTRUCTIONS	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. IPP are to ship samples to the designated laboratory as soon as collected and during the next available FedEx pickup. IPP are to ship samples refrigerated or frozen, depending on establishment practices. IPP are to use sufficient frozen coolant to keep samples cold during transit. IPP are to ship samples Monday through Friday so that they arrive at the laboratory overnight. IPP are not to ship samples on Saturdays or on the day before a Federal Holiday	
REFERENCES	Directive 10,240.4, Rev. 3	