

UNITED STATES DEPARTMENT OF AGRICULTURE  
FOOD SAFETY AND INSPECTION SERVICE  
WASHINGTON, DC

# FSIS DIRECTIVE

10,240.3

3/25/22

## FSIS READY-TO-EAT SAMPLING PROGRAMS

### CHAPTER I - GENERAL

#### I. PURPOSE

A. FSIS product sampling for *Listeria monocytogenes* (*Lm*) and *Salmonella* are important food safety verification activities that support FSIS' food safety and public health goals. This directive provides instructions to inspection program personnel (IPP) to collect and submit ready-to-eat (RTE) meat and poultry product samples to FSIS laboratories and, when appropriate, to take enforcement action in response to positive test results. Instructions concerning *Lm* verification activities other than sampling and responses to positive results are contained in [FSIS Directive 10.240.4, Listeria Rule Verification Activities](#).

B. The directive has been revised to reflect changes to product sampling for *Lm* (RTEPROD\_RISK and RTEPROD\_RAND projects) and updates to the sampling selection criteria (RTEPROD\_RISK samples) to improve sampling program efficiency. The directive also includes RTEPROD scheduling information in the [Attachment](#). The directive has been revised to clarify that both post-lethality exposed and not post-lethality exposed products are subject to RTEPROD sampling and that IPP are not to collect samples that are pass-through products. Pass-through products are those products that the establishment sends into commerce without further post-lethality exposure, processing, or repackaging. The directive has also been revised to indicate that IPP are to collect one-pound samples of RTE product to ship to FSIS laboratories, which has been changed from the previous requirement of two pounds. The directive explains where in the process and at which establishment IPP are to collect samples of products that receive high pressure processing (HPP) treatment, whether HPP is used as a pathogen control intervention or to extend shelf life. The directive also explains that IPP are to verify that positive product is appropriately transported to pet food manufacturers.

#### KEY POINTS:

- *Collecting and submitting FSIS verification samples under the revised RTEPROD (sample project code for RTE product) sampling algorithm*
- *Taking enforcement actions in response to a positive sample result and verifying product disposition*
- *Collecting one-pound samples of RTE product for sample submission to the FSIS laboratories is required*

#### II. BACKGROUND

A. Under the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA), FSIS considers any RTE product to be adulterated if it contains a pathogen of public health concern (depending on the type and level) or its toxin that can cause illness in humans. There are some pathogens where any level would make the RTE product adulterated (such as *Lm* and *Salmonella*) because presence of the pathogen could be injurious to health (21 U.S.C. 601(m)(1) and 453(g)(1)). If any level of *Lm* or *Salmonella* is detected in an RTE product or on a food contact surface (FCS)

that RTE product has passed over, the product is adulterated.

B. FSIS collects samples for its RTE sampling program under the RTEPROD sampling project. The RTEPROD project uses two project codes:

1. RTEPROD\_RAND for post-lethality exposed and not post-lethality exposed product samples selected randomly; and
2. RTEPROD\_RISK for post-lethality exposed product samples selected based on risk.

C. On September 30, 2016, FSIS made changes to the RTE sampling scheduling criteria used to assign sampling tasks at establishments ([Attachment 1](#)). FSIS made these changes after review of the existing sampling algorithm identified new trends in *Lm* positives across product group types and risk. FSIS moved to this targeted approach for scheduling samples to better assess establishment process control, assess risk, and enforce zero tolerance of *Lm*.

D. FSIS also analyzed products collected under the RTEPROD\_RISK project and found that there was no statistically significant difference in the percent *Lm*-positive between the highest priority products (Other Fully Cooked – Sliced Product) and the lowest priority (RTE salt-cured meat or poultry products). In this directive revision, the Agency is therefore changing the priority order used to select RTEPROD\_RISK samples for testing to be based on the *Lm* Control Alternative, with Alternative 3 being highest priority, to make the program more targeted.

## **CHAPTER II - FSIS RTE SAMPLING PROGRAMS**

### **I. FSIS RTEPROD SAMPLING CODES**

A. IPP are to collect samples using the following sampling codes. [Attachment 1](#) has information about RTEPROD sample scheduling.

1. RTEPROD\_RAND: Random sampling of RTE products, including both post-lethality exposed and not post-lethality exposed products (e.g., cook-in-bag products); and
2. RTEPROD\_RISK: Risk-based sampling of post-lethality exposed RTE products.

### **II. PRODUCTS SUBJECT TO SAMPLING**

A. Both post-lethality exposed products and not post-lethality exposed products are eligible for sampling under the RTEPROD\_RAND sampling program. Although the *Listeria* Rule (9 CFR 430) does not apply to not post-lethality exposed products, these products are subject to FSIS sampling under RTEPROD\_RAND.

B. Therefore, IPP are not to cancel RTEPROD\_RAND samples just because an establishment only produces not post-lethality exposed products.

C. IPP are to collect samples of post-lethality exposed and not post-lethality exposed products.

D. Only post-lethality exposed RTE products are eligible for sampling under the RTEPROD\_RISK sampling program.

E. To determine product sampling eligibility, IPP are to consider if the establishment's hazard analysis intended use statement, and flow chart, and Hazard Analysis and Critical Control Point (HACCP) plan, are consistent with production of an RTE product. According to [FSIS Directive 5.300.1](#), *Managing the Establishment Profile in the Public Health Information System (PHIS)*, FSIS

considers products in the Fully Cooked – Not Shelf Stable HACCP category to be RTE. HACCP categories that may contain either RTE or not ready-to-eat (NRTE) products include Not Heat-Treated – Shelf Stable, Heat Treated – Shelf Stable, and Product with Secondary Inhibitors – Not Shelf Stable.

F. FSIS considers a product to be RTE and subject to sampling if it meets one or more of the following criteria:

1. The product meets the definition of an RTE product in the *Listeria* Rule ([9 CFR 430.1](#)). The *Listeria* Rule defines an RTE product as a meat or poultry product that is edible without additional preparation to achieve food safety. This includes products that have been processed to meet the requirements of [9 CFR 318.17](#), [9 CFR 318.23](#), or [9 CFR 381.150](#) or undergone other processing to render them RTE.
2. IPP are to be aware that not all RTE products are required to meet a standard of identity. There is a standard of identity requiring that certain products be fully cooked according to [9 CFR 319](#) and [9 CFR 381](#) (e.g., hot dogs or barbeque). For other RTE product, the establishment identifies the intended use of the product as RTE based on consumer expectation and the product name (e.g., pâtés or deli meat).

**NOTE:** IPP are to be aware that the establishment may consider certain products (e.g., hams) as either RTE or NRTE if there is no standard of identity defining the product as RTE or the intended use is not typically RTE even if the product receives a full lethality treatment (e.g., meat casserole). Products that receive a full lethality treatment but are classified by the establishment under a NRTE HACCP plan, are not eligible for FSIS sampling under RTEPROD (e.g., hams, tamales).

3. The product is not labeled with safe handling instructions (SHI), as required for NRTE products by [9 CFR 317.2\(l\)](#) and [9 CFR 381.125\(b\)](#). According to [9 CFR 430.1](#), RTE products are not required to bear SHI or other labeling that directs that the product be cooked or otherwise treated for safety (although RTE products may bear heating instructions). FSIS considers products labeled with SHI and cooking instructions to be NRTE and not subject to sampling under the RTE sampling projects.

G. FSIS considers the product to be post-lethality exposed and subject to sampling under the RTEPROD\_RISK and RTEPROD\_RAND sampling projects if it is RTE and it meets one or more of the following criteria:

1. The product is exposed to the establishment's environment after the lethality step. These products may include those that are exposed after the lethality step in the same establishment, or they may include products that received a lethality at another establishment and are then exposed post-lethality to produce a final product, such as a chicken salad or sliced meat and poultry product.
2. The product is removed from a cooking bag or sealed container after cooking, and the product comes in contact with an FCS (including brine when it is in direct contact with the product) or other environmental conditions during cooling, processing, slicing, or packaging steps.
3. Cook-in-bag products are exposed because the bag is punctured (e.g., with a thermometer or has holes punctured for air removal) and the product is not resealed or not thoroughly sealed (e.g., the bags are clipped, but product routinely leaks or presses out through the clips) and reprocessed.

H. FSIS considers the product to be not post-lethality exposed and subject to sampling only under the RTEPROD\_RAND sampling project if it meets one or more of the following criteria:

1. The product is cooked in a moisture impermeable bag and remains in the cooking bag until it enters commerce. If the establishment punctures the impermeable bag (e.g., with a thermometer) and repackages and reprocesses the product before distributing it, the product is **not** categorized as not post-lethality exposed.
2. The product is treated with a process (e.g., high pressure processing (HPP)) that achieves a full lethality (e.g., 5-log reduction of *Salmonella*) in the product, once it is in its final packaging.
3. The product is hot-filled (e.g., soup) at a temperature sufficient to achieve full lethality of the product (e.g., using one of the time/temperature combinations in the [FSIS Cooking Guideline for Meat and Poultry Products \(Revised Appendix A\)](#)).

### III. THE SAMPLED LOT

A. The **sampled lot** is product that is represented by the sample FSIS collects and analyzes for *Lm* and *Salmonella*. The establishment is responsible for defining the sampled lot.

B. FSIS generally considers the sampled lot to be the product produced from “**clean-up to clean-up**,” unless the establishment has a different supportable definition of the lot (e.g., products that are produced on different lines and that are microbiologically distinct from one another).

C. An official establishment may reduce its lot size on a day when FSIS collects a routine RTE sample to facilitate holding the product if the change does not interfere with FSIS’ ability to collect a representative sample.

**NOTE:** For example, an establishment that normally produces product over an 8-hour shift, followed by a complete clean-up, may reduce its lot size when FSIS collects a sample. The establishment may then produce product over a 4-hour period, followed by a complete clean-up.

D. There are other options that establishments may use to reduce lot size, if FSIS can still collect a representative sample. Instructions to verify an establishment’s written sampling program design and execution can be found in [FSIS Directive 10.240.4, Listeria Rule Verification Activities](#), Chapter III.

1. IPP are to be aware that establishments may reduce the lot size even when using source materials that are post-lethality exposed and do not undergo further lethality treatment. The establishment is not required to hold other lots using the same source materials because the sampled lot is those products produced from clean-up to clean-up.
2. For example, if an establishment reduces the lot (as outlined in C.1. of this section) in the production of prepared chicken salad using RTE post-lethality exposed chicken from another supplier, the establishment may reduce its lot size to a 4-hour period of chicken salad production, followed by a complete clean-up. The establishment can make another lot of chicken salad using the same source materials and not hold that lot. In the event of a positive, the establishment will need to provide a scientific basis to justify why the other lots should not be implicated.
3. IPP are to be aware of the difference between the **sampled lot** and the **implicated lot** in the event of a positive.
  - a. The **sampled lot** is product that is represented by the sample FSIS collects and analyzes

for *Lm* and *Salmonella*. The establishment is responsible for defining the sampled lot.

- b. The **implicated lot (or lots)** is the product that may be connected to a sampled lot that tested positive through common source material or other root cause findings as described below. The implicated lots are determined by root cause findings and may be defined through investigations by FSIS, other public health agencies, the establishment, or foodborne illness findings.
- c. The establishment is required per [9 CFR 417.5\(a\)\(3\)](#) to retain HACCP records for two years documenting the product code, product name or identity, or slaughter lot. The product code is used by the establishment to identify a particular lot of product and is needed to identify the implicated lots should the establishment need to recall additional product made using positive source materials.

E. IPP are to consider the impact that decreasing the lot size may have on sample collection. FSIS recommends samples be collected at least 3 hours into operations, if possible, to allow *Lm* to work its way out of the equipment. As a result, if the establishment produces a very small lot on the day FSIS collects a sample when it typically produces a larger lot, then FSIS may not be able to collect a representative sample. In this case, IPP are not to collect a sample and are to reschedule the sample for another day. If the establishment typically produces RTE product for less than 3 hours, then the samples can be collected less than 3 hours into operations.

F. IPP are to ensure that establishments do not reduce the lot size to a single piece of one-pound product (e.g., a single deli chub) or other unrepresentative lot size.. A representative sample does not mean a lot that is comprised of a single one-pound piece of product.

G. As stated in B. above, FSIS generally considers the sampled lot to be the product produced based on the establishment's supported lot definition or from "clean-up to clean-up." However, in the event of a positive result or harborage findings, additional product may be included in the implicated lot.

1. The implicated lot may include other products using the same RTE source materials:

- a. If an establishment uses RTE source materials received from another establishment, and there is reason to conclude that those products are the source materials for a *Lm* positive, additional product may be included in the lot, outside the establishment's clean-up to clean-up lotting procedures (e.g., if there are positive test results for an individual source material).
- b. For example, if the establishment uses a RTE chicken source material to make different lots or types of chicken salad, and FSIS sampling finds a *Lm* positive in the chicken and it matches a *Lm* positive in the chicken salad by Whole Genome Sequencing (WGS), then all the different lots of chicken salad that used the same RTE chicken source material would be part of the implicated lot.
- c. Ingredients (e.g., pepper or other spices) added to post-lethality exposed RTE products can affect the lot definition. The establishment is required to evaluate the possible hazards from all ingredients it uses, as per [9 CFR 417.2\(a\)\(1\)](#).

2. The implicated lot may include other products using the same processing steps:

- a. If the root cause of the positive is due to under-cooking or under-processing, then other products using the same processing method can be implicated. Since *Salmonella* can contaminate RTE products because of under-processing, the adequacy of the lethality step may be in question.

- b. For example, if one lot of RTE product tests positive by FSIS and the root cause identified under-cooking, and a subsequent lot of product received the same lethality treatment, a scientific basis is necessary to justify why the later lot should not be included in the implicated lot.
- c. The establishment's brine, used to chill product, is reused across lots and can cross-contaminate the lots and prevent them from being microbiologically distinct.

3. Harborage findings:

- a. Harborage or reintroduction of *Lm* occurs when *Lm* persists in the processing environment over time. Harborage may be identified based on FSIS test results when closely related *Lm* isolates (as determined by the Office of Public Health Science (OPHS) using WGS) are found in product, food contact, or environmental samples collected over multiple days, weeks, months, or years.
- b. Evidence of harborage may indicate insufficient sanitary measures to prevent contamination of the production environment and the products with *Lm* and may result in additional product associated with the lot, outside the establishment's clean-up to clean-up lotting procedures.

- 4. Cross-contamination findings: Cross-contamination occurs when *Lm* moves from one site (e.g., a non-FCS) to an FCS or product in the establishment. Cross-contamination is identified based on FSIS test results when closely related *Lm* isolates (as determined by OPHS using WGS) are found in product, food contact, and environmental (non-food contact) samples collected during the same sampling event. If *Lm* is isolated from a post-lethality exposed product sample and from an FCS sample, the FCS is more likely to be the source, unless under-processing of RTE product is suspected.

H. If IPP have questions about whether an establishment is altering routine production, sanitation, or food safety practices, they are to discuss the issue with their supervisor, and if additional help is needed, can submit questions through [askFSIS](#) following the instructions in [Chapter VII, Questions](#).

I. IPP are to be aware of the following factors or conditions that may determine a sampled lot:

- 1. Frequency of cleaning and sanitizing: The establishment may perform a complete cleaning and sanitizing (following the procedures in its Sanitation Standard Operating Procedure (Sanitation SOP)) to differentiate lots.
- 2. Separation between processing lines:
  - a. Products produced in the same room can be considered part of the same lot or different processing lots, depending on how the lots are separated by time and space.
  - b. Products produced on different processing lines can be considered different lots if the lines are microbiologically and physically independent (e.g., equipment, personnel, utensils, and RTE source materials are not shared among the lines).
  - c. Products produced on the same line can be considered different processing lots if their production is separated by complete cleaning and sanitizing, and if they differ according to the other factors described above.
  - d. Products stored in a common cooler would not necessarily be considered part of the same lot. IPP are to be aware that the establishment's Sanitation SOP should address possible



cross-contamination if exposed products from different lots are stored in the same cooler.

## CHAPTER III – COLLECTING AND SUBMITTING FSIS VERIFICATION SAMPLES

### I. PREPARATION FOR SAMPLE COLLECTION

#### A. Sampling Eligibility:

1. For RTEPROD\_RAND sample requests, IPP are to select randomly from eligible samples, which include RTE:
  - a. Post-lethality exposed meat and poultry product;
  - b. Post-lethality exposed meat and poultry product labeled “For Further Processing,” in which the product does not receive a lethality treatment at another federally inspected establishment;
  - c. Not post-lethality exposed meat and poultry product (e.g., cook-in-bag products; *sous vide* is a type of cook-in-bag);
  - d. Not post-lethality exposed meat and poultry product labeled “For Further Processing,” in which the product does not receive a lethality treatment at another federally inspected establishment;
  - e. Popped pork skins, pork rinds, dried soup bases, concentrated (high salt content) soup mixes, and pickled pig’s feet;
  - f. Products that are hot shipped, such as pasties, hot meat pies, or convenience meals that are cooked and shipped hot without cooling;
  - g. Products that will later be processed at establishments that apply HPP to extend shelf life (collect prior to HPP application);
  - h. Products that are treated with HPP as an intervention (either as a post-lethality 1-log treatment or lethality 5-log treatment). IPP are to collect the sample either after the product returns from the HPP establishment or at the HPP establishment if the product will not be returned to the originating establishment; and
  - i. Siluriformes fish as instructed in [Directive 14.010.1](#), *Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes from Domestic Establishments*.
2. For RTEPROD\_RISK sample requests, IPP are to select **only post-lethality exposed** samples according to the Product Sampling Priority ([Table 1](#)), which include RTE:
  - a. Post-lethality exposed meat and poultry products;
  - b. Post-lethality exposed meat and poultry product labeled “For Further Processing,” in which the product does not receive a lethality treatment at another federally inspected establishment;
  - c. Post-lethality exposed popped pork skins, pork rinds, dried soup bases, concentrated (high salt content) soup mixes, and pickled pig’s feet;
  - d. Post-lethality exposed meat and poultry products that are hot shipped, such as pasties,

hot meat pies, or convenience meals that are cooked and shipped hot without cooling;

- e. Post-lethality exposed meat and poultry products that will later be processed at establishments that apply HPP to extend shelf life (collect prior to HPP application); and
- f. Products that are treated with HPP as an intervention (as a post-lethality 1-log treatment). IPP are to collect the sample either after the product returns from the HPP establishment or at the HPP establishment if the product will not be returned to the originating establishment.

B. Sampling Ineligibility:

1. For RTEPROD\_RAND sample requests, IPP are **not** to collect samples of pass-through product, which is fully packaged finished product that the establishment has received and kept in its package without further post-lethality exposure, processing, or repackaging. For example, pass-through products, such as pre-packaged deli meat that the establishment combines with cheese and crackers and are not comingled, are not to be sampled.
2. For RTEPROD\_RISK sample requests, IPP are **not** to collect not post-lethality exposed products (e.g., cook-in-bag products, products that undergo HPP treatment validated to achieve at least a 5-log reduction of *Lm* in the package).
3. IPP are **not** to collect the following under either RTEPROD\_RISK and RTEPROD\_RAND:
  - a. Oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats because there is no validated method for testing these products for *Lm*.
    - i. IPP are to ensure lards and oils are appropriately entered into the PHIS profile so that sampling tasks are not assigned in establishments that only produce lards/oils.
    - ii. IPP are to enter the products under the HACCP Category of *Heat Treated-Shelf Stable*, the Finished Product Category of *RTE dried meat*, and the Product Group as *Lard/oils*. For information on how to update the PHIS profile, see [FSIS Directive 5,300.1](#).
  - b. Product labeled “For Further Processing,” in which the product will receive a lethality treatment at another federally inspected establishment.
    - i. If all products within a product group receive a lethality treatment at another federally inspected establishment, IPP are to select the intended use in the PHIS profile as “Receives additional lethality treatment at a federally inspected establishment.”
    - ii. IPP are to verify that the establishment’s hazard analysis and flow chart show that the product is intended for receiving a lethality treatment at another federally inspected establishment.
    - iii. IPP are to be aware that establishments may continue to receive sampling tasks when this intended use is checked. If all products within a product group are intended for further processing in which the product receives a lethality treatment at another federally inspected establishment, IPP are to cancel the sampling tasks with the justification “requested sample unavailable during sampling timeframe.”



## C. Sampling Priority For RTEPROD\_RISK

**Table 1: *Listeria* Control Alternatives and FSIS Product Sampling Priority for RTEPROD\_RISK**

<b><i>Listeria</i> Control Alternative Type</b>	<b><i>Listeria</i> Control Alternative Description</b>	<b>FSIS Sampling Priority</b>
<b>Alternative 1 (Alt. 1)</b>	The establishment uses a post-lethality treatment ( <b>PLT</b> ) to reduce or eliminate <i>Lm</i> in the product <u>and</u> an Antimicrobial Agent or Antimicrobial Process ( <b>AMAP</b> ) to limit or suppress growth of <i>Lm</i> in the product	Low
<b>Alternative 2, Choice 1 (Alt. 2a)</b>	The establishment uses a PLT to reduce or eliminate <i>Lm</i> in the product	Medium
<b>Alternative 2, Choice 2 (Alt. 2b)</b>	The establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product	Medium
<b>Alternative 3 (Alt. 3)</b>	The establishment relies on sanitation alone to prevent <i>Lm</i> in the processing environment and on the product	High
<b>Alternative 3 (Alt. 3)</b>  <b><i>Additional Requirements for Deli Meats and Hot Dogs</i></b>	The establishment relies on sanitation alone to prevent <i>Lm</i> in the processing environment and on the product and must meet additional regulatory requirements for production of deli meats and hot dogs	High

## II. SCHEDULING THE SAMPLE

A. IPP are to discuss sample scheduling with the establishment at the weekly meeting and document the discussion in a Memorandum of Interview (MOI), as described in [FSIS Directive 5.000.1, Verifying An Establishment's Food Safety System](#). As part of this discussion, IPP are to determine:

1. The types of RTE products produced by the establishment, and whether they are post-lethality exposed, or not post-lethality exposed; and
2. How much notice to give the establishment when collecting a sample. IPP are to familiarize themselves with the establishment's production practices so that they can provide adequate time to allow the establishment to hold all product represented by the sample, (i.e., the sampled lot) but not alter its production practices.

B. When IPP receive an RTEPROD\_RAND or RTEPROD\_RISK request in the PHIS, they are to schedule sample collection within the sampling window timeframes given.

1. IPP are to add the sampling task to the task calendar and set up a collection date and parcel pickup date, in accordance with [FSIS Directive 13.000.2, Performing Sampling Tasks in Official Establishments Using the Public Health Information System](#). Any rescheduled or canceled sampling tasks are to be recorded in PHIS.

2. IPP are not to 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 the sample is available, and that capacity is available at the labs during the sampling window.
3. To schedule the sample, IPP are to randomly select a day, shift, and time within the sample window timeframe.
4. IPP are to schedule samples from all shifts in which the establishment produces RTE products. There should be an equal chance that sampling will occur during any shift where eligible product is produced.
5. If IPP try to schedule a sampling task, but PHIS says there is “no lab capacity available,” they are to consult [IPP Help](#), *Requesting Lab Capacity*.

**NOTE:** There is generally more laboratory capacity early in sampling windows as well as earlier in a work week.

C. Before collecting a sample, to provide establishments enough time to hold the entire sampled lot, but not enough time to alter their production practices, IPP are to:

1. Generally, provide one day’s notice if such advanced notice is sufficient for the establishment to hold the sampled lot, but not to change practices. IPP may provide two days’ notice, if necessary.
2. Consider the establishment’s request for more than two days’ notice, in the rare case that more notice is needed based on the establishment’s product and process flow. If the establishment can support that more notice is necessary because of the innate characteristics of the process (e.g., less-than-daily sanitation, use of brine, or processes that span more than two days), IPP may provide more than two days’ notice. If IPP have questions about an establishment’s basis for requesting more notice, they are to discuss them with their supervisor, and if additional help is needed, are to submit them through [askFSIS](#) following the instructions in [Chapter VII, Questions](#).
3. Inform the establishment that if routine practices are changed without justification for doing so, FSIS may provide less than one day’s notice, if less time is sufficient to hold the sampled lot, but not change routine practices.
4. Inform the establishment that it is responsible for supporting the basis for defining the product represented by the sample (i.e., the sampled lot); and
5. Inform the establishment that it is required to hold or control the sampled lot when FSIS collects RTE products until negative results become available.

D. When notifying the establishment that FSIS will collect a sample, IPP are to:

1. Confirm the establishment will be producing applicable product on the day sampling is scheduled;
2. Confirm the establishment is planning to implement its documented routine production, Sanitation SOP, and food safety practices on the day the sample is scheduled; and
3. Inform the establishment that, if it intends to modify its documented routine production, sanitation, or food safety practices before the sampling, the establishment should inform IPP as soon as possible, so that sampling can be rescheduled.

- a. If the establishment continues to change routine practices and cannot support the changes, noncompliance is to be documented as specified in [Chapter IV, Documenting Noncompliance](#). IPP are to also work through supervisory channels to request a Public Health Risk Evaluation (PHRE), as appropriate ([FSIS Directive 5,100.4, Enforcement, Investigations, and Analysis Officer \(EIAO\) Public Health Risk Evaluation \(PHRE\) Methodology](#)).
  - b. 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.
  - c. At the next weekly meeting, IPP are to discuss with the establishment the changes to routine production, sanitation, or food safety practices. IPP are to inform the establishment that if it continues to change its practices, FSIS may collect more samples or give less than one day's notice.
- E. In PHIS, after collecting the sample, IPP are to:
1. Verify that the establishment is holding or controlling the product represented by the sampled lot and record the information in PHIS under the Sample Collection Data tab as:
    - a. "Yes," if product is held on-site or off-site under company control; or
    - b. "No," if the sampled lot was not held or controlled by the establishment because the product was denatured on-site or because the establishment did not wait to complete pre-shipment review following availability of all relevant test results, as set out in [9 CFR 417.5\(c\)](#).
  2. Immediately contact the District Office (DO) through supervisory channels if the establishment does not hold or maintain control of the sampled lot and the sampled lot was not denatured on-site.

### III. COLLECTING THE SAMPLE

- A. When collecting an RTEPROD\_RAND sample, IPP are to randomly select a product produced at the time the sample is scheduled, **regardless of whether the product is post-lethality exposed or not**. IPP are to make efforts to cycle through all the products produced by the establishment. If the product tests positive, IPP should consider the establishment's hazard analysis and supporting documentation prior to issuing a noncompliance record (NR) as described in [Chapter IV, Documenting Noncompliance](#).
- B. When collecting an RTEPROD\_RISK sample, IPP are to sample according to the *Listeria* Control Alternatives and the FSIS product sampling priorities in [Table 1](#). Within the highest alternative priority level available, IPP are to select samples by rotating randomly through available post-lethality products produced by the establishment on the day the sample is scheduled. If the establishment produces the highest priority product across multiple lines, IPP are to sample product from each of the lines over time.
- C. **IPP are to collect one pound of RTE product.** The labs require at least 1 pound of meat or poultry product to analyze the sample and failure to collect the minimum amount will result in a sample discard. For examples and photos of how to determine how much product to collect, IPP are to review IPP Help, *Multi-component RTE Product Sampling*. IPP are to ensure that:
1. 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, bread product stuffed with meat), IPP are to collect a one-pound sample of the final product (including the meat or poultry and non-meat or poultry component).

2. If the meat and non-meat 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 one-pound sample of the meat or poultry component in the final package. Generally, multiple entrees are necessary to ensure there is sufficient meat or poultry available for laboratory testing.

**NOTE:** To reduce the sample discard rate, when IPP do not submit at least 1-pound sample, the laboratories may reach out to IPP to request that they collect an additional 1-pound sample from the **same lot** and submit it to the FSIS laboratories.

D. IPP are to collect the sample after the establishment has applied all interventions except any microbiological testing. 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 before collecting a sample.

1. If the establishment treats the product with an intervention (e.g., HPP), either at the establishment or at another establishment, IPP are to review the documentation that the establishment keeps as part of its HACCP program to verify the purpose of the treatment to prevent or control *Listeria* and whether the sample is to be collected.
  - a. Products that are treated with HPP, whether for a lethality treatment or to extend shelf life, are eligible for RTEPROD sampling.
  - b. IPP are to be aware that the producing establishment, if separate from the HPP establishment, should be in communication with the establishment applying the HPP intervention to ensure that the lethality treatment is applied, if product is not returned to the producing establishment. IPP are to be aware that although the product is not returned, the establishment cannot sign off on pre-shipment review ([9 CFR 417.5\(c\)](#)) until all test results have been received and that the critical limits and critical operational parameters were met. For more information regarding ongoing communication and recordkeeping requirements, IPP are to refer to [Chapter V, Product Disposition](#) below and [FSIS Directive 5.000.15, Verification Activities for High Pressure Processing, Irradiation, and Microwave Tempering](#).

**NOTE:** If the establishment's scientific support demonstrates 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.

2. If off-site interventions, such as HPP, are applied to prevent or control *Listeria*, and the product is **returned** to the producing establishment, IPP are to sample the product **after** the off-site intervention is applied and the product is returned to the producing establishment.
  - a. IPP at HPP establishments are not to collect a RTEPROD sample if the product is being returned to the producing establishment.
  - b. IPP are to enter or update each product group in PHIS separately by intended use per [FSIS Directive 5.300.1](#). IPP are to select the appropriate intended use for each product, as shown below in [Figure 1](#). If product is returned to the producing establishment, IPP at the HPP establishment are to check the box, "*Not sampled at HPP or IR establishment because returned to producer or shelf life extension applied.*"

**Figure 1. PHIS Products Entry Based on Intended Use**

Non RTE Raw Egg Products

HACCP Category\*: Select

HACCP Plan: Select

Finished Product Category\*: Select

Species\*:

Intended Use:

☐ For RTE Cooking Only

☐ Other

☐ Not sampled at HPP or IR establishment because returned to producer or shelf life extension applied

No. of days of production:

Save Cancel

3. If off-site interventions, such as HPP, are applied to prevent or control *Listeria*, and the product is **not returned** to the producing establishment, IPP are not to collect a sample at the producing establishment, because the product **is eligible for FSIS sampling at the off-site establishment**.

E. If the establishment treats the product with HPP for quality purposes to extend shelf life (i.e., HPP is not applied as a lethality treatment for a target pathogen such as *Lm*), then IPP are to collect the sample **before** the product is treated with HPP.

1. IPP at HPP establishments are not to collect a RTEPROD sample if the establishment has records on file supporting that the treatment was applied to only extend the shelf life.
2. IPP are to select the appropriate intended use for each product, as shown above in [Figure 1](#). If product is being treated to extend shelf life, IPP at the HPP establishment are to check the box, *“Not sampled at HPP or IR establishment because returned to producer or shelf life extension applied.”*

F. IPP are to collect the product at least **three** hours after the start of production, whenever 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 may collect samples on the first shift or second shift (or other shifts, as applicable). IPP are to vary the shifts in which they collect samples, if possible.

G. IPP are to collect a **one-pound** sample of product in the final packaging (i.e., packaging that is normally shipped by the establishment into commerce). Collecting products in the final package will help ensure that the product does not become contaminated with *Lm* from the environment during the sample collection process. A one-pound sample is needed for all products, including jerky, because FSIS tests products for multiple analytes.

H. 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.

I. IPP are to be aware that FSIS collects samples in the final package after all interventions are complete, even if the establishment has recooked, reprocessed, or repackaged the product.

J. IPP are to submit the samples to the laboratory for microbiological analysis in the final package. 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 an exposed RTE product is collected.

**NOTE:** Final packaging may include butcher paper, wax paper, plastic wrap, or any packaging that is not sealed.

K. If the final package or product container is too large, heavy, or costly to ship to the laboratory or the establishment only ships product in bulk, IPP can contact the laboratory through PHIS to request a larger shipping container or ask the establishment to slack-fill or short-weight a product for a one-pound sample and send it in the usual establishment packaging, such as the container liner. IPP are not to cut the product to fit it inside the shipping container. The following are additional instructions regarding slack-filling or short-weighting:

1. If possible, IPP are to ensure the establishment slack-fills or short-weights a one-pound sample in the usual establishment packaging and seal it (e.g., vacuum seal).
2. If the product is shipped in bulk using a liner bag inside a box, IPP are to ensure the establishment slack-fills or short-weights a one-pound sample into the container liner. IPP are to tie off the liner bag (e.g., by knotting the bag or using a rubber band) so smaller particles (e.g., shredded meat pieces) or liquid does 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.
3. If the product is shipped in bulk and there is no liner bag (e.g., a wax lined box), IPP are to ensure the establishment slack-fills or short-weights a one-pound sample using its bulk packaging (e.g., the wax lined box with no liner bag) or the establishment may use food-grade packaging or sterile packaging such as Whirl-Pak bags. Laboratory-supplied bags (e.g., zip top bags) provided for FSIS RTE sampling are for secondary containment to protect the shipping container from possible sample leakage and are not sterile. The laboratory-supplied bag protects the box in case the primary container leaks.
4. IPP are not to slack-fill the sample and are not to supply the establishment with a laboratory-supplied bag as the primary wrap or container for the sample. The establishment is responsible for slack-filling the product in packaging that they supply.
5. 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 by the laboratory. Per this directive, IPP are to ensure the sample is short-weighted or slack-filled by the establishment employees or equipment in establishment-supplied packaging.

L. If submitting samples of products that contain lactic acid starter cultures, such as dry and semi-dry fermented sausages, IPP are to answer “yes” to the question “Does this sample contain a lactic acid starter culture?” under the *Additional Info* tab in PHIS. The laboratories use this information to determine the correct method of sample preparation, which differs for products containing lactic acid starter culture as described in the [Microbiology Laboratory Guideline \(MLG\) Chapter 4, Section 4.5](#).

#### IV. SUBMITTING THE SAMPLE

A. IPP are to safeguard the integrity of samples during submission according to [FSIS Directive 7.355.1](#), *Use of Sample Seals for Laboratory Samples and Other Applications*.



B. 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 gel packs to keep samples cold during transit. IPP are to ship samples Monday through Friday. IPP are not to ship samples on Saturdays or on the day before a Federal holiday, or as directed by an Agency user notice via e-mail notification.

C. According to [FSIS Directive 13.000.2](#), IPP are to submit information through PHIS to transfer electronic records to the lab. To submit samples to the lab, IPP are to apply the bar code label from the sample seal set to the designated location at the top of the lab form and sign and date the form before placing it in the shipping container. Additional information on the use of sample seals can be found in [FSIS Directive 7.355.1](#).

D. IPP are to respond in a timely manner to any requests from the FSIS laboratories regarding sample or form information (e.g., if the sample is missing a form that IPP need to submit) to avoid the sample being discarded.

E. IPP are to use **Table 2** below to reference RTE sampling instructions.

**Table 2: Summary of RTE Sampling Instructions**

Sampling Project Name	RTEPROD_RISK	RTEPROD_RAND
Sampling Project Description	Risk-based sampling of post-lethality exposed RTE products.	Random sampling of RTE products, including both post-lethality exposed and not post-lethality exposed products (e.g., cook-in-bag products)
Sample Collector	IPP in establishments that produce post-lethality exposed RTE product.	IPP in establishments that produce <u>all RTE products</u> , regardless of whether the product is post-lethality exposed or not.
Eligible Product to Sample	<p><b>Post-lethality exposed RTE products.</b></p> <p>IPP are to prioritize samples by <i>Listeria</i> control alternative priority level (<a href="#">Table 1</a>). Within the highest priority level available, IPP are to select samples by rotating randomly through available post-lethality exposed products.</p>	<p><b>Both post-lethality exposed and not post-lethality exposed products.</b></p> <p>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.</p>
Product Not to be Sampled	<p>Not post-lethality exposed product.</p> <p>Oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats.</p> <p>Product labeled “For Further Processing,” in which the product is expected to receive a lethality treatment at another federally inspected establishment.</p>	<p>Pass-through product: not post-lethality exposed fully packaged finished products that the establishment has received and passes through without further processing, repackaging, or post-lethality exposure.</p> <p>Oils, shortening, lard, margarine, oleomargarine, or mixtures of rendered animal fats.</p>

	Product labeled “For Further Processing,” in which the product is expected to receive a lethality treatment at another federally inspected establishment.
Analyzed for	<i>Listeria monocytogenes</i> and <i>Salmonella</i>
Collection Instructions	IPP are to submit a one-pound sample of product in the establishment’s final packaging.
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 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	<p>IPP are to safeguard the integrity of samples during submission according to <a href="#">FSIS Directive 7,355.1</a>.</p> <p>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 gel packs to keep samples cold during transit. IPP are to ship samples Monday through Friday. IPP are not to ship samples on Saturdays or on the day before a Federal holiday or as directed by an Agency user notice via e-mail notification.</p>

## CHAPTER IV – DOCUMENTING NONCOMPLIANCE

### I. ESTABLISHMENT TEMPORARILY CHANGES PRACTICES

A. IPP are to issue an NR under the following circumstances:

1. If IPP find that the establishment has made changes in its food safety systems on the day the sample is collected (e.g., temporarily changing its supplier of RTE product or purchasing new source material for the sampled lot) and does not have documents supporting the appropriateness of the change, IPP are to issue an NR. The NR would be recommended 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\(a\)\(1\)](#).
2. 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](#).

### II. SAMPLING RESULTS FROM RTEPROD

A. Sampling results will be reported to IPP in PHIS. IPP are to review the testing results and inform the establishment of the results, according to [FSIS Directive 5.000.1](#).

B. Whenever IPP are notified that a sample has been discarded and will not be analyzed by the FSIS laboratory, and product is being held on-site or controlled off-site, IPP are to notify the establishment immediately so the product can be released.

C. FSIS will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all FSIS test results that bear on the determination have been received.

D. If an RTE product sample collected by IPP tests positive for *Lm* or *Salmonella*, product from the sampled lot is considered adulterated. IPP are to follow the instructions in [FSIS Directive 5.000.1](#) to take regulatory action in response to positive sampling results. For information on product disposition options see [Chapter V, Verifying Product Disposition](#).

E. If FSIS finds the product to be positive and the establishment tested the product under its documented sampling programs, IPP are to check the establishment's *Lm* or *Salmonella* testing results to determine whether the establishment also found the sampled product to be positive for *Lm* or *Salmonella*.

F. IPP are to determine whether the establishment held the product or otherwise maintained control of the product (e.g., the establishment moved the product off-site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending FSIS test results. If IPP find that the establishment did not hold or maintain control of the product, they are to issue an NR because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as set out in [9 CFR 417.5\(c\)](#). IPP are to immediately contact the DO through the supervisory chain of command. If the results are confirmed positive for *Lm* or *Salmonella*, the DO is to take appropriate regulatory action and contact the Recall Management and Technical Analysis Division (RMTAD) and Office of Investigation, Enforcement and Audit, Compliance and Investigation Division (CID), Regional Director (RD). As appropriate, FSIS will request a recall or detain the product. The CID RD, in consultation with Headquarters, will consider whether additional enforcement actions or sanctions are necessary.

G. Generally, if FSIS finds the product positive for *Lm* or *Salmonella*, IPP are to issue an NR (cite [9 CFR 417.4\(a\)](#)). However, if the establishment also found the product to be positive for *Lm* or *Salmonella* 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.

H. IPP are to be aware that WGS is performed on all *Lm* and *Salmonella* isolates and *Lm* results are shared with DO personnel and in quarterly letters.

### **III. VERIFYING CORRECTIVE ACTIONS IN RESPONSE TO AN FSIS POSITIVE RESULT**

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

B. 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.

1. IPP are also to verify that the establishment implemented corrective actions according to [9 CFR 417.3\(a\) or \(b\)](#) 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.
2. FSIS will perform a PHRE for *Lm*, as described in [FSIS Directive 10.300.1, Intensified Verification Testing \(IVT\) Protocol for Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for \*Listeria monocytogenes\* \(\*Lm\*\) or \*Salmonella\* Spp.](#)
3. If the establishment considers *Listeria* NRLTO because the establishment has a prerequisite program, IPP may also perform a directed HAV task as described in [FSIS Directive 5.000.6, Performance of the Hazard Analysis Verification \(HAV\) Task](#) to verify the establishment can continue to support its decisions in its hazard analysis.

C. 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](#). As stated previously, FSIS considers RTE products to be adulterated if products or FCS test positive for *Lm* and *Salmonella*. Therefore, establishments are required to take corrective actions in response to positive results and to reassess their HACCP plan if they haven't addressed these hazards. FSIS will perform a PHRE in response to *Lm* or *Salmonella* positives, as described in [FSIS Directive 5.100.4](#).

**NOTE:** IPP are to be aware that establishments should take action in response to multiple *Listeria* positives that show relatedness through whole genome sequencing results. A trend of related positives may be an indicator of *Listeria* harborage.

D. If FSIS develops a verification plan (under [FSIS Directive 5.100.3, Administrative Enforcement Action Decision-Making and Methodology](#)) in response to an establishment's corrective actions and preventive measures, and 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.

E. IPP are to verify that the establishment took the following actions:

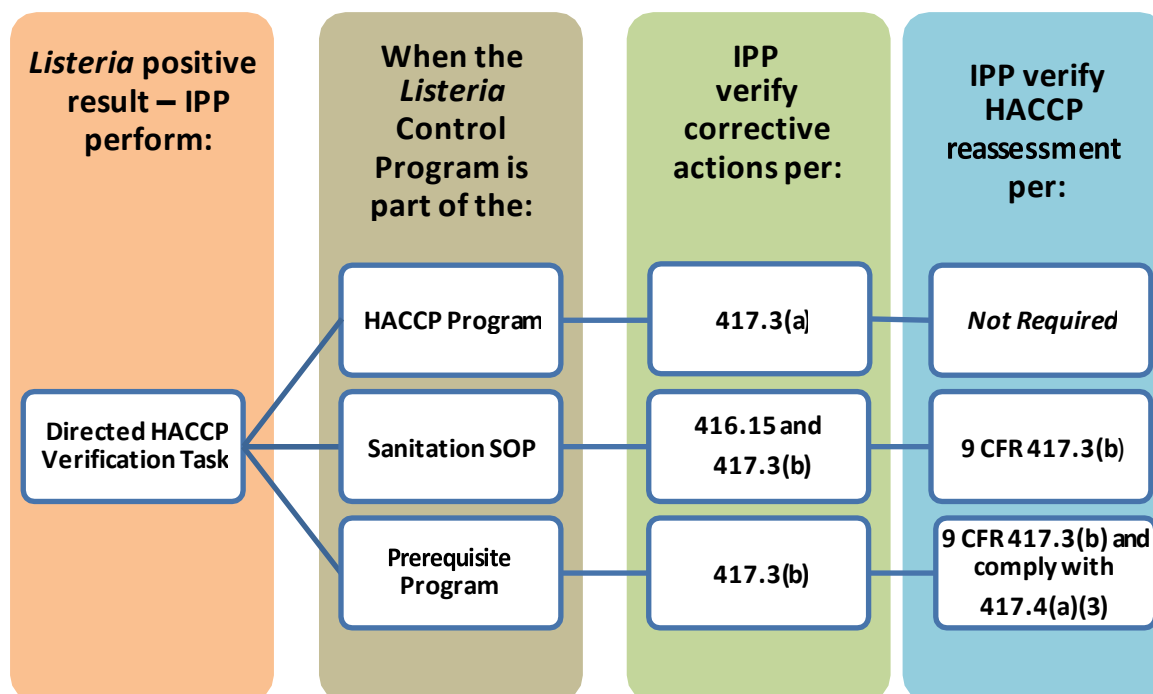
1. If *Lm* control is addressed as a CCP in the HACCP plan (e.g., PLT), the establishment must meet the requirements of [9 CFR 417.3\(a\)](#), which requires that corrective action be taken but does not require reassessment of the HACCP plan.
2. If *Lm* is addressed in the Sanitation SOP, then the establishment must implement corrective actions in accordance with [9 CFR 417.3\(b\)](#), which includes reassessment of the HACCP plan. In addition, it is to implement the corrective action requirements for the Sanitation SOP in [9 CFR 416.15](#), which includes appropriate reevaluation or modification of the Sanitation SOP.
3. 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 [9 CFR 417.4\(a\)\(3\)](#). As part of this, the establishment must perform a HACCP reassessment to determine whether the newly identified deviation or other unforeseen hazard should be incorporated into the HACCP plan.
4. The establishment is required under [9 CFR 417.4\(a\)\(3\)](#) to document the reassessment and the reasons for any changes that it made to its HACCP plan as a result of the reassessment, or, if it did not make any changes, to document the reasons why it did not.

**NOTE:** IPP are to refer to [FSIS Directive 10.240.4](#), *Listeria Rule Verification Activities*, Chapter III, Section III for instructions to verify corrective actions in response to establishment positives.

F. If an establishment reclassifies an RTE product as a NRTE product in its HACCP plan in response to a positive result, IPP are to verify that:

1. The product is not defined by a standard of identity as fully cooked (e.g., hot dogs) or the intended use is not typically RTE (e.g., pâtés or deli meats).
2. The establishment labels the product as one that is NRTE and requires validated cooking instructions for safety so that the product label is accurate and not misleading, in compliance with [9 CFR 317.8](#) or [381.129](#). For example, use of the terms "Baked" or "Broiled" on the label of a NRTE product (e.g., baked chicken on the label) would be false and misleading because they indicate that the product is cooked and, therefore, suggest to the consumer that the product is RTE.
3. The establishment has chosen a HACCP category consistent with that for a NRTE product. As explained in [FSIS Directive 5.300.1](#), *Attachment 1: HACCP Processing Categories*, FSIS regards products in the Fully Cooked – Not Shelf Stable processing category as RTE. Therefore, categorizing the product in a Fully Cooked – Not Shelf Stable HACCP processing category would not make it a NRTE product.
4. The establishment clearly identifies the intended use of the product in the flow chart or hazard analysis according to [9 CFR 417.2\(a\)\(2\)](#). For the description to be consistent with that for an NRTE product, the establishment must describe the customary preparation practices for the safe consumption of the product. The establishment should also state why these practices can be regarded as customary preparation.
5. The establishment takes corrective actions (e.g., intensified cleaning and sanitizing) and maintains sanitation in its environment according to [9 CFR 416.4\(b\)](#) so that insanitary conditions, leading to product contamination, do not exist.

**Figure 2. Steps for Verifying an Establishment's Corrective Actions**



G. If the establishment decides to produce not post-lethality exposed (i.e., cook-in-bag product) in response to a positive result, IPP are to verify that the establishment:

1. Revises its flow chart or hazard analysis according to [9 CFR 417.2\(a\)\(2\)](#) to include the cook-in-bag step.
2. Ensures that the cooking bag is completely sealed (impermeable), so that moisture is contained within the bag or contaminants do not enter the bag. Cooking bags may be compromised during steps such as molding or shaping. The establishment should have a process to verify the package integrity, and if leakers are observed, to reprocess or recook the product.

**NOTE:** If the product is dried before cooking, it would not be appropriate to recook the product multiple times using the [FSIS Cooking Guideline for Meat and Poultry Products \(Revised Appendix A\)](#) as support for the process. For dried products that are cooked multiple times, the establishment would need to provide additional scientific support for the cooking process.

3. Uses a supportable process to recook the product to address potential cross-contamination from a thermometer stem if the establishment punctures the bag when taking the temperature of the product.
4. The establishment takes corrective actions (e.g., intensified cleaning and sanitizing) and maintains sanitation in the processing environment, according to [9 CFR 416.4](#) to ensure that insanitary conditions do not exist, leading to product contamination.

**NOTE:** It is not enough to seal and recook the product if sanitation is not maintained. The establishment, while not required to sample for *Lm* in the environment, is required to maintain sanitary conditions in the facility so that product does not become adulterated ([9 CFR 416.4](#)).



- A. 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* to be sufficient for reworking contaminated product.
- B. For cooked products, establishments may use the time-temperature tables in the [FSIS Cooking Guideline for Meat and Poultry Products \(Revised Appendix A\)](#) to recook the product.
- C. For dried products, it would not be sufficient to recook the product using the time-temperature tables in the [FSIS Cooking Guideline for Meat and Poultry Products \(Revised Appendix A\)](#), unless the establishment provides additional support for process effectiveness.
- D. If the establishment chooses to dispose of the product, it may do so either on-site or off-site.
1. If the product is disposed of on-site, IPP are to verify that the establishment maintains records showing that the positive product received the proper disposition.
  2. If the establishment transports positive product off-site for appropriate disposition, IPP are to verify that the establishment:
    - a. Maintains records identifying the official establishment, renderer, or landfill operation that received positive product;
    - b. Maintains control of product that was destined for a landfill operation or renderer while the product was in transit (e.g., through company seals);
    - c. Maintains 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;
    - d. Maintains 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;
    - e. Completes pre-shipment review for the positive product only after it has received the records described above for that particular product; and
    - f. If an establishment ships adulterated product to a renderer or landfill operation, IPP are to verify the establishment denatures the product before it leaves the establishment ([9 CFR 314](#)).
  3. If the establishment transports positive product to a pet food manufacturer, IPP are to verify the product is made inedible prior to shipment. IPP are to be aware that the product does not need to be denatured first, it could be placed in an inedible container and shipped under permit from the DO (9 CFR 314). IPP are also to be aware that the establishment is not required to maintain records showing that the positive pet food product received the proper disposition.
- E. 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 Directive 5.000.1](#).
- F. In situations where the establishment has not properly moved or disposed of the product, IPP are to notify their DO through supervisory channels.

## CHAPTER VI – DATA ANALYSIS

The Office of Policy and Program Development (OPPD) will work with the Office of Planning, Analysis and Risk Management (OPARM) to track *Lm* sampling data every year. The tracked data will include the number of samples scheduled, the number of samples collected, and the number of positives for each RTE project code. In addition, OPPD will work with OPHS to track WGS results from RTE sampling programs and recalls from RTE meat and poultry products. OPPD will analyze these data to determine whether new policy is needed to address positive results.

## CHAPTER VII – QUESTIONS

Refer questions regarding this directive to your supervisor or as needed to the Office of Policy and Program Development through [askFSIS](#) or by telephone at 1-800-233-3935. When submitting a question, complete the [web form](#) and select “**Sampling**” for the Inquiry Type.

**NOTE:** Refer to [FSIS Directive 5,620.1](#), *Using askFSIS*, for additional information on submitting questions.



Assistant Administrator  
Office of Policy and Program Development

## Attachment. Updates to Random and Risk-based Scheduling Criteria for the RTE Product Routine Sampling Program

FSIS uses a statistical algorithm to assign RTEPROD sampling tasks at establishments that produce RTE products. Typically, tasks are assigned on or around the 25th day of each month and are to be completed the following month. Either the random sampling project (RTEPROD\_RAND) or the risk-based sampling project (RTEPROD\_RISK), sampling task will be assigned in the Public Health Information System (PHIS) to an eligible establishment. There is a limit of 1 RTEPROD sample (either RAND or RISK) per establishment per month.

The type of project, random or risk-based, refers to how establishments are selected by the statistical algorithm. Project designation as random or risk-based also refers to how inspection program personnel (IPP) are directed to select the RTE product sample to be collected at the establishment. Instructions for the selection of samples by IPP are in [Chapter II, Section II, Products Subject to Sampling](#).

FSIS allocates sampling resources evenly between the two RTEPROD sampling projects to ensure broad sampling coverage of all RTE products. The following criteria are used to select an eligible establishment for an RTE product sampling task (random or risk-based).

1. Each eligible RTE establishment is selected for a random sample at least once every 6 months.
2. Any eligible establishment with a positive result (either *Lm* or *Salmonella*) in an RTEPROD sampling project (either random or risk-based) will be selected for an RTEPROD\_RAND sampling task in each of the following 6 months.
3. The remaining number of random sampling tasks each month will be randomly assigned to eligible establishments not already selected under the above criteria.
4. Establishments that have at least one post-lethality exposed product in their plant profile and do not already have a random sampling task assigned will be assigned a risk ranking. Establishment selection for risk-based sampling tasks will be based on this risk ranking. The risk ranking takes into account:
  - a. The historical percent positive for each product produced at the establishment.
  - b. The daily production volume of each product at the establishment.
  - c. The *Listeria* alternative used for each product at the establishment.