

VERMONT AGENCY OF AGRICULTURE, FOOD & MARKETS
FOOD SAFETY CONSUMER PROTECTION
Meat Inspection Service
MONTPELIER, VT
Chuck Ross, Secretary



MIS DIRECTIVE

Adopted from FSIS Directive 10240.3

10240.3

12/23/2022

VERMONT READY-TO-EAT (RTE) SAMPLING PROGRAMS

CHAPTER I – GENERAL

I. PURPOSE

A. VAAFM product sampling for *Listeria monocytogenes* (*Lm*) and *Salmonella* are important food safety verification activities that support VAAFM's 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 the laboratory 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 [VT Directive 10.240.4](#), *Listeria Rule Verification Activities*.

B. This program is the VT Agency of Agriculture's Ready to Eat (RTE) product verification sampling program, and is a means of sampling RTE products for *Listeria monocytogenes* (*Lm*) and *Salmonella*, and FCS and environmental surfaces within the plant for *Lm*. Post-lethality exposed and non-exposed RTE products are subject to sampling, based on both risk and random sampling.

C. The directive has been revised to reflect changes to product sampling for *Lm* (RTE Product Risk based and RTE Product Random) and updates to the sampling selection criteria (RTE Product Risk based 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 the laboratory, 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 VAAFM 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 laboratory 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. VAAFM collects samples for its RTE sampling program under the RTE Product sampling project:

1. **RTE Product Random** for product samples selected randomly; and
2. **RTE Product Risk Based** for post-lethality-exposed product samples selected based on risk.
3. Both types of product samples are also tested for *Salmonella*. Additionally, VAAFM collects surface swabs of FCS (food contact surface) and ENV (environmental surfaces) to be tested for *Lm*.

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. RTE PRODUCT SAMPLING CODES

A. For the RTE Sampling Program, IPP are to collect samples under the RTE project using the following nomenclature.. [Attachment 1](#) has information about RTEPROD sample scheduling.

1. **RTE PRODUCT RANDOM:** Random sampling of RTE products, including both post-lethality exposed and non post-lethality exposed products (e.g., cook-in bag products).
2. **RTE PRODUCT RISK BASED:** Risk-based sampling of post lethality exposed RTE products.
3. **RTE Environmental/FCS Swab:** Sampling of Food Contact Surfaces in the RTE production area or non-food contact surfaces in the RTE production area.

II. PRODUCTS SUBJECT TO SAMPLING

A. Both post-lethality exposed products and not post-lethality exposed products are eligible for

sampling under the RTE Product sampling program. Although the *Listeria* Rule (9 CFR 430) does not apply to not post-lethality exposed products, these products are subject to VAAFM sampling under RTE Product random.

B. Therefore, IPP are not to cancel RTE Product Random 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 RTE Product 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 VT [Directive 5.300.1](#), *Managing the Establishment Profile in the Public Health Information System (PHIS)*, VAAFM 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. VAAFM 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 VAAFM sampling under RTE Product sampling (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). VAAFM considers products labeled with SHI and cooking instructions to be NRTE and not subject to sampling under the RTE sampling projects.

G. VAAFM considers the product to be post-lethality exposed and subject to sampling under the RTE Product risk and RTE Product random 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. VAAFM considers the product to be not post-lethality exposed and subject to sampling only under the RTE Product Random 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 \(Revised Appendix A\)](#)).

- I. VAAFM considers the following for sampling and testing of surfaces in the production areas:
 - a. **Food Contact Surface** – A food contact surface sample is a sample that reflects the condition of a surface of equipment or utensil that comes into direct contact with a post-lethality exposed RTE product. Food contact surface samples are to be taken so that they reveal the conditions under which the establishment processes the sampled lot. Some examples of food contact surfaces include conveyor belts, tabletops, slicer blades, knife blades, chutes, and cooling racks. Aprons and gloves can be considered food contact surfaces if the inspector observes direct contact of the apron or glove with the product. A positive FCS test for *Listeria monocytogenes* implies that the finished product has touched that area and may be contaminated with Lm.
 - b. **Environmental Surface** – Any surface in the ready-to-eat processing area/environment that does not come into contact with cooked, ready to eat product. Examples include but are not limited to: drains, table legs, wheels on carts, door handles, tops/sides of equipment, conveyor belts, light switches, etc. A positive environmental test for *Listeria monocytogenes* can indicate reservoirs and harborages of Lm in the ready to eat processing environment that could lead to contamination of product.

III. THE SAMPLED LOT

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

B. VAAFM 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 VAAFM collects a routine RTE sample to facilitate holding the product if the change does not interfere with VAAFM’s 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 VAAFM 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 VAAFM can still collect a representative sample. Instructions to verify an establishment’s written sampling program design and execution can be found in [VT 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 VAAFM 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 VAAFM, 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. VAAFM

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 VAAFM collects a sample when it typically produces a larger lot, then VAAFM 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, VAAFM 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 VAAFM 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 VAAFM 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 VAAFM 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 RTE PRODUCT RANDOM sample requests, IPP are to select samples from all of the RTE products produced at the establishment, including non-post-lethality exposed product, and both low-risk and high-risk products:
 - 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
2. For RTE Product 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.
3. For FCS, IPP are to select Food Contact Surfaces in the RTE production area to sample. For ENV, IPP are to select non-food contact surfaces in the RTE production area to sample.

B. Sampling Ineligibility:

1. For RTE Product Random 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 RTE Product 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 RTE Product Risk and RTE Product Random:
 - 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 [VT 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 or state- 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.

C. Sampling Priority For RTE Product Risk

Table 1: *Listeria* Control Alternatives and VAAFM Product Sampling Priority for RTE Product Risk

<i>Listeria</i> Control Alternative Type	<i>Listeria</i> Control Alternative Description	VAAFM Sampling Priority
Alternative 1 (Alt. 1)	The establishment uses a post-lethality treatment (PLT) to reduce or eliminate <i>Lm</i> in the product <u>and</u> an Antimicrobial Agent or Antimicrobial Process (AMAP) to limit or suppress growth of <i>Lm</i> in the product	Low
Alternative 2, Choice 1 (Alt. 2a)	The establishment uses a PLT to reduce or eliminate <i>Lm</i> in the product	Medium
Alternative 2, Choice 2 (Alt. 2b)	The establishment uses an AMAP to limit or suppress growth of <i>Lm</i> in the product	Medium

Alternative 3 (Alt. 3)	The establishment relies on sanitation alone to prevent <i>Lm</i> in the processing environment and on the product	High
Alternative 3 (Alt. 3) <i>Additional Requirements for Deli Meats and Hot Dogs</i>	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

D. Sampling Frequency

1. The sampling frequency will be based on FSIS' Guidance to the states on the average frequency of testing done at very small federal establishments.
2. In addition to product samples, FCS and environmental surfaces may be sampled periodically throughout the year.
3. Every 4 years, VT will take 5 environmental, 10 FCS, and 5 product samples per line in each establishment as part of an FSA RLM.
4. VT reserves the right to alter the frequency at any given establishment based on information from, but not limited to, frequency in federal establishments of the same size, inspection activity, sampling results, and food safety assessments, in order to tailor the Lm verification sampling program to address any perceived increase in risk.

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 [VT 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. A sample request spreadsheet, request letter and informational packet can be found in the State plant sampling folder on Sharepoint, with the types of scheduled samples for Lm and Salmonella on a monthly basis for the entire year.

1. 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.
2. To schedule the sample, IPP are to randomly select a day, shift, and time within the sample window timeframe.

3. 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.

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, VAAFM 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 VAAFM collects RTE products until negative results become available.

D. When notifying the establishment that VAAFM 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 ([VT 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, VAAFM may collect more samples or give less than one day's notice.

E. 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 on the Findings Tab.
2. Immediately contact the Chief of Inspection if the establishment does not hold or maintain control of the sampled lot and the sampled lot was not denatured on-site.

II. COLLECTING THE SAMPLE

Inspectors are to verify that proper sample supplies are present, and request any supplies needed from the Meat Inspection Office. There is a list of sample supplies located in the Sample Folder.

A. **For RTE Product - Random**

When collecting an RTE Product random 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. **For RTE Product – Risk**

When collecting an RTE Product – Risk sample, IPP are to sample according to the *Listeria* Control Alternatives and the 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 laboratory may reach out to IPP to request that they collect an additional 1-pound sample from the **same lot** and submit it to the laboratory.

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 RTE Product 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 RTE Product - Random.

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 RTE Product 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

The screenshot shows a web form for entering product information. At the top, there are three tabs: "Non RTE" (selected), "Raw", and "Egg Products". Below the tabs are four dropdown menus, each with "Select" as the current value: "HACCP Category*", "HACCP Plan:", "Finished Product Category", and "Species*:". Under "Species*", there are three checkboxes: "For RTE Cooking Only", "Other", and "Not sampled at HPP or IR establishment because returned to producer or shelf life extension applied". Below these is a text input field labeled "No. of days of production:". At the bottom right, there are two buttons: "Save" and "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 VAAFMM 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 RTE Product 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 VAAFMM 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 VAAFMM 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 Office 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. Supplied bags (e.g., zip top bags) provided for VAAFM RTE sampling are for secondary containment to protect the shipping container from possible sample leakage and are not sterile. The supplied bags 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 supplied bags 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 task in PHIS, they are to follow [VT Notice A-13](#). On the Findings Tab in the task, indicate if the sample was short-weighted/slack-filled. 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 indicate on the laboratory form. The laboratory uses 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](#).

M. Food Contact Surface (FCS) and Environmental Surface Sponge Sampling:

1. Food contact surface and environmental sampling, when scheduled, will be done at the same time as product sampling, and will consist of a sponge swab sample.
2. Of all food contact surfaces available or environmental surfaces available, two FCS surfaces and one environmental surface will be randomly selected (see calendar for schedule of sampling). Unless a follow up sample is being taken, different surfaces will be selected each time sampling is conducted.
3. Pre-chill the shipping container **and the spongcicles** supplied by the VT Meat Inspection Office.
Keep samples refrigerated at all times. Do not freeze. Use only frozen gel pack in shipping containers. Do not use ice or dry ice.
4. Marking Sample Bag: Before sampling, each sterile bag should be marked with the following information:
 - (a) Establishment #
 - (b) Last Name of Person Who Collected Sample
 - (c) Date and Time Sampled – e.g. 6-10-03, 9:00 AM
 - (d) Type Test – i.e. *Listeria*

(e) Type of surface Sampled

4. IPP are to:

1. wash and sanitize their hands to the mid-forearm. Evenly moisten the Sponge by using hand pressure on the outside of the bag to massage the sponge;
2. Aseptically place a sterile glove on the hand he or she will use for swabbing by:
 - a) positioning the glove package so that the L and R (L=left, R=right) are facing the Inspector. When the package is open, the gloves are folded, forming a cuff on the sleeve and lying palm up. Leave them in the package until ready for use;
 - b) holding the glove for the hand that will be used for swabbing by the inside cuff area. Inserting hand into the glove, palm side up, and lifting the glove from the package.
 - c) pulling the glove completely on, touching only the fold cuff with your ungloved hand. Do not touch the sterile outside surface of the glove with your ungloved hand. Unroll the fold of the glove (see FSIS Directive 10,230.5 for an illustrated guide on the proper use of sterile disposable gloves). Do not touch any non-sterile surface (clothes, counter tops, or the outside of the Whirl-Pak[®] bag) with the sterile glove.
 - d) The other hand can be left ungloved for the manipulation of non-sterile surfaces and materials.
5. manipulate the outside of the whirlpak bog to position the Sponge so that it is at the top of the Whirlpak bag.
6. Using the ungloved hand, open the bag containing the sterile sponge by pulling off the clear perforated strip at the top of the bag;
7. pull apart the white tabs to open the mouth of the bag;

NOTE: The Food and Drug Administration determined that this standard use of D/E enrichment broth on food contact surface swabs does not result in unsafe exposure to product, therefore, for the swabbed sites the inspector no longer needs to request that the establishment rinse the swabbed surfaces.

8. through the bag, squeeze the excess broth gently out of the sponge.
9. carefully take the Sponge out of the bag by grasping it with your sterile glove. Maintain sanitary conditions when sampling and collect samples aseptically. Do not touch the sponge with your unsterile gloved hand.
10. swab at least a 1' X 1' square of food contact or environmental surface area, if possible;
11. swab the chosen area using firm and even pressure:
 - a. vertically (approximately 10 times); then
 - b. flip the sponge and use the other side to swab horizontally (approximately 10 times); then
 - c. swab diagonally, using the same surface side as you used for horizontal (approximately 10 times);
12. open the bag and insert the sponge back into the bag;
13. squeeze as much air out of the bag as possible and fold the top of the bag down at least 3 times. Fold in the tabs to lock the fold in place;
14. place a small bar-code VT seal identifying label on the bag (primary container);

15. place the primary container (bag with the sponge) into a small sealable plastic ziplock bag, and seal with the long VT seal identifying label over the zip of the small sealable plastic bag;
16. place the bagged sponge inside an insulated sample shipper as soon as possible (see below for further information on shipping the sample).
17. The laboratory form is placed in a separate plastic bag, and put in the shipper as well.
18. Sterile Gloves – New sterile gloves will be used for each sample.

IV. SUBMITTING THE SAMPLE

- A. IPP are to safeguard the integrity of samples during submission according to [VT Directive 7,355.1](#), *Use of Sample Seals for Laboratory Samples and Other Applications*.
- B. See VT Notice 13-A for instructions on how to document in PHIS
- C. 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 the Agency.
- D. IPP are to fill out the South Dakota laboratory form electronically on their web site. To submit samples to the lab, IPP are to print out the lab form after electronically filling it out. Apply the bar code label from the sample seal set to 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 [VT Directive 7,355.1](#).
- E. IPP are to respond in a timely manner to any requests from the lab 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.
- F. IPP are to use **Table 2** below to reference RTE sampling instructions.

Table 2: Summary of RTE Sampling Instructions

Sampling Project Name	RTE Product Risk	RTE Product Random
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	Post-lethality exposed RTE products.	Both post-lethality exposed and not post-lethality exposed products.
	IPP are to prioritize samples by <i>Listeria</i> control alternative priority level (Table 1). Within the highest priority level available, IPP are to select samples by rotating randomly through available post-lethality exposed products.	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.
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> <p>Product labeled “For Further Processing,” in which the product is expected to receive a lethality treatment at another federally inspected establishment.</p>
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 VT Directive 7.355.1.</p> <p>IPP are to ship samples to the 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 the Agency.</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 [VT Directive 5,000.1](#).

B. Whenever IPP are notified that a sample has been discarded and will not be analyzed by the 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. VAAFM will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all VAAFM 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 [VT 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 VAAFM 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 VAAFM 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 VAAFM 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 Chief of Inspection. If the results are confirmed positive for *Lm* or *Salmonella*, the Program is to take appropriate regulatory action and contact the Recall Management Team and the Meat Safety and Compliance Enforcement Specialist. As appropriate, VAAFM will request a recall or detain the product. The Program, in consultation with the Director and AAG, will consider whether additional enforcement actions or sanctions are necessary.

G. Generally, if VAAFM 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.

III. VERIFYING CORRECTIVE ACTIONS IN RESPONSE TO A VAAFM POSITIVE RESULT

A. If VAAFM finds a product positive for *Lm* or *Salmonella* under the RTE Product 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. VAAFM will perform a PHRE for *Lm*, as described in [VT 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 [VT 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, VAAFM 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. VAAFM will perform a PHRE in response to *Lm* or *Salmonella* positives, as described in [VT 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 VAAFM 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.

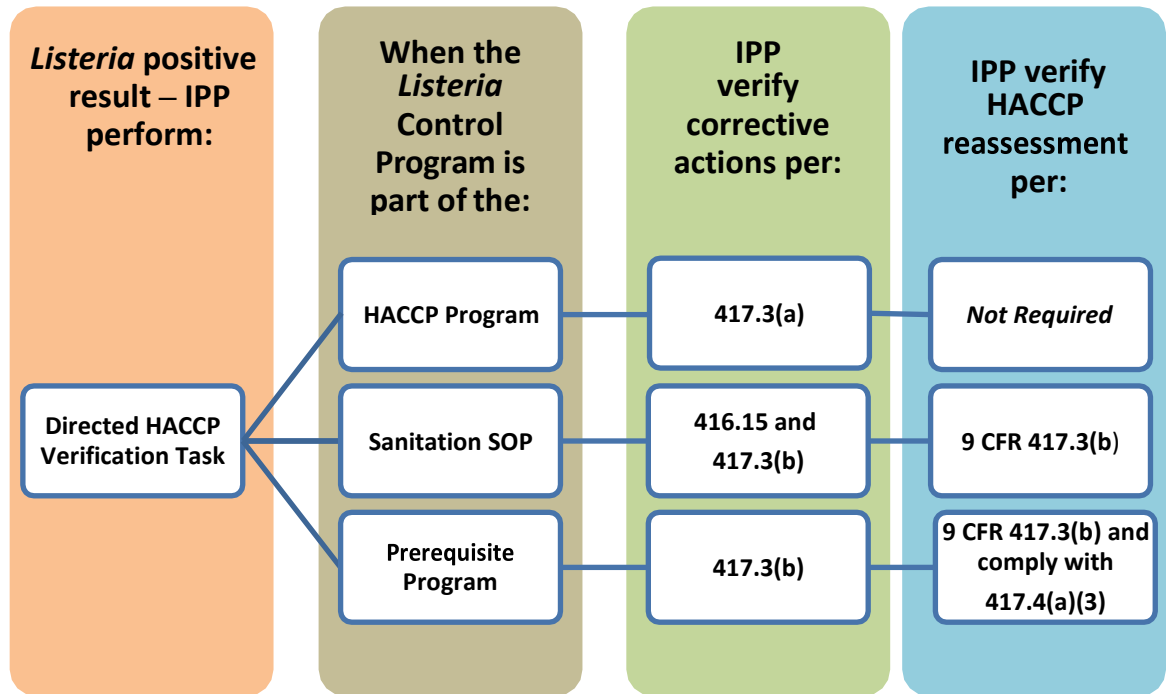
3. If *Lm* is addressed in a prerequisite program (e.g., *Listeria* control program) that is used to support the decision that *Lm* is not a hazard reasonably likely to occur in the product, then the establishment must implement the corrective actions in [9 CFR 417.3\(b\)](#) and comply with [9 CFR 417.4\(a\)\(3\)](#). 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 [VT 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*, VAAFMs 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](#)).

CHAPTER V – VERIFYING PRODUCT DISPOSITION

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. VAAFM 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.

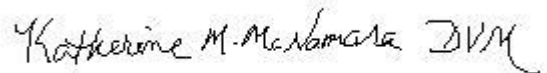
1. If the product is disposed of on-site, IPP are to verify that the establishment maintains records showing that the positive product received the proper disposition.
2. If the establishment transports positive product off-site for appropriate disposition, IPP are to verify that the establishment:
 - 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 VAAFM 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 Office (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 [VT Directive 5,000.1](#).

F. In situations where the establishment has not properly moved or disposed of the product, IPP are to notify the Chief of Inspection.

CHAPTER VIII – QUESTIONS

Questions can be referred to the meat inspection office at 802-828-2426.

A handwritten signature in black ink that reads "Katherine M. McNamara DVM". The signature is written in a cursive style.

Katherine M. McNamara, DVM
Assistant State Veterinarian
Meat Inspection Service

Attachment 3: Potential *Lm* Harborage Sites



A cart wheel with rust and product residue build up. The wheel can be contaminated with *Lm* when it is rolled across drains and wet areas in the floor. The *Lm* can then spread through the establishment when the cart is pushed into different areas.



A light switch with residue build-up and grime. The switch could be contaminated with *Lm* by employees' hands during operation, and may not be cleaned during sanitation. When the light is turned on the next day, the hands could be re-contaminated.



A drain at the entrance of a cooler doorway. The drain could become contaminated with *Lm*, and when employees step on the drain to enter the cooler, the *Lm* can spread into the cooler.



A conveyor belt with a hollow roller under the belt. *Lm* could be harbored in the hollow roller and spread to the belt.



A rusty water spigot with a dirty, cracked insulated pipe. *Lm* could spread to the hose and be sprayed in the establishment.



A slicer blade with grime and black residue under the blade. The blade can be contaminated with *Lm* and spread to the product that is sliced. The slicer handle, controls, and seals may also be contaminated, as these areas may not be frequently cleaned.