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

MIS DIRECTIVE **Adopted from FSIS Directive 10240.5 Rev. 3**	10240.5 Revision 3	11/1/13

VERIFICATION PROCEDURES FOR ENFORCEMENT, INVESTIGATIONS AND ANALYSIS OFFICERS (EIAOs) FOR THE *Listeria monocytogenes* (*Lm*) REGULATION AND ROUTINE RISK-BASED *Listeria monocytogenes* (RLm) SAMPLING PROGRAM

I. PURPOSE

A. This directive provides Enforcement, Investigations and Analysis Officers (EIAOs) with instructions for collecting samples under Routine Risk-based sampling program, including the collection of product, food contact, and environmental (non-food contact) samples, tested for *Lm*, in conjunction with a routine Food Safety Assessment (FSA). In addition, this directive provides instructions for scheduling Routine Risk-based sampling.

B. This Directive provides EIAOs with instructions for performing Routine Risk-based sampling in establishments that temporarily alter their routine practices. In addition, this directive provides EIAOs with instructions for collecting product samples. Under this program, the number of product samples has increased from 3 to 5 per unit. This directive also provides EIAOs with instructions for verifying that establishments hold or control ready-to-eat (RTE) products that are tested for pathogens or that have passed over direct food contact surfaces that the Agency has tested for pathogens pending the results of that testing. In addition, this directive provides new instructions for submitting samples when interventions such as high-pressure processing (HPP) are applied.

KEY POINTS:

- *EIAO sampling procedures for the* Routine Risk-based sampling *Program*
- *Actions in establishments that temporarily alter routine practices during sampling*

II. CANCELLATION

FSIS Directive 10,240.5, Revision 2, Verification Procedures for Enforcement, Investigations, and Analysis Officers (EIAOs) for the *Listeria monocytogenes* (*Lm*) Regulation and Routine Risk-Based *Listeria monocytogenes* (RLm) Sampling Program, dated 2/3/09

III. BACKGROUND

A. Under 9 CFR part 430, post-lethality exposed RTE products are adulterated if they test positive for *Lm* or come into direct contact with a food contact surface that tests positive for *Lm*. The Agency utilizes microbial testing as a tool to verify the adequacy of an establishment's food safety system, including the measures that the establishment implements for the control of *Lm.*

B. In the Routine Risk-based sampling Program, EIAOs collect intact product samples and food contact and environmental (non-food contact) surface swabs during the production of RTE meat and poultry products that are exposed to the post-lethality environment. In addition, EIAOs assess whether the establishment's food safety system is controlling *Lm* by performing an FSA in the establishment.

C. To make sampling programs more consistent with sampling procedures in use internationally, the number of products sampled under the Routine Risk-based sampling program has increased from 3 to 5.

D. FSIS has determined that some establishments may temporarily alter their routine production, sanitation, or food safety practices during Routine Risk-based sampling sampling. By altering routine practices, establishments may make changes that are not consistent with their documented food safety system and that impede FSIS's ability to assess the safety of the product. This directive provides EIAOs with instructions for taking action in establishments that change practices.

E. On December 10, 2012, FSIS issued a Federal Register notice, Not Applying the Mark of Inspection Pending Certain Test Results, announcing that it is changing its procedures and will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received. The new procedures went into effect February 8, 2013.

IV. RESPONSIBILITIES FOR Routine Risk-based sampling SCHEDULING

A. Office Responsibilities for Routine Risk-based Sample Scheduling

1. Food safety assessments will be scheduled according to VT Directive 5100.2

B. EIAO Responsibilities for Routine Risk-based Sample Scheduling

1. Prior to the scheduled FSA, the EIAO is to perform the following items:

    a. Randomly select the 1st or 2nd shift Monday through Thursday or the 1st shift Friday for collection of Routine Risk-based sampling samples within the week the FSA is scheduled; and

    b. Inform the Inspector-In-Charge (IIC) at the establishment that an Routine Risk-based sample collection activity is scheduled in conjunction with an FSA, how the sampling is conducted, and the day when the sampling will occur. The EIAO is to determine the following:

        i. The production schedule and types of post-lethality exposed RTE products produced;

        ii. The number of production lines producing post-lethality exposed RTE products; and

        iii. Whether the establishment uses brine or ice water to chill product. EIAOs are also to determine whether the brine or ice water comes in direct contact with post-lethality exposed product. If it does, the EIAO is to treat the sample as an food contact sample, or if the brine or ice water is used for product in an impermeable casing, the EIAO is to treat it as an environmental sample.

2. When determining the number of sample units to collect, EIAOs are to:

a. Collect samples based on establishment size;

   i. Sample a maximum of 3 lines on which post-lethality exposed product is produced (3 sample units) in large establishments.

   ii. Sample a maximum of 2 lines on which post-lethality exposed product is produced (2 sample units) in small establishments.

   iii. Sample a maximum of 1 line on which post-lethality exposed product is produced (1 sample unit) in very small establishments.

NOTE: Establishment size is based on establishment categories in the HACCP preamble (61 FR 38806). Establishment size is defined based on the number of employees: large establishments – 500 or more employees, small establishments – 10 or more employees but fewer than 500, and very small establishments – fewer than 10 employees or annual sales of less than $2.5 million.

b. Only collect samples on days and shifts when the establishment is producing VT regulated post-lethality exposed meat or poultry products. Generally, an EIAO is to collect 1 sampling unit for each post-lethality exposed RTE line, except in cases when the establishment is not producing on a particular line;

c. If the establishment uses brine or ice water to chill the product, EIAOs are to:

   i. Collect brine or ice water samples as one of the 10 food contact samples he or she collects per unit. If the sample is collected as an environmental sample, EIAOs are to collect a separate sample.

   ii. Collect 1 brine or ice water sample per unit (e.g., if an EIAO is collecting 3 units and the establishment is only using 2 brine chillers on 2 separate lines, then the EIAO is to collect 2 brine samples); and

   iii. Collect a maximum of 3 brine or ice water samples per establishment, if available on the lines sampled.

3. Sampling supplies are requested from the Office.

4. At least 1 week before the Routine Risk-based sample collection date, the EIAO is to notify establishment management that the Agency has scheduled an Routine Risk-based sampling collection activity at that establishment and document the notification in a Memorandum of Interview (MOI). The EIAO is to perform the following actions:

   a. Confirm that the establishment will be producing post-lethality exposed RTE product on the day Routine Risk-based sampling is scheduled and is planning to implement its documented routine production, Sanitation Standard Operating Procedures (Sanitation SOPs) and food safety practices;

   b. Inform the establishment that, if it intends to modify its documented routine production, sanitation, or food safety practices before the sampling, it should inform the EIAO as soon as possible so that the EIAO can determine whether sampling should be rescheduled; and

   c. Advise the establishment that if it changes its practices temporarily during the Routine Risk-based sampling without notifying the EIAO in advance, and cannot provide a justifiable reason for doing so, the sampling may be rescheduled, and further regulatory actions may

be taken, which could delay completion of the FSA.

NOTE: See section VI below for instructions for EIAOs in establishments that alter routine practices during Routine Risk-based sampling sampling.

d. EIAOs are to document in the MOI whether the establishment is holding or controlling product when VAAFM collects samples of product of food contact surfaces.

V. EIAO SAMPLING PROCEDURES UNDER the Routine Risk-based SAMPLING PROGRAM

A. The IVT trained EIAO is to hold the entrance meeting with the establishment as described in FSIS Directive 10,300.1.

B. EIAOs are to conduct the Routine Risk-based testing as early in the FSA as possible to facilitate receiving the results and the completion of the FSA report without unnecessary delay.

C. In conjunction with performing the Routine Risk-based testing, EIAOs are to conduct an FSA in accordance with VT Directive 5100.1.

NOTE: EIAOs may find useful information in this link: FSIS Compliance Guideline: Controlling *Listeria monocytogenes* in Post Lethality Exposed Ready-to-Eat Meat and Poultry Products.

D. For product samples, EIAOs are to:

1. Collect 5 separate product samples per sampling unit from a particular line and processing lot following the instructions in this directive;

2. Collect products from the highest risk alternative and the highest risk post-lethality exposed RTE product category using the instructions in a and b below;

    a. Select product from the highest-risk alternative (Risk: Alternative 3 > Alternative 2 > Alternative 1);

        i. For each sampling unit, select product from only *one Lm* control alternative. For example, if an EIAO is collecting one unit, and the establishment produces products under all three alternatives, then the EIAO is to select Alternative 3 product;

        ii. If the EIAO is collecting more than one unit, then the EIAO may select product from more than one alternative (if all the products selected within a given unit are produced under a single alternative).

    b. Collect product from the highest risk level, according to Product Sampling Priority List in Attachment 5. Products from multiple product categories/groups may be collected as part of the same sampling unit; however, all the samples in each unit must be from the same production lot, processing line, and control alternative;

3. Collect enough product in the final intact package so that at least ONE pound of meat or poultry per sample is submitted to the lab for analysis. The samples may be collected on a different day than the food contact and environmental samples, as long as the same production lot is represented by all three sample types, and each unit is composed of product samples from the same lot, line, and alternative. If an intact sample of product is too large to submit to the lab, ask the establishment to slack-fill or short-weight a package to one pound without making any changes to its processing operations. If the establishment is not able to do so, contact the office to see if a larger shipping container is available;

D. Fill out a VDH sample form for each product collected.

E. Record the following information for each unit collected:

1. Line ID: Use the line ID in use by the establishment.

2. Product Line Alternative: Include products from only one alternative.

3. Product Type

4. Product Name: Use the product name in use by the establishment (i.e., the name on the product's label).

5. Lot Code: Use the lot code in use by the establishment.

6. Time Collected: Use the time that the product is collected. EIAOs are to collect product at multiple times during a single production shift, if possible.

F. Use a separate sample seal set for each individual sample collected. Place one separately numbered identification label on each sample, and place a corresponding identification label on the VDH sample form.

G. If it is necessary to send a unit of product samples in multiple boxes, include the completed corresponding forms in each box (i.e. each product sample in the box has its form in the box too).

H. For food contact surface samples, EIAOs are to:

1. Collect 10 food contact samples per unit. Collect samples starting closest to the product areas and then move further out (i.e., collect food contact surfaces first and then environmental samples);

2. Collect most swabs during operations, ideally at the start of routine breaks scheduled by the establishment. EIAOs are to follow "lock-out, tag-out" procedures for equipment. "Lock-out, tag-out" is controlling energy sources while working on or around equipment.

NOTE: Food contact and environmental samples may be collected on different days from the product samples as long as the same product lot is represented by all three sample types.

a. EIAOs may collect some swabs at the end of pre-operational sanitation activities, before the start of production. Doing so will allow EIAOs to sample areas that are hard to reach or unsafe to sample during operations (e.g., slicer blades); and

b. EIAOs are to take post-operation samples as quickly after operations end as practical and before the implementation of establishment sanitation procedures.

3. If an establishment does not produce product on a particular line on the day an EIAO conducts an Routine Listeria sampling, the EIAO can still sample that line, as long as the establishment is producing some post-lethality exposed RTE product that day. If the EIAO collects samples of equipment that is not in operation, he or she is to:

a. Sample food contact surfaces and environmental surfaces and record that the line is not in use;

b. Collect the 5 product samples from the unit from another line that is in operation at the establishment. The contact and environmental samples may be collected from a different

line than the one from which the product samples were taken, as long as all of the product samples are collected from the same line and alternative, and all three sample types (product, food contact, and environmental) represent the same production lot; and

c. If the equipment tests positive, the EIAO is not to recommend that inspection program personnel (IPP) issue a non-compliance record (NR) because the equipment was not in operation at the time the sample was collected, and there is no reason to consider the product to be adulterated. However, if the establishment later decides to use the equipment and does not conduct a full cleaning and sanitizing per its Sanitation SOP before using the equipment, the EIAO is to recommend that IPP issue an NR. The NR would be appropriate because the positive result would establish that the equipment was not maintained in sanitary condition and the product would be considered adulterated (cite 9 CFR 416.3(a) and 430.4(a)).

D. For environmental samples, EIAOs are to:

1. Collect environmental (non-food contact surface) samples in areas of the establishment where products are being processed, stored, or held, including smokehouses, coolers, and production rooms;

2. Collect 5 separate environmental swabs per sampling unit following the instructions in FSIS Directive 10,300.1.

3. Fill out a VDH sample form for each swab collected., along with a short written description of the sites swabbed;

4. Place each swab in a separate whirl-pak bag. The EIAO is to use a separate sample seal set for each individual swab sample collected. Place one separately numbered identification label on each swab sample and place a corresponding identification label on the form.

5. For each sampling unit, place all 5 of the swab samples, which will be in separate whirl-pak bags, and the corresponding forms in a large Ziploc bag. Fold over the top of the bag and seal it with a bar-coded identification label.

VI. EIAO ACTIONS IN ESTABLISHMENTS THAT ALTER ROUTINE PRACTICES DURING Routine Listeria Sampling

A. FSIS has determined that establishments may temporarily alter their routine production, sanitation, or food safety practices during routine listeria sampling. By altering routine practices, establishments may make changes that are not consistent with their documented food safety system and that impede the ability to assess the safety of the product.

B. Examples of an establishment altering their routine practices may include:

1. Temporarily increasing the use or concentration of a sanitizer, or changing the type of sanitizer during the Routine Listeria sampling;

2. Drastically reducing the typical production time (e.g., by more than 2 hours in a typical 8-hour shift or other significant reduction);

3. Reducing the production lot size (except to facilitate holding the product, see the note below);

4. Reducing the number of employees handling post-lethality exposed product; or

5. Selectively not producing higher risk post-lethality product (e.g., sliced deli product); and not using

particular equipment that previously has tested positive.

C. Such practices can interfere with VAAFM's assessment of routine conditions or corrective actions at the establishment and may limit VAAFM's ability to determine whether post-lethality exposed RTE meat and poultry products are not adulterated as required by the Federal Meat Inspection Act and Poultry Products Inspection Act and 6 V.S.A Chapter 204. In addition, such changes may not have been considered in the establishment's hazard analysis or accompanied by supporting documentation in accordance with 9 CFR 417.2(a) and 417.5(a)(1).

D. Prior to the Routine Listeria sampling, if an establishment informs the EIAO that it no longer plans to produce post-lethality exposed RTE product, or that it has modified its production, sanitation, or food safety practices, the EIAO is to document in the MOI the date of the notification, and the reason the change was made. The EIAO is to consider and document the following issues in the MOI:

1. If the establishment can provide a supportable rationale for not producing the product (such as intermittent production to fill customer orders), then the EIAO is to collect similar post-lethality exposed RTE product (e.g., produced using equipment that has previously tested positive for *Lm*) during the Routine Listeria sampling sampling, if available. If similar product is not available, the EIAO is to reschedule the Routine Listeria sampling as in paragraph VI.D.3 below;

2. Likewise, if the establishment can support that the production, sanitation, or food-safety practices were implemented as part of reasonable program modifications that the establishment intends to make permanent, the EIAO is to assess the program changes as part of the Routine Risk-based testing, if possible. If the EIAO is unable to assess the program changes, he or she is to reschedule the Routine Risk-based testing ; and

3. If the establishment can provide a supportable rationale for not producing the product, or for modifying the production, sanitation, or food safety practices, the EIAO is to work with the designated FSIS laboratory to reschedule Routine Risk-based testing sampling to the next time in which the product or production practice of interest can be assessed by the EIAO. The EIAO is to reschedule the sampling for a time when the FSA is underway at the establishment, if possible.

E. On the day of the Routine Risk-based testing, if the EIAO determines that the establishment has temporarily decided not to produce post-lethality exposed RTE product or has altered its documented routine production, sanitation, or food-safety practices, and the establishment cannot provide a supportable rationale for doing so, then the EIAO is not to perform sampling and is to contact the DO through his or her supervisory chain.

F. If the EIAO finds that the establishment has made changes in its food safety systems (e.g., changing its supplier of RTE product only during the Routine Risk-based testing) and does not have documents supporting the appropriateness of the changes, the EIAO is to recommend to supervisory personnel that the in-plant inspection team 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), or did not support the changes to its hazard analysis as in 9 CFR 417.5(a)(1). When recommending the issuance of an NR, the EIAO is to follow the instructions in chapters 3, 13, and 15 in FSIS Directive 5100.1. Likewise, if the EIAO finds that the establishment has made changes in its sanitation practices (e.g., temporarily increasing the use of sanitizer during the Routine Risk-based testing) and did not revise its Sanitation SOP to reflect these changes, he or she is to recommend to supervisory personnel that the in-plant inspection team issue an NR under 9 CFR 416.14.

NOTE: If an establishment decides to limit its product lot size solely to facilitate holding of the product during the Routine Risk-based testing sampling, it would not be considered to have significantly altered its production practices, as long as the EIAO can collect samples that accurately represent routine

production. If the EIAO has questions about whether an establishment is altering routine production, sanitation, or food-safety practices, he or she can submit them through askFSIS.

G. If the EIAO is unable to collect Routine Risk-based samples as in paragraph VI.E and is therefore unable to assess whether the establishment is controlling *Lm* on its FCS and is preventing the product from becoming adulterated in accordance with 9 CFR 430.4(a), the office may determine that further actions are warranted. These may include the following:

1. The DO may initiate product sampling or schedule an IVT with a "for cause" FSA; and

2. The DO may issue a Notice of Suspension in situations where IPP personnel have found insanitary conditions at the establishment, or where IPP have found that the food safety system is inadequate, in accordance with 9 CFR 500.4(a) or (b) or 9 CFR 500.3(a)(4).

VII. EIAO SAMPLE SUBMISSION RESPONSIBILITITES

A. For sample submission, the EIAO is to:

1. Follow the instructions in FSIS Directive 10,300.1.

2. Ship the sample after the establishment has completed the production lot (as defined by the establishment) and applied all of the interventions for *Lm* control. EIAOs are to:

    a. Submit samples the same day if collected Monday through Thursday;

    b. Samples should not be sent on Friday, Saturday or a day before a holiday. EIAOs are to store the samples refrigerated when holding the samples overnight for shipping; and

    c. If the product is sent to another establishment for a *Listeria* control intervention (e.g., HPP), the EIAO is not to ship the sample until the intervention is complete. If the product will not be returned to the establishment, the EIAO is to sample another product (if possible). If the process is being applied to extend the shelf life of the product, and not as a *Listeria* control intervention, the EIAO is to collect the sample and ship the product before the process is applied.

B. When submitting collected samples, the EIAO is submit the type of sample collected (e.g., food contact); and

C. Record the following information for each unit collected:

1. Line ID: Use the line ID in use by the establishment.

2. Product Line Alternative: Include products from only one alternative.

3. Product Type

4. Product Name: Use the product name in use by the establishment (i.e., the name on the product's label).

5. Lot Code: Use the lot code in use by the establishment.

6. Time Collected: Use the time that the product is collected. EIAOs are to collect product at multiple times during a single production shift, if possible.

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D. The EIAO is to safeguard the security of samples during preparation, storing, packaging, and submission of samples for testing

VIII. SAMPLING RESULTS AND ENFORCEMENT

A. When checking the sampling results, EIAOs are to immediately report test results to establishment management.

B. If any RTE product sample collected by the EIAO tests positive for *Lm*, product in the sampled lot is adulterated.

C. If a post-lethality exposed RTE food contact surface sample collected by the EIAO tests positive for *Lm*, any product in direct contact with the surface is adulterated.

NOTE: If the establishment treats the product that passed over the food contact surface with a post-lethality treatment (e.g., HPP) that has been validated to achieve at least a 5-log reduction of *Lm*, the product would not be considered to be adulterated. EIAOs are to consider all processing steps before making a determination of adulteration.

D. If a post-lethality exposed RTE environmental (non-food contact) surface sample collected by the EIAO tests positive for *Lm*, the EIAO is to consider whether product may have been produced under insanitary conditions before recommending the issuance of an NR. EIAOs are to recommend that IPP issue an NR if there is evidence of insanitary conditions that could lead to product contamination.

EXAMPLE: A drain tests positive for *Lm*. The EIAO observes an establishment employee spraying a high pressure hose in the drain. Water droplets landed on a conveyor belt and exposed RTE product. The positive results from the drain, taken along with the observation of possible cross contamination, would be adequate to support the issuance of an NR. The drain positive alone, without any further observations of conditions that could lead to insanitary conditions, would not warrant the issuance of an NR.

E. EIAOs are to follow the instructions in VT Directive 5100.1 regarding enforcement actions. In addition, EIAOs are to take the following into consideration when making recommendations:

1. If VAAFM finds the product or food contact surface positive, and the establishment tested the product or food contact surface under its documented sampling programs, EIAOs are to check the establishment's *Lm* testing results to determine whether the establishment also found the sampled product or food contact surface positive for *Lm;*

2. EIAOs are to determine whether the establishment held the product or 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 its own test results. Establishments are required to hold or control shipments of RTE products containing meat or poultry products pending the results of VAAFM product and food contact surface testing.

3. If the EIAO finds that the establishment did not hold or maintain control of product when VAAFM collects product or food contact surface samples, he or she is to recommend to the in-plant supervisory personnel that the inspection team issue an NR. The NR would be recommended 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 CFR417.5(c). When recommending the issuance of an NR, the EIAO is to follow the instructions in chapters 3, 13, and 15 in VT Directive 5100.1; and

4. Generally, if VAAFM finds the product or food contact surface positive for *Lm*, EIAOs are to recommend that IPP issue an NR (cite 9 CFR 417.4(a)). However, if the establishment also found the product or food contact surface to be positive for *Lm* and held the product, EIAOs are not to recommend the issuance of an NR. They are to verify that the establishment performs the appropriate corrective actions as part of the FSA.

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

Katherine M. McNamara DVM

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VT Meat Inspection Service

Attachment 1

PROJECT CODE AND NAME	Routine risk-based sampling of post-lethality exposed RTE meat and poultry products. Samples will be collected separately
SAMPLE COLLECTOR	personnel trained in IVT aseptic sample collection techniques.
PRODUCT TO SAMPLE	Select the highest risk post-lethality exposed RTE product produced at the time of collection using the Product Sampling Priority List in Attachment 5.
ANALYZED FOR	*Listeria monocytogenes*
SPECIAL COLLECTION INSTRUCTIONS	Collect 5 samples per unit. Collect samples in the final, intact package. Randomly select either the Monday through Thursday Collect the samples from each unit from one production lot, line, and control alternative. Product samples may be collected on a different day than the food contact and environmental samples, as long as all three sample types represent the same production lot. Collect enough product so that at least ONE pound of meat or poultry per sample is submitted to the lab for analysis. If an intact sample of product is too large to submit to the lab, ask the establishment to slack-fill or short-weight a package to one pound without any changes to its processing operations. If this is not possible, contact the office to see if a larger shipping container is available.
SAMPLE REQUEST FORM	Use one VDH form for each of the 5 product samples per unit. Use a separate sample seal set for each individual sample collected. Place one separately numbered identification label on each sample, and place a corresponding identification label on the form. Place the sample form in a plastic bag and place the plastic bag into the shipping container with the sample, and seal container per FSIS Directive 7355.1, Rev. 2, Use of Sample Seals for Laboratory Samples and Other Applications
ESTABLISHMENT NOTIFICATION	Notify the establishment at least 1 week before Routine Risk-based testing sampling.
SPECIAL SHIPPING INSTRUCTIONS	Ship immediately after product represented by the sample has passed all establishment interventions for *Lm*. Ship samples refrigerated or frozen, depending on establishment practices. Use sufficient frozen coolant to keep samples cold during transit. Ship samples Monday through Thursday so that they arrive at the laboratory overnight. Do not ship samples on Saturdays or on the day before a Federal holiday.
REFERENCES	FSIS Directive 10,240.5; FSIS Directive 7355.1, Rev. 2

Attachment 2

PROJECT CODE AND NAME	Routine risk-based sampling of food contact surfaces during the production of post-lethality exposed RTE meat and poultry products.
SAMPLE COLLECTOR	personnel trained in IVT aseptic sample collection techniques.
PRODUCT TO SAMPLE/SAMPLE SITE SELECTION	Swab surfaces that have direct contact with post-lethality exposed RTE product in the RTE production area (e.g., conveyor belts, cooler storage racks, luggers, slicers, peelers, loaders, table tops). Brine or chill water samples are considered to be contact surface samples (and collected under the program), if they come in direct contact with post-lethality exposed product, or the product is in a semi-permeable casing. Contact and environmental samples may be collected on different days than product as long as all three sample types represent the same production lot. **NOTE:** Gloves or garments worn by employees may be sampled if directly observed to contact food.
ANALYZED FOR	*Listeria monocytogenes*
SPECIAL COLLECTION INSTRUCTIONS	Collect 10 samples per unit. Collect samples that represent the conditions under which the sampled product lot was produced. The majority of the samples should be collected during the production shift with a lesser number collected before start of operations. Ideally, when collecting samples during operations, do so without disrupting production, such as at the start of company breaks and at the end of a shift.
SAMPLE REQUEST FORM	Use a separate form for each sample collected. Place the sample form in a plastic bag and place the plastic bag into the shipping container with the sample and seal per FSIS Directive 7355.1, Rev. 2.
ESTABLISHMENT NOTIFICATION	Notify the establishment at least 1 week before Routine Risk-based sampling.
SPECIAL SHIPPING INSTRUCTIONS	Ship samples as soon as possible to the laboratory. Ship refrigerated. Use sufficient frozen coolant to keep samples cold during transit. Ship samples Monday through Thursday so that they arrive at the laboratory overnight. Do not ship samples on Saturdays or on the day before a Federal holiday. Notify the laboratory if the samples will be collected on different days.
REFERENCES	FSIS Directive 10,240.5; FSIS Directive 7355.1, Rev. 2

Attachment 3

PROJECT CODE AND NAME	Routine risk-based sampling of environmental (non-food contact) surfaces during the production of post-lethality exposed RTE meat and poultry products. Samples will be collected separately and composited at the laboratory.
SAMPLE COLLECTOR	personnel trained in IVT aseptic sample collection techniques.
PRODUCT TO SAMPLE/SAMPLE SITE SELECTION	Swab surfaces having indirect (e.g., mop handles or outer garments that may be handled by a person who may touch RTE product) or no contact (e.g., floors, drains, walls, air-vents, overhead structures) with the sampled product lot. Collect samples anywhere in the establishment where post-lethality exposed RTE product is produced, held, or stored. Contact and environmental samples may be collected on different days than product as long as all three sample types represent the same production lot. Brine or chill water samples are considered to be environmental samples if the product is in an impermeable casing or otherwise packaged. The samples will be collected under the sampling program
ANALYZED FOR	*Listeria monocytogenes*
SPECIAL COLLECTION INSTRUCTIONS	Collect 5 samples per unit. Collect samples that represent the conditions under which the sampled product lot was produced. Ideally, when collecting during operations, do so without disrupting production, such as at the start of company breaks and at the end of a shift.
SAMPLE REQUEST FORM	Use one form for each of the 5 environmental samples per unit. Use a separate sample seal set for each individual sample collected. Place one separately numbered identification label on each sample. Place the sample form in a plastic bag and place the plastic bag into the shipping container with the sample and seal per FSIS Directive 7355.1, Rev. 2.
ESTABLISHMENT NOTIFICATION	Notify the establishment at least 1 week before Routine Risk-based testing sampling.
SPECIAL SHIPPING INSTRUCTIONS	Ship samples as soon as possible to the laboratory. Ship refrigerated. Use sufficient frozen coolant to keep samples cold during transit. Ship samples Monday through Thursday so that they arrive at the laboratory overnight. Do not ship samples on Saturdays or on the day before a Federal or state holiday.
REFERENCES	FSIS Directive 10,240.5; FSIS Directive 7355.1, Rev. 2

Attachment 4

PROJECT CODE AND NAME	Routine sampling of brine or chill water that does not come into direct contact with post-lethality exposed RTE product.
SAMPLE COLLECTOR	personnel trained in IVT aseptic sample collection techniques.
PRODUCT TO SAMPLE/SAMPLE SITE SELECTION	Collect brine or chill water that does not come in direct contact with post-lethality exposed RTE product. If the product is in an impermeable casing or otherwise packaged, the brine is an environmental surface sample.
ANALYZED FOR	*Listeria monocytogenes*
SPECIAL COLLECTION INSTRUCTIONS	Collect one sample per unit. Collect samples that represent the conditions under which the sampled product lot was produced. Ideally, when collecting during operations, do so without disrupting production, such as at the start of company breaks and at the end of a shift.
SAMPLE REQUEST FORM	Use a separate form for each sample collected. Place the sample request form in a plastic bag and place the plastic bag into the shipping container with the sample and seal per FSIS Directive 7355.1, Rev. 2.
ESTABLISHMENT NOTIFICATION	Notify the establishment at least 1 week before sampling.
SPECIAL SHIPPING INSTRUCTIONS	Ship samples as soon as possible. Ship refrigerated. Use sufficient frozen coolant to keep samples cold during transit. Ship samples Monday through Thursday so that they arrive at the laboratory overnight. Do not ship samples on Saturdays or on the day before a Federal holiday. Notify the laboratory if samples will be sent on different days.
REFERENCES	FSIS Directive 10,240.5; FSIS Directive 7355.1, Rev. 2

Attachment 5

Product Sampling Priority List

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

[1]Post-lethality exposed product.
[2] Product type to be used on Form 10,210-3.