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

FSIS DIRECTIVE

10240.5
Revision 4

11/2/22

VERIFICATION PROCEDURES FOR ENFORCEMENT, INVESTIGATIONS AND ANALYSIS OFFICERS FOR THE *LISTERIA MONOCYTOGENES* REGULATION AND ROUTINE RISK-BASED *LISTERIA MONOCYTOGENES* SAMPLING PROGRAM

I. PURPOSE

A. This directive provides Enforcement, Investigations and Analysis Officers (EIAOs) with instructions for collecting samples under the Routine risk-based *Listeria monocytogenes* (RLm) sampling program. The RLm sampling program includes the collection of product, food contact surface (FCS), and environmental, non-food contact surface (NFCS) samples, tested for the presence of *Listeria monocytogenes* (*Lm).* In addition, this directive provides instructions to District Office (DO) personnel and EIAOs for scheduling RLm sampling.

NOTE: In this directive, the term EIAO also includes EIAO-trained Public Health Veterinarians and other EIAO-trained personnel.

B. FSIS is revising this directive in its entirety to make it consistent with FSIS Directive 5100.4, *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology*. This revision describes changes made to the PHRE Scheduling spreadsheets provided to DOs each month by the Office of Planning, Analysis and Risk Management (OPARM) and used for scheduling PHREs at establishments. This revision provides EIAOs with the additional option to perform RLm sampling as part of a PHRE and to use the RLm results to support the PHRE outcome, which is a decision to perform or not perform a food safety assessment (FSA). This revision also includes updated sampling instructions.

KEY POINTS:

- *Incorporates the PHRE methodology in FSIS Directive 5100.4., Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology.*
- *Replaces the use of a four-year cycle with risk factors. The order of establishments listed in the routine section of the RLm tab of the PHRE Scheduling spreadsheets will now be based on risk factors as described in this directive, not the time elapsed since the last FSA.*
- *Includes a new option to perform RLm sampling to inform the PHRE recommendation as to whether to conduct an FSA or not, rather than to only inform the FSA outcome.*
- *Eliminates the Product Sampling Priority List (Attachment 5 in the previous version of this directive).*
- *Updates the sample collection instructions.*

- *Reduces the minimum RLm product sample weight from one pound to one quarter pound.*

II. CANCELLATION

FSIS Directive 10,240.5, Revision 3, *Verification Procedures for Enforcement, Investigations, and Analysis Officers for the Listeria monocytogenes Regulation and Routine Risk-Based Listeria monocytogenes Sampling Program*, 3/28/13.

III. BACKGROUND

A. Under 9 CFR part 430, post-lethality exposed (PLE), ready-to-eat (RTE) meat and poultry products are adulterated if they test positive for *Lm* or come into direct contact with an FCS 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. Under the RLm sampling program, EIAOs collect intact product samples (RLMPRODC), FCS swabs (RLMCONT) and environmental, NFCS swab samples (RLMENVC) during the production of RTE meat and poultry products that are exposed to the environment post-lethality. RLm sampling has been performed by FSIS to inform the outcome of an FSA.

C. FSIS Directive 5100.1, *Enforcement, Investigations, and Analysis Officer Comprehensive Food Safety Assessment Methodology,* issued in May 2015, shortened the allowable timeframe for FSAs and instructed EIAOs that when a PHRE indicates that an FSA is needed and if the FSA is to include RLm sampling, then the EIAO is to perform RLm sampling before the start of the FSA so the RLm sampling results will be available to inform the FSA outcome. This directive revision provides EIAOs with the additional option to perform RLm sampling during the PHRE so that the RLm results can be used to inform the PHRE recommendation as to whether an FSA is warranted.

D. OPARM conducted an analysis which determined that there is a higher risk of finding RLm positive samples in post lethality exposed, RTE producing establishments which have had a positive RLm product, FCS, or NFCS sample within the last three years and in those producing post-lethality exposed, RTE products using Alternative 3 with average production volume less than or equal to 1,000 pounds per day. These two factors were then used to create a risk ranking algorithm.

E. The RLm sampling is intended to be performed in a set number of establishments within each District every month. The planned frequency collects RLm samples from a portion, but not all, RLm eligible establishments within the District each year.

IV. DO AND EIAO RESPONSIBILITIES FOR PHRE and RLm SCHEDULING

A. DO Responsibilities for Scheduling.

1. DOs are to follow the instructions in FSIS Directive 5100.4 for completing each PHRE;

2. As described in FSIS Directive 5100.4, a "PHRE Scheduling spreadsheet" is provided each month and lists the establishment by PHRE trigger priority order. The "RLm" tab of the spreadsheet lists all establishments that produce PLE, RTE product and orders by PHRE trigger reason priority;

3. The PHRE Scheduling spreadsheet is one of several pieces of information DOs are to utilize when assigning PHREs, or any RLm sampling to a specific establishment. Depending on the PHRE trigger, RLm sampling may not be recommended because the PHRE and any subsequent FSA is focused on the non-RTE areas or because IVT sampling is recommended;

4. The DO is not required to schedule the exact establishments for RLm sampling based on the those identified in monthly PHRE Spreadsheet; however, the DO is to ensure that it does schedule the same number of establishments as identified on the spreadsheet each month;

5. The PHRE Scheduling spreadsheet ranks establishments eligible for PHREs in the following priority order. DOs are to use this order for informing the scheduling of PHREs, not for determining the priority of RLm sampling:

a. RTE establishments with a "for cause" PHRE trigger, as listed in Table 1 of FSIS Directive 5100.4 appear first under the RLm tab of the PHRE Scheduling spreadsheet.

    i. A "for cause" trigger not related to RTE production is not intended to prioritize RLm sampling. If the "for cause" trigger is not relevant to RTE production (e.g., Category 3 for *Salmonella*), then the PHRE should be focused on those relevant non-RTE aspects that contributed to the PHRE trigger, not used to determine whether an FSA or RLm sampling is recommended for the RTE processes. RLm sampling could be performed at the DO's discretion to help inform the PHRE recommendation for a PLE, RTE process or could be used as a part of an Assessment Plan when an FSA is recommended to assess the PLE, RTE processes.

    ii. If a "for cause" trigger is relevant to RTE production, i.e., a positive pathogen test result in RTE product, and if sampling is desired, then "for cause" IVT sampling is to be performed, not routine, risk-based, RLm sampling.

b. New establishments with an inauguration date between four and eight months appear next on the RLm tab of the PHRE Scheduling spreadsheet. PHREs should be performed in all new establishments, but these risk-based PHREs are a lower priority than for cause PHREs. RLm sampling in new PLE, RTE establishments is optional. Per table 1 of FSIS Directive 5100.4, a new establishment is a routine, risk-based trigger, not a "for cause" trigger. Therefore, if sampling is to be performed as part of the PHRE or as part of an Assessment Plan for a PLE, RTE process, then routine, risk-based RLm sampling is to be performed.

c. The remaining establishments are sequenced using an OPARM algorithm based on two risk factors associated with an increased risk of finding *Lm*, as determined by an analysis of FSIS RLm sampling data. When the PHRE is performed at these establishments, the DO and EIAOs are to consider the sequence of the list, input from Inspection Program Personnel (IPP), and other risk-based factors such as the examples in Section IV. B. 2, below, to determine whether RLm sampling should be performed as part of the PHRE or as part of an Assessment Plan. The algorithmic risk ranking is as follows:

    i. Establishments with a positive Lm from a RLm product, FCS, or NFCS sample in the last three years and produce post-lethality exposed RTE products using control Alternative 3 with an average daily production volume between 1-1,000 pounds.

ii. Establishments with a positive Lm sample on a RLm product, FCS, or environmental sample in the last three years.

iii. Establishments that produce post-lethality exposed RTE products using Alternative 3 with an average daily production volume for RTE between 1-1,000 pounds.

d. The PHRE Scheduling spreadsheet may include other information that is not part of the risk ranking algorithm but is included to assist with DO and EIAO decision making.

B. Options for Conducting RLm Sampling.

1. DOs have the following options, including one which is new with this revision, for conducting RLm sampling:

i. If the recommendation of the PHRE is to conduct an FSA for Post-Lethality Exposed (PLE), RTE processes, RLm sampling is to be performed in advance of the FSA to facilitate receiving the RLm lab results prior to the completion of the FSA, per FSIS Directive 5100.1; or

NOTE: The following option and instructions are new with this Directive revision.

ii. Conduct RLm sampling to inform the PHRE recommendation. The DO may choose to do RLm sampling to help inform the PHRE decision. RLm sampling results, in conjunction with all other findings, will be used to determine the recommendation following the PHRE, per FSIS Directive 5100.4

iii. To utilize the new option, Supervisory EIAOs must ensure that RLm sampling tasks and forms are available to the EIAO that is to be assigned the PHRE. This is done at the time the establishment and workflow are assigned in the Public Health Information System (PHIS) by checking the box Samples will be collected as part of FSA. The EIAO will then be able to schedule and perform the RLm sampling.

iv. Once results are received from the FSIS laboratory, the EIAO is to add the RLm sampling results to the PHRE report.

2. To assist with RLm decision making, suggested risk-based factors for *Lm* contamination that DOs and EIAOs may consider based on communication with IPP, include but are not limited to:

a. A change in the establishment's HACCP plan or the addition of a new HACCP plan;

b. Addition by the establishment of a new post-lethality exposed (PLE), RTE product;

c. Any conditions that negatively impact sanitation or increase the probability of *Lm* contamination:

i. Recent or ongoing construction activities.

ii. Condensation issues.

iii. Use of high-pressure hoses in the PLE, RTE area.

iv. Worn out equipment or equipment breakdowns, roof leaks, or other events that increase the probability of *Lm* contamination.

v. An increase in *Lm*, or indicator organism positives obtained through establishment sampling and testing;

vi. Anything indicating that the establishment may be having issues with sanitation such as repetitive sanitation related noncompliance records (NRs), increased adenosine triphosphate (ATP) or aerobic plate counts (APC) values; or

vii. Any other concerns from IPP.

V. EIAO RESPONSIBILITIES for RLm SAMPLE SCHEDULING

A. The EIAO is to maintain ongoing communication with the IPP and frontline supervisor (FLS) beginning with the discussion of risk factors and concerns in IV.B.2 through completion of RLm sampling and or any RTE related subsequent FSA. EIAOs are to discuss with IPP and the FLS any discrepancies they might discover with the establishment profile, such as HACCP size, whether a product is considered post lethality exposed, etc. The EIAO is also to provide frequent updates to inform them of the EIAO's findings and of any recommendations that the EIAO is planning to make. See section IX.A. on communicating with IPP and the FLS about NRs and vulnerabilities.

B. Prior to scheduling a specific RLm sampling date with FSIS laboratories, the EIAO must complete or address 1 through 5 below.

1. The EIAO is to inform the Inspector-In-Charge (IIC) at the establishment that a RLm sample collection activity will occur. With the assistance of the IIC, the EIAO is to determine the following:

    a. The production schedule and types of PLE, RTE products produced at the establishment;

    b. The number of production lines producing PLE, RTE products at the establishment; and

    c. 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 PLE, RTE product. If it does, the EIAO is to collect brine as an FCS sample using an RLMCONT sample form. Conversely, if the brine or ice water does not come into direct contact with the product or is used for product in an impermeable casing, the EIAO is to collect the brine as a NFCS sample using an RLMENVR sample form.

NOTE: If a RTE product is treated with a lethality treatment that has been validated to achieve at least a 5-log reduction of *Lm* and other pathogens of concern in the packaging, then the RTE product would not be considered PLE and would not be eligible for RLm sampling.

2. If the establishment has multiple shifts, the EIAO is to randomly select the 1st or 2nd shift Monday through Thursday or the 1st shift Friday for collection of RLm samples within the week identified in the monthly RLm scheduling list. Units may be collected from both shifts. However, this will probably require that the sampling units collected from the two shifts be shipped on different days, per sections VII. A. 2 and 3 below. EIAOs must ensure that the receiving lab is aware of this at the time of scheduling and requesting supplies, per section V. A. 6 below.

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

    a. Sample a maximum of three lines on which PLE, RTE product is produced (three sample units) in large establishments;

    b. Sample a maximum of two lines on which PLE, RTE product is produced (two sample units) in small establishments; or

    c. Sample one line on which PLE, RTE product is produced (one sample unit) in very small establishments.

NOTE: The above are maximums. Fewer units may be collected. If the maximum number of units is not needed, then supplies for a fewer number of units should be requested from the laboratories by the EIAO. Establishment HACCP size is defined as: 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.

4. EIAOs are to only collect samples on days and shifts when the establishment is producing FSIS regulated, PLE, RTE meat or poultry products. Using the maximums in section V. B. 3, EIAOs are to collect each sampling unit from a single, PLE, RTE line.

5. If the establishment uses brine or ice water to chill the meat or poultry product sampled, EIAOs are to collect one brine or ice water sample per unit sampled (e.g., if an EIAO is collecting three units and the establishment is only using two brine chillers on two separate lines, then the EIAO is to collect two brine samples).

    a. If a brine or ice water sample is collected as an FCS, submit the brine to the laboratory using one of the 10 individual RLMCONT sample forms per sampling unit; or

    b. Alternatively, if a brine or ice water sample is collected as an NFCS, environmental sample, EIAOs are to submit it using an RLMENVR sample form.

NOTE: Brine or ice water samples submitted with RLMENVR sample forms will not be composited and analyzed along with the RLMENVC swab samples.

6. When requesting sample forms and supplies, EIAOs are to:

    a. Send the following information to the FSIS - RLm Sample Scheduling mailbox (rlmsamplescheduling@usda.gov) in Outlook at least two weeks before the week sampling will occur:

        i. Sample collection date and production shift;

        ii. Number of sample units required based on the establishment HACCP size;

        iii. FSIS laboratory designated in the monthly PHRE Scheduling spreadsheet;

        iv. Establishment number;

        v. Contact name and phone number;

        vi. Location/address to send the supplies;

vii. Requests for special supplies (e.g., smaller gloves or larger shipping containers, if needed; and

viii. Requests for brine or ice water sampling supplies, if needed.

NOTE: When sending the scheduling email to the FSIS - RLm Sample Scheduling mailbox, the EIAO should make it clear to the laboratory when the samples will be shipped. FSIS labs will typically assume that samples collected from the first shift will be shipped on the day of collection using overnight delivery, while samples collected from the 2nd shift will be shipped the day following collection using overnight delivery.

b. Within 2 weeks after submitting the information to the FSIS - RLm Sample Scheduling mailbox, the EIAO should receive the sampling supplies. Upon receipt, the EIAO is to ensure everything needed has been received. Then, the EIAO is to refrigerate the neutralizing broth and swabs pre-moistened with neutralizing broth. If additional items are needed, the EIAO is to send an e-mail to the "FSIS – RLm Sample Scheduling" distribution list (rlmsamplescheduling@usda.gov) to request additional supplies or shipping containers. To be thoroughly frozen, gel packs must be frozen for a minimum of 24 hours. Mini refrigerators do not freeze gel packs thoroughly and are not to be used.

c. At least one week before the RLm sample collection date, the EIAO is to notify establishment management that the Agency has scheduled a RLm collection activity at the establishment and document the notification in a Memorandum of Interview (MOI) within PHIS and provide establishment management with a copy. The EIAO is to perform the following actions:

i. Confirm that the establishment will be producing PLE, RTE product on the day and shift that the RLm sampling is scheduled and is planning to implement its documented routine production, Sanitation Standard Operating Procedures (sanitation SOPs) and food safety practices;

ii. Tell the establishment that, if it intends to modify its documented routine production, sanitation food safety practices or cancels production before the RLm sampling, it should inform the EIAO as soon as possible so that he or she can determine whether FSIS sampling should be rescheduled; and

iii. Advise the establishment that if it changes its routine practices temporarily during RLm sampling without notifying the EIAO in advance, and cannot provide a justifiable reason for doing so, the sampling may be rescheduled, and further regulatory action may be pursued, which could delay completion of the PHRE or FSA.

NOTE: See Section VII of this directive for instructions for EIAOs in establishments that alter routine practices during RLm sampling.

VI. EIAO SAMPLING PROCEDURES UNDER THE RLm SAMPLING PROGRAM

A. The EIAO is to hold an entrance meeting with the establishment as described in FSIS Directive 10,300.1, *Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria Monocytogenes* During the entrance meeting, the EIAO is to:

B. Provide an explanation of RLm sampling (refer to the Background, Section III, of this directive);

C. Explain the purpose of the RLm sampling, that it is routine monitoring using risk-based selection criteria;

1. Provide a copy of the Entrance Letter to Establishment Management and review its contents (see Attachment 1 of FSIS Directive 10,300.1);

2. Remind the establishment that it is not necessary to rinse the FSIS swabbed surfaces after samples are collected; and

3. Remind establishments that they are to hold or control RTE products implicated by samples that FSIS has collected and is testing for pathogens, or that have passed over direct FCSs that FSIS has swabbed and is testing for pathogens, pending the results of FSIS testing.

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 five individual product samples per sampling unit from a particular line and processing lot following the instructions in this directive and as is summarized in Attachment 1;

2. Collect products from the highest risk alternative and the highest risk PLE, RTE production line using the instructions in a and b below, whenever possible;

    a. Select product from the highest-risk *Lm* control alternative (Risk: Alternative 3 > Alternative 2b > Alternative 2a > Alternative 1) as follows:

        i. For each sampling unit, select product from only one *Lm* control alternative, processing line, and production lot. For example, if one sampling unit is collected and the establishment produces products under all three alternatives, then select Alternative 3 product; and

        ii. If more than one sampling unit is collected, then product from more than one alternative may be selected. However, all the individual samples in each sampling unit must be from the same *Lm* control alternative, processing line, and sampled lot.

NOTE: Even Alternative 1 products may test positive for *Lm* in cases where sanitation is inadequate, or the contamination level is so high that it overwhelms the PLT and Antimicrobial Agent or Process (AMAP).

3. When selecting production lines, consider other factors, including, but not limited to:

    i. Sampling history (results from both FSIS sampling and the establishment's own sampling);

    ii. Noncompliance history or trends (e.g., noncompliance with 9 CFR 416, 417, and 430);

iii. Evidence of *Lm* harborage;

iv. Past outbreaks or links to illness; and

v. Observations from IPP.

4. Collect product in establishment packaging so that:

   a. At least one quarter pound or four ounces of PLE, RTE meat or poultry product per individual product sample is submitted to the FSIS laboratory for analysis; and

NOTE: The minimum weight required for RLm product samples will be different than the minimum weight needed for IVT product samples when IVT samples will be analyzed for *Salmonella* instead of *Lm*. EIAOs are to submit product samples in intact, retail packages whenever possible.

   b. Individual product samples are collected at different times throughout the production of a specific sampled lot after all official interventions that are documented in the establishment's HACCP plan and hazard analysis have been applied.

NOTE: Product samples may be collected on a different day than the FCS and NFCS environmental samples, as long as the same production lot is represented by all three sample types within a sampling unit.

   c. If the final package or product container is too large, heavy, or costly to ship to the laboratory IPP can contact the laboratory to request a larger shipping container. EIAOs are not to cut the product to fit it inside the shipping container. Alternatively, if the establishment only ships product in bulk, EIAOs may ask the establishment to slack-fill or short-weight a product to at least one quarter pound and send it in the usual establishment packaging, such as the bulk container liner. For example, bulk packages of jerky may be slack filled to one quarter pound in the establishment's usual packaging.

5. Complete information in the **Sample Collection Data** tab of the **Sample Management-Sample Collection** section of PHIS and **Save**;

6. Complete and submit the sample questionnaire under the **Additional Info** tab of the **Sample Management-Sample Collection** section of PHIS;

7. Print the form and sample questionnaire and include them with the sample. Printing on both sides of each sheet of paper is acceptable;

NOTE: When collecting multiple samples from the same line or establishment, EIAOs may use the "COPY" feature in PHIS to complete sample forms to save time. EIAOs are to open each copied sample form to change the **Time Collected** and **Surface Name,** as needed. If necessary, EIAOs are to also edit any of the sampling fields and questionnaire answers.

8. Use a separate sample seal packet (FSIS Form 7355-2A/2B) for each individual RLMPRODC form. Place one small, bar-coded label from one sample seal packet on a RLMPRODC form, and place corresponding bar-coded labels from the same seal packet on the corresponding product packages until the remaining three have been used. See Figure 1 of Directive 7355.1, *Use of Sample Seals for Laboratory Samples and Other Applications*.

9. Place the signed, completed FSIS RLMPRODC sample form into a plastic sleeve and place it in a Ziploc bag along with the corresponding five product samples. Close the Ziploc bag, then place the medium sized, FSIS Laboratory Sample Identification Label from that same seal packet over the closure;

10. Place the samples and form into an FSIS shipping box, and once the box is fully packed, place a FSIS Laboratory Sample Container Seal over the opening, per FSIS Directive 7355.1.;

11. If it is necessary to send a unit of product samples in multiple boxes, e.g., the product packages are too large to fit all five samples in one shipping box, EIAOs may use multiple boxes but are to include a copy of the completed RLMPRODC sample form in each of those boxes. In this situation, EIAOs are to sequentially number each copy of the RLMPRODC sampling form, e.g., "1 of 5, 2 of 5, etc.".;

12. Submit RLMPRODC sample forms for product sampling units electronically in PHIS; and

NOTE: The laboratory will composite the five individual product samples submitted per RLMPRODC sample form into one analytical portion and will post one result on LIMS-Direct. These results will also be available through PHIS.

13. When product is being sent to another establishment for application of an official *Listeria* control intervention (e.g., high pressure processing (HPP)), as is documented in the HACCP plan, hazard analysis, and flow chart, the EIAO is not to collect product samples until after the intervention has been applied and the product has been returned.

    a. If the product will not be returned after application of the *Listeria* control intervention, the EIAO is to sample a different product, if possible.

    b. If a process such as HPP is being applied only for quality purposes, such as to extend the shelf life, the EIAO may collect and submit product samples before such a process is applied.

E. For FCS swab samples, EIAOs are to:

1. Collect 10 FCS swab samples per sampling unit. Collect swab samples starting closest to the product areas and then move further out (e.g., collect swab samples from FCS first and then NFCS, environmental swab samples);

2. Collect most FCS swabs during establishment operations, ideally at the start of routine breaks scheduled by the establishment. EIAOs are to follow "lock-out, tag-out" procedures for equipment, per FSIS Directive 4791.11, *Lockout/Tagout Safety Procedures*. "Lockout, tagout" is a method of controlling energy sources while working on or around equipment.

    a. EIAOs may collect some FCS swabs at the end of pre-operational sanitation activities, before the start of production; 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. Product, FCS, and NFCS samples may be collected on different days, as long as the same sampled lot is represented by all three sample types. For example, for products that are dried or smoked over multiple days, EIAOs may need to collect and ship FCS swab samples over

the course of more than one day or may need to collect and ship product samples on a different day than FCS samples. If this will be the case, EIAOs are to ensure that the recipient lab is aware when each set of sample types will be received by that lab.

4. Place each FCS swab sample back into its own separate whirl-pak bag. Use a separate sample seal packet (FSIS Form 7355-2A/2B) for each RLMCONT form. Place one small, bar-coded label from one sample seal set on the RLMCONT sample form and place a corresponding small, bar-coded label from the same seal packet on the corresponding FCS sample;

5. Place the signed, completed FSIS RLMCONT sample form into a plastic sleeve and place it in a Ziploc bag along with the corresponding FCS swab sample. Close the Ziploc bag, then place the FSIS Laboratory Sample Identification Label from that same seal packet used in the previous step over the closure;

6. Place the FCS samples and forms into an FSIS shipping box and once the box is fully packed, place a FSIS Laboratory Sample Container Seal over the opening, per FSIS Directive 7355.1.

F. For NFCS swab samples, EIAOs are to:

1. Collect NFCS environmental swab samples in areas of the establishment where products are being processed, stored, or held, including smokehouses, coolers, and production rooms for the targeted production line;

2. EIAOs are to associate NFCS swab samples with production lines at their discretion. For example, a drain that is equidistant from two different production lines may be associated with either line;

3. Collect five individual NFCS swabs per sampling unit, placing each back into its own individual whirl-pak bag as samples are collected;

4. In PHIS, state the number of swabs submitted for each site category (i.e., drain, table, floor mat, wheel(s), boot, slicer, floor, squeegee, door, other). The five, NFCS environmental swabs within a sampling unit may be from the same site category or different site categories. If a sample site swabbed does not fit into any of the site categories listed in PHIS, then indicate the number of swabs taken under **Other Locations** and enter a short, written description (not to exceed 50 characters in the space provided next to that option) of the sites swabbed;

5. Use a single sample seal set (FSIS Form 7355-2A/2B) for each RLMENVC sample form. Place one small, bar-coded identification label from the sample seal packet on the RLMENVC form and place a corresponding bar-coded label from the same seal packet on the whirl-pak bags containing the NFCS swab samples until all bar-coded labels have been used;

NOTE: NFCS brine or ice water samples will not be composited with NFCS swab samples. NFCS brine samples are to be collected using a separate RLMENVR sample form, as is summarized in Attachment 4. RLMCONT sample forms will still be used for the collection of brine samples that contact product. If the product is in a permeable or semi-permeable casing, then the brine is considered a FCS and a RLMCONT sample form should be used. If the casing is impermeable, then the brine would be considered an environmental sample and an RLMENVR sample form should be used.

6. Place the signed, completed FSIS RLMENVC sample form into a plastic sleeve and place that in a Ziploc bag along with the corresponding five NFCS samples. Close the Ziploc bag, then place

the FSIS Laboratory Sample Identification Label from that same seal packet used in the previous step over the closure of the bag.

7. Submit all five swabs in the sampling unit with a single RLMENVC sample form. The laboratory will composite the five swab samples and post one result on LIMs-Direct. The results may also be available through PHIS.

G. If an establishment does not produce product on a particular line on the day an EIAO conducts an RLm, the EIAO can still sample that line if there is adequate justification for doing so. For example, an establishment may shut down a problematic line or one from which *Lm* positive samples have been collected in the past through either FSIS or establishment sampling. If the EIAO collects swab samples of equipment that is not in operation and in the environment around that equipment, he or she is to follow the instructions below:

1. Collect FCS swab samples under the RLMCONT project code and NFCS environmental samples under the RLMENVC project code and record in the collection remarks section that the line is not in production;

2. Do not collect any product samples; and

3. Do not recommend that IPP issue a non-compliance record (NR) if the equipment tests positive for *Lm* because the equipment was not in operation at the time the sample was collected, and there is no reason to consider any 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 SOPs before using the equipment, IPP are to issue an NR. The NR would be appropriate because the positive *Lm* result would establish that the equipment was not maintained in sanitary condition and the product would therefore be considered adulterated (cite 9 CFR 416.3(a) and 430.4(a)).

VII. EIAO SAMPLE SUBMISSION RESPONSIBILITIES

For sample submission, the EIAO is to:

1. Place two frozen gel packs at the bottom of each large shipping container. Place corrugated cardboard on top of the gel packs, followed by the samples, and lastly insert the foam plug;

2. Submit samples the same day as collected if collected during first shift Monday through Friday; or

3. Submit samples as soon as possible if collected during the second shift. Do not ship samples on Saturday or the day before a holiday. When holding samples overnight for shipping the following day, EIAOs are to store samples refrigerated and secured by FSIS.

VIII. EIAO ACTIONS IN ESTABLISHMENTS THAT ALTER ROUTINE PRACTICES DURING AN RLm SAMPLING EVENT

A. FSIS has identified that establishments might temporarily alter their routine production, sanitation, or food safety practices during RLm 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 PLE, RTE, meat or poultry 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 used during the RLm;

2. Drastically reducing the typical production time;

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

4. Reducing the number of employees handling PLE, RTE product; or

5. Selectively not producing higher risk PLE product (e.g., Alternative 3, sliced deli product) or not using particular equipment that previously has tested positive.

C. Such practices can interfere with FSIS's assessment of routine conditions or corrective actions at the establishment and may limit FSIS's ability to determine whether PLE, RTE meat and poultry products are not adulterated as required by the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act (PPIA). 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 RLm sampling, if the establishment can provide supportable rationale for not producing the product (such as intermittent production to fill customer orders), then the EIAO is to collect similar PLE, RTE product (e.g., produced using the same Listeria control production alternative) during the RLm sampling, if available. If similar product is not available, the EIAO is to reschedule the RLm sampling as per paragraph VII.E.2. below of this directive.

E. If an establishment informs the EIAO that it no longer plans to produce PLE, RTE product, or that it has modified its production, sanitation, or food safety practices, the EIAO is to document in an MOI within PHIS the date of the notification, and the reason the change was made and to provide the establishment with a copy. The EIAO is to consider and document the following issues in the MOI;

1. 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 RLm sampling, if possible. If the EIAO is unable to assess the program changes, he or she is to reschedule the RLm sampling; and

2. If the establishment can provide a supportable rationale for not producing the product, or for modifying its production, sanitation, or food safety practices, the EIAO is to work with the designated FSIS laboratory to reschedule RLm sampling to the next time in which the product or production practice of interest can be assessed by the EIAO.

3. If the EIAO finds that the establishment has made changes in its food safety system (e.g., adding an additional intervention) and does not have documents supporting the appropriateness of these changes, an NR may 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 changes to its hazard analysis as required in 9 CFR 417.5(a)(1).

4. If the EIAO finds that the establishment has made changes in its sanitation practices (e.g., temporarily increasing the use of sanitizer during the RLm sampling) and did not revise its Sanitation SOPs to reflect these changes, he or she is to recommend to supervisory personnel that the in-plant IPP issue an NR and indicate in the description that the noncompliance was observed as a part of an RLm (9 CFR 416.14).

F. An establishment decision to limit its product lot size solely to facilitate holding of the product during the FSIS, RLm sampling is not considered to have significantly altered production practices, providing the EIAO can collect samples that accurately represent routine production practices. For example, if the establishment's routine practice is to produce a product for less than 3 hours, the establishment may be able to support that producing product for only two hours is still representative of their routine production practices. Conversely, producing a product for only two hours when the establishment typically produces that same product over eight hours would not typically be representative of their routine production practices. It is the establishment's responsibility to provide sufficient support that a reduced lot size or production shift accurately represents their routine production practices.

G. EIAOs are to consider the impact that decreasing the lot size may have on RLm sample collection and whether this prevents FSIS from collecting RLm samples that are representative of routine production practices. This must be determined on a case-by-case basis. Questions about whether an establishment is altering routine production, sanitation, or food-safety practices, should be discussed with the supervisory chain, and if instructed, the EIAO can be submitted through askFSIS.

NOTE: More information on representative sampling can be found in Directive 10,240.3, *FSIS RTE Sampling Programs*.

H. If the EIAO is 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), because on the day of the RLm sampling, the EIAO determines that the establishment has temporarily decided not to produce PLE, 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 RLm sampling and is to contact the DO through his or her supervisory chain.

I. The DO may consider scheduling IVT sampling, per FSIS Directive 10,300.1, rescheduling the RLm sampling event, or whether an enforcement action is appropriate. 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 Intended Enforcement or Notice of Suspension in situations where FSIS personnel have found insanitary conditions at the establishment, or where FSIS personnel 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).

IX. SAMPLING RESULTS AND ENFORCEMENT

A. The EIAO is to communicate with the IPP and frontline supervisor (FLS) throughout the course of the RLm sampling to describe any NRs or vulnerabilities that he or she has identified and to recommend that IPP document appropriate NRs. The EIAO, the IPP, and the FLS are to work collaboratively to ensure that all non-compliances are communicated to establishment management and documented for issuance. The EIAO is to notify the FLS and IPP immediately when a noncompliance that has an immediate impact on food safety is observed.

B. When checking the sampling results, EIAOs are to:

1. Follow FSIS Directive 10,210.5, *FSIS Sampling Data Reporting Through Laboratory Information Management System-Direct*; and

2. Immediately report test results to establishment management.

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

D. If an FCS swab sample collected by the EIAO tests positive for *Lm*, any product that passed over that FCS is adulterated.

E. If a PLE, RTE environmental NFCS 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.

F. EIAOs are to follow the instructions in FSIS Directive 5100.1 when making recommendations to the DM or his/her designee regarding enforcement actions. In addition, EIAOs are to take the following into consideration when making enforcement recommendations:

1. EIAOs are to determine whether the establishment also tested FCSs or product and 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 test results. Establishments are required to hold or control shipments of RTE products containing meat or poultry products pending the results of FSIS product and FCS testing.

2. If the EIAO finds that the establishment did not hold or maintain control of product associated with the RLm product or FCS swab samples collected by FSIS until negative test results were obtained, he or she is to recommend that the in-plant IPP issue an NR. The NR would be recommended because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as required in 9 CFR 417.5(c). When recommending the issuance of an NR, the EIAO is to follow the instructions in FSIS Directive 5100.4; and

3. If FSIS obtains an RLm product or FCS sample positive for *Lm*, EIAOs are to recommend that IPP issue an NR (cite 9 CFR 417.4(a)). However, EIAOs are not to recommend the issuance of an NR if the establishment also found the product or an FCS to be positive for *Lm* through their own testing and held the product. They are to work with IPP to ensure that they verify that the establishment performs the appropriate corrective actions.

4. If FSIS obtains an RLm product or FCS sample positive for *Lm* and the establishment did not hold or maintain control, EIAOs are to immediately contact their DO through their supervisory chain of command. The DO is to take appropriate administrative action and contact the Recall Management and Technical Analysis Division (RMTAD). As appropriate, FSIS will request a recall or detain all RTE products represented by the *Lm* positive sample.

5. IPP are to verify that the establishment adulterated RTE production lot was either reprocessed by the establishment using a lethality treatment that has been validated to achieve at a least a 5 log reduction of *Lm* in that product, or it was destroyed.

X. DATA ANALYSIS

The Office of Public Health Science (OPHS), OPARM, and the Office of Policy and Program Development (OPPD) will analyze data from the RLm sampling program on a quarterly basis. OPARM posts quarterly updates to the FSIS Establishment-Specific Datasets: Laboratory Sampling Data webpage, which includes RLm sampling data, and can be found at: https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/data/datasets-laboratory-sampling. OPPD will evaluate the RLm sampling program to assist the Agency in informing future policy decisions. OPARM will perform data analyses as needed to evaluate trends to inform agency decision-making. OPPD, OPARM, and OPHS will collaborate, as needed.

XI. QUESTIONS

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

NOTE: Refer to FSIS Directive 5620.1, *Using askFSIS*, for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development