MSA DIRECTIVE	10,240.5, Revision 4	11/2/2022

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 the Routine Risk-based *Lm* (RLm) sampling program. The RLm sampling program includes 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 to Central Office (DO) personnel and EIAOs for scheduling RLm sampling.

B. MSA is revising this directive to provide EIAOs with instructions for performing RLm sampling in establishments that temporarily alter their routine practices. In addition, this directive provides EIAOs with instructions for collecting product samples under the RLm sampling program. Under this program, MSA has increased the number of product samples from 3 to 5 per unit. In addition, this directive provides new instructions for submitting samples when interventions such as high-pressure processing (HPP) are applied.

II. CANCELLATION

MSA 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

III. BACKGROUND

A. Under 9 CFR part 430, post-lethality exposed (PLE) 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 RLm 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. MSA has determined that some establishments may 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 the Agencies ability to assess the safety of the product. This directive provides EIAOs with instructions for taking action in establishments that change practices.

IV. EIAO RESPONSIBILITIES FOR RLm SCHEDULING

A. EIAO Responsibilities for RLm Sample Scheduling

1. When scheduling a RLm with a routine FSA, the EIAO is to:

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

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

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

   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.

   Note: EIAOs will coordinate with the MSA Central Office (CO) to obtain supplies. EIAO's will notify the CO to schedule with the Laboratory, at least two weeks in advance and to prepare and send a RLm Letter to the establishment one week in advance.

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

a. Collect samples based on establishment size;

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

    b. 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 MSA- regulated post-lethality exposed RTE 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 meat or poultry product sampled, EIAOs are to collect one brine or ice water sample per unit sampled either as a FCS or NFCS. See section IV.A.1.c (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).

3. When requesting supplies, EIAOs are to coordinate with the MSA CO:

a. Location/address to send the supplies;
b. Requests for special supplies (e.g., smaller gloves or larger shipping containers, if needed; and
c. Requests for brine or ice water sampling supplies, if needed.

4. At least 1 week before the RLm sample collection date, the EIAO is to notify establishment management by certified Entrance Letter that the Agency has scheduled an RLm collection activity at that establishment.

The EIAO is to perform the following actions prior to sampling:

a. Provide a copy of the Entrance Letter to Establishment Management and review its contents.

b. Confirm that the establishment will be producing post-lethality exposed RTE product on the day RLm sampling is scheduled and is planning to implement its documented routine production,

Sanitation Standard Operating Procedures (Sanitation SOPs) and food safety practices;

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

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

e. Strongly recommend to establishments that they should consider holding or controlling RTE products that could be implicated by product samples that MSA intends to collect and test for pathogens, or product that may have passed over direct FCSs that MSA intends to swab and test for pathogens.

NOTE: See section VI below for instructions for EIAOs in establishments that alter routine practices during RLm sampling.

V. EIAO SAMPLING PROCEDURES UNDER THE RLm SAMPLING PROGRAM

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

B. EIAOs are to conduct the RLm 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 RLm sampling, EIAOs are to conduct an FSA in accordance with MSA Directive 5100.1.

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 line using the instructions in a and b below;

a. Select product from the highest-risk *Lm* control alternative (Risk: Alternative 3 > Alternative 2b > Alternative 2a > 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 1. 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 100 grams (4 ounces) of PLE, RTE 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 lab to see if a larger shipping container is available;

4. Include a completed MSA 50-1 form for each of the five product samples. If it is necessary to send a unit of product samples in multiple boxes, EIAOs are to include a copy of the completed MSA 50-1 form in each box. Write "photocopy" on each copy of the original form and number each box (e.g., 1 of 2 and 2 of 2). The original form must be included in one of the boxes; and

E. For food contact surface (FCS) 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 (non-food contact surface-NFCS) 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 RLm, the EIAO can still sample that line, as long as the establishment is producing some MSA 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 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)).

F. For environmental samples (NFCS), EIAOs are to:

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

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

G. Place all FCS swabs together in one new plastic bag and place all NFCS swabs together in a second new plastic bag. Close and seal the bags with tape and then apply the MSA security sticker/tape.

H. MSA 50-1 forms are placed, taped and sealed in a separate plastic bag and secured with an additional MSA security sticker/tape.

I. Frozen gel packs are placed in the bottom of the shipping container, and then packages of swabs, product and labels are placed on top.

J. EIAO personnel shall submit the samples to the laboratory immediately.

Note: The shipping container must be kept refrigerated prior to being picked up by the selected carrier. The laboratory requires that the swab samples to be tested within three days of the sample being collected.

VI. EIAO ACTIONS IN ESTABLISHMENTS THAT ALTER ROUTINE PRACTICES DURING AN RLm

A. Establishments may 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 the Agencies 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 RLm;

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., Alternative 3, sliced deli product); and not using particular equipment that previously has tested positive.

C. Such practices can interfere with MSA's assessment of routine conditions or corrective actions at the establishment and may limit MSA's ability to determine whether post-lethality exposed RTE meat and poultry products are not adulterated as required by the Texas Meat and Poultry Inspection Act. 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 RLm, 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 this in the MSA-20a and include the date of the notification, and the reason the change was made. The EIAO is to consider and document–the following issues:

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 RLm sampling, if available. If similar product is not available, the EIAO is to reschedule the RLm 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 RLm, if possible. If the EIAO is unable to assess the program changes, he or she is to reschedule the RLm; 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 reschedule the sampling for the next time when the RTE products is being produced.

E. On the day of the RLm sampling, 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 Policy, Standard and Quality Assurance – Meat Group Manager.

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 RLm) 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 MSA 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 RLm) 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 RLm 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 contact the Meat Group CO.

G. If the EIAO is unable to collect RLm 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 CO may determine that further actions are warranted. These may include the following:

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

2. The CO may issue a Notice of Intended Enforcement or Notice of Violation, including Emergency Suspension, in situations where MSA personnel have found insanitary conditions at the establishment, or where MSA personnel have found that the food safety system is inadequate, in accordance with Texas Health and Safety Code (HSC) Section 433.100

VII. EIAO SAMPLE SUBMISSION RESPONSIBILITIES

A. For sample submission, the EIAO is to:

1. Follow the instructions in MSA 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 during 1st shift Monday through Wednesday; or

   b. Submit samples as soon as possible if collected during 2nd shift, Monday through Wednesday. 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 to the laboratory, the EIAO is to submit the collected samples with a corresponding MSA 50-1 form.

C. The laboratory will discard samples with incomplete forms.

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. The EIAO is to communicate with the IPP and Circuit Manager (CM) 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 CM 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 CM 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 MSA Directive 10,200.1, 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 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.

E. 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.

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

1. If MSA 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 strongly encouraged to hold or control shipments of RTE products containing meat or poultry products pending the results of MSA product and food contact surface testing.

3. If the EIAO finds that the establishment did not hold or maintain control of product when MSA 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 MSA 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 MSA Directive 5100.1; and

4. Generally, if MSA 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.

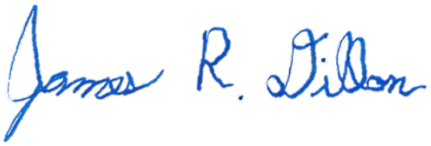
5. If MSA obtains an RLm product or FCS sample positive for *Lm* and the

establishment did not hold or maintain control, EIAOs are to immediately contact the CO through their supervisory chain of command. The CO is to take appropriate administrative action and contact the Recall Management. As appropriate, MSA will request a recall or detain all RTE products represented by the *Lm* positive sample.

6. 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.

IX. QUESTIONS

Refer questions through supervisory channels.



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Attachment 1

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.