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

FSIS DIRECTIVE

10,240.5
Revision 2

2/3/09

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

This directive provides instructions to Enforcement, Investigations and Analysis Officers (EIAOs) for collecting samples under the Routine Risk-based *Lm* (RLm) Sampling Program. In addition, this directive provides instruction to district office personnel on scheduling RLm sampling. The sampling program includes the collection of food contact, environmental (non-food contact), and product samples, as well as completing a Food Safety Assessment (FSA). In addition, the Agency will now include brine sampling as part of the RLm Sampling.

Key Points Covered

- *Changes to the Sampling Policy*
- *Sample collection responsibilities of the EIAO under the RLm Sampling Program*
- *Enforcement*

II. CANCELLATION

FSIS Directive 10,240.5, Revision 1, Enforcement, Investigations, and Analysis Officer (EIAO) Assessment of Compliance With The *Listeria monocytogenes* (*Lm*) Regulation and Introduction Of Phase 2 Of The *Lm* Risk-Based Verification Testing Program, dated 3/15/06

III. REASON FOR REISSUANCE

This directive is being reissued to provide direction to EIAOs regarding changes to the RLm Sampling Program. The changes include:

1. a change in the number of sample units collected depending on the establishment size;

2. the addition of brine sampling;

3. instructions to randomly select the shift on which to collect the samples;

4. the removal of the requirement to submit intact samples after pre-shipment review; and

5. the removal of the requirement to complete and submit the validation checklist.

IV. REFERENCES

21 U.S.C. parts 453 et seq. and 601 et seq.
9 CFR parts 416, 417, 430, and 500
FSIS Directive 5100.1, Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology
FSIS Directive 7355.1, Use of Sample Seals for Program Samples and Other Applications
FSIS Directive 8080.1, Recall of Meat and Poultry Products
FSIS Directive 10,200.1, Accessing Laboratory Sample Information Via LEARN
FSIS Directive 10,300.1, Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact and Environmental Surfaces for *Listeria monocytogenes*

V. BACKGROUND

On June 6, 2003, FSIS published an interim final rule (68 FR 34207) that amended its regulations to require that official establishments that produce certain ready-to-eat (RTE) meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *Lm*. In addition, the interim final rule states that RTE product is adulterated if it contains *Lm,* or if it comes into direct contact with a food contact surface that is contaminated with *Lm*.

Through the RLm Sampling Program, EIAOs verify that an establishment's food safety systems are controlling *Lm* by collecting 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, when headquarters schedules RLm sampling, EIAOs are to complete an FSA to assess whether the food safety systems are controlling *Lm* in establishments producing RTE post-lethality exposed products.

Under the previous version of FSIS Directive 10,240.4, Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes* (*Lm*) Regulation and Introduction of Phase 2 of the *Lm* Risk-Based Verification Testing Program, and under the previous version of FSIS Directive 10,240.5, Enforcement, Investigations and Analysis Officer (EIAO) Assessment of

Compliance with the *Listeria monocytogenes* (*Lm*) Regulation and Introduction of Phase 2 of the *Lm* Risk-Based Verification Testing Program, EIAOs were to collect RTE product samples but not to send them to the laboratory until the establishment completed pre-shipment review for the sampled lot. However, if the establishment collected a sample from the same production lot that EIAOs sampled, and the establishment found its sample positive for *Lm*, the establishment likely would not complete pre-shipment review for the product until there had been proper disposition of the product. Consequently, under the former policy, EIAOs spent work time collecting samples that FSIS laboratories did not analyze, and for which FSIS did not obtain *Lm* test results.

VI. NEW POLICY

A. With the issuance of this directive, EIAOs are not to wait until the establishment completes pre-shipment review before submitting RTE product samples to the laboratory for *Lm* testing. EIAOs are to submit the RTE product samples after the establishment has completed all interventions. If an establishment has any intervention based on microbiological test results, EIAOs are not to wait for the establishment to receive those results before sending the sample to the laboratory. EIAOs, in many cases, will be collecting and submitting FSIS samples to the laboratory before the establishment completes pre-shipment review.

B. From September 2008-June 2009, for the RLm Sampling Program, the Agency will select establishments from a list of those establishments producing 95% of the volume of meat and poultry products. Previously, establishments were selected using a risk-based algorithm. The risk-based algorithm ranked the establishments based on the following factors: the alternative chosen by the establishment for its post-lethality exposed product, the type and volume of RTE product produced, and the establishment's *Lm* testing history. Beginning in July 2009 the Agency will increase the number of RLms to meet the Agency goal of at least one FSA in each establishment every four years.

C. EIAOs are to sample brine as part of the RLm sampling program at establishments that use brine to chill product (see the sampling method set out in FSIS Directive 10,300.1, Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact, and Environmental Surfaces for *Listeria monocytogenes*). Brine samples are either food contact or environmental samples. If the brine comes in direct contact with unpackaged product, or with product in a permeable or semi-permeable casing, then the brine sample is considered a food contact surface sample. If the product is in an impermeable casing or otherwise packaged, the brine sample is an environmental surface sample. In addition, EIAOs will need to consider whether the establishment reuses brine in its process when considering which product may be affected by a positive sample result.

D. In the previous issuance of this directive, the number of units collected was based on the number of lines in the establishment with a maximum of 5 units. The number of units to collect under this directive is based on establishment size and the need to more effectively allocate laboratory resources. In this directive,

EIAOs are to collect 3 sample units from large establishments, 2 sample units from small establishments, and 1 sample unit from very small establishments.

VII. EIAO RESPONSIBILITIES FOR COLLECTING SAMPLES UNDER THE RLm SAMPLING PROGRAM

A. RLm Scheduling

1. Districts will receive the Scheduling Memo via e-mail from the RLm Workgroup 6 weeks before the month in which the sampling is scheduled to begin. The Scheduling Memo lists:

a. the establishments the Agency will sample;

b. the establishment size; and

c. the FSIS laboratory assigned to analyze the samples.

2. After receiving the scheduling memo, the District Manager (DM) or designee is to assign the RLm sample collection activity to an EIAO trained in Intensified Verification Testing (IVT) (see Directive 10,300.1) and select the day of the week on which sampling is to occur.

3. The DM is to schedule an FSA at the establishment in conjunction with the RLm sampling. The DM is to schedule an FSA and RLm sampling so that the EIAO receives the RLm sampling results before he or she completes the FSA, so that he or she may share the results with the establishment at the exit conference.

NOTE: EIAOs may direct questions regarding the RLm Sampling Program to the RLm Sampling Questions Mailbox.

4. In conjunction with performing the RLm sampling, EIAOs are to conduct an FSA in accordance with FSIS Directive 5100.1. EIAOs may find useful information in the "Compliance Guidelines to Control *Listeria monocytogenes* in Post Lethality Exposed Ready-to-Eat Meat and Poultry Products."

http://www.fsis.usda.gov/regulations_&_policies/Compliance_Guides_Index/index.asp

B. EIAO Responsibilities for RLm Sample Scheduling

1. Within the 6 week timeframe before the month scheduled for sampling, the EIAO is to:

a. randomly select the 1st, 2nd, or 3rd shift Monday through Thursday, or the 1st shift Friday for collection of RLm samples within the week identified in the monthly RLm Scheduling Memo;

b. contact the Inspector-In-Charge (IIC) at the establishment to inform

him or her that the Agency has scheduled an RLm sample collection activity in conjunction with an FSA, how the EIAOs conduct the sampling, and the day in which the RLm sampling will occur. Find out the following information from the IIC:

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 to chill product. EIAOs are to obtain information to determine if the brine comes in direct contact with post-lethality exposed product, or if the brine is used for product in an impermeable casing.

NOTE: A standard "sample unit" is 10 food contact surface swabs, 5 environmental swabs, and 3 intact product samples. EIAOs are to collect brine samples as an additional, separate unit. If the establishment uses brine, collect 1 brine 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). The EIAO is to collect a maximum of 3 brine samples per establishment, if available on the lines sampled. Generally, an EIAO is to collect 1 sampling unit for each post-lethality exposed RTE line sampled.

c. determine the number of sample units to collect. Establishment size is based on establishment categories in the HACCP preamble (61 FR 38806); sizes are based on the number of employees. Establishment 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. EIAOs are to:

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; and

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

d. send the following information to the RLm Sample Scheduling Mailbox via Outlook at least 2 weeks before the week sampling is scheduled:

i. sample collection date and production shift;

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

iii. field laboratory designated on the monthly RLm Scheduling Memo;

iv. establishment number;

v. contact name and phone number;

vi. location to send the forms and supplies (FedEx does not deliver to a post office box);

vii. requests for special supplies (e.g., larger gloves) or large shipping containers, if needed; and

viii. requests for brine sampling supplies (requires gloves and a collection container), and forms (RLMCONT if the brine comes in direct contact with post-lethality exposed product or RLMENV if the brine is used for product in an impermeable casing), if needed.

NOTE: The Sample Scheduling Mailbox forwards the information to both the Outlook Sampling Supplies Laboratory and the Sampling Forms-Headquarters mailboxes.

2. Within 2 weeks after submitting the information to the RLm Sample Scheduling mailbox, the EIAO should receive the forms and supplies. If forms are lost, the EIAO can send an e-mail to the Sampling Forms Headquarters address in Outlook to request additional forms as needed.

3. At least 1 week before the RLm sample collection date, the EIAO is to notify establishment management that the Agency has scheduled an RLm collection activity at that establishment. The EIAO is to:

a. allow the establishment time to hold all product represented by the sample. If the establishment uses brine, the EIAO may need to allow more time for the establishment to hold all product represented by the sample;

b. explain how EIAOs conduct the sampling;

c. encourage the establishment to be prepared to hold all affected product represented by the samples; and

d. advise the establishment that if it fails to hold all affected product represented by the positive sample results, the product may be subject to a recall per FSIS Directive 8080.1.

C. Sample Collection Responsibilities for the EIAO

1. For sample collection, the IVT trained EIAO is to:

a. follow the methodology for collecting product, food contact, environmental, and brine samples according to FSIS Directive 10,300.1. EIAOs may collect brine samples as either environmental or food contact samples. 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;

b. collect intact samples of products associated with the same production day and shift represented by the food contact and environmental surface swabs. In all cases, for each line tested, EIAOs are to randomly collect a unit consisting of 3 intact samples of post-lethality exposed products, 10 food contact surface swabs, and 5 environmental swabs. EIAOs are to collect brine samples as a separate additional sample;

NOTE: 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. The EIAO is to sample contact surfaces on the line under the RLm CONT project code and state that the line was not in use under block 28. EIAOs are to sample environmental surfaces as RLMENV. If an establishment does not produce product on a particular line on the day an EIAO conducts an RLm, EIAOs are to consider whether an establishment conducted a full cleaning per its Sanitation SOP on equipment in the establishment when reviewing RLm sample results.

c. collect food contact and environmental (non-food contact) samples using the following guidelines:

i. EIAOs are to collect some food contact surface swabs at the end of pre-operational sanitation activities, if possible, but before the start of production. However, EIAOs are to collect more food contact surface swabs during operations, ideally at the start of routine breaks scheduled by the establishment rather than during pre-operational sanitation;

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

iii. collect 1 brine sample per unit if the establishment uses brine to chill product (e.g., if the establishment is operating 3 lines with 2 of the lines having brine chillers, then the EIAO would collect 3 units with 2 of the units having brine samples representing the 2 brine chillers) as part of the RLm sampling (see FSIS Directive 10,300.1).

d. safeguard the security of samples when preparing, storing, packaging, and submitting samples for testing (see FSIS Directive 7355.1, Use of Sample Seals for Program Samples and Other Applications).

D. Sample Submission Responsibilities of the EIAO

1. For sample submission, the EIAO is to:

a. submit samples without waiting for the establishment to conduct preshipment review. For product samples, EIAOs are to collect the sample after the establishment has completed the production lot (as defined by the establishment) and applied all interventions, except for a microbiological testing intervention. If the establishment intends to test the product for *Lm* before

completing pre-shipment review, EIAOs are not to wait for the establishment to receive the test results. Use the following guidelines:

i. submit samples the same day if collected during 1st shift (i.e., dayshift); or

ii. submit samples using the first available FedEx pick up if collected during 2nd or 3rd shift, Monday through Thursday. EIAOs are to store the samples refrigerated when holding the samples overnight for shipping;

b. when submitting collected samples, submit the type of sample collected (e.g., food contact) with a FSIS Form 10,210-3 having the appropriate corresponding sample project code in block 14, (e.g., RLMCONT) to the laboratory; and

c. complete all requested information in Part II as specified in block 18 of FSIS Form 10,210-3. The laboratory will discard samples with incomplete forms.

VIII. ENFORCEMENT

Sample Collection Results and FSA

1. The EIAO is to:

a. follow FSIS Directive 10,200.1, Accessing Laboratory Sample Information Via LEARN, for obtaining test results through the LEARN System; and

b. immediately report test results to establishment management.

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

3. 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. However, if that product is subjected to a validated post-lethality treatment at a point in the process after the surface that tests positive, product when distributed may not be adulterated.

NOTE: If a post-lethality exposed RTE environmental (non-food contact) surface sample collected by EIAOs tests positive for *Lm*, product may have been produced under insanitary conditions.

4. Follow the instructions in FSIS Directive 5100.1 for making recommendations to the DM or designee regarding enforcement actions. In addition, EIAOs are to take the following into consideration when making recommendations:

a. If FSIS finds the product positive, and the establishment tested the product, EIAOs are to check establishment *Lm* test results to determine whether

the establishment also found the sampled product positive for *Lm*.

b. If 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, and FSIS and the establishment both found the product positive for *Lm*, EIAOs are to verify that the establishment performs the appropriate corrective actions as part of the FSA.

5. Contact the District Recall Officer (DRO) following the directions in FSIS Directive 8080.1 if any adulterated product in the sampled lot has entered commerce.

IX. DATA ANALYSIS

The Office of Public Health Science (OPHS), the Office of Food Defense and Emergency Response (OFDER), and the Office of Policy and Program Development (OPPD) will analyze data from the RLm Sampling Program in accordance with the FSIS Data Analysis Plan for the RLm Sampling Program. OPHS will evaluate the results from the RLm Sampling Program for incorporation into the *Lm* risk assessment model. In addition, OPHS will report results on the FSIS OPHS Microbiology Data Collection and Report internet site. In conjunction with OPHS and OPPD, OFDER will assess data from the RLm Sampling Project and will publish an annual technical report to the FSIS internet. OPPD will evaluate the program to assist the Agency in informing future policy decisions. OPPD, OFDER, and OPHS will collaborate as needed.

Direct all technical questions to the Policy Development Division and all sampling questions to the Risk and Innovations Management Division at 1-800-233-3935 or submit your question through *askFSIS* at http://askfsis.custhelp.com.

Assistant Administrator
Office of Policy and Program Development

PROJECT CODE AND NAME	**RLMCONT –** Routine sampling of food contact surfaces during the production of Ready-to-Eat meat and poultry products
SAMPLE COLLECTOR	FSIS personnel trained in IVT aseptic sample collection techniques.
PRODUCT TO SAMPLE/SAMPLE SITE SELECTION	Swab surfaces that have direct contact with highest risk post-lethality exposed RTE product in the RTE production area (e.g., conveyor belts, cooler storage racks, luggers, slicers, peelers, loaders, table tops). Brine samples can be considered contact (if the brine comes in direct contact with post-lethality exposed product) or environmental (if the brine is used for product in an impermeable package). **NOTE:** Gloves or garments worn by employees may be sampled if directly observed by FSIS to contact food.
ANALYZED FOR	*Listeria monocytogenes*
SPECIAL COLLECTION INSTRUCTIONS	Collect one sample for each form. Randomly select either the 1st, 2nd, or 3rd shift Monday through Thursday or day shift on Friday, within the 1–week window designated on the RLm Scheduling Memo. In all cases, the RLm samples (RLMPROD, RLMCONT, RLMENVR) must be collected on the same production day and shift. 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	Complete part II of the 10,210-3 form. Blocks 19, 20, 22, and 28-32 are required. 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. If no sample is collected, complete block 33 and mail the form to the laboratory listed in block 9.
ESTABLISHMENT NOTIFICATION	Give establishment management sufficient notification of sampling so that the product represented by the sample may be held. Holding product is at the option of the establishment.
SPECIAL SHIPPING INSTRUCTIONS	Ship sample as soon as collected during the next available FedEx pickup to the laboratory designated in the RLm Scheduling Memo. Identify sample and seal according to FSIS Directive 7355.1, Rev. 2. Ship refrigerated. Use sufficient frozen coolant to keep samples cold during transit. Ship samples Monday through Friday 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

PROJECT CODE AND NAME	**RLMENVR -** Routine sampling of environmental (non-food contact) surfaces during the production of Ready-to-Eat meat and poultry products.
SAMPLE COLLECTOR	FSIS personnel trained in IVT aseptic sample collection techniques.
PRODUCT TO SAMPLE/SAMPLE SITE SELECTION	Swab surfaces having indirect or potential contact associated with the highest risk post-lethality exposed RTE product lines in the RTE production area (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).
ANALYZED FOR	*Listeria monocytogenes*
SPECIAL COLLECTION INSTRUCTIONS	Collect one sample for each form. Randomly select either the 1st, 2nd, or 3rd shift Monday through Thursday or day shift Friday, within the 1-week testing window designated on the RLm Scheduling Memo. In all cases, the RLm samples (RLMPROD, RLMCONT, RLMENVR) must be collected on the same production day and shift. 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	Complete part II of the 10,210-3 form. Blocks 19, 20, 22, and 28-32 are required. 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. If no sample is collected, complete block 33 and mail the form to the laboratory listed in block 9.
ESTABLISHMENT NOTIFICATION	Give establishment management sufficient notification of sampling. Generally, a positive result will not implicate product, but holding product is an establishment option.
SPECIAL SHIPPING INSTRUCTIONS	Ship sample as soon as collected during the next available FedEx pickup to the laboratory designated in the RLm Scheduling Memo. Identify sample and seal according to FSIS Directive 7355.1, Rev. 2. Ship refrigerated. Use sufficient frozen coolant to keep samples cold during transit. Ship samples Monday through Friday 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

PROJECT CODE AND NAME	**RLMPROD –**Sampling of intact Ready-to-Eat meat and poultry product concurrently with testing of food contact or environmental (non-food contact) surfaces.
SAMPLE COLLECTOR	FSIS 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 1) Deli-meats that are sliced in the federal establishment 2) Deli-meats shipped whole from the federal establishment (this does not include cook-in-bag products; only those exposed post-lethality) 3) Hotdog Products 4) Deli salads, pâtés, and meat spreads 5) Fully cooked type products (other than cooked products in 1-4 above) 6) Fermented products 7) Dried products 8) Salt-cured products 9) Products labeled as "Keep Frozen" **NOTE:** Do not sample the same lot of a product for more than one sample collection project (RLm, ALLRTE, and RTE001).
ANALYZED FOR	*Listeria monocytogenes*
SPECIAL COLLECTION INSTRUCTIONS	Collect only intact samples. Randomly select either the 1st, 2nd, or 3rd shift Monday through Thursday or day shift on Friday, within the 1-week testing window designated on the RLm Scheduling Memo. In all cases, the RLm samples (RLMPROD, RLMCONT, RLMENVR) must be collected on the same production day and shift. Collect enough intact product so that at least ONE pound of meat or poultry 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 lab to see if a larger shipping container is available.
SAMPLE REQUEST FORM	Complete part II of the 10,210-3 form. Blocks 19, 20, 22, and 28-32 are required. Place the sample request 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. If no sample is collected, complete block 33 and mail the form to the laboratory listed in block 9.
ESTABLISHMENT NOTIFICATION	Give establishment management sufficient notification of sampling so that the product represented by the sample may be held. Holding product is at the option of the establishment.
SPECIAL SHIPPING INSTRUCTIONS	Ship immediately after product represented by the sample has passed all establishment interventions except microbiological testing. Identify sample and seal according to FSIS Directive 7355.1, Rev. 2. Ship refrigerated. Use sufficient frozen coolant to keep samples cold during transit. Ship samples Monday through Friday 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