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

FSIS DIRECTIVE

10,240.5 | 3/15/06

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

I. PURPOSE

This directive provides direction to Enforcement, Investigations, and Analysis Officers (EIAOs) and Public Health Veterinarians (PHVs) trained in the EIAO methodology for collecting samples under the **new** Routine *Lm* Risk-Based (RLm) sampling program. This new testing program is referred to as the Food Contact, Environmental (Non-Food Contact), and Intact Product Verification Testing Program which throughout this issuance will be abbreviated as RLm. This directive also provides EIAOs/PHVs instructions for assessing an establishment's food safety system for compliance with 9 CFR Part 430. In addition, this directive provides EIAOs/PHVs with instructions for verifying the validation data associated with the alternatives selected by the establishment.

NOTE: This directive contains all the information that EIAOs/PHVs need to assess the establishment's compliance with the sections of 9 CFR 430 relating to the control of *Listeria monocytogenes* (*L. monocytogenes*) in post-lethality exposed Ready-To-Eat (RTE) meat and poultry products.

Key Points Covered

- *EIAO/PHV assessment of compliance with 9 CFR part 430*
- *Sample collection responsibilities of the EIAO/PHV for the **new** RLm sampling program*
- *Enforcement*

II. (RESERVED)

III. (RESERVED)

IV. REFERENCES

Title 21 United States Code (U.S.C.) parts 453 et seq. and 601 et seq.
Title 9 Code of Federal Regulations (CFR) Part 416
Title 9 CFR Part 417
Title 9 CFR Part 430
Title 9 CFR Part 500
Food Safety and Inspection Service (FSIS) Directive 5100.1, dated 9/30/05
FSIS Directive 7355.1, Revision 2, dated 12/03/02
FSIS Directive 8080.1, Revision 4, Amendment 3, dated 3/2/06
FSIS Directive 10,200.1, dated 7/19/01

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 post-lethality exposed RTE meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *L. monocytogenes*. In addition, the regulation adopted in this interim final rule, 9 CFR Part 430, states that RTE product is adulterated if it contains *L. monocytogenes,* or if it comes into direct contact with a food contact surface that is contaminated with *L. monocytogenes*. EIAOs/PHVs will verify that an establishment's food safety systems are controlling *L. monocytogenes* by supplementing and expanding the traditional collection of routine intact product samples with the collection of routine food contact and environmental (non-food contact) surface swabs during the production of RTE meat and poultry products that are exposed to the environment following the lethality treatment.

New Testing Programs

1. The new RLm testing program consists of the following sampling projects:

a. RLMCONT – the routine risk-based testing of surfaces that have direct contact with RTE product in the RTE production area, e.g., conveyor belts, cooler storage racks, luggers, slicers, peelers, loaders, table tops (see attachment 1);

b. RLMENVR – the routine risk-based testing of environmental (non-food contact) surfaces in the RTE production areas, e.g., floors, drains, walls, air-vents, overhead structures (see attachment 2); and

c. RLMPROD – the routine risk-based testing of intact product samples collected concurrently with food and environmental contact surface swabs throughout the selected production shift (see attachment 3).

2. Unless otherwise directed, all samples collected for the *L. monocytogenes* risk-based project codes RLMCONT, RLMENVR, and RLMPROD will be analyzed for *L. monocytogenes* only.

3. Samples collected by the EIAO under RLm are limited to establishments subject to 9 CFR Part 430 (i.e., establishments in which RTE products are exposed to the post-lethality environment). FSIS will select establishments for testing based on information provided in FSIS Form 10,240-1, *Production Information on Post-Lethality Exposed Ready-To-Eat Product*s. Under the RLm testing program, FSIS expects to sample more frequently at establishments that produce post-lethality exposed products that the Agency considers to present a relatively high risk than it will at those that produce product that the Agency considers to present a low risk. Generally, those establishments electing to use Alternative 3 control measures will be sampled at the highest frequency. Samples will be collected at a decreasing frequency in establishments electing to use Alternative 2, Choice 2; Alternative 2, Choice 1; and Alternative 1 (see attachment 4 and for more information on the risk-based methodology see attachment 5).

VI. EIAO ASSESSMENT OF COMPLIANCE WITH 9 CFR PART 430

A. Risk Based Testing

The EIAO/PHV should understand the public health risks associated with post-lethality exposed RTE products and processes. Some products and processes pose greater potential risks for *L. monocytogenes,* which can cause human illness and disease in the form of listeriosis than others. For example, product produced under Alternative 3 may present a greater risk than product produced under Alternative 2, and product produced under Alternative 2 may present a greater risk than product produced under Alternative 1. Deli product and hotdog product may present a greater risk than most other product within each alternative. When considering how to focus verification activity within an establishment when the establishment makes a variety of post-lethality exposed RTE products, more attention should be allotted to the products and processes that present the greatest potential for causing illness and disease.

EIAOs/PHVs should follow the methodology in FSIS Directive 5100.1 when conducting a Food Safety Assessment (FSA).

B. Post-Lethality Treatment Assessment

To assess whether establishments have appropriately incorporated the use of a post-lethality step (Alternative 1 or Alternative 2, Choice 1) in the HACCP plans, EIAOs/PHVs should review, as part of the comprehensive food safety system assessment, the establishment's HACCP plan and HACCP supporting documentation to verify that the post-lethality treatment has been adequately validated, so that it prevents, eliminates, or reduces the pathogens of concern on the product to an undetectable level.

C. Validation Assessment

If the establishment has based its validation on challenge studies or research articles from scientific publications, the EIAOs/PHVs should assess whether conditions in the establishment, such as ingredients, concentration of antimicrobial agent, pH, and moisture, are valid for that process in the establishment. If the conditions are not valid, does the establishment have documentation on file to support that the controls in place are adequate to prevent, eliminate, or reduce to undetectable levels pathogens on the product?

D. Antimicrobial Agent or Process Assessment

With regard to the use of an antimicrobial agent or a process used to suppress or limit the growth of *L. monocytogenes* throughout the shelf life of the product (Alternative 1 or Alternative 2, Choice 2), the EIAO/PHV should assess the documentation for whichever program the use of the antimicrobial agent or process is incorporated (i.e., HACCP or Sanitation Standard Operating Procedures (Sanitation SOPs) or other prerequisite program), to determine whether the documentation demonstrates that adulterated product will not be produced.

E. Testing Assessment

If an establishment chooses Alternative 2, Choice 2 or Alternative 3, the EIAO/PHV should assess the adequacy of how the establishment:

1. tests food contact surfaces in the post-lethality processing environment to ensure that the surfaces are sanitary and free of *L. monocytogenes* or of an indicator organism,

2. identifies the conditions under which the establishment implements hold-and-test procedures following a positive test of food contact surfaces *for L. monocytogenes* or of an indicator organism,

3. states the frequency with which the testing is done,

4. identifies the size and location of the sites that are sampled,

5. explains why the testing frequency is sufficient to ensure that effective control of *L. monocytogenes* or of an indicator organism is maintained,

In answering the above questions, the EIAO/PHV should consider:

the sites that are most likely to harbor *L. monocytogenes* or an indicator organism, and

any support for the design of the testing to detect *L. monocytogenes* or an indicator organism.

When the EIAO/PHV completes the FSA, he or she should follow the

directions in FSIS Directive 5100.1 for documenting the FSA on FSIS Form 5000-8 and recommending an enforcement action, if appropriate. The EIAO/PHV should communicate with both their supervisor and establishment management during the FSA. The establishment management should know the outcome of the FSA at the exit meeting.

VII. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES FOR COLLECTING SAMPLES UNDER THE RLm SAMPLING PROGRAM

A. Sample Scheduling for District Office Personnel and EIAO/PHV Responsibilities Prior to Sample Collection

1. Districts should receive the Scheduling Memo (See attachment 6) via e-mail from the Office of Public Health Science (OPHS), to inform them of the establishment selected for the impending RLm sample collection activity. Districts should receive the Scheduling Memo six weeks prior to the month in which the sampling will occur. Each district should randomly select the week the sampling is to occur within the month.

2. After receiving the scheduling memo, the DM or designee is to assign the RLm sample collection activity to an EIAO/PHV trained in Intensified Verification Testing (IVT).

3. The DM should schedule a FSA and the completion of the validation checklist in conjunction with the sample collection activity at an establishment where the RLm sample testing is to be conducted. The validation checklist is to be completed in conjunction with all FSAs conducted in RTE establishments and can be found at the following web address:

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

4. To complete the validation checklist, the EIAO/PHV should follow the instructions found within the validation checklist itself (see link above). The EIAO/PHV should follow the directions in FSIS Directive 5100.1 for conducting the exit conference. The establishment may ask questions regarding the validation checklist during the exit conference and the EIAO/PHV may discuss the validation checklist with the establishment. The EIAO/PHV should scan the completed validation checklist and send it via e-mail to the Program Analysis Staff at the Technical Service Center at mailbox VC430.

5. Within the 6 week timeframe prior to the month scheduled for sampling, the IVT trained EIAO/PHV is to:

a. Randomly select the day Monday through Thursday, or dayshift Friday,

b. Contact the Inspector-In-Charge (IIC) at the establishment to inform him or her that a RLm sample collection activity is scheduled, how the sampling is conducted, and the day in which the sampling will occur. The Consumer

Safety Inspector (CSI) should be present, if possible, in the establishment on the day of sampling. Find out the following information:

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

ii. the number of production lines producing post-lethality exposed RTE products,

iii. which shift operates after pre-operational inspection, that is the shift to be tested

NOTE: A standard "sample unit" is defined as 10 food contact surface swabs, 5 environmental swabs, and 3 intact product samples. Generally, one sampling unit should be collected for each post-lethality exposed RTE line.

c. Determine the number of sample units to collect. EIAOs/PHVs should:

i. only sample a maximum of 5 lines on which post-lethality exposed RTE product is produced. Therefore, a maximum of 5 sample units are collected within any selected establishment. If the establishment has more than 5 lines, product from the higher risk lines should be selected.

ii. sample all lines if the establishment has less than 5 lines on which post-lethality exposed RTE product is produced.

d. Finalize the actual sites for food contact and environmental sampling once the IVT trained EIAO/PHV is on location.

e. Send the following information to the RLm Sample Scheduling Mailbox via Outlook **at least 2 weeks prior** to the date sampling is scheduled. The Sample Scheduling Mailbox forwards the information to both the Sampling Supplies Laboratory and the Sampling Forms-Headquarters mailboxes:

i. sample collection date and production shift,

ii. the number of sample units required based on the number of production lines,

iii. field laboratory designated on the 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); and

vii. request for special supplies (e.g., larger gloves) or large shipping

containers, if needed.

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

7. At least one week prior to the RLm sample collection date, the EIAO/PHV should notify establishment management to:

a. allow the establishment time to hold all product represented by the sample,

b. provide the information that an RLm collection activity is scheduled,

c. explain how the sampling is to be conducted,

d. encourage the establishment to be prepared to hold all affected product represented by the sample, and

e. 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, Revision 4, Amendment 3.

B. Sample Collection Responsibilities for the EIAO/PHV

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

a. Follow the methodology for collecting product, food contact, and environmental samples as taught in the IVT training. The RLm testing should be conducted 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 during the same production day. In all cases, intact samples of 3 post-lethality exposed products must be randomly collected from each line tested throughout the course of the same production day and shift that the food contact and environmental surface sample swabs are collected. The EIAO/PHV should not collect 3 product samples alone. These product samples should be accompanied with food contact and environmental surface sample swabs,

NOTE: The Food and Drug Administration determined that FSIS' standard use of Dey-Engley enrichment broth on food contact surface swabs does not result in unsafe exposure to product, therefore, for the swabbed sites the EIAO/PHV no longer needs to request that the establishment rinse the swabbed surfaces.

c. Collect food contact and environmental (non-food contact) samples

using the following guidelines:

i. More swabs should be collected from food contact surfaces than the number collected from environmental surfaces.

ii. Some food contact surface swabs should be collected at the end of pre-operational sanitation activities but before the start of production. However, more food contact surface swabs should be collected during operations, ideally at the start of routine breaks scheduled by the establishment rather than during pre-operational sanitation.

d. Recommend to establishment management that it hold all product represented by all the samples, and

e. Safeguard the security of samples during preparation, storing, packaging, and submission of samples for testing (see FSIS Directive 7355.1).

C. Sample Submission Responsibilities of the EIAO/PHV

1. For sample submission, the IVT trained EIAO/PHV is to:

a. Always submit food contact and environmental (non-food contact) surface samples to the laboratory designated on the scheduling memo following the time frames below to ensure the viability and integrity of the sample swabs. These samples may be submitted before the establishment conducts pre-shipment review.

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.

b. Submit intact product samples to the FSIS laboratory only **after** the pre-shipment review is completed,

c. 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

d. 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/PHV should:

a. follow FSIS Directive 10,200.1 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 IVT trained EIAO/PHV (after pre-shipment review) tests positive for *L. monocytogenes*, product in the sampled lot is adulterated.

3. If a post-lethality exposed RTE food contact surface sample collected by the EIAO/PHV tests positive for *L. monocytogenes*, product passing over the surface is adulterated. However, if the establishment has a validated post-lethality treatment, product when distributed may not be adulterated.

NOTE: If a post-lethality exposed RTE environmental (non-food contact) surface sample collected by the EIAO/PHV tests positive for *L. monocytogenes*, this may show that product was produced under insanitary conditions.

4. Follow the directions in FSIS Directive 5100.1, Revision 1, for recommendations to the DM or designee regarding enforcement actions. Per the EIAO work methods training, the recommendation should not include both a recommendation of an enforcement action (e.g., NOIE or Suspension) and the recommendation to the CSI that a noncompliance record (NR) be written. If an enforcement action is recommended based on findings in the establishment. The establishment should be informed of the recommendation at the exit conference. The exit conference should promptly occur at the end of the FSA.

5. Contact the District Recall Officer (DRO) following the directions in FSIS Directive 8080.1, Revision 4, Amendment 3, if any adulterated product in the sampled lot has entered commerce.

Contact the TSC at (800) 233-3935 with technical questions.

Assistant Administrator
Office of Policy, Program, and Employee 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). **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 prior to start of operations. 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. A sample box shipped on Fridays must have a Saturday Delivery sticker on it and Saturday Delivery marked on the shipping label to avoid delivery delays and discarded samples. 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. 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. A sample box shipped on Fridays must have a Saturday Delivery sticker on it and Saturday delivery marked on the shipping label to avoid delivery delays and discarded samples. 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 **AFTER** product represented by the sample has passed pre-shipment review. 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. A sample box shipped on Fridays must have a Saturday Delivery sticker on it and Saturday Delivery marked on the shipping label to avoid delivery delays and discarded samples. 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

9 CFR 430.4(b)(1), Alternative 1. Use of a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product and an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

9 CFR 430.4(b)(2), Alternative 2. Use of either a post-lethality treatment (which may be an antimicrobial agent or process) that reduces or eliminates microorganisms on the product OR an antimicrobial agent or process that suppresses or limits the growth of *Lm*.

Choice 1 – An establishment that produces post-lethality exposed product that selects this alternative and chooses to use a post-lethality treatment (which may be an antimicrobial agent) that reduces or eliminates microorganisms on the product

OR

Choice 2 – An establishment that produces post-lethality exposed product and that selects this alternative and chooses to use an antimicrobial agent or process that suppresses or limits growth of *Lm*.

9 CFR 430.4(b)(3), Alternative 3. Use of sanitation measures only.

Risk-Based Methodology

The Agency will utilize a risk-ranking of establishments producing post-lethality exposed RTE meat and poultry product to determine the scheduling of *Lm* testing. This risk ranking is a multivariate equation (algorithm) that is formed by previously developed peer-reviewed risk assessments (FDA-FSIS 2003; FSIS 2003) and the ongoing results from FSIS tests of RTE meat and poultry products. By using the multivariate risk-ranking methodology the Agency ensures that the establishments scheduled for this risk-based sampling program are those with the greatest probability of producing RTE meat and poultry products contaminated by *Lm.*

NOTE: FSIS updated the model used in its 2003 *Lm* Risk Assessment, gathered new data from the regulated establishments, and developed the multivariate equation to rank establishments by individual risk profile.

Once routine environmental sampling has been conducted in an establishment, that establishment will not be eligible for routine scheduling again for a 12-month period. FSIS will seek to limit the burden on those corporations operating more than one establishment by distributing the scheduling of these establishments over time, such that one company likely would not be scheduled for testing in more than one establishment in the same month.

An establishment's risk ranking will be used to allocate sampling resources according to the following hierarchy: 1) RLm sampling projects, RLMCONT, RLMENVR, and RLMPROD (with sampling scheduled in the highest-risk establishments); 2) routine intact product sampling under RTE001; and 3) random sampling under ALLRTE in the remaining RTE establishments.

The Office of Public Health Science (OPHS) will maintain the risk ranking with data from various Agency resources, e.g., information from FSIS Form 10,240-1; the establishment's sample history; findings from completed FSA(s); results/scoring of the validation survey (Procedures for the Evaluation of Establishment Control Programs for *Listeria Monocytogenes*); etc. OPHS will then schedule establishments on a routine basis by focusing on those that pose the greatest risk for *Lm*. The intent is to limit the monthly impact on each district by restricting the total number of establishments scheduled for sampling within each district to a number commensurate with Office of Field Operations and laboratory resources available.

SCHEDULING MEMO TEMPLATE

TO: (Name), District Manager
(City) District Office
(City, State)

FROM: Risk Assessment Division
Office of Public Health Science
OPHS, FSIS

SUBJECT: Notification of Establishments Scheduled for RLm testing

DATE: (m/d/y)

This memo is to notify you that the following establishment within your district has been selected for testing of post-lethality exposed RTE meat and poultry products under the Agency's new RLm program outlined in FSIS Directive 10,240.5.

Est. xxxxx, Establishment Name, City, USA
Est. xxxxx, Establishment Name, City, USA [RAD inserts selected Est.'s]
Est. xxxxx, Establishment Name, City, USA

Districts should receive the Scheduling Memo six weeks prior to the month in which the sampling will occur. Each district should randomly select the week the sampling is to occur within the month.

The samples should be submitted to the [RAD inserts a designated lab] field laboratory.

The RLm sample collection activity will include the following:

1. Performing a food safety assessment, in accordance with FSIS Directive 5100.1, and include the establishment's processes and programs designed to eliminate or reduce the growth of *Lm*.

2. Collecting samples under the following 3 new sample project codes:

- **RLMCONT**, the routine risk-based testing of food contact surfaces that have direct contact with post-lethality exposed RTE product (e.g., conveyor belts, table tops, slicers, peelers, lugger, loaders, cooler storage racks).

- **RLMENVR**, the routine risk-based testing of environmental (non-food contact) surfaces in the RTE production areas, (e.g., floors, drains, walls, air-vents, overhead structures).

- **RLMPROD**, the routine risk-based testing of intact product sample taken concurrently with food contact surface samples (randomly collected throughout the same shift represented by the food contact surface samples).

3. Completing a validation checklist to evaluate the effectiveness of programs used by the establishment to control *Lm* in their post-lethality exposed RTE meat and poultry products.

As a result of the scheduling of establishments in your district, you should assign the RLm sample collection activity to one or more IVT trained EIAOs/PHVs.

Instruct the assigned IVT trained EIAO/PHV to perform the following:

1. contact the establishment management on the sample request form to inform them that: 1) an RLm sample collection activity is scheduled for the following month; and 2) they will be provided sufficient advance notification prior to the day/shift that the sample collection activity will occur to ensure that the establishment can hold all product represented by the sample, and

2. choose a day, Monday through Thursday or day shift on Friday, the RLm sample collection activity is to occur and contact the Inspector-In-Charge (IIC) to inform him or her that the sample collection activity will be conducted on that date.

3. Find out the following information

a. production schedule and types of product produced,

b. the number of production lines producing post-lethality exposed RTE products,

c. which shift operates after pre-operational inspection, that is the shift to be tested.

4. The actual sites for food contact and environmental (non-food contact) sampling can be finalized once on location.

5. order forms and supplies through the RLm Sample Scheduling mailbox on Outlook at least 2 weeks prior to the sample schedule date. Be able to provide the following information:

a. establishment number,

b. sample collection date and production shift to be sampled,

c. number of sample units based on the number of production lines,

d. address where to ship supplies and forms (FedEx does not deliver to

a Post Office box),

e. contact name and phone number, and

f. request for special supplies or large shipping containers, if needed.

6. contact the establishment management on the sample request form to inform them that an RLm sample collection activity is scheduled for the designated day/shift. Recommend the establishment hold all product represented by the sample.

NOTE: The EIAO/PHV should send the above information to the RLm Sample Scheduling mailbox at least 2 weeks prior to the day for sample collection so that the necessary forms and supplies can be ordered and mailed well enough in advance of the date selected for sample collection.

We appreciate your cooperation and assistance in executing this high priority food-safety program. For additional questions, please contact the Technical Service Center.

Thank You!