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

FSIS DIRECTIVE

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INTENSIFIED VERIFICATION TESTING (IVT) PROTOCOL FOR SAMPLING OF PRODUCT, FOOD CONTACT SURFACES, AND ENVIRONMENTAL SURFACES FOR *LISTERIA MONOCYTOGENES*

I. PURPOSE

The purpose of this directive is to provide instructions to Enforcement, Investigation, and Analysis Officers (EIAOs) on collecting product, food contact surface, and environmental (non-food contact surface) samples using the Intensified Verification Testing (IVT) Methodology. The Agency will now include brine sampling as part of the IVT methodology. This document also provides EIAOs with instructions for packing and shipping these samples for testing by Food Safety and Inspection Service (FSIS) laboratories.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

9 CFR part 430
FSIS Directive 5100.1, Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology
FSIS Directive 7355.1, Use of Sample Seals for Laboratory 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 10,210.1, Unified Sampling Form
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
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 or the *Lm* Risk-based Verification Testing Program

V. BACKGROUND

Under 9 CFR part 430, post-lethality exposed ready-to-eat (RTE) products are adulterated if they test positive for *Listeria monocytogenes (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.*

IVT is a sampling protocol for meat and poultry products under which FSIS tests product, food contact surfaces, and environmental surfaces (non-food contact surfaces) for *Lm*. The Agency will typically schedule an IVT for cause, e.g., following an ALLRTE or RTE001 *Lm* positive sample finding or at the discretion of the District Manager. In most cases, an EIAO will conduct the IVT in conjunction with a food safety assessment (FSA), except when an EIAO conducts an IVT during an abeyance of a suspension or a deferral of an enforcement action. In addition, the Routine *Lm* Risk-based Sampling (RLm) Program uses the IVT methodology.

Under directives 10,240.4 and 10,240.5, EIAOs are not to send RTE product samples to the laboratory until the establishment has completed pre-shipment review for the sampled lot. Current policy allows EIAOs to collect RTE product samples from an establishment before the establishment has completed pre-shipment review. However, if the establishment collects a sample from the same production lot that EIAOs sampled, and the establishment finds its sample positive for *Lm*, the establishment likely will not complete pre-shipment review for the product until there has been proper disposition of the product. Consequently, under this current policy, EIAOs spend work time collecting samples that FSIS laboratories do not analyze, and for which FSIS does not obtain *Lm* test results.

VI. NEW POLICY CHANGE

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. Instead, EIAOs are to submit the RTE product samples to the laboratory after the establishment has completed all interventions, except for an intervention based on microbiological test results. If an establishment has any intervention based on microbiological test results, EIAOs are not to wait for the establishment to receive microbiological test 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.

The Unified Sampling Form, FSIS Directive 10,210.1, describes each project and provides instructions for sample collection, completing sample request forms, notifying establishment management of the option to hold the product, and properly packing and shipping samples for product (INTPROD), product contact (INTCONT), and environmental (INTENV) surface samples for *Lm*.

Definitions

Food Contact Surface Sample (INTCONT)

A food contact surface sample is a sample that reflects the condition of a surface of equipment or utensil that comes into direct contact with a post-lethality exposed RTE product. Food contact surface samples are to be taken so that they reveal the conditions under which the establishment processes the sampled lot. Some examples of food contact surfaces include conveyor belts, tabletops, slicer blades, knife blades, chutes, and cooling racks. EIAOs may consider aprons and gloves food contact surfaces if the inspector observes direct contact of the apron or glove with the product.

Environmental Surface Samples (INTENV)

An environmental surface sample is a sample of a surface that would not normally come into contact with the product. Examples of environmental surfaces are floors, drains, walls, overhead structures, equipment, aprons, trucks, or car wheels.

NOTE: Brine samples are either contact or environmental samples. If the brine comes in direct contact with unpackaged product, or with product in a permeable or semi-permeable casing, a sample of the brine is a food contact surface sample. If the product is in an impermeable casing or otherwise packaged, a sample of the brine is an environmental surface sample.

VII. PRE-SAMPLE COLLECTION PLANNING

A. Information Exchange Before Conducting the IVT

1. EIAOs are to contact the Inspector-In-Charge (IIC) at the establishment to inform him or her that the District Office (DO) has scheduled an IVT sample collection activity, how the EIAO will conduct the sampling, and the day on which the sampling will occur. The EIAO is to find out the following information:

a. the production schedule for, and types of, post-lethality exposed RTE products to be produced;

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

c. the number of shifts and the hours of operation of each shift during which the establishment produces post-lethality exposed RTE products; and

d. whether the establishment uses brine to chill the product. If it does, whether the brine comes in direct contact with post-lethality exposed RTE products.

2. EIAOs are to notify the establishment at least 48 hours before IVT sample collection, or if needed, in enough time for the establishment to hold the product but not enough time to alter the routine processes.

B. Determining the Number of Samples to Collect

EIAOs are to determine the number of sample units to collect. EIAOs are to:

1. collect samples in units. A unit consists of 10 food contact surface samples (INTCONT), 5 environmental samples (INTENV), and 3 product samples (INTPROD) per processing line in operation on the day of sampling. Generally, EIAOs are to collect 1 sampling unit for each post-lethality exposed RTE line;

2. collect no more than 5 units (or 90 samples) because of laboratory constraints;

3. sample all lines if the establishment has less than 5 lines on which it produces post-lethality exposed RTE product;

NOTE: If an establishment does not produce product on a particular line on the day an EIAO conducts an IVT, the EIAO can still sample that line. The EIAO is to sample the line under the CONT project code and state that the line is not in use under block 28.

4. if the establishment uses brine, collect 1 brine sample per unit (e.g., if an EIAO is collecting 5 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 5 brine samples per establishment, if available; and

5. finalize the actual sites for food contact and environmental sampling once the EIAO is on location.

C. Notifying the Laboratory and the Office of the Chief Information Officer (OCIO)

EIAOs are to:

1. request sample collection forms and supplies through an e-mail message to the IVT Scheduling Mailbox that forwards the information to both the Sampling Supplies-Western Laboratory and the Sampling Forms-Headquarters Mailboxes. If advance scheduling of the IVT by the DO allows, then EIAOs are to make every effort to contact the laboratory at least 2 weeks before conducting the IVT sampling. EIAOs are to include the following information in the e-mail message:

   a. the scheduled sample collection date and production shift;

   b. the number of sample units required based on the number of production lines;

   c. the establishment number;

   d. the contact name and phone number of the EIAO;

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

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

g. requests for brine sampling supplies, if needed. For sampling of brine, EIAOs will need gloves and a bottle.

NOTE: The OCIO will send EIAOs a separate FSIS 10,210-3 form for each sample the EIAOs are to collect. Use the correct form for the type of sample taken. EIAOs are to identify each sample type by a project code (INTPROD, INTCONT, INTENV) in block #14 (see Unified Sampling Form Directive). EIAOs are not to change the project code (INTPROD, INTCONT, INTENV) on the form. For this reason, EIAOs are to order extra forms for a specific project code for additional samples in advance.

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

VIII. SAMPLE COLLECTION RESPONSIBILITIES FOR THE EIAO

A. Entrance Meeting and other Activities Before Sampling

1. When EIAOs conduct an IVT in conjunction with an FSA, they are to follow the directions in FSIS Directive 5,100.1, Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology, for conducting an entrance meeting.

2. If EIAOs only conduct an IVT because an FSA has recently been conducted, they are to meet with FSIS personnel, if available, and then conduct an entrance meeting with both FSIS personnel and establishment officials.

3. Some of the topics to discuss during the entrance meeting include:

a. an explanation of an IVT (see background);

b. the purpose of the IVT (e.g., positive *Lm* finding, for cause, sanitation issues);

c. a copy of the Entrance Letter to Establishment Management (see attachment 1);

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

e. advising the establishment to hold all affected product represented by the sampling; and

f. advising the establishment that if it fails to hold all affected product represented by positive sample results, the product may be subject to a recall per FSIS Directive 8,080.1, Recall of Meat and Poultry Products.

B. Product and General Sample Information

EIAOs are to:

1. conduct the IVT as early as possible during the FSA, when the DO schedules an IVT in conjunction with an FSA, to facilitate receiving the results before the completion of the FSA report;

2. collect, randomly, intact samples of post-lethality exposed products from each line tested throughout the course of the same production day and shift that the EIAO collects the food contact and environmental surface sample swabs. EIAOs are to take product samples after the lethality step in the final, intact package. In all cases, EIAOs are not to collect product samples alone. EIAOs are to accompany the product samples with food contact and environmental surface sample swabs (see VII. B. for the number of samples to collect).

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

a. for food contact surfaces, collect samples starting closest to the product areas and then moving further out;

b. collect more swabs from food contact surfaces than from environmental surfaces;

c. collect some food contact surface swabs at the end of pre-operational sanitation activities but before the start of production. However, 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.

d. collect operational samples, i.e., during the production shift (including during the breaks), and post-operation samples. EIAOs are to take post-operation samples as quickly after operations end as practicable and before the implementation of establishment sanitation procedures. 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;

e. collect surface samples from areas with recent sanitation problems based on non-compliance records and establishment Sanitation Standard Operating Procedure records;

f. collect surface samples from lines or areas that have tested positive for *Lm* in FSIS or establishment testing;

g. collect environmental surface samples in areas in close proximity to RTE

product lines and from sides of equipment;

h. take into consideration the following additional points that might increase chances of detecting *Lm* when collecting food contact and environmental samples (The following examples are good places to sample):

i. steps between cooking and packing (slicing, dicing, or peeling operations);

ii. movement of personnel and machinery (forklifts, swinging doors, and pallets) from non-RTE areas to RTE areas;

iii. rework, returned product, and any associated areas;

iv. any recent construction activity;

v. structures close to the floor;

vi. areas near water puddles or low areas on the floor;

vii. condensation, drip pans, and evaporator coils;

viii. any recessed or hollow surface areas;

ix. sponges and brushes for cleaning;

x. drains and drain covers;

xi. recent equipment repairs by the establishment;

xii. not in use or stored equipment in RTE areas;

xiii. air ventilation hoods above product conveying routes;

xiv. electrical boxes, gear boxes, and switches on equipment in the RTE area where moisture can collect; and

xv. underneath tables and conveyor belts.

C. Sampling Using SpongeSicles® For Food Contact and Environmental Sampling

EIAOs are to:

1. wash and sanitize their hands to the mid-forearm. The EIAO is to aseptically place a sterile glove on the hand he or she will use for swabbing, by:

a. positioning the glove package so that the L and R (L=left, R=right) are facing the EIAO. When the package is open, the gloves are folded, forming a cuff on the sleeve and lying palm up. Leave them in the package until ready for use;

b. holding the glove for the hand that will be used for swabbing by the inside cuff area. Inserting hand into the glove, palm side up, and lifting the glove from the package.

c. pulling the glove completely on, touching only the fold cuff with your ungloved hand. Do not touch the sterile outside surface of the glove with your ungloved hand. Unroll the fold of the glove (see FSIS Directive 10,230.5 for an illustrated guide on the proper use of sterile disposable gloves). Do not touch any non-sterile surface (clothes, counter tops, or the outside of the Whirl-Pak© bag) with the sterile glove. The other hand can be left ungloved for the manipulation of non-sterile surfaces and materials.

2. using the ungloved hand, open the bag containing the SpongeSicle® by pulling off the clear perforated strip at the top of the bag;

3. pull apart the white tabs to open the mouth of the bag;

4. aseptically pour 9-10 ml of sterile Dey-Engley (D/E) broth into the bag to hydrate the SpongeSicle®, being careful not to contaminate the broth or sponge during the transfer. If the D/E broth is not purple, EIAOs are to discard the tube;

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

5. press the mouth of the bag back together;

6. evenly moisten the SpongeSicle® by using hand pressure on the outside of the bag to massage the sponge;

7. position the SpongeSicle® so that the handle is sticking out of the bag. Press the top of the bag back together around the handle;

8. through the bag, squeeze the excess broth gently out of the sponge. Do not let your hand go past the thumb stop on the handle;

9. carefully take the SpongeSicle® out of the bag by grasping the handle and swab the area selected. EIAOs are to maintain sanitary conditions when sampling and are to collect samples aseptically. Do not let your hand go past the thumb stop on the handle;

10. swab at least a 1' X 1' square of food contact or environmental surface area, if possible;

11. swab the chosen area using firm and even pressure:

a. vertically (approximately 10 times); then

b. flip the sponge and use the other side to swab horizontally (approximately 10 times); then

c. swab diagonally, using the same surface side as you used for horizontal (approximately 10 times);

12. open the bag and insert the sponge portion of the SpongeSicle® back into the bag;

13. grip the SpongeSicle® through the bag and bend the handle of the SpongeSicle® back and forth with slight force, while gripping the sponge through the bag. The stick should break easily within the sponge (do not break the handle at the thumb stop). Discard the broken handle. If the handle is sticking out above the sponge, discard the sample. Take a new sample following the same steps in VIII. C. 2-14;

14. squeeze as much air out of the bag as possible and fold the top of the bag down at least 3 times. EIAOs are to fold in the tabs to lock the fold in place;

15. place a small bar-code identifying label on the bag (primary container);

16. place the primary container (bag with the sponge) into a small sealable plastic bag and the identifying label over the zip of the small sealable plastic bag; and

17. place the bagged sponge inside an insulated sample shipper as soon as possible (see IX. B. for further information on shipping the sample).

D. Liquid Sampling for Brine

EIAOs are to:

1. wash and sanitize their hands to the mid forearm. Wear sterile gloves on both hands when collecting a sample;

2. aseptically pull a 500 ml sterile pitcher (beaker with a handle) from its packaging, being careful not to let the pitcher touch any non-sterile surface, including the exterior of the packaging;

3. open a collection bottle and with the pitcher aseptically transfer 500 ml of the chill water or brine using the gradations on the side of the collection bottle to ensure the proper volume;

4. aseptically add 90 ml of D/E to each sample collected to neutralize chlorine and other disinfectants;

5. tightly cap the collection bottle and gently mix by rotating back and forth;

6. place a small bar-code sticker over the junction between the bottle and cap and place into a small sealable plastic bag and seal the bag; and

7. place the bagged sample inside an insulated sample shipper as soon as possible.

IX. SAMPLE SUBMISSION RESPONSIBILITIES OF THE EIAO

A. Filling Out Forms

EIAOs are to:

1. fill out each form as soon as practicable after collecting the sample;

2. use clear and accurate descriptions of surface sampling sites to ensure that the sites are identifiable if samples test positive;

3. not leave required blocks blank. The laboratories cannot analyze samples with incomplete forms; and

4. complete FSIS Form 10,210-3 for each sample by:

a. entering the collection date of the sample and the date the sample is sent to the laboratory in blocks #19 and #20, respectively (the dates should be the same);

b. checking “yes” if the establishment is holding the product in block #22;

c. entering the product name for product samples (INTPROD), the production date, the date or lot code, whether the sample is short-weighted/slack-filled, and the establishment contact person and phone number under block #28**;**

d. entering the time the EIAO collects the sample for an environmental or food contact surface (INTCONT or INTENV), the shift, the line, a description of the sample site, whether the sample is an environmental sample (i.e., indirect food-contact surface or a non food-contact surface), and the establishment contact person and phone number under block #28;

e. signing and printing the EIAO’s name and entering the office telephone number under blocks #29, #30, and #32, respectively; and

f. using the instructions in block #18 for completing the rest of the form.

B. Sample Shipment

EIAOs are to:

1. pre-chill shipping containers by placing 3 pre-frozen gel packs at the bottom;

2. place a coolboard (corrugated cardboard) on top of the gel packs, followed by the samples, and lastly, add a foam plug or another coolboard, if provided by the laboratory;

3. submit samples without waiting for the establishment to conduct pre-shipment 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:

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

b. submit samples using the first available FedEx pick up if collected during 2nd or 3rd shift, Monday through Thursday.

4. place all food contact surface samples in 1 or more large bags, environmental samples in separate large bags, and place product samples in 1 or more separate large bags if using the same shipping container. EIAOs may place all food contact surface samples in 1 shipping container, all environmental surface samples in 1 shipping container, and all product samples in 1 shipping container if room allows;

5. contact the Western laboratory to let it know how many samples to expect; and

6. safeguard the security of samples during preparation, storing, packaging, and submission of samples for testing (see FSIS Directive 7355.1, Use of Sample Seals for Program Samples and Other Applications).

X. SAMPLE COLLECTION RESULTS AND ENFORCEMENT

A. Sample Collection Results

The EIAO is to:

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

2. immediately report test results to establishment management.

NOTE: The Agency is now reporting the results of the environmental sampling through the Biological Information Transfer E-mail System (BITES).

B. Enforcement

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

2. If a post-lethality exposed RTE food contact surface sample collected

by the EIAO tests positive for *Lm*, product passing over the surface is adulterated. However, if the establishment has a validated post-lethality treatment, product when distributed may not be adulterated.

3. If a post-lethality exposed RTE environmental (non-food contact) surface sample collected by EIAOs tests positive for *Lm*, this may show that product was produced under insanitary conditions.

4. Follow the directions in FSIS Directive 5100.1 for recommendations to the District Manager or designee regarding enforcement actions. EIAOs are to take the following into consideration when making recommendations per FSIS Directive 5100.1:

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 found the product positive for *Lm*, EIAOs are to verify the establishment performs the appropriate corrective actions as part of the FSA.

NOTE: The Agency will only conduct an FSA as a result of a positive food contact or product sample from an RLm collection activity if 6 months has elapsed since the previous FSA. However, the Agency may elect to conduct an IVT.

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.

XI. DATA ANALYSIS

The results of the food contact surface, environmental samples, and product samples, will provide information to verify and enhance the adequacy of an establishment's food safety system. In addition, product sample results will be summarized by calendar year and product type and posted on FSIS's website by FSIS Headquarters staff.

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 questions through *askFSIS* at http://askfsis.custhelp.com.

Assistant Administrator
Office of Policy and Program Development

Attachment 1

ENTRANCE LETTER TO ESTABLISHMENT MANAGER

To Establishment Manager:

The Food Safety and Inspection Service Agency has identified your establishment for intensified verification sampling. EIAOs will collect RTE product, food contact, and environmental samples for the laboratory to test for *Listeria monocytogenes* (*Lm*). FSIS recommends that you hold all products represented by the samples until the laboratory issues confirmed test results.

The EIAO will not wait for your establishment to complete pre-shipment review before he/she sends product samples to the laboratory for analysis. For product samples, EIAOs will 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.

The EIAOs will be using sterile sponges hydrated with Dey-Engley broth to take samples. It is not necessary that you rinse or wipe food-contact surfaces after the EIAO takes the samples. 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.

The laboratory issues most negative results within 3 days. Confirmed positive results may take up to 8 days. The District Office (DO) will provide presumptive *Lm* positive results to you. For results of future analysis, you can receive results by e-mail. Inspection program personnel may enter establishment addresses into the PBIS profile under the block titled "Establishment e-mail addresses" under the "addresses" tab.

If a recall is necessary because you did not hold all products represented by the sample, FSIS expects that you will initiate the recall in a timely fashion, usually the same day. See FSIS Directive 8,080.1, Recall of Meat and Poultry Products for details.

It is your responsibility to determine the amount of product represented by the sample. For more information, see FSIS Directives 10,240.4, and 10,010.1 and accompanying questions and answers.

If a product or product contact surface sample confirms positive for *Lm*, FSIS may determine that more products or fewer products constitute the sampled lot than the establishment has considered in its lot definition, based on a review of the rationale for how the establishment defined the production lot. In making this determination, FSIS will consider such factors as the establishment's coding of product; the processing and packaging; the equipment; the establishment's testing under its food safety system; the establishment's HACCP plan monitoring and verification activities performed in accordance with 9 CFR 417.2 and 417.4; Sanitation SOP records as required in 9 CFR 416.6; and whether some or all of the products controlled by the same or substantially similar HACCP plans have been affected.