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

# FSIS DIRECTIVE	10,300.1 Revision 1	3/28/13

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

I. PURPOSE

A. This directive provides Enforcement, Investigation, and Analysis Officers (EIAOs) with instructions for collecting samples as part of the IVT sampling program. The IVT sampling program includes the collection of product, food contact surface, and environmental (non-food contact surface) samples for testing for *Lm* or *Salmonella*. In addition, this directive provides instructions to District Office (DO) personnel and EIAOs for scheduling IVT sampling.

B. FSIS is revising this directive to include instructions to EIAOs for performing IVT sampling in response to *Salmonella* positive verification testing results in ready-to-eat (RTE) meat and poultry products. Previous versions of the directive only included sampling instructions for *Lm*. It also provides EIAOs with instructions for performing IVT sampling in establishments that temporarily alter their routine practices. In addition, this directive provides EIAOs with instruction to increase the number of IVT product samples they collect from 3 to 5 samples per unit, consistent with changes FSIS made in January 2013. This directive also provides EIAOs with instructions for verifying that establishments hold or control RTE products that FSIS has tested for pathogens, or that have passed over direct food contact surfaces that FSIS has tested for pathogens, pending the results of FSIS testing. In addition, this directive provides new instructions for submitting samples when interventions such as high-pressure processing (HPP) are applied.

KEY POINTS:

- *DO scheduling of IVT Sampling*
- *EIAO sampling procedures in the IVT Sampling Program*
- *Actions in establishments that temporarily alter routine practices during sampling*

II. CANCELLATION

FSIS Directive 10,300.1, Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for *Listeria monocytogenes,* dated 2/3/10

III. BACKGROUND

A. Under 9 CFR part 430, post-lethality exposed RTE products are adulterated if they test positive for *Lm* or come into direct contact with a food contact surface that tests positive for *Lm*. The Agency utilizes microbial testing as a tool to verify the adequacy of an establishment's food safety system, including the measures that the establishment implements for the control of *Lm.* RTE products are also considered adulterated if the products or food contact surfaces test positive for *Salmonella* or other pathogens.

B. 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* or *Salmonella*. The Agency will schedule an IVT for cause, e.g., following an ALLRTE or RTE001 *Lm* or *Salmonella* positive sample finding or at the discretion of the District Manager (DM). The EIAO will conduct the IVT in conjunction with a 'for cause' food safety assessment (FSA). In addition, EIAOs are instructed to use the IVT sampling methodology for the Routine *Lm* Risk-based Sampling (RLm) Program, as described in FSIS Directive 10,240.5.

C. In 2009, FSIS began performing IVTs for *Salmonella* in response to positive testing results from other sampling programs. This directive provides instructions for EIAO's in performing IVTs for *Salmonella,* as well as *Lm*. In addition, in order to make FSIS's sampling programs more consistent with sampling procedures in use internationally, FSIS has increased the number of products sampled under the IVT sampling program from 3 to 5 samples per unit. This directive provides EIAOs with instructions for collecting the additional samples.

D. FSIS has determined that some establishments may temporarily alter their routine production, sanitation, or food safety practices during IVT sampling. By altering routine practices, establishments may make changes that are not consistent with their documented food safety system and that impede FSIS's ability to assess the safety of the product. This directive provides EIAOs with instructions for taking action in establishments that change practices.

E. On December 10, 2012, FSIS issued a Federal Register notice, Not Applying the Mark of Inspection Pending Certain Test Results announcing that it is changing its procedures and will withhold its determination as to whether meat and poultry products are not adulterated, and thus eligible to enter commerce, until all test results that bear on the determination have been received. The policy and procedures announced in this *Federal Register* became effective February 8, 2013.

IV. DO AND EIAO RESPONSIBILITIES FOR IVT SCHEDULING

A. DO Responsibilities for IVT Scheduling

1. The Office of Data Integration and Food Protection (ODIFP), Data Analysis and Integration Group (DAIG), schedules "for cause" FSA performed with an IVT as described in FSIS Directive 5100.4. This directive provides further information specific to scheduling IVT FSAs.

2. The District Case Specialist (DCS) is to schedule an IVT FSA within 30 days of receiving the weekly "for cause" list from the ODIFP/DAIG. The DCS is to schedule the IVT so that it can be completed within 90 days of receiving notification.

NOTE: If the DCS is unable to schedule an FSA and IVT within 30 days of receiving the weekly "for cause" list, or if the district is unable to complete the IVT within 90 days, the DM is to document the reason in the case file. The DM is also to notify ODIFP/DAIG by sending an email to the "FSIS - IVT Sample

Scheduling - FSIS" mailbox in Outlook.

3. The DO is to schedule an EIAO to conduct an IVT FSA under the following conditions:

    a. As stated in FSIS Directive 5100.4, an FSIS RTE product sample tests positive for *Lm* or *Salmonella* under the ALLRTE or RTE001 sampling programs;

NOTE: FSIS no longer tests RTE products for *E. coli* O157:H7 under the ALLRTE and RTE001 sampling programs, so IVTs will not be routinely scheduled in response to positive results for this pathogen.

    b. A product or a food contact surface sample tests positive for *Lm* during an RLm;

NOTE: A comprehensive FSA is normally not conducted during an IVT performed in response to RLm contact or product positive results, unless more than 6 months has elapsed since an EIAO last performed an FSA at the establishment, or if the establishment has made significant changes in its food safety control programs. See section V.A.2. for more information.

    c. An RTE product sample from another government entity (e.g., Food and Drug Administration (FDA)) tests positive for *Lm* or *Salmonell; and*

    d. The in-plant inspection team has documented repetitive occurrences of noncompliance in the establishment's *Lm* control program, including sanitation issues.

NOTE: Repeated *Listeria* spp. positives from establishment testing of food contact surfaces are an indicator of sanitation issues in the establishment.

4. The DO is to schedule an EIAO to perform an IVT to verify corrective actions before closing out an enforcement action.

NOTE : IVTs performed to verify corrective actions do not need to be scheduled in 30 days and completed within 90 days, because these activities may be performed over a longer timeframe. Also, a comprehensive FSA would not be performed, unless more than 6 months has elapsed since the last FSA at the establishment, see section V.A.2.

B. **EIAO Responsibilities for IVT Sample Scheduling**

1. EIAOs are to contact the Inspector-In-Charge at the establishment to inform him or her that the DO has scheduled an IVT sample collection activity, how the EIAO will conduct the sampling, and the day on which the EIAO will perform the sampling. The EIAO is to determine the following:

    a. The production schedule for, and types of, post-lethality exposed RTE products that are to be produced on the sampling date;

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

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

    d. Whether the establishment uses brine or ice water to chill product. EIAOs are also to determine whether the brine or ice water comes in direct contact with post-lethality exposed

product. If it does, the EIAO is to treat the sample as an INTCONT sample, or if the brine or ice water is used for product in an impermeable casing, the EIAO is to treat it as an INTENV sample.

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

    a. Collect samples in units. For ***Lm* IVTs**, a unit consists of:

        i. 5 product samples (INTPROD);

        ii. 10 food contact surface samples (INTCONT); and

        iii. 5 environmental samples (INTENV);

    b. For ***Salmonella* IVTs**, a unit consists of:

        i. 5 product samples (INTPROD);

        ii. 5 food contact surface samples (INTCONT); and

        iii. 8 environmental samples (INTENV);

    c. Generally, EIAOs are to collect 1 sampling unit for each post-lethality exposed RTE line;

    d. Collect no more than 5 units (90 or 100 samples) because of laboratory constraints;

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

    f. Only collect samples on days and shifts when the establishment is producing FSIS-regulated post-lethality exposed meat or poultry products;

    g. If the establishment uses brine or ice water to chill the product, EIAOs are to:

        i. Collect the brine or ice water samples as one of the 10 INTCONT or 5 INTENV samples they collect per unit;

        ii. Collect 1 brine or ice water 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, the EIAO is to collect 2 brine samples); and

        iii. Collect a maximum of 5 brine or ice water samples per establishment, if available on the lines sampled; and

    h. Finalize the actual sites for food contact and environmental sampling once the EIAO is on location.

3. EIAOs are to request sample collection forms and supplies by sending an e-mail message to the FSIS - IVT Sample Scheduling - FSIS mailbox. If advance scheduling of the IVT by the DO allows, 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 line

c. The establishment number;

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

e. The location to send the forms and supplies;

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

g. Requests for brine sampling supplies, if needed. Extra forms are not needed for IVT brine samples because they will be collected as part of the 10 INTCONT or 5 INTENV samples per unit.

4. Within two weeks after submitting the information to the IVT Scheduling Mailbox, found in Outlook at FSIS - IVT Sample Scheduling – FSIS, 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.

5. EIAOs are to notify the establishment at least 48 hours before IVT sample collection, or if necessary, in enough time in advance for the establishment to hold the product but not enough time for the establishment to alter its routine processes. The EIAO is to:

   a. Document the notification in a Memorandum of Interview (MOI);

   b. Confirm that the establishment will be producing post-lethality exposed RTE product on the day IVT sampling is scheduled, and that the establishment is planning to implement its documented routine production, Sanitation Standard Operating Procedures (Sanitation SOP), and food safety practices;

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

   d. Advise the establishment that if it changes its practices temporarily during the IVT without notifying the EIAO in advance, and cannot provide a justifiable reason for having done so, the sampling may be rescheduled and further regulatory actions may be taken.

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

6. FSIS's policy and procedures for not applying the mark of inspection pending Agency test results for adulterants became effective February 8, 2013. Therefore, EIAOs are to inform the establishment that it must hold or control shipments of RTE products containing meat and poultry pending the results of FSIS product and food-contact surface testing. EIAOs are to document in the MOI

whether the establishment will hold and control product when FSIS collects samples of product of food contact surfaces.

V. EIAO SAMPLING PROCEDURES UNDER THE IVT SAMPLING PROGRAM

A. Entrance Meeting and other Activities before Sampling

1. The EIAO is to hold an entrance meeting with the establishment. 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); and

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

2. In conjunction with performing the IVT sampling, EIAOs are to conduct an FSA in accordance with FSIS Directive 5100.1. If the EIAO is not performing a comprehensive FSA because it has been less than 6 months since the last FSA at the establishment, he or she is to complete the following sections in FSIS Directive 5100.1:

    a. The General Sanitation FSA tool; and

    b. The appropriate Processed Product FSA tools for the RTE products produced by the establishment, including:

        i. The General Hazard Analysis, Flow Diagram and HACCP sections; and

        ii. The relevant Post-lethality Exposed RTE Product sections of each Processed Product FSA tool.

NOTE: EIAOs may find useful information in the "FSIS Guideline Controlling Listeria monocytogenes in Post Lethality Exposed Ready-to-Eat Meat and Poultry Products.

B. EIAO Responsibilities for Product Sampling

For product samples, EIAOs are to:

1. Collect samples of products in an intact package associated with a particular production lot. The samples may be collected on a different day from the food contact and environmental samples, as long as the same production lot is represented by all three-sample types;

2. Collect enough intact product so that at least ONE pound of meat or poultry per sample 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 making any changes to its processing operations. If this is not possible, contact the lab to see if a larger shipping container is available; and

3. Collect product samples over the production shift, if possible.

C. **EIAO Responsibilities for Food Contact Surface Sampling**

For food contact surface samples, EIAOs are to:

1. Collect food 10 contact samples per unit from the post-lethality exposed processing area where the sampled product lot was produced using the methodology in section VII below;

NOTE: Food contact and environmental samples may be collected on different days from the product samples as long as the same product lot is represented by all three sample types;

2. Collect samples starting closest to the product areas and then move further out (i.e., collect food contact surfaces first and then environmental samples);

3. Collect most swabs during operations, ideally at the start of routine breaks scheduled by the establishment. EIAOs are to follow "lock-out, tag-out" procedures for equipment. "Lock-out, tag-out" is controlling energy sources while working on or around equipment;

    a. EIAOs may collect some swabs at the end of pre-operational sanitation activities, before the start of production. Taking swabs at this time will allow EIAOs to sample areas that are hard to reach or unsafe to sample during operations (e.g. slicer blades);

    b. EIAOs are to take post-operation samples as quickly after operations end as practical and before the implementation of establishment sanitation procedures;

4. 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, as long as the establishment is producing some FSIS-regulated post-lethality exposed RTE product that day. If the EIAO samples equipment that is not in operation, he or she is to:

    a. Sample food contact surfaces under the INTCONT, and environmental surfaces under the INTENV, project codes and record that the line is not in use under block 28;

    b. Collect product samples from the unit under the INTPROD project code from another line that is in operation at the establishment. The contact and environmental samples may be collected from a different line than the one from which the product samples were taken as long as all three sample types (product, food contact, and environmental) represent the same production lot;

    c. If the equipment tests positive, the EIAO is not to recommend that IPP issue an NR because the equipment was not in operation at the time the sample was collected, and there is no reason to consider the product to be adulterated. However, if the establishment later decides to use the equipment and does not conduct a full cleaning and sanitizing per its Sanitation SOP before using the equipment, the EIAO is to recommend that IPP issue an NR. The NR would be recommended because the equipment was not maintained in sanitary condition and the product would be considered adulterated (cite 9 CFR 416.3(a) and 430.4(a));

5. Collect samples from areas with recent sanitation problems based on non-compliance records and establishment Sanitation SOP records; and

6. Collect samples from lines or areas that have tested positive for *Lm* in FSIS or establishment testing.

D. EIAO Responsibilities for Environmental Sampling

For environmental samples, EIAOs are to:

1. Collect environmental surface samples anywhere in the establishment where RTE product is processed, stored, or held;

2. Collect samples in areas such as the following additional points that might increase chances of detecting *Lm*:

    a. Areas associated with RTE production lines;

    b. Steps between cooking and packing (slicing, dicing, or peeling operations);

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

    d. Any areas associated with rework or returned product;

    e. Areas of any recent construction activity;

    f. Structures close to the floor and floor mats;

    g. Areas near water puddles or low areas on the floor;

    h. Condensation drip pans and evaporator coils;

    i. Any recessed or hollow surface areas;

    j. Squeegees and brushes for cleaning;

    k. Drains and drain covers;

    l. Recent equipment repairs by the establishment;

    m. Not in-use or stored equipment in RTE areas;

    n. Air ventilation hoods above product routes;

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

    p. Underneath tables and conveyor belts.

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

A. FSIS has determined that establishments may temporarily alter their routine production, sanitation, or food safety practices during IVT sampling. By altering routine practices, establishments may make

changes that are not consistent with their documented food safety system and that impede FSIS's ability to assess the safety of the product.

B. Examples of an establishment changing practices may include:

1. Temporarily increasing the use of sanitizer during the IVT;

2. Drastically reducing the typical production time (e.g. by more than 2 -hours in a typical 8-hour shift or other significant reduction);

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

4. Reducing the number of employees handling the product;

5. Selectively not producing higher risk post-lethality exposed product (e.g. sliced product); or

6. Not using particular equipment that previously has tested positive (e.g., equipment associated with positive product).

C. Such practices can interfere with FSIS's assessment of routine conditions or corrective actions at the establishment and may limit FSIS's ability to determine whether post-lethality exposed RTE meat and poultry products are not adulterated as required by the Federal Meat Inspection Act and Poultry Products Inspection Act. In addition, such changes may not have been considered in the establishment's hazard analysis or accompanied by supporting documentation in accordance with 9 CFR 417.2(a) and 417.5(a)(1).

D. Prior to the IVT, if an establishment informs the EIAO that it no longer plans to produce post-lethality exposed RTE product, or that it has modified its production, sanitation, or food safety practices, the EIAO is to document in the MOI the date of the notification, and the reason the change was made. The EIAO is to consider and document the following issues in the MOI:

1. If the establishment can provide a supportable rationale for not producing the product (such as intermittent production to fill customer orders), then the EIAO is to collect similar post-lethality exposed RTE product (e.g., produced using equipment that has previously tested positive for *Lm*) during the IVT sampling, if available. If similar product is not available, the EIAO is to reschedule the IVT as in paragraph VI.D.3 below.

2. Likewise, if the establishment can support that the production, sanitation, or food-safety practices were implemented as part of reasonable program modifications that the establishment intends to make permanent, the EIAO is to assess the program changes as part of the IVT, if possible. If the EIAO is unable to assess the program changes, he or she is to reschedule the IVT as in paragraph VI.D.3 below.

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

E. On the day of the IVT sampling, if the EIAO determines that the establishment has temporarily decided not to produce post-lethality exposed RTE product or has altered its documented routine production, sanitation, or food-safety practices, and the establishment can not provide a supportable rationale for

doing so, then the EIAO is not to perform sampling and is to contact the DO through his or her supervisory chain.

F. If the EIAO finds that the establishment has made changes in its food safety systems (e.g., changing its supplier of RTE product only during the IVT), and does not have documents supporting the appropriateness of the changes, the EIAO is to recommend to supervisory personnel that the in-plant inspection team issue an Non-compliance Record (NR). The NR would be recommend because the establishment did not consider the changes in its hazard analysis in accordance with 9 CFR 417.2(a), or did not support the changes to its hazard analysis as in 9 CFR 417.5(a)(1). When recommending the issuance of an NR, the EIAO is to follow the instructions in chapters 3, 13, and 15 in FSIS Directive 5100.1. Likewise, if the EIAO finds that the establishment has made changes in its sanitation practices (e.g., temporarily increasing the use of sanitizer during the IVT) and did not revise its Sanitation SOP to reflect these changes, he or she is to recommend to supervisory personnel that the in-plant inspection team issue an NR under 9 CFR 416.14.

NOTE: If an establishment decides to limit its product lot size **solely** to facilitate holding of the product during the IVT sampling, it would not be considered to have significantly altered its production practices, as long as the EIAO can collect samples that accurately represent routine production. If the EIAO has questions about whether an establishment is altering routine production, sanitation, or food-safety practices, he or she can submit them through askFSIS at askFSIS, following the directions in Section XI of this directive.

G. If the EIAO is unable to collect IVT samples as in paragraph VI.E and is therefore unable to assess whether the establishment is controlling *Lm* on its food contact surfaces and is preventing the product from becoming adulterated in accordance with 9 CFR 430.4(a), the DO may determine that further actions are warranted. These may include the following:

1. The DO may instruct IPP to tag the equipment if the EIAO can not collect samples in order to determine whether the product is not adulterated, in accordance with 9 CFR 500.2(a)(3). The tag is to remain on the equipment until such a time when the establishment decides to use the equipment and then demonstrates that it can produce safe, unadulterated product. The IVT will be rescheduled to the next time the EIAO can assess the production practices of interest. If the establishment permanently stops producing a particular product, the EIAO is to document this change in the MOI; and

2. The DO may issue a Notice of Intended Enforcement or Notice of Suspension in situations where FSIS personnel have found insanitary conditions at the establishment, or where FSIS personnel have found that the food safety system is inadequate, in accordance with 9 CFR 500.4(a) or (b) or 9 CFR 500.3(a)(4).

VII. SAMPLING METHODOLOGY

A. Food Contact and Environmental Swab Samples

EIAOs are to:

1. Wash and sanitize their hands to the mid-forearm;

2. Using the ungloved hands, 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 (or, in certain instances where D/E broth cannot be used, Neutralizing Buffer)[1] 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 FDA 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. EIAOs are not to let their hand go past the thumb stop on the handle;

9. EIAOs are to aseptically place a sterile glove on the hand they will use for swabbing, by:

    a. Position 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. Hold the glove for the hand that will be used for swabbing by the inside cuff area , and Insert the hand into the glove, palm side up, lifting the glove from the package;

    c. Pull 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;

10. Using the gloved hand, 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. They are not to let their hand go past the thumb stop on the handle;

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

12. Swab the chosen area using firm and even pressure;

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1. Dey-Engley broth used for hydrating sampling sponges contains tryptone, a trypsin digest of the milk protein, casein. In certain establishments, religious dietary laws require a separation of meat and dairy products. FSIS established in 2010 that Neutralizing Buffer (NB) contains only chemicals, no peptones or other (potential) food products. Therefore, the use of NB for hydrating sampling sponges should present no problem in these establishments.

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).;

13. Open the bag and insert the sponge portion of the SpongeSicle® back into the bag;

14. 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 VII. A. 1-14;

15. 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;

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

17. 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

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

B. **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.

VIII. EIAO SAMPLE SUBMISSION RESPONSIBILITIES

For sample shipment, EIAOs are to:

1. Pre-chill shipping containers by placing 2 pre-frozen gel packs at the bottom;

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

3. Ship the sample after the establishment has completed the production lot (as defined by the establishment) and applied all of the interventions for *Lm* control;

    a. Submit samples the same day if collected during 1st shift Monday through Friday; or

    b. Submit samples as soon as possible if collected during 2nd shift, Monday through Thursday. Samples should not be sent on Saturday or a day before a holiday. EIAOs are to store the samples refrigerated when holding the samples overnight for shipping;

    c. If the product is sent to another establishment for a *Listeria* control intervention (e.g.,HPP), the EIAO is not to ship the sample until the intervention is complete. If the product will not be returned to the establishment, the EIAO is to sample another product (if possible). If the process is being applied to extend the shelf life of the product, and not as a *Listeria* control intervention, the EIAO is to collect the sample and ship the product before the process is applied;

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

5. Contact the appropriate 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).

IX. SAMPLING RESULTS AND ENFORCEMENT

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

B. If a post-lethality exposed RTE food contact surface sample collected by the EIAO tests positive for *Lm*, any product in direct contact with the surface is adulterated.

NOTE: If the establishment treats the product that passed over the food contact surface with a post-lethality treatment (e.g. HPP) that has been validated to achieve at least a 5-log reduction of *Lm*, the product would not be considered to be adulterated. EIAOs are to consider all processing steps before making a determination of adulteration.

C. If a post-lethality exposed RTE environmental (non-food contact) surface sample collected by the EIAO tests positive for *Lm*, the EIAO is to consider whether product may have been produced under insanitary conditions before recommending the issuance of an NR. EIAOs are to recommend that IPP issue an NR if

there is evidence of insanitary conditions that could lead to product contamination.

EXAMPLE: A drain tests positive for *Lm*. The EIAO observes an establishment employee spraying a high pressure hose in the drain. Water droplets landed on a conveyor belt and exposed RTE product. The positive results from the drain, taken along with the observation of possible cross contamination would be adequate to support the issuance of an NR. The drain positive alone, without any further observations of conditions that could lead to insanitary conditions, would not warrant the issuance of an NR.

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

1. If FSIS finds the product or food contact surface positive, and the establishment tested the product or food contact surface under its documented sampling programs, EIAOs are to check the establishment's *Salmonella* or *Lm* testing results to determine whether the establishment also found the sampled product or food contact surface positive for *Salmonella* or *Lm*;

2. EIAOs are to determine whether the establishment held the product or maintained control of the product (e.g., the establishment moved the product off site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results. Establishments are required to hold or control shipments of RTE products containing meat and poultry pending the results of FSIS product and food-contact surface testing for *Salmonella* or *Lm*;

3. If the EIAO finds that the establishment did not hold or maintain control of product when FSIS collects product or food contact surface samples, he or she is to recommend to the in-plant supervisory personnel that the inspection team issue an NR. The NR would be recommended because the establishment shipped product before FSIS found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as set out in 9 CFR 417.5(c). When recommending the issuance of an NR, the EIAO is to follow the instructions in chapters 3, 13, and 15 in FSIS Directive 5,100.1; and

4. Generally, If FSIS finds the product or food contact surface positive for *Salmonella* or *Lm*, EIAOs are to recommend that IPP issue an NR (cite 9 CFR 417.4(a)). However, if the establishment also found the product or food contact surface to be positive for *Salmonella* or *Lm* and held the product, EIAOs are not to recommend the issuance of an NR. They are to verify that the establishment performs the appropriate corrective actions as part of the FSA.

X. DATA ANALYSIS

The DAIG within ODIFP will perform data analyses on a quarterly basis to determine whether IVTs are scheduled within 30 days and completed within 90 days after receiving the weekly "for cause" list, as described in this directive. In addition, the Risk, Innovations, and Management Division (RIMD), OPPD will work with ODIFP to analyze FSA and IVT results on a quarterly basis to identify potential trends and relationships, as results are available. RIMD will use the results of this data analysis to inform future FSIS policy and program development.

XI. QUESTIONS

Refer questions regarding this directive to the Risk, Innovations, and Management Division through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab,

and enter the following information in the fields provided:

Subject Field: Enter **Directive 10,300.1**
Question Field: **Enter question with as much detail as possible**.
Product Field: Select **General Inspection Policy** from the drop-down menu.
Category Field: Select Sampling: ***Listeria monocytogenes*** from the drop-down menu.
Policy Arena: Select **Domestic (U.S.) Only** or **International (Import/Export)** from the drop-down menu.

When all fields are complete, press the **Submit** button.

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*) or *Salmonella.* FSIS requires producers to hold or control RTE products containing meat and poultry that FSIS has tested for *Lm* or *Salmonella* or that has passed over food-contact surfaces that FSIS has tested for these pathogens, pending the results of FSIS product and food-contact surface testing.

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.

For food contact and environmental samples, the EIAO will use sterile sponges hydrated with Dey Engley (D/E) 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's standard use of D/E 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 6 days. The DO will provide presumptive *Lm* positive results to you. For results of future analysis, you can receive results by e-mail. IPP may enter establishment addresses into the PHIS profile so you can receive the results.

An RTE product lot is usually defined as the product produced from clean-up to clean-up. However 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. This determination would be made 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 use of the same RTE source material over multiple lots;

--The establishment's sanitation practices, including the potential for cross contamination between processing lines; and

--Whether the establishment performed a complete cleaning and sanitizing between lots produced on the same day, following its Sanitation SOP.

For more information on establishment lotting practices, see Chapter 3, Page 15 of the revised *Listeria* Guidelines available at http://www.fsis.usda.gov/PDF/Controlling_LM_RTE_guideline_0912.pdf.

Attachment 2

PROJECT CODE AND NAME	**INTPROD -** Intensified sampling of post-lethality exposed RTE meat and poultry products.
SAMPLE COLLECTOR	FSIS personnel trained in IVT aseptic sample collection techniques.
PRODUCT TO SAMPLE	Randomly collect five samples per unit for *Lm* and *Salmonella* IVTs. All of the samples per unit should be from the same product lot and line. Note: Do not sample the same lot of product for more than one sample collection project.
ANALYZED FOR	*Listeria monocytogenes* or *Salmonella*
SPECIAL COLLECTION INSTRUCTIONS	Collect 5 samples per unit for both *Lm* and *Salmonella* IVTs. Collect samples in the final, intact package. Randomly select either the 1st or 2nd shift Monday through Thursday or day shift on Friday, within the 1-week testing window. Collect samples from one production lot. Product samples may be collected on a different day than the food contact and environmental samples, as long as all samples represent the same production lot. Collect enough product in the final, intact package so that at least ONE pound of meat or poultry per sample 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	Use a separate 10,210-3 form for each INTPROD sample collected. 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, place the plastic bag into the shipping container with the sample, and seal per FSIS Directive 7355.1, Rev. 2, Use of Sample Seals for Laboratory Samples and Other Applications. If no sample is collected, complete block 33 and mail the form to the laboratory listed in block 9.
ESTABLISHMENT NOTIFICATION	Notify the establishment at least 48 hours notice 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.
SPECIAL SHIPPING INSTRUCTIONS	Ship immediately after product represented by the sample has passed all establishment interventions for *Lm*. Ship samples refrigerated or frozen, depending on establishment practices. 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 10,300.1;, FSIS Directive 7355.1 Rev. 2

Attachment 3

PROJECT NUMBER AND NAME	**INTCONT** - Intensified sampling of food contact surfaces during the production of post-lethality exposed RTE 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 post-lethality exposed RTE product in the RTE production area (e.g., conveyor belts, cooler storage racks, luggers, slicers, peelers, loaders, tabletops). Brine or chill water samples are considered to be contact surface samples (and collected under the INTCONT program), if they come in direct contact with post-lethality exposed product, or the product is in a semi-permeable casing. Contact and environmental samples may be collected on different days than product as long as all three sample types represent the same production lot. **NOTE:** Gloves or garments worn by employees may be sampled if directly observed by FSIS to contact food.
ANALYZED FOR	*Listeria monocytogenes* or *Salmonella*
SPECIAL COLLECTION INSTRUCTIONS	Collect 10 samples per unit for *Lm* IVTs and 5 samples per unit for *Salmonella* IVTs. Randomly select either the 1st or 2ndshift Monday through Thursday or day shift on Friday, within the 1–week scheduling window. 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	Use a separate 10210-3 form for each INTCONT sample collected. 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, 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	Notify the establishment at least 48 hours notice 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.
SPECIAL SHIPPING INSTRUCTIONS	Ship samples as soon as possible to the designated laboratory. 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. Notify the laboratory if samples will be sent on different days.
REFERENCES	FSIS Directive 10,300.1; FSIS Directive 7355.1 Rev. 2

Attachment 4

PROJECT CODE AND NAME	**INTENV -** Intensified sampling of environmental (non-food contact) surfaces during the production of post-lethality exposed RTE meat and poultry products.
SAMPLE COLLECTOR	FSIS personnel trained in IVT aseptic sample collection techniques.
SAMPLE TO COLLECT/ SAMPLE SITE SELECTION	Swab surfaces having indirect (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) with the sampled product lot. Collect samples anywhere in the establishment where post-lethality exposed RTE product is produced, held, or stored. Brine or chill water samples are considered to be environmental samples if the product is in an impermeable casing or otherwise packaged. The samples will be collected under the INTENV sampling program because they will not be composited.
ANALYZED FOR	*Listeria monocytogenes* or *Salmonella*
SPECIAL COLLECTION INSTRUCTIONS	Collect 5 samples per unit for *Lm* IVTs and 8 samples per unit for *Salmonella* IVTs. Randomly select either the 1st or 2nd, shift Monday through Thursday or day shift Friday. 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	Use a separate 10210-3 form for each INTENV sample collected. 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, 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	Notify the establishment at least 48 hours notice 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.
SPECIAL SHIPPING INSTRUCTIONS	Ship samples as soon as possible to the designated laboratory. 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. Notify the laboratory if samples will be sent on different days.
REFERENCES	FSIS Directive 10,300.1, FSIS Directive 7355.1 Rev. 2