MSA DIRECTIVE	10,300.1 Rev. 1	10/1/2022

Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria Monocytogenes

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 Central Office (CO) personnel and EIAOs for scheduling IVT sampling.

B. MSA 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. This directive also provides EIAOs with instructions for verifying that establishments hold or control RTE products that MSA has tested for pathogens, or that have passed over direct food contact surfaces that MSA has tested for pathogens, pending the results of MSA testing.

II. CANCELLATION

MSA 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 MSA 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 MSA tests product, food contact surfaces, and environmental surfaces (non-food contact surfaces) for *Lm* or *Salmonella*. MSA will schedule an IVT for cause, e.g., following an *Lm* or *Salmonella* positive sample finding or at the discretion of the CO. 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 MSA Directive 10,240.5.

C. This directive provides instructions for EIAO's in performing IVTs for *Salmonella,* as well as *Lm*. In addition, MSA 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. MSA 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 MSA'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. MSA will also adopt the policy and procedures announced in this Federal Register which became effective February 8, 2013.

IV. CO AND EIAO RESPONSIBILITIES FOR IVT SCHEDULING

A. 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 MSA Central Office (CO) 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.

Note: EIAOs will coordinate with the CO to determine how to perform the sampling and to obtain supplies.

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;

      ii. 10 food contact surface samples; and

      iii. 5 environmental samples;

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

      i. 5 product samples;

      ii. 5 food contact surface samples; and

      iii. 8 environmental samples;

   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 MSA- regulated post-lethality exposed meat or poultry products;

   g. 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 coordinating with the MSA CO.

4. 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.

e. EIAOs are to inform the establishment that it must hold or control shipments of RTE products containing meat and poultry pending the results of MSA product and food-contact surface testing. EIAOs are to document in the MOI whether the establishment will hold and control product when MSA 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;

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

   c. 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 MSA 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 shall conduct Directive Observations of all establishment activities and HACCP Records Review in accordance with Section V and VI of MSA Directive 5100.1.

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 for each sample submitted to the lab for analysis. When testing for both Salmonella and Listeria, submit at least a 500-gram sample. When testing only for Listeria, submit at least a 100-gram sample. 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 CO 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 contact samples as described in section IV, A, 2 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 MSA 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 and record that the line is not in use;

   b. Collect product samples from the unit from another line that is in operation at the establishment. The contact and environmental samples may be collected from a different line than the one from which the product samples were taken as long as all 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 MSA 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. MSA 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 the Agencies 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 MSA's assessment of routine conditions or corrective actions at the establishment and may limit MSA's ability to determine whether post-lethality exposed RTE meat and poultry products are not adulterated as required by the 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 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 cannot provide a supportable rationale for doing so, then the EIAO is not to perform sampling and is to contact the CO 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 a 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 MSA Directive 5100.1. Likewise, if the EIAO finds that the establishment has made changes in its sanitation practices (e.g., temporarily increasing the use of sanitizer during the 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.

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 CO may determine that further actions are warranted. These may include the following:

1. The CO may instruct IPP to tag the equipment if the EIAO cannot 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;

NOTE: The FDA determined that 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.

4. Position the SpongeSicle© so that the handle is sticking out of the bag. Press the top of the bag back together around the handle;
5. 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;
6. 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. 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;

7. 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;

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

9. 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).;

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 section VII. 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;

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 DSHS 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.

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 MSA Directive 5100.1, when making recommendations to the CM or designee regarding enforcement actions. In addition, EIAOs are to take the following into consideration when making recommendations:

1. If MSA finds the product or food contact surface positive, and the

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

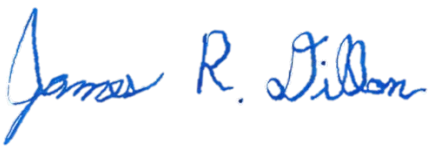
2. EIAOs are to determine whether the establishment held the product or maintained control of the product (e.g., the establishment moved the product off site but did not complete pre-shipment review or transfer ownership of the product to another entity) pending its own test results. Establishments are required to hold or control shipments of RTE products containing meat and poultry pending the results of MSA 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 MSA collects product or food contact surface samples, he or she is to recommend to the in-plant supervisory personnel that the inspection team issue an NR. The NR would be recommended because the establishment shipped product before MSA found that the product was not adulterated, and because the establishment did not complete pre-shipment review following availability of all relevant test results, as set out in 9 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 MSA 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. QUESTIONS

Refer questions through supervisory channels.



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