

OKLAHOMA DEPARTMENT OF AGRICULTURE,
FOOD, AND FORESTRY
MEAT AND POULTRY INSPECTION SERVICE
OKLAHOMA CITY, OK

MPI NOTICE	606	6/8/2011
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CONDUCTING INTENSIFIED VERIFICATION TESTING (IVT)

I. PURPOSE

This notice provides updated instructions to ODAFF personnel regarding the protocol and procedures to be followed when conducting Intensified Verification Testing (IVT) in establishments that produce post-lethality exposed Ready-To-Eat (RTE) meat and poultry products. The sampling program includes the collection of food contact, environmental (non-food contact), and product samples, as well as completing a Food Safety Assessment (FSA). It cancels OK MPI Notice 02-08 and it contains updated references that reflect the revised MPI numbering system. The changes include:

1. a change in the number of sample units collected depending on the establishment size;
2. the removal of the requirement to submit intact samples after pre-shipment review; and
3. the removal of the requirement to complete and submit the validation checklist.

II. CANCELLATION

OK MPI Notice 02-08

III. REFERENCES

2 O.S. § 6-182(j)

68 FR 34207, June 6, 2003

9 CFR Part 430

FSIS Directives 5100.1, Revision 2; 10,240.4, Revision 2; 10,240.5, Revision 2; and 10,300.1

OK MPI Notices 602; 603; and 801

III. BACKGROUND

On June 6, 2003, FSIS published an interim final rule (68 FR 34207) that amended its regulations to require that official establishments that produce post-lethality exposed RTE meat and poultry products prevent product adulteration by the pathogenic environmental contaminant *Listeria monocytogenes* (*L. monocytogenes* or *Lm*). In addition, the regulation adopted in this interim final rule (9 CFR Part 430) states that RTE product is adulterated if it contains *L. monocytogenes*, or if it comes into direct

contact with a food contact surface that is contaminated with *L. monocytogenes*. The ODAFF MPI Program will verify that an establishment's food safety systems are controlling *L. monocytogenes* by supplementing and expanding the traditional collection of routine intact product samples with the collection of routine food contact and environmental (non-food contact) surface swabs during the production of RTE meat and poultry products that are exposed to the environment following the lethality treatment.

The ODAFF MPI Program intends to randomly conduct Intensified Verification Testing (IVT) in each inspected establishment that produces post-lethality exposed RTE meat and poultry products. This testing will also be conducted for cause in inspected establishments that produce post-lethality exposed RTE meat and poultry products. A "for cause" FSA is one that is prompted by a positive sample result, production and shipment of adulterated product, or any other high priority food safety related incident. The collection of all IVT samples will be conducted by an ODAFF employee trained in IVT methodology and will be collected in conjunction with a Food Safety Assessment (FSA). All samples will be analyzed by the ODAFF Laboratory for the presence of *Listeria monocytogenes*. Any samples that are found to be positive for the presence of *Listeria monocytogenes* will be submitted to the Oklahoma State Department of Health Laboratory to be further tested to obtain the serotype and the Pulsed Field Gel Electrophoresis patterns and entered into the PulseNet data base.

IV. ODAFF INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES FOR COLLECTING IVT SAMPLES

A. Sample Scheduling for Oklahoma City Meat and Poultry Inspection (MPI) Office Personnel and EIAO Responsibilities Prior to Sample Collection.

1. The Oklahoma City MPI Office is to assign the IVT sample collection activity to an EIAO trained in Intensified Verification Testing (IVT)

2. The Oklahoma City MPI Office will schedule an FSA in conjunction with the IVT sampling. The EIAO must receive the IVT sampling results before the FSA is completed, so they may share the results of the sampling with the establishment at the exit conference.

3. In conjunction with performing the IVT sampling, EIAOs are to conduct an FSA in accordance with FSIS Directive 5100.1, Revision 2. EIAOs may find useful information in the "Compliance Guidelines to Control *Listeria monocytogenes* in Post Lethality Exposed Ready-to-Eat Meat and Poultry Products."

[http://www.fsis.usda.gov/regulations & policies/Compliance Guides Index/index.asp](http://www.fsis.usda.gov/regulations_and_policies/Compliance_Guides_Index/index.asp)

4. Within the time frame prior to the scheduled IVT sampling the IVT trained EIAO is to:

- a. Randomly select the day,

b. Contact the Inspector-In-Charge (IIC) at the establishment to inform him or her that an IVT sample collection activity is scheduled, how the sampling is conducted, and the day in which the sampling will occur. The Consumer Safety Inspector (CSI) should be present, if possible, in the establishment on the day of sampling. Find out the following information:

- i. the production schedule and the types of post-lethality exposed RTE products produced; and
- ii. the number of production lines producing post-lethality exposed RTE products.

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

c. Determine the number of sample units to collect. Establishment size is based on establishment categories in the HACCP preamble (61 FR 38806); sizes are based on the number of employees. Establishment size is defined as: Large establishments – 500 or more employees, small establishments – 10 or more employees but fewer than 500, and very small establishments – fewer than 10 employees or annual sales of less than \$2.5 million. EIAOs are to:

- i. sample a maximum of 3 lines on which post-lethality exposed RTE product is produced in large establishments;
- ii. sample a maximum of 2 lines on which post-lethality exposed RTE product is produced in small establishments; and
- iii. sample a maximum of 1 line on which post-lethality exposed product is produced (1 sample unit) in very small establishments.

NOTE: Any IVT that is conducted “for cause” will have a higher number of sample units collected as described in FSIS Directive 10,300.1, Part VII. B.

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

e. Coordinate with the Oklahoma City Office and the ODAFF Laboratory to ensure that all sample supplies, forms, etc., are ready and available for the IVT sampling

5. At least one week prior to the IVT sample collection date, the EIAO should notify establishment management (see Attachment 1) to:

- a. allow the establishment time to hold all product represented by the sample,
- b. provide the information that an IVT collection activity is scheduled,

- c. explain how the sampling is to be conducted,
- d. encourage the establishment to be prepared to hold all affected product represented by the sample, and
- e. advise the establishment that if it fails to hold all affected product represented by the positive sample results, the product may be subject to a recall as described in OK MPI Notice 801.

B. Sample Collection Responsibilities for the EIAO

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

a. Follow the methodology for collecting product, food contact, and environmental samples described in FSIS Directive 10,300.1, Part VIII. The IVT testing should be conducted as early in the FSA as possible to facilitate receiving the results and the completion of the FSA report without unnecessary delay.

b. Collect intact samples of products associated with the same production day and shift represented by the food contact and environmental surface swabs. In all cases, intact samples of 3 post-lethality exposed products must be randomly collected from each line tested throughout the course of the same production day and shift that the food contact and environmental surface sample swabs are collected. The EIAO/PHV should not collect 3 product samples alone. These product samples should be accompanied with food contact and environmental surface sample swabs,

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

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

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

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

NOTE: It is recommended that 2 pre-operational food contact surfaces be sampled and the balance of the samples should be collected during operations.

d. Each sample collected must be identified on the sterile plastic bag in which

the swab is placed and the identification must also be included on the ODAFF Laboratory Analysis Form (FSD-MIS 222).

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

f. Safeguard the security of samples during preparation, storing, packaging, and submission of samples for testing (see MPI Notices 602 and 603).

V. ENFORCEMENT

1. The EIAO/PHV should immediately report test results to establishment management.

2. If any RTE product sample collected by the IVT trained EIAO/PHV tests positive for *L. monocytogenes*, product in the sampled lot is adulterated.

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

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

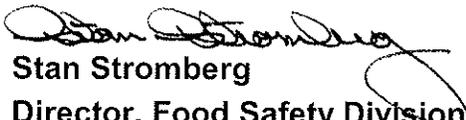
4. Follow the instructions in FSIS Directive 5100.1, Revision 1, for making recommendations to the Oklahoma City MPI Office regarding enforcement actions. In addition, EIAOs are to take the following into consideration when making recommendations:

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

5. Contact the Director of Meat Inspection at the Oklahoma City MPI Office following the directions in OK MPI Notice 801 if any adulterated product in the sampled lot has entered commerce. The establishment will be expected to issue a voluntary recall of the lot(s) of adulterated product that have entered commerce.

Any questions about this notice should be referred through normal supervisory channels.


Stan Stromberg
Director, Food Safety Division

DISTRIBUTION:
All MPI Personnel
ODAFF Laboratory

SUBJECT CATEGORY:
HACCP/SSOP

Plant Manager
Oklahoma Meat Processing, Est. 001
101 S. Main Street
Anywhere, OK 74147

As discussed in the interim final rule that addressed *Listeria monocytogenes* (*Lm*) in post-lethality exposed ready-to-eat (RTE) meat and poultry products (68 FR 34207, June 6, 2003), ODAFF MPI Program is committed to verifying through risk-based inspection verification activities that official establishments producing certain RTE meat and poultry products are preventing *Lm* from adulterating product. ODAFF has instituted a sampling project as part of their risk-based verification program. As part of the implementation of this project, ODAFF MPI Program has selected your establishment to be a participant.

- ODAFF will perform a comprehensive assessment of your food safety systems (FSA).
- We have reserved (day of week, month, date, year) at (time) for the entrance meeting at your establishment.
- The entrance meeting will introduce the participants and outline the process.
- ODAFF expects you to supply at least the last 60 days of HACCP and SSOP records along with all records documenting and/or supporting decisions made in your food safety systems; records such as scientific studies, prerequisite programs, and manufacturers instructions, etc.
- A room to conduct the assessment would expedite the process along with telephone connections.
- ODAFF will also perform risk-based verification sampling of post lethality exposed RTE products and their production environment. FSIS will collect samples from post lethality exposed RTE products, product-contact surfaces and environmental sites.
- ODAFF will use risk-based sampling as a tool in verifying the effectiveness of your *Lm* control program.
- ODAFF will expect you to supply verification results and other documentation relevant to your *Lm* control program.
- ODAFF sampling will use sterile sponges hydrated with D/E broth to take samples. D/E broth is Generally Recognized as Safe (GRAS) by the FDA; therefore, there is no need to rinse the D/E broth from food-contact surfaces after ODAFF takes samples.
- A team of ODAFF personnel including the IIC and EIAOs will perform the sampling and corresponding documentation.

- ODAFF has scheduled the collection of one unit representing the line producing post lethality exposed RTE product. If this IVT has been scheduled "for cause" all lines producing RTE product will be sampled up to a maximum of 5 lines. The unit will consist of ten product contact samples, five non-product contact samples, and three product samples.
- ODAFF has scheduled the collection of the samples to take place on (day of week, month, date, year). This notification is to allow you sufficient time to hold all product represented by the samples. ODAFF recommends that you hold all product represented by the sample until confirmed test results are received.
- ODAFF may determine that more or less product than that produced from clean-up to clean-up under the HACCP plan is represented by the sample. In making this determination, ODAFF will consider such factors as product coding, processing and packing, equipment involved, sampling, monitoring, verification activities and recordkeeping. See FSIS Directive 10,240.4, Revision 2 with emphasis on the Question and Answer document (Resource 3) for guidance on determining product represented by a sample.
- Currently, ODAFF collects environmental samples and sends them to the laboratory the same day.
- ODAFF obtains most negative results within three days; confirmed positive results may take up to eight days. The Oklahoma City MPI Office will provide presumptive *Lm* positive results to you.
- If a test result is positive and you have distributed the product, ODAFF will request that you conduct a recall. See OK MPI Notice 801 – Recall of Meat and Poultry Products for guidance on recalls.

Thank you in advance for your cooperation and support during this process. Please call (405) 522-6119 with any questions or comments.

Sincerely,