

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

FSIS NOTICE	64-09	9/21/09
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**INTENSIFIED VERIFICATION TESTING
AND “FOR CAUSE” FOOD SAFETY ASSESSMENTS IN RESPONSE TO READY-
TO-EAT TESTING RESULTS**

I. PURPOSE

This notice cancels FSIS Notice 78-08 and provides further information for scheduling a “for cause” Food Safety Assessment (FSA) performed with Intensified Verification Testing (IVT). It also clarifies that an IVT FSA will be performed in response to positive food contact surface and product tests from routine Risk Based *Listeria monocytogenes* (RLm) testing. In addition, it provides instructions for performing an IVT and “for cause” FSA in response to a ready-to-eat (RTE) product positive for *Salmonella*. Further information about the incidence of *Salmonella* is provided in Attachment 1.

II. SCHEDULING A “FOR CAUSE” FSA PERFORMED WITH AN IVT

A. A “for cause” FSA performed with an IVT will be scheduled by the Office of Data Integration and Food Protection (ODIFP) Data Analysis and Integration Group (DAIG) as described in Directive 5100.4, Prioritized Scheduling of Food Safety Assessments (FSAs). This notice provides further information specific for scheduling IVT FSAs.

B. The District Case Specialist (DCS) is to schedule an IVT FSA within 30 days of receiving notification from the ODIFP/DAIG. The EIAO conducting the IVT is to follow the sample selection and sample size instructions contained in FSIS Directive 10,300.1, Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for *Listeria monocytogenes*. The EIAO is to conduct an IVT FSA when:

1. As stated in Directive 5100.4, the FSIS RTE product sample tests positive for *E. coli* O157:H7, *Lm*, or *Salmonella* (ALLRTE or RTE001), or a food contact surface or product 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, unless more than 6 months have elapsed since an EIAO last performed an FSA, or significant changes have been made in the establishment’s food safety control programs.

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2. An RTE product sample from another government entity under section I, above, tests positive for *E. coli* O157:H7, *Salmonella*, or *Lm*; or
3. The in-plant inspection team has documented repetitive occurrences of noncompliance in the establishment's *Lm* control program, including sanitation issues.

NOTE: According to Directive 10,300.1, samples from food contact surfaces (FCS) for production lines that are not in use on the day of sampling may be collected. If a sample is collected from a FCS for a production line not in use, the EIAO is to record this information in Box 28 on the FSIS Form 10,210-3. If a sample from a FCS that was not in use tests positive, all the information gathered in conjunction with the FSA should be considered. The IVT should be performed if the FCS was not cleaned and sanitized before use, and if product was affected.

4. The DO is to schedule an EIAO to perform an IVT within 30 days of the issuance of a deferral on a Notice of Intended Enforcement (NOIE) or a decision to hold in abeyance a suspension, because of the establishment's failure to control *Lm*, to close out the action.
5. If DO personnel are unable to schedule an FSA and IVT within 30 days of the notification, or to schedule an IVT to close out an enforcement action and to complete the IVT within 90 days of the notification, the DM is to document the reason in the case file and notify ODIFP/DAIG.

III. SAMPLING INSTRUCTIONS FOR CONDUCTING SALMONELLA IVTs

A. The EIAO is to:

1. Follow the IVT methodology as according to FSIS Directive 10,300.1.
2. Collect 1 unit per line, with a maximum of five units collected. A unit for a *Salmonella* IVT consists of 5 product samples, 8 environmental samples, and 5 food contact samples.
3. Perform an FSA along with the IVT.

IV. EIAO RESPONSIBILITIES

A. When an EIAO conducts an IVT, he or she is to contact the laboratories through the Outlook "IVT Sample Scheduling" mailbox, approximately 2 weeks before the scheduled IVT sample collection date, unless circumstances require otherwise. This contact will ensure that the laboratory that is involved has the resources available to receive and process the samples in a timely manner and allows time for the laboratory to ship sample supplies to the appropriate site. The IVT Sample Scheduling mailbox automatically forwards the information to the laboratories' mailboxes and the forms mailbox. The sampling supplies and forms are to be shipped at least 10 days before the IVT, when practicable. The e-mail to the "IVT Sample Scheduling" mailbox is to include all of the following:

1. The sample collection date and production shift;
2. The type of samples the EIAO is collecting (*Lm* or *Salmonella*);
3. The number of sample units required based on the number of production lines;
4. The establishment number;
5. The contact name and phone number for the EIAO conducting the IVT;
6. The location to send the forms and supplies (FedEx does not deliver to a post office box); and
7. Requests for special supplies (e.g., larger gloves) or larger shipping containers, if needed.

V. DATA ANALYSIS

ODIFP will conduct data analyses on a quarterly basis to determine whether FSAs are scheduled within 30 days and completed within 90 days of the notification, as called for in this notice. In addition, ODIFP will analyze on a quarterly basis FSA and IVT results to identify trends and relationships in those results. ODIFP will stratify those results by FSA cause. Those analysis results will inform future FSIS policy and program development.

Refer questions regarding this notice to the Policy Development Division through askFSIS at <http://askfsis.custhelp.com> or by telephone at 1-800-233-3935.



Assistant Administrator
Office of Policy and Program Development

Information on the Incidence of *Salmonella*

While the incidence of *Salmonella* in RTE is lower than *Lm* in RTE products, the presence of *Salmonella* in RTE products may evidence a more serious processing and public health problem compared to the presence of *Lm*. While *Salmonella* in an establishment may be an environmental contaminant in some circumstances, its presence implies underprocessing or serious deficiencies for sanitary practices.

Salmonella can contaminate RTE products in the following ways:

1. Underprocessing

a. Underprocessing occurs when the process is not adequate to eliminate the pathogens of concern. For heat-treated products, underprocessing may be the result of applying an inadequate temperature for an inadequate time to the product or the development of bacterial heat resistance before completion of the lethality step.

b. For cured and fermented products, inadequate drying, curing, or fermentation are causes of underprocessing.

2. Contamination from raw materials

a. Raw or partially processed produce (e.g., raw or perhaps blanched), egg, spices, or other ingredients that are introduced to the processed products after the primary lethality event can be a source for *Salmonella*.

b. *Salmonella* from raw meat or poultry products that are processed in the same physical area can contaminate processed products by direct or indirect (e.g., environmental sources or food handlers) contamination routes.

3. Contamination from food handlers

a. Given the incidence of human salmonellosis in the U.S. and the potential for asymptomatic carriage in humans, there is potential for product contamination from establishment employees.

b. The food industry has a high turnover of food handlers. History has shown that training for personal hygiene and proper handling of foods may not be adequate in some circumstances.

4. Contamination from animal vectors

a. Animals (e.g., birds, rodents) and insects have been shown to contaminate produce with *Salmonella*.

b. It is possible for animal fecal contamination within and outside the establishment to be introduced into the RTE production area.