

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

FSIS NOTICE

07-12

1/25/12

**INTENSIFIED VERIFICATION TESTING
AND “FOR CAUSE” FOOD SAFETY ASSESSMENTS IN RESPONSE TO
READY-TO-EAT TESTING RESULTS**

I. PURPOSE

This notice reissues the content of FSIS Notice 60-10, which expired on November 1, 2011. FSIS is reissuing this notice because it provides important information for scheduling a “for cause” Food Safety Assessment (FSA) performed with Intensified Verification Testing (IVT). It also specifies the conditions that trigger scheduling a “for cause” IVT FSA, including *Salmonella* positive results from ready-to-eat (RTE) product. Further information about the incidence of *Salmonella* is provided in Attachment 1. This notice has been revised to clarify that FSIS will no longer perform IVT sampling in response to *E. coli* O57:H7 positive results from RTE products because routine sampling has been discontinued for the pathogen in these products.

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

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

B. 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 IVT is to be scheduled so that it can be completed within 90 days of receiving notification. If the DCS is unable to schedule an FSA and IVT within 30 days of receiving the weekly “for cause” list, or to complete the IVT within 90 days, the District Manager (DM) is to document the reason in the case file. The DM is also to notify ODIFP/DAIG by sending an email to the “IVT Sample Scheduling - FSIS” mailbox in Outlook. The DAIG will use this information as part of the data analysis to help determine policy effectiveness.

C. The Enforcement, Investigations, and Analysis Officer (EIAO) conducting the IVT is to follow the sample selection and sample size instructions contained in FSIS Directive 10,300.1, IVT Protocol for Sampling of Product, Food Contact Surfaces, and

DISTRIBUTION: Electronic

NOTICE EXPIRES: 2/1/13

OPI: OPPD

Environmental Surfaces for *Listeria monocytogenes* (*Lm*). The EIAO is to conduct an IVT FSA under the following conditions:

1. As stated in Directive 5100.4, an FSIS RTE product sample tests positive for *Lm* or *Salmonella* under the ALLRTE or RTE001 sampling programs. IVTs will no longer be performed in response to *E. coli* O157:H7 positives in RTE products, because FSIS no longer tests for the pathogen under the ALLRTE and RTE001 sampling programs.
2. A product or a food contact surface sample tests positive for *Lm* during an RLm.
3. An RTE product sample from another government entity (e.g., FDA) tests positive for *Lm* or *Salmonella*.
4. The in-plant inspection team has documented repetitive occurrences of noncompliance in the establishment's *Lm* control program, including sanitation issues.

D. The District Office (DO) is to schedule an EIAO to perform an IVT to verify corrective actions before closing out an enforcement action. Because the IVT is being performed to verify corrective actions, it does not need to be scheduled in 30 days and completed within 90 days

III. SAMPLING INSTRUCTIONS FOR CONDUCTING IVTs

A. For *Lm* IVTs, the EIAO is to:

1. Follow the IVT methodology according to FSIS Directive 10,300.1;
2. Generally, collect 1 unit per line, with a maximum of five units collected. A unit for an *Lm* IVT consists of 3 product samples, 5 environmental samples, and 10 food contact samples (FCS); and
3. Perform an FSA along with the IVT.

NOTE: A comprehensive FSA is normally not conducted during an IVT performed in response to RLm contact or product positives, 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.

B. For *Salmonella* IVTs, the EIAO is to:

1. Follow the IVT methodology according to FSIS Directive 10,300.1;
2. Generally, 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; and
3. Perform an FSA along with the IVT.

IV. EIAO RESPONSIBILITIES

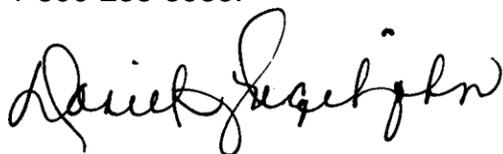
A. When an EIAO conducts an IVT, he or she is to contact the FSIS laboratories through the Outlook “IVT Sample Scheduling - FSIS” mailbox approximately 2 weeks before the scheduled IVT sample collection date, unless circumstances require otherwise. This contact will ensure that the laboratory involved has the resources available to receive and process the samples in a timely manner and allows time for the laboratory to ship the sample supplies to the appropriate site. The “IVT Sample Scheduling - FSIS” 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 practical. The email to the “IVT Sample Scheduling - FSIS” mailbox is to include all of the following information:

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 name and phone number of 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 AND POLICY EFFECTIVENESS

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 the receiving the weekly “for cause” list, as called for in this notice. 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 made available. ODIFP will provide this quarterly analysis to the Assistant Administrator (AA) of the Office of Field Operations (OFO). RIMD will use the results of this data analysis to inform future FSIS policy and program development.

Refer questions regarding this notice to the Risk, Innovations, and Management 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 products 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 deficiencies for sanitary practices. This attachment provides information about possible sources of *Salmonella* contamination in RTE establishments.

Salmonella can contaminate RTE products in the following ways:

1. Under processing
 - a. Under processing 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 under processing.
2. Contamination from raw materials
 - a. Raw or partially processed produce (e.g., raw or perhaps blanched), egg, peppers, 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. Effective employee training programs and consistent execution of Sanitation Standard Operating Procedures (Sanitation SOPs) are necessary to ensure that contamination does not occur.
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.