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

FSIS NOTICE

03-12 | 1/9/12

FSIS ACTIONS IN ESTABLISHMENTS THAT TEMPORARILY ALTER ROUTINE PRACTICES DURING ROUTINE RISK-BASED *LISTERIA MONOCYTOGENES* (RLM) SAMPLING OR INTENSIFIED VERIFICATION TESTING (IVT)

I. PURPOSE

This notice cancels FSIS Notice 78-11, and is being reissued to clarify the instructions for Enforcement, Investigations, and Analysis Officers (EIAOs) when recommending the issuance of NRs. FSIS has determined that some establishments may temporarily alter their routine practices during Routine Risk-Based *Listeria monocytogenes* (RLm) Sampling or Intensified Verification Testing (IVT). 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 notice provides instructions to EIAOs in performing RLm and IVT sampling in establishments that temporarily alter their routine practices in response to notification of FSIS sampling.

II. BACKGROUND

A. RLm and IVT sampling are performed along with a Food Safety Assessment (FSA) according to the following directives:

1. FSIS Directive 10,240.5, Verification Procedures for Enforcement, Investigations and Analysis Officers (EIAOs) for the *Listeria monocytogenes* (*Lm*) Regulation and Routine Risk-Based *Lm* (RLm) Sampling Program, and

2. FSIS Directive 10,300.1, Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for *Lm*.

B. By performing RLm and IVT sampling along with the FSA, FSIS can gain important information about the sanitary conditions in the establishment during production. RLm sampling is conducted along with a routine FSA to assess conditions at ready-to-eat (RTE) establishments once every four years. IVT sampling is conducted along with a "for cause" FSA in response to a positive product or food contact surface (FCS) sample found through another FSIS sampling program or because of other food safety issues at the

establishment.

C. A recent analysis of data from FSIS *Lm* verification programs showed that some establishments have altered routine production, sanitation, or food safety practices during RLm or IVT sampling. These changes typically are temporary, in that they are applied only during FSIS RLm or IVT sampling, and normal production processes are resumed at the completion of the RLm or IVT sampling.

D. Examples of an establishment changing practices may include temporarily increasing the use of sanitizer only during the RLm or IVT; drastically reducing the typical production time (e.g. by more than 2 hours in a typical 8-hour shift or other significant reduction), lot size, or number of employees handling the product; selectively not producing product with a higher risk for becoming contaminated post-lethality (e.g. sliced product); and not using particular equipment that previously has tested positive (e.g. equipment associated with positive product).

E. 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 (FMIA) and Poultry Products Inspection Act (PPIA). 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).

III. INSTRUCTIONS TO EIAOs

A. Upon notification that an RLm or IVT is scheduled, EIAOs are to contact inspection program personnel (IPP) at the establishment, to determine the production schedule for post-lethality exposed RTE product and to identify a sample-collection date.

B. EIAOs are to notify the establishment at least one week before RLm sampling or at least 48 hours (or other reasonable timeframe) before IVT sampling, to allow the establishment the opportunity to hold product. This notification gives establishments an opportunity to keep contaminated products from entering commerce and thus prevents the need for a recall if the product or FCS is subsequently found to be positive for *Lm*. The EIAO is to document the notification in a Memorandum of Interview (MOI). As part of this notification:

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

2. The EIAO is to inform the establishment that, if it intends to modify its documented routine production, sanitation, or food-safety practices before the RLm or IVT sampling, it should inform the EIAO as soon as possible, so that the EIAO can determine whether RLm or IVT sampling should be rescheduled.

3. The EIAO is to advise the establishment that, if it changes its practices temporarily during the RLm or IVT sampling, without notifying the EIAO in advance, and can not provide a justifiable reason for doing so, the sampling may

be rescheduled and further regulatory actions may be taken, which could delay completion of the FSA.

C. Prior to the RLm or IVT, 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 he or she was notified of the change, 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 RLm or IVT sampling, if available. If similar product is not available, the EIAO is to reschedule the RLm or IVT as in paragraph III.C.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 RLm or IVT, if possible. If the EIAO is unable to assess the program changes, he or she is to reschedule the RLm or IVT as in paragraph III.C.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 RLm or IVT sampling to the next time in which the product or production practice of interest can be assessed by the EIAO. The EIAO is to reschedule the sampling for a time when the FSA is underway at the establishment, if possible.

D. On the day of the RLm or 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, then the EIAO is not to perform sampling and is to contact the District Office (DO) through his or her supervisory chain.

E. If the EIAO finds that the establishment has made changes in its food safety systems and did not consider the changes in its hazard analysis in accordance with 9 CFR 417.2(a), or that it did not document the changes as in 9 CFR 417.5(a)(1), he or she is to recommend to supervisory personnel that the in-plant inspection team issue an NR. 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, EIAO Food Safety Assessment Methodology. Likewise, if the EIAO finds that the establishment has made changes in its sanitation practices (e.g. temporarily increasing the use of sanitizer only during the RLm or IVT) that are not documented in its Sanitation SOP, he or she is to recommend to supervisory personnel that the in-plant inspection team issue an NR under 9 CFR 416.12(a).

NOTE: If an establishment decides to limit its product lot size **solely** to facilitate holding of the product during the RLm or 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 http://askfsis.custhelp.com.

IV. DISTRICT OFFICE RESPONSIBILITIES

A. If the EIAO is unable to collect RLM or IVT samples as in paragraph III.D. and is therefore unable to assess whether the establishment is controlling *Lm* on its FCS 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. In the case of an RLm, the DO may initiate product sampling or schedule an IVT with a "for cause" FSA.

2. In the case of an IVT, the DO may instruct IPP to reject 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 equipment will be rejected until such a time as 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 practice of interest. If the establishment permanently stops producing a particular product, the EIAO is to document this change in the MOI.

3. The DO may issue a Notice of Intended Enforcement (NOIE) or Notice of Suspension (NOS) 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).

V. DATA ANALYSIS

On a quarterly basis, the Office of Policy and Program Development (OPPD), with the support of the Data Analysis and Integration Group (DAIG) in the Office of Data Integration and Food Protection (ODIFP), will review data from FSAs from establishments where RLms or IVTs were held to determine whether new policy or guidance is needed.

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