FSIS Directives 10,240.4, 10,240.5, and 10,300.1 Directives Regarding Sampling of Ready-to-Eat Products

OPPD/PID

DO Correlation

2/5/09

FSIS Directives 10,240.4, 10,240.5, and 10,300.1

- Why were these directives revised?

- To reflect changes in Agency policies relating to risk based sampling and meeting the Agency's performance measure for Lm

10,240.4 Directive

- Provides directions to CSIs on submitting RTE product samples under the ALLRTE and RTE001 sampling projects
- Provides instructions for verifying whether establishments are complying with 9 CFR Part 430

Changes to the 10,240.4 dir.

- CSI Responsibilities for Collecting Samples
  - Will collect all *Lm* samples scheduled at the same establishment over the same time period;
    - This provides overall verification of an establishment's process

Changes to the 10,240.4 dir.

- CSI Responsibilities for Collecting Samples
  - No longer required to submit intact samples after pre-shipment review;
    - Previously, CSIs collected samples that the lab did not analyze
    - Previously, no test results obtained

Changes to the 10,240.4 dir.

- CSI Responsibilities for Collecting Samples
  - Certain products are no longer exempt to Lm sampling under the ALLRTE sampling project (see Attachment 2)
    - Agency revising the 10,210.1 Directive
    - **Products labeled for further processing still exempt**

Changes to the 10,240.4 dir.

- Enforcement
  - The issuance of NRs based on FSIS results, depending on whether the establishment also found the positive product and held affected product;
  - Instructions for completing disposition of product occurring off-site

10,240.5 Directive

- Provides instructions to EIAOs for collecting samples under the Routine Risk-based *Lm* (RLm) Sampling Program
- The sampling program includes the collection of food contact, environmental, and product samples, and completing a FSA

Changes to the RLm Sampling Program

- Agency will select establishments from a list of those establishments producing 95% of the volume of meat and poultry products
  - Previously, establishments selected using a risk-based algorithm

EIAO Responsibilities for Collecting Samples under RLm

- No longer required to submit and complete the validation checklist– it is now in the new EIAO tool
  - FSIS is using a new FSA methodology
  - New methodology collects findings in a configuration that allows for data analysis

EIAO Responsibilities for RLm Sample Scheduling

- A change in the number of sample units collected depending on the establishment size
  - Previously, the number of units collected was based on the number of lines in the establishment up to a maximum of 5 units
  - More effectively allocates Agency resources

EIAO Responsibilities for RLm Sample Scheduling

- A change in the number of sample units collected depending on the establishment size
  - EIAOs are to collect 3 sample units from large establishments, 2 sample units from small establishments, and 1 sample unit from very small establishments
  - Based on establishment size in the HACCP preamble (61 FR 38806)

EIAO Responsibilities for RLm Sample Scheduling

- Randomly select the shift on which to collect the sample
  - Select the 1st, 2nd, or 3rd shift Monday through Thursday, or the 1st shift Friday within the week identified in the monthly RLm Scheduling Memo

EIAO Sample Collection Responsibilities

- The addition of brine sampling
  - Methodology in the 10,300.1 Directive
  - Food contact sample if the brine comes in direct contact with unpackaged product or with product in a permeable or semi-permeable casing
  - Environmental sample if the product is in an impermeable casing, or otherwise packaged

EIAO Sample Submission Responsibilities

- The removal of the requirement to submit intact samples after pre-shipment review
  - Previously, EIAOs collected samples that the lab did not analyze and results were not obtained
  - Submit samples after the establishment has completed all interventions, unless the establishment has any intervention based on microbiological test results

Directive 10,300.1

- The purpose of this directive is to provide direction to EIAOs on collecting product, food contact, and environmental samples using the IVT Methodology
- The Agency will now include brine sampling as part of the IVT methodology

Background

- Agency will schedule an IVT for cause at the discretion of the DM
- Conduct IVT in conjunction with a food safety assessment
- RLm sampling program

Definitions

- Food Contact Surface Sample
  - EIAOs may consider aprons and gloves food contact surfaces if the EIAO observes direct contact of the apron or glove with the product
- Environmental Surface Sample
- Brine samples may be either food contact or environmental

Pre-Sample Collection Planning

- Contact the establishment at least 48 hours before IVT sample collection, or if needed enough time for the establishment to hold the product
- Collect no more than 5 units
  - Sample all lines if the establishment has less than 5 lines

Pre-Sample Collection Planning

- If an establishment does not produce product on a line on the day of the IVT
  - EIAO can still sample the line
  - Sample under the CONT project code
  - State that the line is not in use under block 28

Pre-Sample Collection Planning

- If an establishment uses brine:
  - Collect 1 brine sample per unit
  - Collect a maximum of 5 brine samples

Notifying the Lab and OCIO

- Requests forms and supplies through the IVT scheduling mailbox
- Make every effort to contact the lab 2 weeks before conducting the IVT sampling
- Request brine sampling supplies

Notifying the Lab and OCIO

- Use a separate form for each sample the EIAO collects
- Use the correct form for the type of sample taken
- Don’t change the project code on the form
- Order extra forms for additional samples

Sample Collection Responsibilities

- Entrance meetings
- Conduct the IVT as early as possible during the FSA
- Guidelines for collecting food contact and environmental samples
  - Recent sanitation problems
  - Lines or areas that tested positive
- Examples of places to sample

Sample Collection and Submission Responsibilities

- Sampling Using SpongeSicles for Food Contact and Environmental Sampling
- Liquid Sampling for Brine
- Submit samples without waiting for the establishment to conduct pre-shipment review
- Submit samples after the establishment has applied all interventions except for a microbiological testing intervention

Enforcement

- If the establishment held the product or maintained control of the product pending its own test results, and FSIS and the establishment found the product positive for *Lm*, EIAOs are to verify the establishment performs the appropriate corrective actions as part of the FSA

Enforcement

- The Agency will only conduct an FSA as a result of a positive food contact or product sample from an RLm collection activity if 6 months has elapsed since the previous FSA. However, the Agency may elect to conduct an IVT.