Ready-to-Eat (RTE) Sampling

This document has been created to be used for reference purposes only. The information in this document is not all-inclusive. Please refer to the FSIS directives and notices for detailed policy and procedural information.

- FSIS Sampling programs are designed to verify that food safety systems are effective and that performance standards/regulations are met.
- RTE products pathogens of concern: *Listeria monocytogenes (Lm)*, and *Salmonella*
  - Salmonella is associated with under processing or cross contamination post-processing
  - *Lm* – more often associated with cross-contamination post-processing
- RTE product = adulterated;
  - when contains -> *Listeria monocytogenes*, *Salmonella* + any other pathogen that causes illness, including *E. coli* O157:H7.
  - when comes into direct contact sampled positive food contact surface.
- **NO** "collector generated" sample requests for RTE product sampling.
- Directed Sampling tasks - request additional directed tasks through the supervisory chain of command.

Action items to perform **before** starting Sampling task:

- Determine which product to sample
- Schedule task in PHIS. **RTEPROD_RAND** or **RTEPROD_RISK**
  NOTE: Be sure to rotate products each time performing task to make sure they are all sampled.
- Check collection date range;
- Consider the priority of sampling tasks relative to other tasks
- Give establishment management advance notice so they can place product **ON HOLD**
  - Inform management that they are responsible for defining the sampled lot and holding or controlling the product represented by the sampled lot.

Perform Sampling Task

- **Collect the sample**:
- Document the sample in PHIS.
- Pack & Ship the sample & form - **Be sure to sign the sample form!**

Action items to perform **after** collection and shipment of sample:

- Respond to the results - access Laboratory Information Management System (LIMS) Direct to track sample receipt and detailed information on sample results or discards, in real time.
- Notify establishment of all results – even if establishment management receives email notifications automatically.

IPP must reference FSIS Directive 10,240.4, *Verification Activities for the Listeria monocytogenes (LM) Regulation and the Ready-to-Eat (RTE) Sampling Program*, for specific details that must be followed when performing RTE Sampling.

Altered practices:

- If establishment alters their process/practices on sampling day and cannot support the change
    - **Do Not** collect sample
    - Reschedule sampling task, if possible.
    - Issue a Noncompliance Report (NR) **if the establishment cannot support the change**.

      NOTE: If this is a recurring problem:
        - Discuss situation with supervisor
        - Discuss with establishment management at weekly meeting
- Verify results of RTE product contact surfaces for Lm

Action items to perform after a positive FSIS verification sampling result

- Obtain lab results from LIMS Direct and report them to the establishment management.
- Document this notification in a MOI.

NOTE: When notified that a sample has been discarded and it is not going to be analyzed at a FSIS laboratory, notify the establishment immediately so that they can release any product that has been held on-site or controlled off-site.

Enforcement Actions in Response to Positive Results from the RTEPROD Sampling Project

IPP collected samples:

- (+) Salmonella or Lm results under RTEPROD_RAND or RTEPROD_RISK project codes = adulterated product.
    - Follow instructions in FSIS PHIS Directive 5000.1
    - Issue NR:
        - FSIS finds + product and the establishment tested product under their documented sampling programs -> check establishment's testing results to see if they have (+) Salmonella or Lm results for the sampled product.
        - Make sure establishment held product or maintained control of product pending its own test results.
            - If product was not held or control maintained -> issue NR.
            - If establishment found sampled product to be Salmonella or Lm (+) and they held the product, DO NOT issue NR. IPP must verify that the establishment performs appropriate corrective actions , using directed HACCP Verification Task.

Verifying Corrective Actions

- If an RTE product contact surface tests positive for *Lm*, the product passing over the surface is adulterated unless a validated 5-log reduction in *Lm* was applied to it.
- Depending on what program the pathogen is to be controlled by the corrective actions would follow the regulatory requirements:
    - 417.3(a) if pathogen addressed in HACCP plan.
    - 416.15 & 417.3(b) if pathogen is addressed in SSOP (unforeseen hazard).
    - 417.3(b) & 417.4(a)(3) if pathogen addressed in pre-requisite program (unforeseen hazard).

- IPP should verify disposition of the affected product.
- Can the establishment support that contamination would be limited to that product lot or individual production lines?
- Was product destroyed?
- Was product reworked with a validated process to achieve adequate lethality for *Lm* and *Salmonella*?
- Off Site Disposition of Product: Adulterated product can be shipped under appropriate controls to another federally inspected facility, renderer, or landfill operation for disposition.
- Maintained records identifying establishment, renderer, or landfill operation that received positive product
- Maintained control of product destined to landfill operation or renderer while it was in transit (e.g., through company seals)
- Verify Establishment-maintained records showing that positive product received the proper disposition, including documentation showing proper disposal of the product from the establishment, renderer, or landfill operation where disposition occurred.

Verifying Product Disposition

The establishment may reprocess or dispose of the adulterated product.

- If establishment reprocesses the product – IPP should verify that they use a process that achieves adequate lethality of pathogens.

  NOTE: FSIS considers a process that has been validated to achieve a 5-log reduction of Lm sufficient for reworking contaminated product.

- The establishment can dispose of the product on-site or off-site. If it is done on-site, IPP should verify that establishment maintains records showing the (+) product received proper disposition.

- If the (+) product is transported to another site, IPP should verify that the establishment has met all corrective action requirements by verifying that the establishment:

  - Maintained records identifying the official establishment, renderer, or landfill operation that received the (+) product.
  - Maintained control of product that was destined for a landfill operation or renderer while the product was in transit.
  - Maintained control of product destined for an official establishment while the product was in transit or ensured the product was moved under FSIS control.
  - Maintained records showing (+) product received proper disposition, including documentation showing proper disposal of the product from the official establishment, renderer, or landfill operation where disposition occurred; and
  - Completed pre-shipment review for the (+) product only after it has received the records described above for that particular product.

If there is a noncompliance with the corrective action requirements for disposal of the (+) product -> IPP should document it according to instructions in FSIS PHIS Directive 5000.1.

If establishment ships adulterated product to a renderer or landfill operation, IPP should verify that the establishment denatures the product before the product leaves the establishment.

If the establishment has not properly moved or disposed of the product, IPP should notify their District Office through their supervisory channels.

IVT Sampling Program

These samples are collected as part of Routine Risk-based Lm (RLm) and Intensified Verification (IVT) Sampling.

- Results from RLm or IVT Sampling

    - Review **FSIS Directives 10240.5***, Verification Procedures for EIAOs for Lm Regulation and RLm Sampling Program* and **FSIS Directive 10300.1**, *Intensified Verification Testing (IVT) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria Monocytogenes.*

    - If environmental (non-food contact) sample tests (+) for Lm during RLm or Lm or Salmonella during an IV -> product NOT considered to be adulterated. Issue NR, if there is evidence of insanitary conditions that could lead to product contamination.