Ready-To-Eat Sampling Job Aid

Instructions: Review this Job Aid and policy documents, regulations, and inspection methodologies with a mentor.

Acronyms/Definitions

- Ready-to-Eat (RTE) Product – A meat or poultry product that is in a form that is edible without additional preparation to achieve food safety and may receive additional preparation for palatability or aesthetic, epicurean, gastronomic, or culinary purposes.
- Post-Lethality Exposed Product – RTE product that comes into direct contact with a food contact surface after the lethality treatment in a post-lethality processing environment.
- *Listeria monocytogenes* (*Lm*) – Foodborne pathogen. *Lm* contamination is a food safety hazard that may occur during the processing of post-lethality exposed RTE products.
- *Salmonella* – Foodborne pathogen. *Salmonella* contamination in RTE products usually indicates under-processing and the adequacy of the lethality step may be in question.
- Final Package – Packaging that is normally shipped by the establishment into commerce
- Food Contact Surface (FCS) – Any surface that may come in direct contact with exposed meat or poultry product (e.g., conveyor belts, tabletops, saw blades, augers, and stuffers).
- Sampled Lot – The production lot represented by the sample. The establishment is responsible for defining the sampled lot.
- Laboratory Information Management System (LIMS) – System used by FSIS personnel to view testing results for samples submitted to FSIS labs.

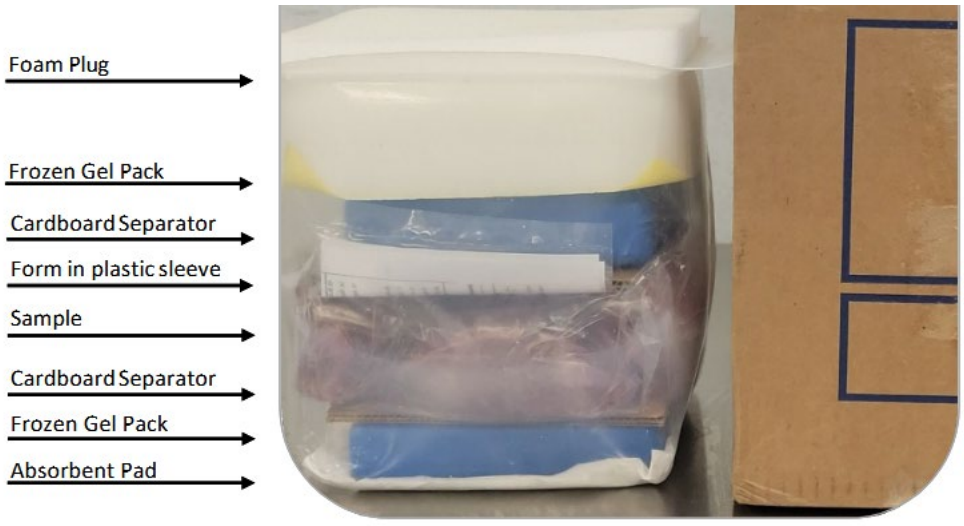
Task Overview

- IPP collect samples of RTE meat and poultry products under FSIS's RTEPROD sampling program.
- FSIS tests RTE product samples for *Listeria monocytogenes*, non-*Lm Listeria* species, and *Salmonella*. FSIS conducts Whole Genome Sequencing (WGS) on *Lm* positives.
- *Lm* and *Salmonella* are adulterants in all RTE product.
- If any level of *Lm* or *Salmonella* is detected in an RTE product or on a food contact surface that RTE product has passed over, the product is adulterated.
- Eligible products: All RTE meat and poultry products are subject to RTEPROD sampling including both post-lethality exposed and not post-lethality exposed products.
- Ineligible products:
    - Pass-through product
    - Oils, shortening, lard, margarine, oleomargarine or mixture of rendered animal fat
    - Product labeled "For Further Processing"
- PHIS assigns and displays RTEPROD sampling tasks on the Establishment Task List. PHIS uses the establishment profile to assign appropriate sample requests.

Basic Procedure

- Randomly select a day, shift, and time within the sample window timeframe to schedule the sampling task in PHIS.

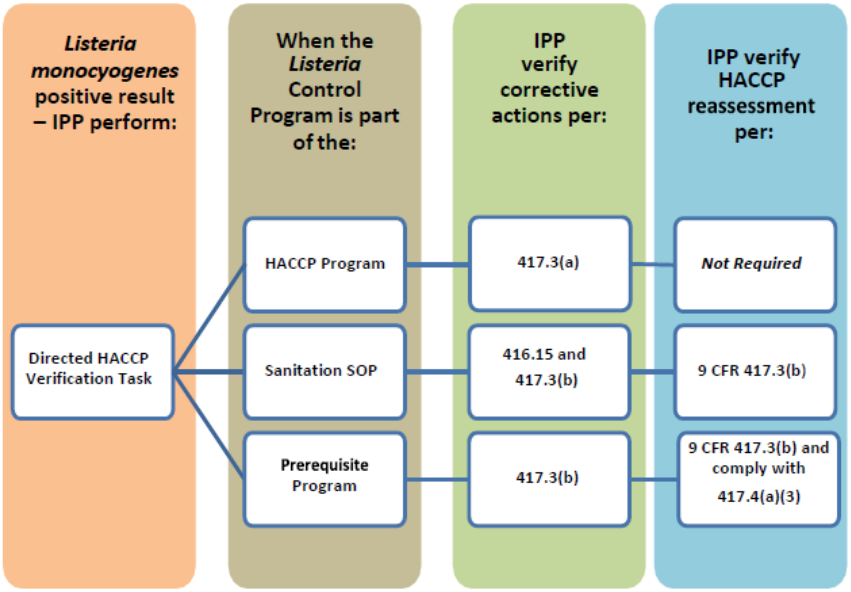
- Before collecting sample, notify the establishment:
    - To hold the entire sampled lot; provide enough time for the establishment to hold the sampled lot but not enough time to alter its process, generally 1-2 days' notice.
    - That it is responsible for supporting the basis for defining the sampled lot.
    - That it is required to hold or control the sampled lot until negative results become available.
- Confirm the establishment is producing applicable product on the day sampling is scheduled.
- Randomly select a product produced at the time the sample is scheduled, regardless of whether the product is post-lethality exposed or not (FSIS Directive 10240.3, Ch. III., Sec. II., A.).
    - Make efforts to cycle through all the products produced by the establishment (i.e., post-lethality exposed and not post-lethality exposed products, products produced under different *Listeria* alternatives, and also different product types).
- Collect **one pound** of RTE product (FSIS Directive 10240.3, Ch. III., Sec. II., B. & C.):
    - In the establishment's **final packaging** after all interventions are complete.
    - At least three hours after the start of production, whenever possible, to allow *Lm* to work its way out of the equipment.
    - **Note:** See Multi-component RTE Product Sampling to determine how much product to collect when products sampled under the RTEPROD sampling code contain non-meat and poultry components.
- Document the sampling task and complete the questionnaire in PHIS within the task.
- Pack, label, and ship the sample.



- Access test results using the LIMS-Direct.
- Respond to the results (FSIS Directive 10240.3, Ch. IV., Sec. II. & III.):
    - Negative *Lm* and *Salmonella*: Notify the establishment that it can release the held product.

- Positive for non-*Lm Listeria* spp. but negative for *Lm*: Perform an Operational SSOP Review and Observation task to verify the establishment takes corrective actions as required by 9 CFR 416.15.
- Positive for *Lm* or *Salmonella*:
  - Notify the establishment that they produced adulterated product.
  - Confirm that the establishment held or otherwise maintained control of the product (e.g., controlled by the establishment off-site). Notify your supervisor immediately if product is not held or under control.
  - Perform a directed HACCP Verification task for the specific production lot that tested positive to verify the establishment implemented corrective actions according to 9 CFR 417.3(a) or (b), or 9 CFR 416.15.
  - When WGS results indicate there is harborage in the establishment, verify corrective actions such as intensified sanitation and sampling in response to repeated *Lm* positive results.
  - Collect follow-up samples assigned in PHIS.

Steps for Verifying an Establishment's Corrective Actions



- Document noncompliance when FSIS test results are positive for *Lm* or *Salmonella* and:
  - The establishment's HACCP system did not identify the adulterated product being produced (i.e. through an establishment-collected positive sample from the same lot);
  - The establishment did not hold or maintain control of the product. IPP are to also immediately notify their supervisor if the establishment did not hold or maintain control of the product; or
  - The establishment did not take corrective actions.
- Generally, if the product is negative for *Lm* and *Salmonella* but positive for a non-*Lm Listeria* spp., product can move in commerce, and IPP are not to issue an NR solely based on the positive result. If the establishment does not restore sanitary conditions of

surfaces associated with the non-*Lm Listeria* spp. positive test, then IPP are to document an NR for failure to comply with 9 CFR 416.15(b).

- Consider whether pathogen positives are associated with past noncompliances or other findings that may indicate systemic problems or trends.
- Repetitive non-*Lm Listeria* spp. findings indicate a trend. The establishment's *Listeria* control program is not effective in controlling the presence of *Lm* in the post-lethality processing environment. These findings indicate the establishment's need to evaluate the Sanitation SOPs (9 CFR 416.14).

Discussion Points

- Discuss the significance of *Lm* vs. *Listeria* species.
- Discuss the significance of a trend of positive *Listeria* results.
- Review the establishment profile and discuss the fields that impact eligibility for sampling programs.

Knowledge Check

- What RTE products are eligible under the RTEPROD sampling program?
- What size sample do IPP collect under RTEPROD sampling?
- What are IPP to do if the establishment does not hold product that IPP sampled, pending FSIS test results?

Resources

- FSIS Directive 10240.3 – *FSIS Ready-To-Eat Sampling Programs*
- FSIS Directive 10240.4 – *Listeria Rule Verification Activities*
- FSIS Directive 7355.1 – *Use of Sample Seals for Laboratory Samples*
- FSIS Notice 50-24 – *FSIS Testing for Non*-Listeria Monocytogenes Listeria *Species*
- IPP Help: RTE Sampling
- PHIS Help: Lab Sampling Alerts
- IM Workbook – Sampling Ready-to-Eat (RTE) Product