Food Safety and Inspection Service
U.S. DEPARTMENT OF AGRICULTURE

Overview of RLm and IVT sampling

Brad Webb
Senior Staff Microbiologist
FSIS, OPPD, RMIS

Overview

- Purpose of FSIS sampling.
- Pathogens and products of concern.
- FSIS **Directive 10,240.5**, Rev. 3 – The RLm Sampling Directive.
- FSIS **Directive 10,300.1**, Rev. 1- The IVT Sampling Directive.
- Common Instructions for both RLm and IVT sampling.
  - When establishments change practices.
  - Results and Enforcement.
- FSIS **Directive 5100.1**, Rev. 4 – The FSA Directive.
- FSIS **Directive 5100.4**, Rev. 1 - The PHRE Directive.

Sampling Purposes

- **Help** verify that the plant's process is producing safe, wholesome, unadulterated product
- **Help** verify the adequacy of a plant's HACCP plan, Sanitation SOP, and prerequisite programs.
- The RLm sampling program is "routine, risk based" and is intended to **help** verify the adequacy of a plant's *Listeria* control program, per 9 CFR 430.4.
- The IVT sampling program is done for cause, e.g., to **help** verify corrective actions, typically following a previous positive.

Products of Concern for RLm or IVT sampling

- Ready-to-eat (RTE) products.
- RLm sampling is only for PLE, RTE products (9 CFR 430).
- Production lots are typically defined as from clean-up to clean-up.

RTE product (9 CFR 430.1) - 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.

Primary Pathogens of Concern

Listeria monocytogenes (Lm) and *Salmonella* spp.

- Both can cause human disease.
- Both can be cross contaminated to products from contaminated plant equipment or the environment.

The presence of *Lm* in a RTE product is typically due to post-lethality contamination.

The presence of *Salmonella* in a RTE product may be an indicator of a lethality process failure, but it can also be a result of post-lethality contamination.

FSIS Directive 10,240.5

Verification Procedures for EIAOs for the *Lm* Regulation and Routine, Risk-Based *Lm* (R*Lm*) Sampling Program.

"*The RLm Directive.*"

FSIS Directive 10,240.5

- Provides instructions for collecting RLm samples.
- An updated version of 10,240.5 was published on 11/02/2022.
- Significant changes include;
  - Prioritizing line sampling based on the risk of the 430-production alternative (future slide).
  - Sequence of establishments eligible for RLm sampling on the monthly spreadsheet is now sequenced based on risk, instead of a 4-year FSA cycle (next presentation).
  - The option for DOs to use RLm sampling to inform a PHRE vs. using R*Lm* sample results to inform an FSA.

FSIS Directive 10,240.5

RLm testing is;

- **R**outine, risk-based, sampling for ***Lm*** (abbreviated **RLm**).
- Intended for producers of PLE, RTE products only.
- Samples always tested for *Lm*. (RLm Sal testing is not an option.)
- Used to **help** verify compliance with 9 CFR 430.
- RLm results help inform an FSA outcome or;
- New option - use RLm sampling to **help** inform a PHRE outcome.

However;

- Listeria contamination is typically intermittent and non-homogenous.
- Sampling is a snapshot in time.
- **All negative results do not confirm that Lm is being controlled**.

FSIS Directive 10,240.5

Rlm sampling uses IVT methodology;

- Consists of product, FCS, and NFCS swab samples.
- Multiple samples collected as a part of sampling "units".
- Each unit has a defined composition, e.g., 5 product, 10 FCS, and 5 NFCS samples per unit.

Examples of significant differences with IVT sampling:

- RLm sampling is “routine, risk-based”. IVT sampling “for cause”.
- Different method for determining the number of units to collect.
- IVT samples are never composited.
- IVT samples may be tested for Lm or Sal (rare).
- Establishment notification timeframe is different.

FSIS Directive 10,240.5

Prior to RLm scheduling, the EIAO is to:

- Contact in plant inspection personnel (IPP) to gather information (typically a part of the PHRE).
- Ask about risk factors and any IPP concerns.
- Identify eligible products.
- Determine overall RTE production steps and processes.
- Is brine utilized to cool the PLE, RTE products?
- Identify possible day for sampling.
- Determine number of sample units to collect.

FSIS Directive 10,240.5

The number of RLm units to collect is based on establishment size;

- Large establishments = up to a maximum of 3 units
- Small establishments = up to a maximum of 2 units
- Very small establishments = maximum of 1 unit

Each unit must always be associated with one line, one production lot, and one production alternative.

Establishment size is based on establishment categories in the HACCP preamble (61 FR 38806);

- large establishments – 500 or more employees
- small establishments – 10 or more employees but fewer than 500
- very small establishments – fewer than 10 employees or annual sales of less than $2.5 million.

FSIS Directive 10,240.5

- Each RLm unit is composed of;
  - 5 **prod**uct samples, **c**omposited by the labs- one RLM**PRODC** form.
  - 10 food **cont**act surface (FCS) swab samples, not composited – 10 RLM**CONT** forms.
  - 5 **env**ironmental, nonfood contact surface (NFCS) swab samples, **c**omposited by the labs - one RLM**ENVC** form.

- **Brine** samples might be FCS or NFCS.
  - Permeable casing ➡ FCS – use one of the FCS forms (RLMCONT).
  - Impermeable casing ➡ NFCS - brine NOT composited with NFCS swab samples. Requires an extra form (RLMENVR).

FSIS Directive 10,240.5

Production Line (from the Lm CG): A line refers to the flow of product during production. This includes all equipment, personnel, and utensils that contact the RTE product. Multiple individual product lines can meet at a piece of equipment (e.g., packaging machine), but can still be considered multiple lines.

Prioritize sampling of lines based on risk;

- 9 CFR 430 Lm control Alternative.
- Sampling history (both FSIS and establishment sampling).
- Other risk factors such as recent or ongoing construction, condensation issues, use of high-pressure hoses in PLE, RTE area, etc.

FSIS Directive 10,240.5

According to the Listeria rule (9 CFR 430.4) *Lm* contamination of post-lethality exposed (PLE) products must be controlled using one of three Lm control alternatives.

Risk of 9 CFR 430.4 production alternatives, from most risky to least risky:

Alt 3 (sanitation alone to control *Lm*)
Alt 2b (AMAP + sanitation)
Alt 2a (PLT + sanitation)
Alt 1 (PLT + AMAP + sanitation)

Decreasing Risk

FSIS Directive 10,240.5

- Notify the establishment 1 week prior to Rlm collection date.
- Once at the establishment, hold entrance meeting;
  - ✓ Inform them of the sampling and how it will be conducted – may use entrance letter in Directive 10,300, attachment 1.
  - ✓ Must hold the sampled lot(s), pending the results of FSIS testing.
  - ✓ Confirm that they will produce PLE, RTE product and won't change routine production practices (because you will be sampling).
- Conduct walk-through.
- Prepare for sampling, e.g., stage supplies, etc.

FSIS Directive 10,300.1

Intensified Verification Testing (IVT) Protocol For Sampling of Product, Food Contact Surfaces, and Environmental Surfaces for *Listeria monocytogenes* (*Lm*) or Salmonella spp.

"*The IVT Directive.*"

FSIS Directive 10,300.1

Provides instructions on collecting product, FCS, and NFCS samples (that are never composited).

IVT sampling is always performed “for cause”, at the discretion of the District Office.

IVT sampling is usually, but not always, done in conjunction with an FSA.

FSIS Directive 10,300.1

Examples of for cause reasons (in Directive 5100.4) that could lead to IVT sampling;

- A pathogen positive from an FSIS RTE sampling program (*Lm* or *Salmonella* spp.).
- Product has been associated with human illness.
- To verify corrective actions before closing out an enforcement action.
- A RTE positive from another government entity.

FSIS Directive 10,300.1

The number of IVT units determined by the number of RTE lines;

- 1 IVT unit per line, up to 5 units maximum.
- Vs. RLms where units is based on establishment size.

IVT samples are never composited, thus an extra form for NFCS brine samples is **not** needed.

One unit for ***Lm*** IVTs consist of:

- 5 intact product samples, 5 forms (INTPROD).
- 10 FCS samples, 10 forms (INTCONT)
- 5 NFCS samples, 5 forms (INTENV).

FSIS Directive 10,300.1

Number of units is determined by number of lines, 1 unit per line, up to 5 units max. However;

One unit for ***Salmonella*** IVTs consists of:

- 5 intact, product samples - 5 INTPROD forms.
- 5 food contact swab samples – 5 INTCON forms
- 8 non-food contact (environmental) samples – 8 INTENV forms.

FSIS Directive 10,300.1

Notify the establishment 48 hours before the IVT (time to hold the product, but not time to change practices). Document this in a Memorandum of Interview (MOI) in PHIS.

At establishment;

- Conduct an entrance meeting (see IVT entrance letter).
  - ✓ Inform them of the sampling and how it will be conducted.
  - ✓ Must hold all sampled production lots, pending lab testing results.
  - ✓ Confirm that they will be producing RTE product and won't change routine production practices.
- Conduct walk through.
- Prepare for sampling, e.g., stage supplies, etc.

Same for both RLm and IVT sampling

- RTE sampled lots are typically defined as all product produced from clean-up to clean-up.
- Samples must be collected during conditions that are representative of routine processing.
- Collect product after the establishment has applied all interventions intended to reduce or control pathogens of concern, per their HACCP program and Hazard Analysis (HA).
- If a treatment is applied only for quality purposes, e.g., to extend shelf life, then product samples may be collected before such a process has been applied.

Same for both RLm and IVT sampling

- Instructions for establishments that change practices.
- Results and enforcement actions.

Changing Practices During RLm or IVT sampling

Changing practices = implementing changes that are not consistent with their documented food safety system;

- Drastically reducing the typical production time and/or the lot size.
- Temporarily increasing the use of sanitizer.
- Selectively not producing higher risk product (e.g., PLE, RTE line with history of previous Listeria positives).
- Not using a line or specific equipment that previously has tested positive (e.g., equipment associated with positive product or FCSs).

Changing practices interferes with FSIS's assessment of the adequacy of their process and food safety system.

Changing Practices During RLm or IVT sampling

If the establishment changes practices and cannot provide a **supportable rationale;**

- Contact your District Office (DO).
- Do not collect samples if they are not representative of routine processing conditions or practices.
- May recommend that IPP issue a noncompliance report (NR);
  - 416.14 – changes were not incorporated into their SSOP.
  - 417.2(a) - the establishment did not consider or document the changes in its hazard analysis (HA).
  - 417.5(a)(1) - the establishment did not incorporate the supporting documentation from 417.2(a) in its HA.

Changing Practices During RLm or IVT sampling

If an EIAO is prevented from collecting samples (no supportable rationale):

- In the case of an RLm, the DO may schedule an IVT with a “for cause” FSA - less advance notification.
- In the case of an IVT, if the EIAO cannot collect samples in order to determine that the product is not adulterated, the DO may instruct IPP to reject equipment in accordance with Rules of Practice - 9 CFR 500.2(a)(3).
- The DO may issue a NOIE or NOS when insanitary conditions are found or where the food safety system is inadequate, in accordance with 9 CFR 500.4(a) or (b) or 9 CFR 500.3(a)(4).
- OFO has final say in all regulatory enforcement decisions.

Changing Practices During RLm or IVT sampling

If a risky line is not operating - samples can potentially be collected with a justifiable reason for doing so, e.g., a risky or previously positive line is shut down because FSIS is going to sample it.

1. Determine if the establishment cleaned and sanitized the line.
2. Document that the line is not in operation.
3. Collect FCS and NFCS samples associated with the line.
4. Ensure that the receiving lab knows that no product will be samples submitted with the unit of samples prior to receipt.

Results and Enforcement

- Check LIMS or PHIS for results.
- Ensure that the establishment has the results.
- If any product sample tests positive, the entire sampled lot is adulterated.
- If a FCS sample tests positive, all product which passed over the FCS (the sampled lot) is adulterated.

Results and Enforcement

Actions in response to adulterated product released into Commerce;

- If FSIS obtains a product or FCS sample positive for *Lm* and the establishment did not hold or maintain control, **EIAOs are to immediately contact their DO**.

- The DO will take appropriate administrative action and contact the Recall Management and Technical Analysis Division (RMTAD).

- As appropriate, FSIS will request a recall or detain the product.

FSIS Directive 5100.1, revision 4

Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive **F**ood **S**afety **A**ssessment Methodology - Revision 4 (5/29/15).

"The FSA Directive."

FSIS Directive 5100.1, revision 4

- FSAs are performed based on results from a completed Public Health Risk Evaluation (PHRE).
- When an FSA is necessary, based on the PHRE outcome, the EIAO is to define the scope in advance of the FSA;
  - Determine which FSA tools will be completed, e.g., General Tool, Meat, Poultry, Ready-to-Eat (RTE), Not Ready-to-Eat (NRTE), etc.
  - Determine if sampling will occur.
- Any sampling (e.g., RLm or IVT) is to be conducted before the start of an FSA.
- The FSA is to be completed within 7 production days.

FSIS Directive 5100.1, revision 4

The EIAO should arrive at establishment the day before an FSA to;

- Hold a pre-entrance meeting with IPP at the establishment to discuss the FSA process and answer any questions.
- Meet with establishment management to explain the reason for the FSA and answer questions about the overall process.
    - 5100.1 contains a detailed topic list.
- Describes EIAO communication with the establishment, DO, FLS and IPP during FSA.
- Instructions for exit conference

FSIS Directive 5100.1, revision 4

During FSAs in establishments producing post-lethality exposed (PLE), RTE product, compliance with 9 CFR 430 is assessed.

- Review their *Lm* control prerequisite program.

Validation consists of two components;

1. Scientific Support – will it work in theory?
2. Establishment data – has the establishment implemented it as intended, using the critical operational parameters from 1?

Review their validation documentation for use of;

- Post Lethality Treatments (PLT)
- Antimicrobial agent or processes (AMAP)

FSIS Directive 5100.1, revision 4

- **The EIAO is to communicate with the IPP and frontline supervisor (FLS) throughout the course of the FSA** to describe any NRs or vulnerabilities that he or she has identified and to recommend that IPP document appropriate NRs.

- **The EIAO, the IPP, and the FLS are to work collaboratively** to ensure that all non-compliances are communicated to establishment management and documented for issuance.

- **The EIAO is to notify the FLS and IPP immediately** when a noncompliance that has an immediate impact on food safety is observed.

FSIS Directive 5100.4, Revision 2

Enforcement, Investigations and Analysis Officer (EIAO) **P**ublic **H**ealth **R**isk **E**valuation (PHRE) Methodology

"*The PHRE Directive*."

FSIS Directive 5100.4, Revision 2

PHRE;

1. PHRE Decision - Perform an FSA, take enforcement action, or take no action.
2. If PHRE outcome is an FSA, develop an Assessment Plan.
    - Summarize PHRE findings.
    - Determine scope of FSA and tools to be used.
    - Will sampling occur to inform FSA?

Type of sampling is determined by “risk type” in table 1 of 5100.4;

- “For cause” PHRE IVT sampling.
- “Routine, risk based” PHRE RLm sampling (if PLE, RTE).

FSIS Directive 5100.4, Revision 2

- Any sampling that may occur derives from a PHRE.
- The monthly scheduling spreadsheets are about prioritizing PHREs, not any type of sampling.

Table 1 of Directive 5100.4, “for cause” determinants for PHREs:

- FSIS positive *Listeria monocytogenes* (*Lm*) or *Salmonella* in ready-to-eat (RTE) product.
- Human illness linked to FSIS-regulated product (if RTE).
- Establishment with a history of public health-related noncompliance records in the highest percentile of health-related NR rates (if RTE related).

FSIS Directive 5100.4, Revision 2

Table 1 of Directive 5100.4, “risk-based” determinants for PHREs:

- New establishments coming under a permanent grant of inspection.
- Instructed in FSIS Notice or Directive.
- Establishment producing post-lethality exposed ready-to-eat (RTE) products without positive sample results.

Once Lm related risk factors and any concerns from IPP are considered, a risk-based PHRE done on a 430 establishment could lead to RLm sampling.

Process Overview

1. Conduct PHRE per Directive 5100.4;
- Complete assessment plan prior to performing an FSA.
- Determine scope of FSA and tools to be used.
- Will sampling occur to inform FSA?
  - RTE “for cause” from Table 1 IVT sampling.
  - RTE “risk-based” from Table 1 RLm sampling.

2. Conduct sampling:
- For IVTs, follow Directive 10,300.
- For RLms, follow Directive 10,240.5.

3. Complete an FSA, per Directive 5100.1.

Questions?