


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

Overview of RLm and IVT sampling

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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
 - When establishments change practices.
 - Results and Enforcement.
- FSIS **Directive 5100.1**, Rev. 4 - FSA Directive.
- FSIS **Directive 5100.4**, Rev. 1 - The PHRE Directive.

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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 intended to help verify the adequacy of a plant's *Listeria* control program, per 9 CFR 430.4. Is *Lm* adequately controlled?

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Products of Concern for RLm or IVT sampling

- All 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.

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Primary Pathogens of Concern

Listeria monocytogenes (*Lm*) and *Salmonella* spp.

- Both have the ability to cause human disease.
- Both can be spread 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 or it can result from post-lethality contamination.

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FSIS Directive 10,240.5

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

The RLm Directive.

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FSIS Directive 10,240.5

- Provides instructions for collecting RLM samples.
- 10,240.5 has been revised and is in clearance.
- Significant changes include;
 - Use of the production alternative instead of the *Product Sampling Priority List* for line selection (future slides).
 - Sequence of establishments eligible for RLM sampling on the monthly spreadsheet sequenced based on risk, instead of a 4-year cycle (future slides).
 - The option for DOs to use RLM sampling to inform the PHRE vs. using RLM sample results to inform an FSA.

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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.
- Used to **help** verify compliance with 9 CFR 430.
- Samples always tested for **Lm**. (Sal testing is never an option.)
- RLM sampling typically performed in advance of an FSA.
- RLM results help inform FSA outcome or;
- New option is to use RLM sampling to help inform a PHRE outcome.

However;

- *Listeria* contamination is typically non-homogenous and intermittent.
- All negative results do not confirm that Lm is controlled.

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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:

- IVT sampling is done for cause.
- Different method for determining the number of units.
- IVT samples are never composited.
- IVT samples may be tested for Lm or Sal (rare).
- Establishment notification timeframe is different.

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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 and processes.
- Identify possible day for sampling.
- Determine number of sample units to collect.

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FSIS Directive 10,240.5

The number of RLM units 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

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.

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FSIS Directive 10,240.5

Notify the establishment 1 week prior to Rlm collection date.

Once at the establishment;

- Hold entrance meeting with the establishment to inform them of the sampling and how it will be conducted – may provide entrance letter from Directive 10,300.
- Confirm that they will produce post lethality exposed (PLE) RTE product and do not plan to change practices.
- Inform them that they are required to hold the sampled lot(s) pending the results of FSIS testing.

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FSIS Directive 10,240.5

Each RLM unit is composed of;

- 5 **product** samples, composited by the labs- one form (RLM**PROD**C).
- 10 food **contact** surface (FCS) swab samples, not composited - 10 forms (RLM**CONT**).
- 5 **environmental**, nonfood contact surface (NFCS) swab samples, composited - one form (RLM**ENV**C).
- **Brine** samples might be FCS or NFCS.
 - Permeable casing ➡ FCS – use one of the FCS forms (RLMCONT).
 - Impermeable casing ➡ NFCS –will not be composited with the other NFCS samples. Requires an extra form (RLMENVR) .

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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.

Line selection:

- **Each “unit” of samples must be associated with a single line, lot, Lm control alternative under 9 CFR 430 .**
- Collect samples from the lines with the highest level of risk.
- Always consider sampling history (both FSIS and establishment, possibly FDA, sampling).

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FSIS Directive 10,240.5

Product Sampling Priority List

HACCP Processing Categories	Finished Product Categories	Production Volume Categories (by Product)	Risk Level
Fully Cooked-Not Shelf Stable	RTE fully-cooked meat (PLE)/ RTE fully-cooked poultry (PLE)	Other Fully Cooked Sliced Product	1
		Hot Dog Products	2
		Salad/Spread/Pate	3
		Diced/Shredded Meat ¹ Nonmeat Components	4
		Sausage Products	5
		Patties/Hamburgers	6
		Other Fully Cooked Not Sliced Product	7
		RTE fermented meat (sliced or not sliced)/ RTE fermented poultry (sliced or not sliced) (Acidified)/fermented Product ²	8
Not Heat Treated- Shelf Stable/Heat Treated-Shelf Stable	RTE acidified/fermented meat (without cooking)- PLE/ RTE acidified/fermented poultry (without cooking)-PLE	RTE fermented meat (sliced or not sliced)/ RTE fermented poultry (sliced or not sliced) (Acidified)/fermented Product ²	9
	RTE dried meat (PLE)/ RTE dried poultry (PLE)	RTE dried meat (sliced or not sliced)/ RTE dried poultry (sliced or not sliced) (Dried Products) ²	10
	RTE salt-cured meat (PLE)/ RTE salt cured poultry (PLE)	RTE salt-cured meat (sliced or not sliced)/ RTE salt-cured poultry (sliced or not sliced) (Salt-cured Products) ²	11
Product with Secondary Inhibitors – Not Shelf Stable	RTE salt-cured meat (PLE)/ RTE salt cured poultry (PLE)	RTE salt-cured meat (sliced or not sliced)/ RTE salt-cured poultry (sliced or not sliced) (Salt-cured Products) ²	11

¹Post lethality exposed product

²Product type to be used on Form 10.210-3.

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FSIS Directive 10,240.5

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

Risk of 9 CFR 430.4 production alternatives:

Alt 3
Alt 2b
Alt 2a
Alt 1

↓

Decreasing Risk

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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.

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FSIS Directive 10,300.1

Provides instructions on collecting product, FCS, and NFCS samples.

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

May or may not have an FSA conducted along with IVT sampling.

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FSIS Directive 10,300.1

Examples of for cause reasons 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.

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FSIS Directive 10,300.1

Number of IVT units is determined by number of lines;

- 1 IVT unit per line, up to 5 units max.
- number of RLM units is based on establishment size.

IVT samples are never composited. More forms but extra form for brine NFCS samples 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).

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FSIS Directive 10,300.1

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

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

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

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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 entrance meeting.
- Inform them of the sampling and how it will be conducted (entrance letter - Attachment 1).
- Confirm that they will produce RTE product and that they don't plan to change practices.
- Inform them that they are required to hold all product pending lab testing results.
- Conduct walk through, stage supplies, etc.

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Same for both RLm and IVT sampling

- IVT Directive has entrance letter that may be used for RLm or IVT sampling.
- Use of seals, bar coded labels, packing, shipping, submitting samples.
- Sampled lot - typically defined as all product produced from clean-up to clean-up.
- Collect product, FCS, and NFCS samples at various times throughout the production shift.

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Same for both RLm and IVT sampling

- 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 (e.g., HPP) is applied to only for quality purposes, product samples may be collected before the process has been applied.
- Samples must be collected during conditions that are representative of routine processing.
- Instructions for establishments that change practices.
- Results and enforcement actions.

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Changing Practices During RLM or IVT sampling

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

- Temporarily increasing the use of sanitizer.
- Drastically reducing the typical production time and/or the lot size.
- 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 routine processing conditions and of their process.

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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.
 - 9 CFR 417.2(a) - the establishment did not consider or document the changes in its hazard analysis (HA).
 - 9 CFR 417.5(a)(1) - the establishment did not incorporate the supporting documentation from 417.2(a) in its HA.

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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.

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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.

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Results and Enforcement

- Check LIMS or PHIS for results.
- Ensure that the establishment has the results.
- If any RTE product tests positive, the entire sampled lot is adulterated.
- If a PLE, RTE, FCS sample tests positive for *Lm*, all product which passed over the FCS (the sampled lot) is adulterated.
- Contact DO if adulterated product has entered commerce.

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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** through their supervisory chain of command.
- The DO is to 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.

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FSIS Directive 5100.1, revision 4

Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology - Revision 4 (May 29, 2015).

FSA Methodology for EIAOs.

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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 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 5-7 production days.

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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.
- Time to complete FSA = 5-7 production days.
- Instructions for exit conference

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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 program, including establishment sampling.

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)

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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.

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FSIS Directive 5100.4, Revision 2

Enforcement, Investigations and Analysis Officer (EIAO) **Public Health Risk Evaluation (PHRE) Methodology**

PHRE METHODOLOGY

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FSIS Directive 5100.4, Revision 2

PHRE- two major outcomes;

1. PHRE Decision - EIAO determines and documents the recommended action to take following the PHRE, e.g., perform an FSA, take enforcement action, or take no action.
2. If FSA, then develop an Assessment Plan.
 - Complete assessment plan prior to performing an FSA.
 - Determine scope of FSA and tools to be used, e.g., RTE production area using the General tool and the RTE tool.
 - Will sampling occur to inform FSA?

Sampling may be used to inform a PHRE or an FSA.

- For cause PHRE (e.g., positive RTE product) → FSA and IVT.
- Routine risk based PHRE → RLM sampling if PLE, RTE.

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FSIS Directive 5100.4, Revision 2

- The monthly PHRE scheduling spreadsheet is about PHREs.
- Any sampling that may occur derives from a PHRE.

Examples of "For cause" determinants for PHREs from Table 1 of Directive 5100.4:

- 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).

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FSIS Directive 5100.4, Revision 2

"Risk based" determinants for PHREs from table 1 of Directive 5100.4:

- 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 in a 430 establishment could lead to RLM sampling.

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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” factors from Table 1 ➡ IVT sampling.
 - RTE “risk-based” factors 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.

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Questions?

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