Purpose of Presentation.

- The RTE WG is concerned that the RLm collection rate has decreased significantly over time. This presentation will convey the importance and purpose of RLm sampling program.
- Data analyses have shown that for cause IVT sampling has been done in instances when routine, risk-based RLm sampling should have been performed.
- This presentation will review RLm scheduling guidance and using OPARM's scheduling spreadsheet to decrease confusion and increase the number of RLms performed.

Overview

- History of FSIS Lm testing and Listeriosis
- Health impacts of Lm vs. other pathogens
- Purpose of the RLm Sampling Program
- WGS and Outbreak Investigations
- RLm Collection Rate and Results
- RLm Scheduling Allocation
- Scheduling Guidance
FSIS Testing for Lm in RTE Products & Listeriosis Incidence by Calendar Year

![Graph showing FSIS Lm product testing percent positive and Listeria infections (FoodNet sites; all tests methods) by calendar year.]

*Source: USDA-FSIS regulatory testing results in RTE meat and poultry products (1990-2020)
**Source: FoodNet, Centers for Disease Control and Prevention (1996-2019), includes all Listeriosis infections in the U.S. from all food sources.

Health Impacts vs. Other Pathogens

<table>
<thead>
<tr>
<th>Bacteria</th>
<th>Cases/Year</th>
<th>Deaths/Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>L. monocytogenes</td>
<td>1,591</td>
<td>255</td>
</tr>
<tr>
<td>Salmonella</td>
<td>1,027,561</td>
<td>378</td>
</tr>
<tr>
<td>E. coli O157:H7</td>
<td>63,153</td>
<td>20</td>
</tr>
</tbody>
</table>

- Compare the number of cases vs. number of deaths.
- Very high hospitalization rate for Lm.
- Very high mortality rate for Lm.
- The FDA estimates that Listeriosis has a mortality rate of 20% to 30%, even in patients taking antibiotics.
- Lm has a disproportionately high impact and cost.

*Estimate of overall cases/deaths per year in the U.S from Scallan, E. et al. 2011.

Who is most at risk of Listeriosis?

- The elderly
- Pregnant women
- Pre-nates
- Neonates
- The immunocompromised
Purpose of the RLm Program

- Intended to detect Lm presence that product verification activities cannot.
- Listeria forms biofilms which can’t be seen.
- Establishments that have a good compliance history may still have Lm harborage and contamination.
- May help proactively verify that establishments are controlling Lm before adulterated production lots lead to outbreaks or recalls.
- FSIS sampling verification activities are spot checks and are not intended to support lot by lot safety. All RLm negative results do not mean that there is no Lm present.

WGS and Listeriosis outbreaks

- FSIS transitioned fully to Whole Genome Sequencing (WGS) in January of 2018.
- Since then, we have investigated seven listeriosis outbreaks, three were linked to FSIS regulated products:
  - 2018 Cooked Country-cured Ham Outbreak (4 cases, 1 death)
  - 2018 Pork Roll Outbreak (4 cases, 0 deaths)
  - 2021 Ready-to-eat Chicken Outbreak (3 cases, 1 death)

RLm Collection Rate and Results
RLm Scheduling

- Unlike most other sampling projects, RLm annual targets are based on an estimate of the number of eligible lg, sm., and v. sm. establishments and the number of units that will be collected per establishment.
- Each District receives between 1 to 3 establishment RLm slots per month.
- The number of slots assigned to each District has been revised to be proportional to the number of PLE, RTE producing establishments in each District. This change was implemented in June 2021.
- It is important for DOs to fulfill the monthly RLm sampling allocation.

Update of District RLm Scheduling Allocation

<table>
<thead>
<tr>
<th>District</th>
<th># RLm Eligible Est. in FY 21</th>
<th>% of All RLm Eligible Est. in District</th>
<th># RLm ORARM Schedule Monthly (Revised 5/21)</th>
<th>% of Monthly Scheduling Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>278</td>
<td>13%</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>2</td>
<td>259</td>
<td>12%</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>3</td>
<td>237</td>
<td>11%</td>
<td>3</td>
<td>11%</td>
</tr>
<tr>
<td>4</td>
<td>199</td>
<td>9%</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>5</td>
<td>216</td>
<td>10%</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>6</td>
<td>316</td>
<td>15%</td>
<td>3</td>
<td>12%</td>
</tr>
<tr>
<td>7</td>
<td>316</td>
<td>15%</td>
<td>3</td>
<td>12%</td>
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<td>10%</td>
<td>3</td>
<td>12%</td>
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<td>9</td>
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<td>10%</td>
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<td>12%</td>
</tr>
<tr>
<td>10</td>
<td>116</td>
<td>7%</td>
<td>2</td>
<td>8%</td>
</tr>
<tr>
<td>11</td>
<td>100%</td>
<td>100%</td>
<td>30</td>
<td>100%</td>
</tr>
</tbody>
</table>

Why is Using All of the Allocation Each Month Important?

- The FY 2022 FSIS target is to perform RLm sampling in 23 eligible establishments each month, for a total of 276 establishments sampled annually.
- 1 single establishment missed represents 4.35% of the monthly goal.
- 10 single establishments missed represent 3.62% of the annual goal.
- Each time an RLm that is not completed puts FSIS significantly farther from the targeted number.
Difference Between RLm and IVT Sampling

RLm and IVT sampling projects are not interchangeable. Examples of the differences include:

<table>
<thead>
<tr>
<th>RLm</th>
<th>IVT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine, risk-based criteria, not for-cause</td>
<td>For-cause criteria</td>
</tr>
<tr>
<td>Predetermined number of sampling units collected, based on establishment size</td>
<td>Flexible, based on outcome of collection and screening</td>
</tr>
<tr>
<td>Two 430 samples per RLm at the same time</td>
<td>One IVT sample per RLm at any time</td>
</tr>
</tbody>
</table>

Every month, OPARM provides each DO with a PHRE Scheduling Spreadsheet, as described in FSIS Directive 5100.4. The PHRE Scheduling Spreadsheet is divided into two tabs:

**Non-430 Tab**

- RLM Tab

**RLm Tab**

- The RLM tab of PHRE Scheduling spreadsheet ranks establishments eligible for PHREs in the following order. The “schedule type” column in the spreadsheet corresponds to the basis for selection and risk type in Table 1 of FSIS Directive 5100.4.

1. PLE, RTE establishments with for-cause criteria. Top priority for a PHRE related to the for-cause criteria. For-cause criteria related to RTE processes typically triggers IVT sampling.

2. New establishments (risk-based). Second priority for PHREs. RLm sampling is optional, depending on risk factors, the PHRE outcome, or to inform the PHRE.

3. The “routine” portion (risk-based). Currently sequenced by the last ISA data. Plan to sequence with the last ISA algorithm. RLm sampling may be performed depending on additional risk factors, the PHRE outcome, or to inform the PHRE.
Using the RLM Tab

The RLM tab of PHRE scheduling spreadsheet ranks establishments eligible for PHREs in the following order:

1. For-cause criteria = top priority for PHREs. For-cause criteria not related to RTE does not justify IVT or RLM sampling in the RTE area.
2. For-cause criteria related to RTE may justify IVT sampling (but not RLM).
3. Routine, risk-based. Establishments that have never had an FSA – next priority for PHREs. RLM sampling optional, dependent on all risk factors and the PHRE outcome. Optionally, to inform the PHRE.
4. Routine, risk-based. Currently sequenced based on when last FSA was performed. Other risk factors through correlation with IPP should always be considered.

Scheduling of Risk-based PHREs (Directive 5100.4)

1. Consider IPP input/concerns.
2. Schedule RLM allocation even if PHRE shows no significant risk factors.

Indications for a PHRE or RLM Sampling

- Conditions that negatively impact sanitation or increase the probability of Lm contamination such as:
  - Recent or ongoing construction activities.
  - Condensation issues.
  - Use of high pressure hoses in the PLE, RTE area.
  - Worn-out, old equipment, roof leaks, or other events that increase the probability of Lm contamination.

- Addition by the establishment of a new product.

- Indicators that the establishment may have sanitation issues such as:
  - Increased ATP or APC values, etc.

Summary

- RLM sampling is important because:
  - This is our only routine sampling program which includes FCSs, NFCSs, and product samples. Positives from NFCS locations have proven to be important.
  - The rate of Listeria infections and outbreaks has remained steady.
  - Listeriosis has a disproportionate human health impact and is deadly for the at-risk population.
  - It’s important to fulfill the monthly RLM allocation.
  - RLM sampling is risk based, not for cause.
  - Many of the best Lm related risk factors are not recorded in PHIS and must be obtained from IPP, e.g., condensation, construction, high pressure hoses, etc.
  - NFCS, FCS, and product data together can show evidence of cross contamination or harborage.
  - Past and current isolates may indicate that previous corrective actions were not effective.