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

District Scheduling of RLms

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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.

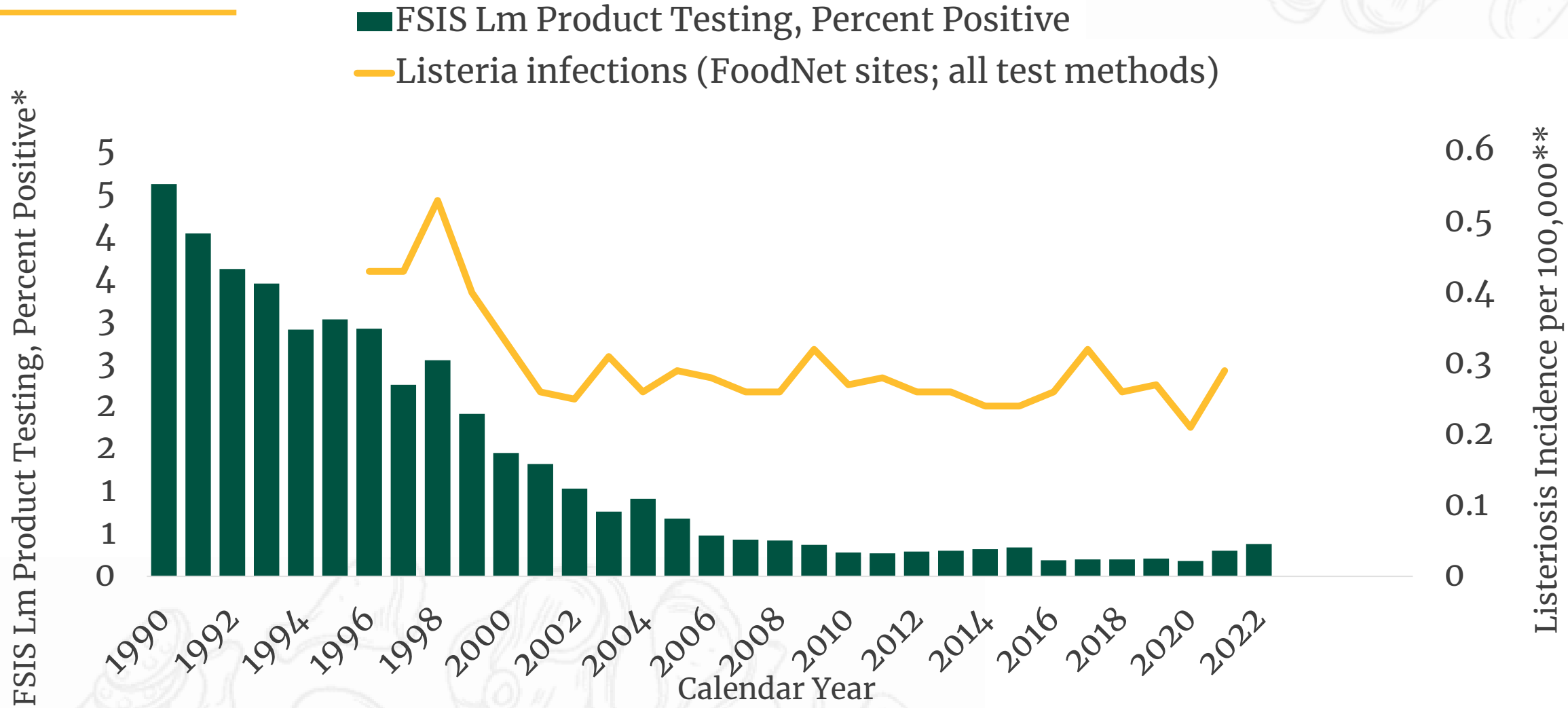
- Data analyses have shown that for cause IVT sampling has been done in instances when routine, risk-based Rlm sampling should have been performed.

- 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 Meat and Poultry Products & Listeriosis Incidence by Calendar Year



*Source: USDA-FSIS regulatory testing results in RTE meat and poultry products (1990-2022)

Source: Foodnet, Centers for Disease Control and Prevention (1996-2019), includes all Listeriosis infections in the U.S. from **all food sources.

Majority of *Listeria* illnesses (**75%**) attributed to dairy and fruit, but rarity of outbreaks makes it hard to estimate **(Interagency Food Safety Analytics Collaboration, 2019)**

Health Impacts vs. Other Pathogens

Bacteria	Cases/Year	Deaths/Year*
L. monocytogenes	**1,591**	**255**
Salmonella	**1,027,561**	**378**
***E. coli* O157:H7**	**63,153**	**20**

- Compare the number of cases vs. number of deaths.
- Very high hospitalization rate for *Lm*.
- Very high mortality rate for *Lm*.
- The FDA estimated 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, Et al. 2011.

Who is most at risk of Listeriosis?

- Pre-nates
- Neonates
- Pregnant women
- The elderly
- The immunocompromised

Purpose of the RLm Program

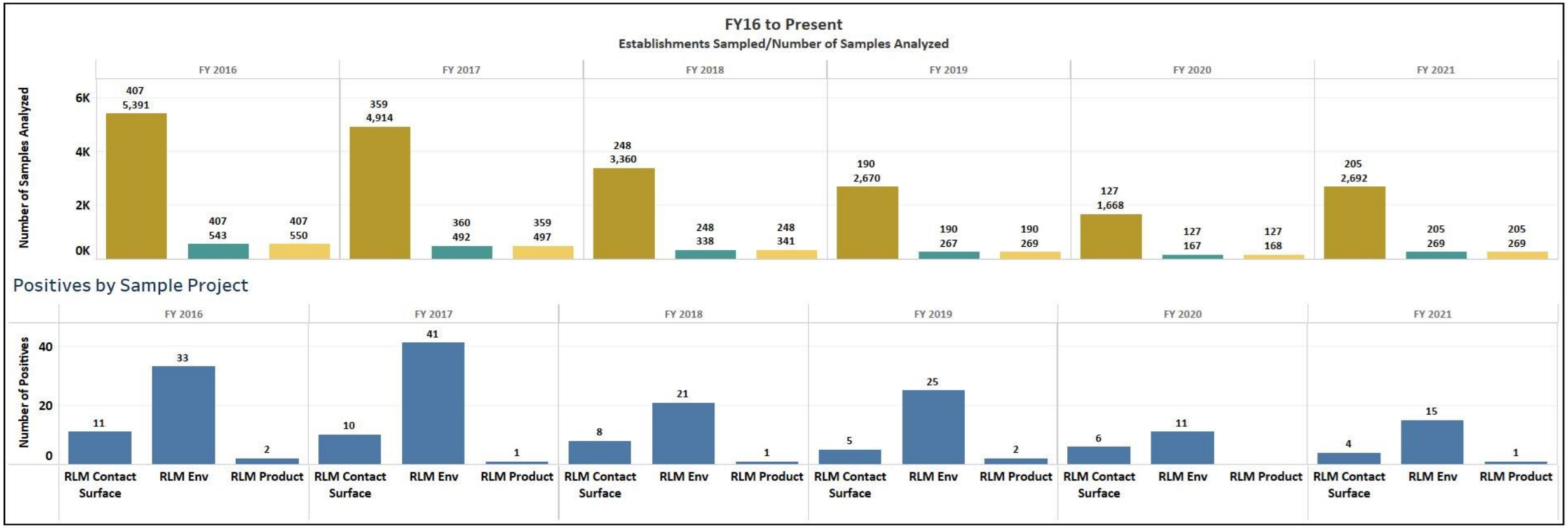
- Intended to detect *Lm* presence that product verification activities cannot.
  - Listeria forms biofilms which can't be seen.
  - Establishments that have a good compliance history may still have *Lm* harborage and contamination.
  - May help proactively verify that establishments are controlling *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.

Listeriosis Outbreaks Associated with FSIS Products

- FSIS transitioned fully to Whole Genome Sequencing (WGS) in January of 2018.
- Since then, we have investigated eight listeriosis outbreaks, three were linked to FSIS regulated products and led to a recall:
  - 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)
- In FY22, there were no listeriosis outbreaks associated with meat and poultry products

RLm Collection Rate and Results

RLms continue to be an effective means for verifying *Lm* control and prioritizing establishments that do not have *Lm* under control for more follow-up (e.g., IVT). The data supports that routine NFCS sampling is very effective for detecting *Lm* in the establishment's environment.



NOTE: There were fewer RLm samples collected in FY20 due to restrictions put in place due to the COVID-19 pandemic

For-cause (IVT) and Risk-Based (RLm) *Lm* Results

***Lm* Results for For-cause and Risk-based Samples Collected During Food Safety Assessments FY22 (October 1, 2021 – September 31, 2022)**

Project Code	Positive #	% Positive	Difference in % Positive From 2021
For-cause, IVT FCS sampling	10/740	1.35	-0.20
For-cause, IVT NFCS sampling	33/375	8.80	+3.03
For-cause IVT Product	2/345	0.58	-1.40
Routine, risk-based (RLm) FCS	4/2963	0.13	-0.02
Routine, risk-based (RLm) NFCS	32/294	10.88	+5.32
RLm product sampling (composite)	2/298	0.67	+0.30

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 R*Lm* 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

Revision of RLm Scheduling to Ensure 23 Establishments are Sampled per Month Across All Districts.

District #	# RLm Eligible Est. in FY 21	% of All RLm Eligible Est. in District	# Ests. OPARM Schedules Monthly (2019-21)	% of Monthly Scheduling Total	# Ests. OPARM Schedules Monthly (Revised 5/21)	% of Monthly Scheduling Total
5	278	13%	2	8%	3	13%
15	259	12%	3	12%	3	13%
25	237	11%	3	12%	2	9%
35	99	4%	2	8%	1	4%
40	219	10%	3	12%	2	9%
50	313	14%	3	12%	3	13%
60	326	15%	3	12%	3	13%
80	216	10%	3	12%	2	9%
85	146	7%	2	8%	2	9%
90	116	5%	2	8%	1	4%
Total	2209	100%	26	100%	23	100%

Why is Using All of the Allocation Each Month Important?

- The 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, it puts FSIS significantly farther from the targeted number.

Difference Between R*Lm* and IVT Sampling

R*Lm* and IVT sampling projects are not interchangeable. Examples of the differences include:

RLm

Routine, risk-based criteria, not for-cause

Never performed due to for-cause criteria in the PLE, RTE production area

Predetermined number of sampling units collected, based on establishment size.

- Very small establishments - 1 unit
- Small establishments - up to 2 units
- Large establishments - up to 3 units

Product and NFCS samples composited by the laboratories.

Results reported collectively for composited sample types.

IVT

Only conducted for-cause

Greater flexibility in number of sample units.

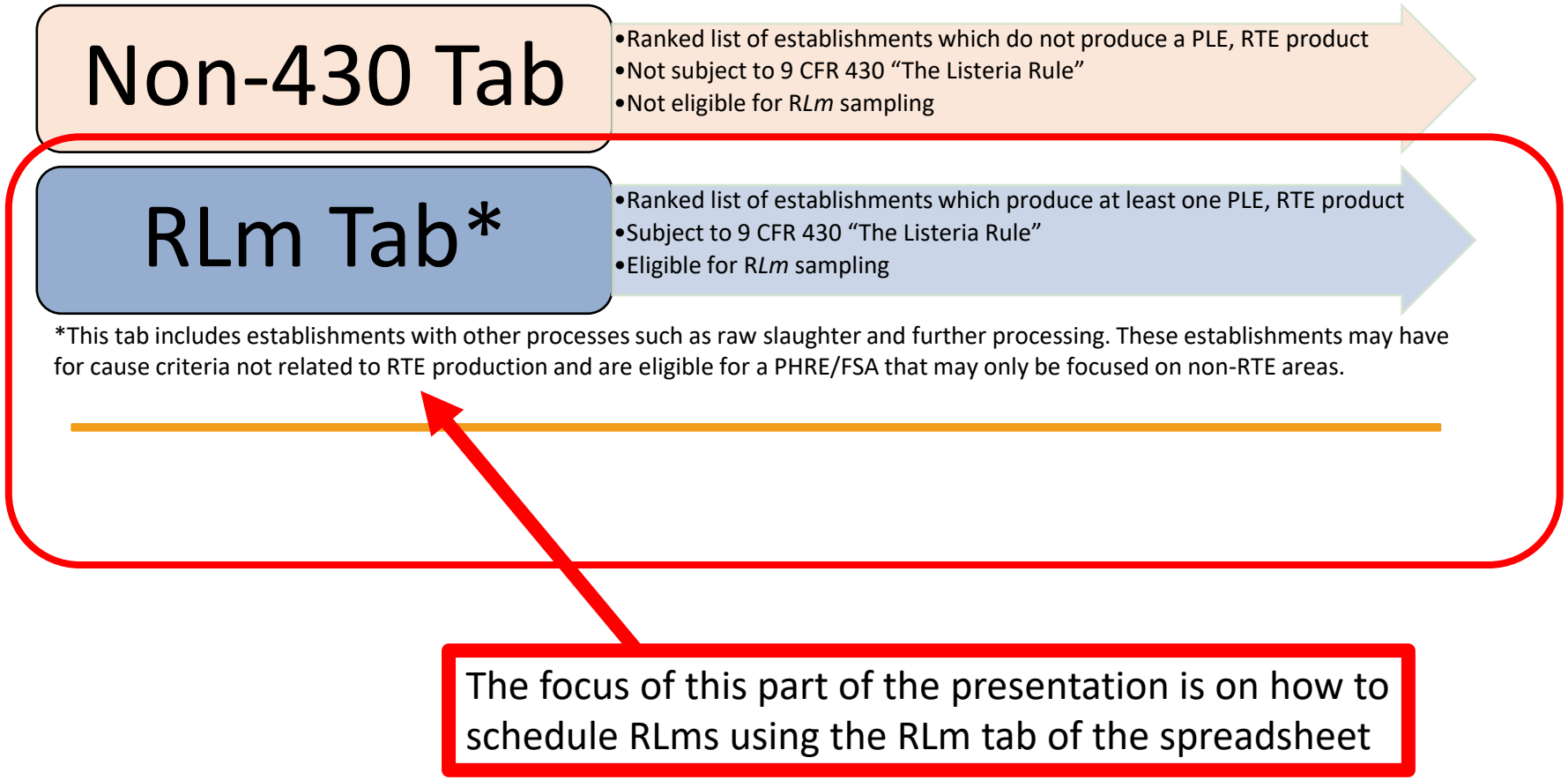
- Collect 1 unit per line
- Up to maximum of 5 units

No sample compositing. Greater sensitivity for detecting very low levels.

All results reported individually. Exact location of all positives is identified.

OPARM PHRE Scheduling Spreadsheet

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.



Using the 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 process typically triggers IVT sampling.**

For-cause RTE criteria = IVT

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.**

Routine, risk-based = RLm

3. **The "routine" portion (risk-based). Previously sequenced by the last FSA date. Now sequenced with the *Lm* risk algorithm. RLm sampling may be performed depending on risk factors, the PHRE outcome, or to inform the PHRE.**

Routine, risk-based = RLm

Using the *RLm* Tab

The RLm tab of PHRE Scheduling spreadsheet ranks establishments eligible for PHREs in the following order;

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.
For-cause criteria related to RTE may justify IVT sampling (but not RLm).

D3 | Western

	A	B	C	D	E
1	Priority	Schedule Type	For Cause Reason	Lab	Sampling Wee
2	1	For Cause	Recall: 045-2018 Class: 1	Western	03SEP
3	2	For Cause	High rate of Public Health Noncompliances (PHRs)	Western	10SEP
4	3	For Cause	Recall: 048-2018 Class: 2		
5	4	For Cause	Category 3 - Salmonella - Chicken Parts		
6	5	For Cause	High rate of Public Health Noncompliances (PHRs)		
7	6	For Cause	High rate of Public Health Noncompliances (PHRs)		
8	7	For Cause	High rate of Public Health Noncompliances (PHRs)		
9	8	New Establishment			
10	9	New Establishment			
11	10	Routine			
12	11	Routine			
13	12	Routine			
14	13	Routine			
15	14	Routine			
16	15	Routine			
17	16	Routine			

RLm | Non430

Routine, risk-based. 430 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.

Routine, risk-based. Now sequenced based on a risk algorithm (next slide). Other risk factors through correlation with IPP should always be considered.

The Risk Algorithm for the Routine Section of the RLm Tab

Data analysis has shown that;

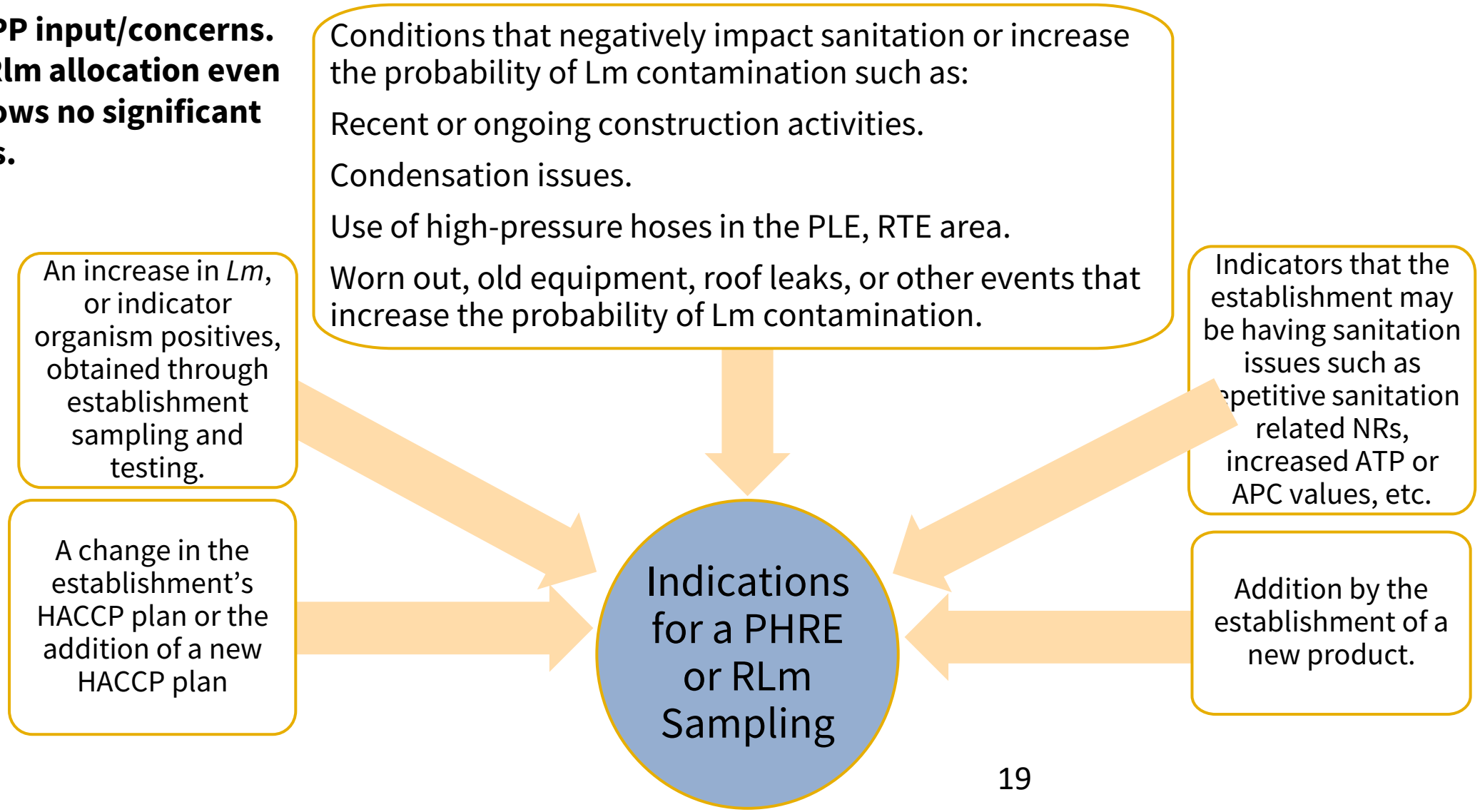
- 430 establishments are more likely to have a future positives if they have had a *Lm* positive within past 3 years.
- Alternative 3 had the highest percentage of *Lm* positives, followed by 2B, 2A, then Alt 1.
- Approximately 66% of all positive RLm positives and 80% of all *Lm* positives came from establishments with low production volumes, 1-1,000 pounds.

Thus, the routine section of the RLm tab of the PHRE scheduling spreadsheets is now sequenced based on the following risk factors, as described in Directive 10,240.5 (the RLm Directive);

1. A previous positive in the past 3 years **and** small production volume of 1-1,000 pounds in PLE, RTE producing establishments which utilize Alternative 3.
2. A previous positive in the past 3 years.
3. Small production volume of 1-1,000 pounds in Alternative 3 establishments.

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.**



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 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.

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Questions??

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Lm WGS Results

RTE FY 21 vs. 22 Positive Sampling Results – Harborage and Cross-contamination

Potential for Harborage or cross-contamination identified using WGS results by establishment	Number of Establishments 2021	Number of Establishments 2022
Neither harborage nor cross-contamination	30	53
Potential for cross-contamination only	3	3
Potential for harborage only	6	20
Potential for harborage and cross-contamination	7	7
Total # establishments with positive Lm samples	46	83
Total # establishments with at least 1 RTE sample collected	2,234	2,219
Total # establishments where an RLm was performed	205	227