

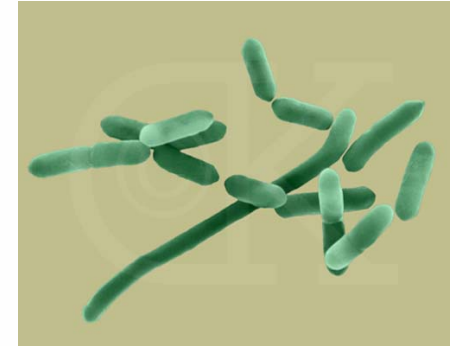
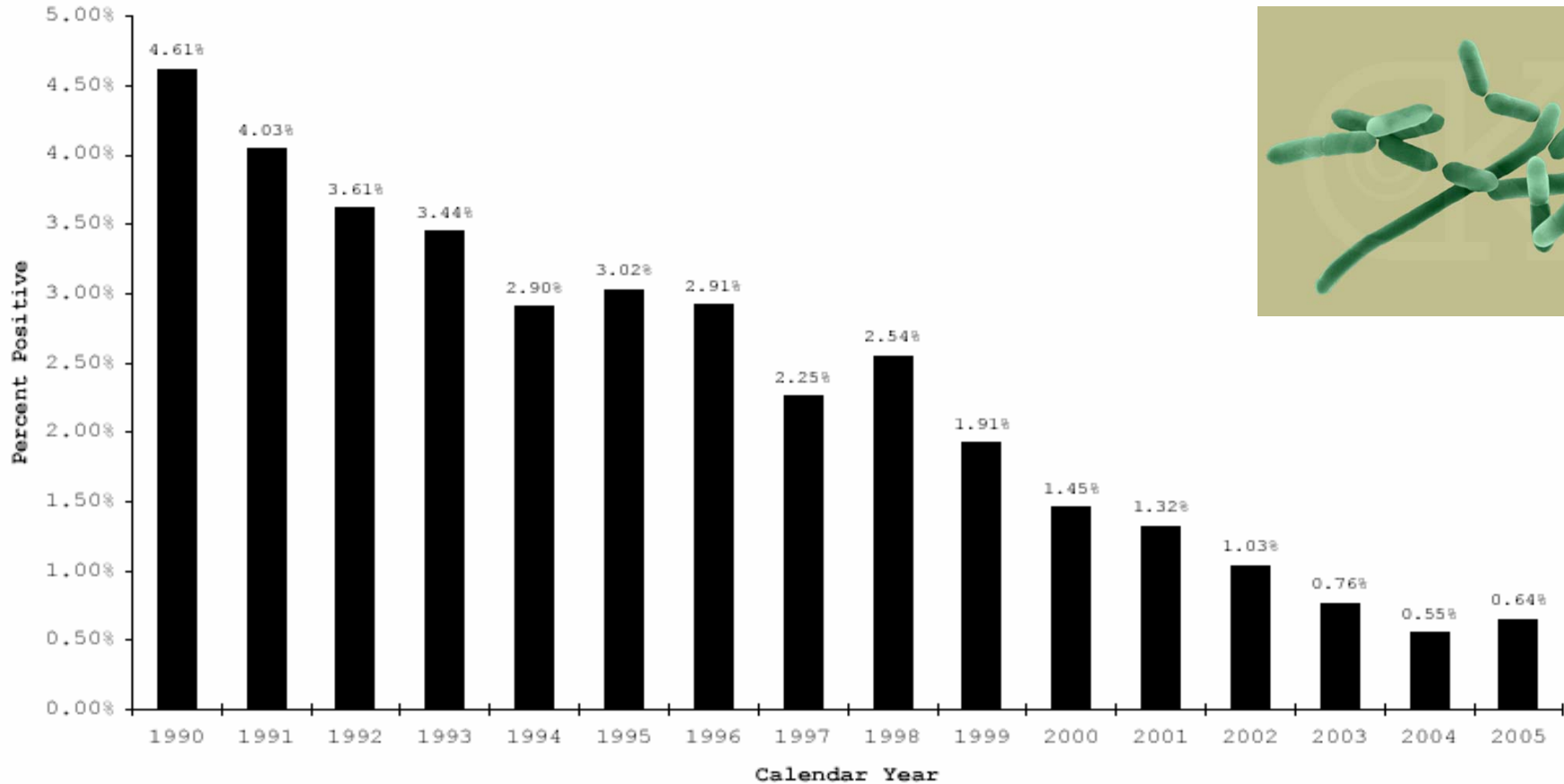


FSIS Routine *Listeria* *Monocytogenes* Risk-Based (*RLm*) Sampling

**Tracie Sheehan
Sara Lee Corporation
AMI-FMI Joint Meeting
April 24, 2007**

FSIS Sampling *Listeria Monocytogenes* in RTE Products Historical Trend

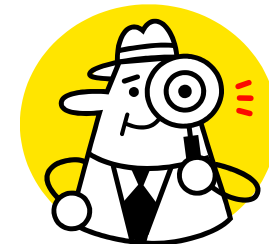
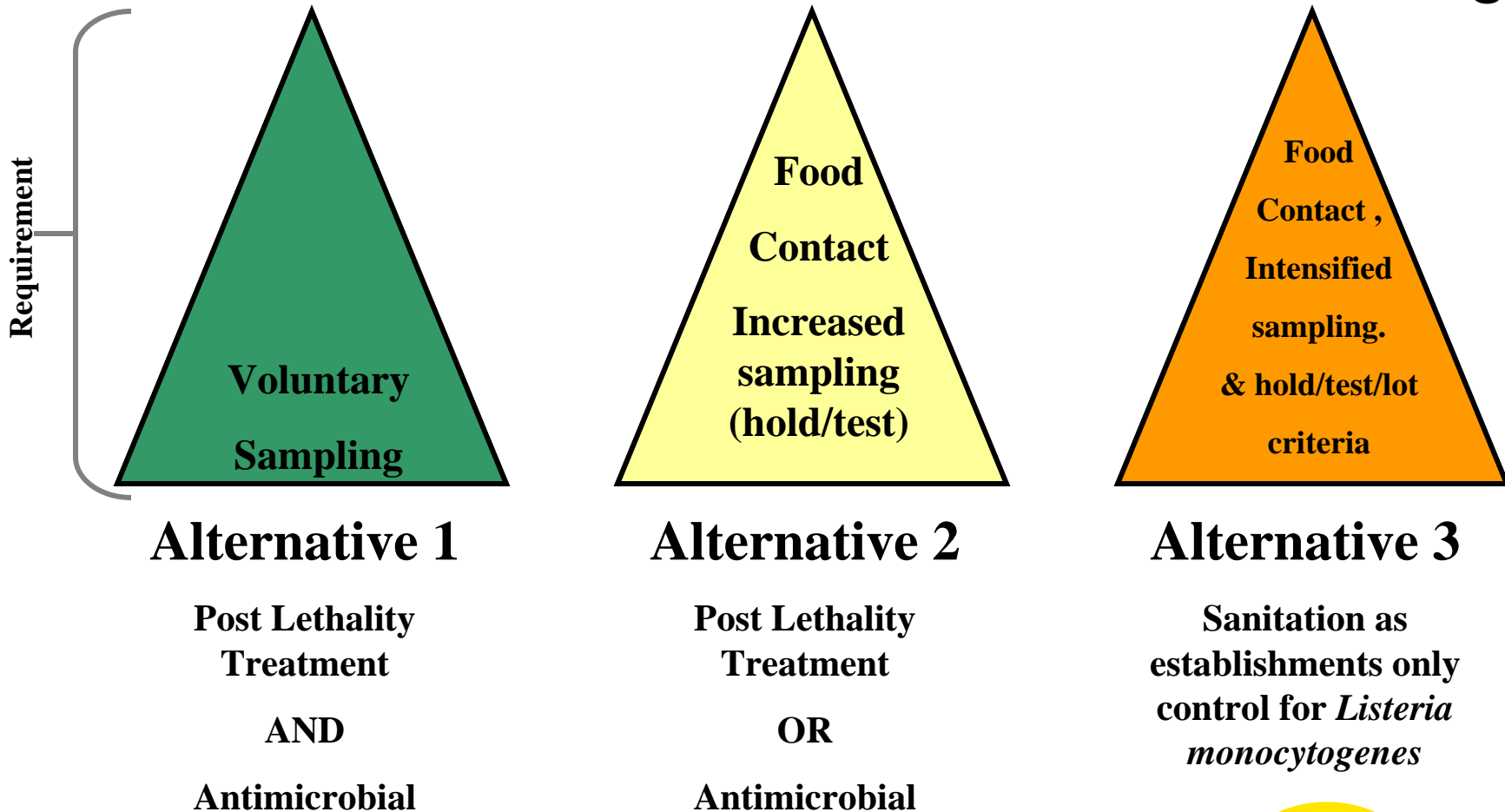
FSIS Regulatory Testing for LM in RTE Products
By Calendar Year
1990 - 2005



What is “Routine *Lm* Risk-Based (*RLm*) Sampling” ?

- March 15th, 2006 FSIS published 2 new directives:
 - Directive 10,240.4 “Verification Procedures for Consumer Safety Inspectors for the *Listeria monocytogenes* (*Lm*) Regulations and Introduction of Phase 2 of the *Lm* Risk-Based Verification Testing Program”.
 - Directive 10,240.5 “EIAO Assessment of Compliance with the *Listeria monocytogenes* (*Lm*) Regulations and Introduction of Phase 2 of the *Lm* Risk-Based Verification Testing Program”.

Background – FSIS Alternative Classification & Environmental Monitoring

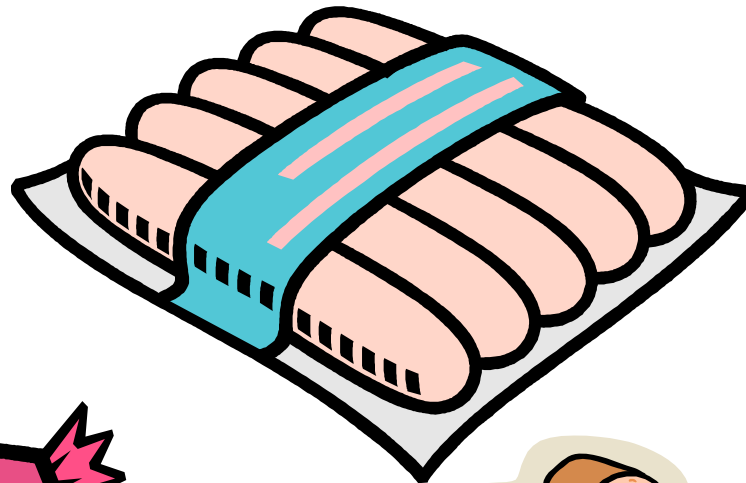


Breakdown of USDA RTE Facilities by Alternative

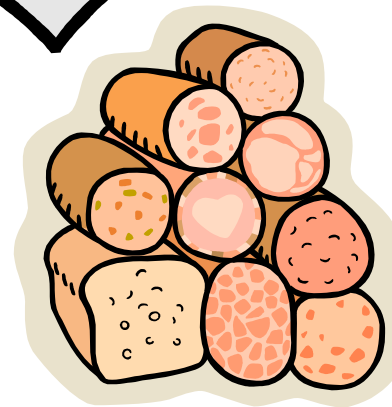
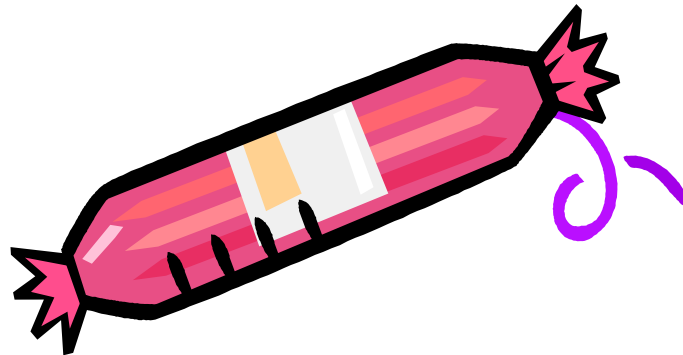
	Large	Small	Very Small	Total (%)
Alt. 1	24	77	60	5%
Alt. 2 A	39	198	129	12%
Alt. 2 B	72	300	142	18%
Alt. 3	50	726	1113	64%
Total RTE Facilities	185	1301	1444	2930

FSIS Sampling Projects -Currently 2 for RTE

1. RTE001



2. ALLRTE



Selecting Establishments for Sampling

RTE001 Project

1. Rank all RTE establishments (~2800) monthly based on a OPHS risk algorithm.
2. Top 800 establishments selected each month (~550 samples submitted).
3. Establishments are selected on a weekly basis (i.e. rolling across the month).

ALLRTE Project

1. If an establishment is selected for RTE001 sampling they are removed from this project (monthly).
2. 250 sample requests are randomly generated from the remaining establishments (~235 samples submitted).

USDA RTE001

Sampling by Alternative

Plant Alternative	Percent of Samples Taken
1	0.1%
2A	0.4%
2b	22.5%
3	77.0%

USDA Total Positives by Plant Size

HACCP Size	Number Positives	Percent of Total Positives
Large	1	1.7%
Small	34	56.7%
Very Small	25	41.7%

Breakdown FSIS USDA Product Positives by Plant Volume

Pounds per Year RTE Product	Number Positives	Percent of Total Positives
Less than 100,000	25	42.4%
100,000 to 1,000,000	13	21.7%
1,000,000 to 10,000,000	18	30.0%
> 10,000,000	4	6.7%

Average RTE plant volume 22.6 million pounds per year, only 1 positive in plant with greater than average production volume

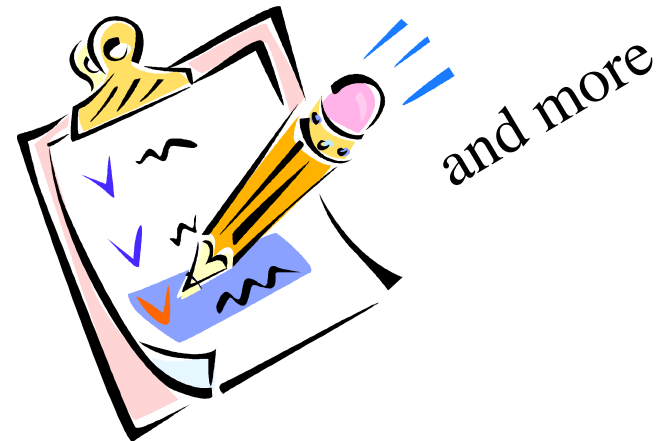
All USDA Sampling Data

Project Code	2006 Product Positives	Food Contact	Non-contact	Total swabs
ALL RTE*	18 of 2937 (0.61%)	-	-	-
RTE001*	40 of 8,577 (0.47%)	-	-	-
RLm (63 plants)	0 of 530 (0.0%)	4 of 1786 (0.22%)	17 of 959 (1.8%)	21 of 2745 (0.77%)
IVT - for cause (60 plants)	6 of 418 (1.1%)	12 of 959 (1.3%)	56 of 1066 (5.3%)	68 of 2025 (3.36%)

*Note: ALL RTE sampling random; RTE001 sampling selected based on volume, Lm control method, product risk ranking, & previous results

CSI - Questions related to establishment sampling (Alt. 2 or 3)

1. Does the establishment test food contact surfaces for *Listeria* species?
2. Does the testing verify the effectiveness of its sanitation procedures?
3. Does the establishment state the frequency of sampling and does it describe the size and location of sites tested?
4. Does the establishment support (explain) why the sampling frequency is sufficient (supported) to ensure effective control of *Lm*?
5. Does the establishment identify conditions...for hold-and-test?



10,240.4: CSI Enforcement Actions “Routine *Lm* Risk-Based (*RLm*) Sampling”

- Positive product sample OR food contact the CSI should issue a NR
- Note: This is because the agency is testing for *Listeria monocytogenes* and not *Listeria* species during production



L. Monocytogenes Risk-Based Verification Testing Program

- Only FSIS personnel trained in IVT aseptic sample techniques should collect environmental and food-contact samples.
- All samples will be analyzed for *Listeria monocytogenes*.
- Samples may be collected on 1st, 2nd or 3rd shift Monday through Thursday or on day shift Friday.

Number of RLM Samples

- Up to 5 lines may be selected at each establishment
- Up to 10 Contact surface samples may be collected per line
- Up to 5 Non-contact samples may be collected per line
- Total of 3 Product samples will be selected per line sampled.
- Total (up to): 18 samples per line (env., f.c., product)
- **Up to 90 samples per establishment**



Which products will they sample?

- Select the **highest risk post-lethality exposed RTE product** produced at the time of collection
 - 1) Deli-meats that are sliced in the federal establishment
 - 2) Deli-meats shipped whole from the federal establishment (this does not include cook-in-bag products; only those exposed post lethality)
 - 3) Hotdog Products
 - 4) Deli salads, pâtés, and meat spreads
 - 5) Fully cooked type products (other than cooked products in 1-4 above)
 - 6) Fermented products
 - 7) Dried products
 - 8) Salt-cured products
 - 9) Products labeled as "Keep Frozen"



Preparation for RLM Sampling – HOLDING THE RIGHT PRODUCT!

- Factors to consider when selecting and tracking product for RLM :
 - Common food contact surfaces – brine, employee contact, rack contact
 - Employee traffic including mechanical
 - Potential cross-over areas
 - Storage of cooked product prior to further processing
 - Rework

If there was a positive, would the USDA question your methods of isolation?

Sampling Technique

- FSIS sampling was aseptic including changing gloves between each sample
- FSIS sampling is aggressive and very targeted.
- FSIS is trying to verify if you are controlling Lm

FSIS *Listeria monocytogenes* questionnaire

COMPLIANCE GUIDELINES TO CONTROL

LISTERIA MONOCYTOGENES IN POST- LETHALITY EXPOSED READY-TO-EAT MEAT AND POULTRY PRODUCTS

Published Oct 2004 & Up-dated 2006

http://www.fsis.usda.gov/PDF/LM_checklist_guidelines.pdf

SECTION I – Post-Lethality Treatment (PLT)

Product (Group) Name: _____

Post-lethality Treatment used: _____

For the following questions, please place an X in the appropriate response column.

(NOTE: If needed, please refer to the establishment’s FSIS Form 10.240-1 to answer these questions and use your best judgment based on how the process is being controlled in accordance with 9 CFR 430. Rate and score responses using the scoring instructions at the end of these questions.)

Questions	Yes	No	Not Sure	N/A
1. Is the post-lethality treatment validated and documented? <i>(Note: See APPENDIX for examples of validation.)</i>				
2. Has the establishment identified the critical variables (e.g., time, temperature, pressure, concentration, pH, etc.) used in the validation? <i>(Note: Examples of validation methods that can be used are challenge study for the product, published study, modeling program.)</i>				
3. If the critical variables have been identified for PLT, are they being applied in the HACCP plan in a similar manner?				
4. Is the product or product formulation used in the validation the same as or similar to the product or product formulation for which the establishment is using the PLT?				
5. Is the establishment using the PLT as described in the validation with regards to equipment and procedures?				
6. If the critical variables, product formulation, procedure or equipment used by the establishment are not the same as or similar to those used in the validation, did the establishment conduct additional validation that demonstrated the changes are effective? <i>(Note: Place an X on N/A if you answered “YES” to questions 2-5)</i>				
7. If the establishment did not conduct additional validation, did it provide any rationale to explain why the PLT is effective and has the same impact even though the critical variables, product formulation, procedure or equipment are different? <i>(Note: Place an X on N/A if you answered “YES” to questions 2-5)</i>				
8. Did the establishment conduct an initial validation to test the adequacy of the CCP, critical limits, monitoring and recordkeeping procedures, and corrective actions as stated in the HACCP plan? <i>(This would be evident by data to demonstrate that the CCP was applied and the process was tested, e.g., product was tested prior to the treatment for presence/absence, and/or level of LM, and tested after the treatment for the same attributes in order to find low level of LM contamination using appropriate number of tests from randomly selected samples. Reliance only on tests with negative results after treatment is not considered product validation and should be marked as ‘No’- not validated.)</i>				

Establishment Rating Based on Questionnaire

- Establishment will be rated in 4 areas
 1. Post Lethality Treatment
 2. Antimicrobial Agent
 3. Sanitation Program
 4. On-going Verification System
- Recommend each facility filled out a draft questionnaire and compile a notebook with support to each answer question

Finding in compiling notebooks

- Demonstration of compliance should include operational and pre-operational data
 - TPC data
 - Bioluminescence data
 - Listeria species data separated by
 - Contact
 - Non-contact
 - Listeria monocytogenes data for product verification
- Sanitation and GMP procedures including verification forms

Include Shelf Life Supporting Documentation

- Best: Inoculated study on your specific product
- 2nd Best: Published study of similar product
- 3rd Best: Computer modeling

- Worst: No support or if actual shelf life exceeds your support

Summary

- FSIS is actively testing for *Listeria monocytogenes* in product, on food contact equipment and in the environment in Federally inspected establishments.
- Plants must conduct internal testing to actively seek out *Listeria* and implement effective sanitation and redesign of equipment to eradicate the organism.