Introduction to the Control of *Listeria monocytogenes* (*Lm*) in Ready-to-Eat Products; Interim Final Rule

Small and Very Small Establishment Implementation Workshop

1

Control of *Lm* in RTE products

- Background
  - FMIA, PPIA, EPIA
    - wholesome, not adulterated, and properly marked, labeled, and packaged.
  - FMIA and PPIA: *Adulteration*
    - bears or contains any poisonous or deleterious substance that may render it injurious to health
    - been prepared, packed, or held under insanitary conditions

2

Control of *Lm* in RTE products

- **Background:**
  - During the 1980's, *Lm* began to emerge as a problem in processed meat and poultry products.
  - In the 1990's, outbreaks of foodborne illness caused by *Lm.*
  - From 1999-2003 various Agency publications were issued addressing *Lm*

3

Control of *Lm* in RTE products

- **Background:**
  - Federal Register Interim Final Rule 6/6/2003
    - Control of *Listeria monocytogenes* in RTE Meat and Poultry Products; Final Rule
    - 9 CFR Part 430

4

Control of *Lm* in RTE products

- Implementation of new RTE regulations
  - Why do I need to make changes?
  - How does this affect establishment's producing RTE products?
  - What are the changes or new requirements?
  - When will I be required to make the change?
  - Will I need to modify my SSOP and/or HACCP plan?

5

§430.4 Control of Lm in Post-lethality Exposed RTE Products

- *Lm* can contaminate RTE products that are exposed to the environment after a lethality treatment (destroy/kill).
- *Lm* is a hazard that an establishment must control through its HACCP plan, or prevent in the environment through a SSOP or other prerequisite program if it produces RTE product that is exposed post-lethality.
- RTE product is adulterated if it contains *Lm* or if it contacts surfaces contaminated with *Lm*.

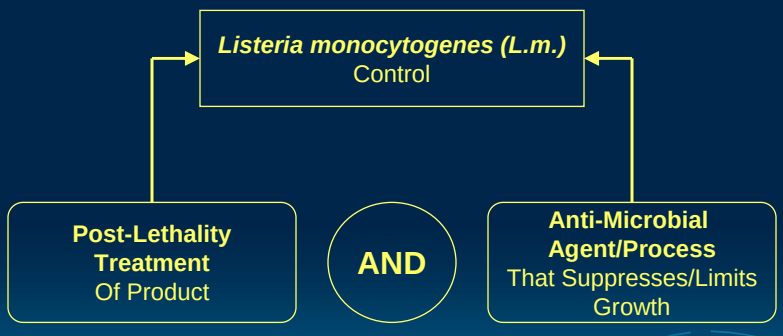
6

Control of Lm in Post-lethality Exposed RTE Products

- In order to maintain sanitary conditions necessary to meet this requirement, an establishment producing post-lethality exposed RTE product must comply with one of three alternatives.

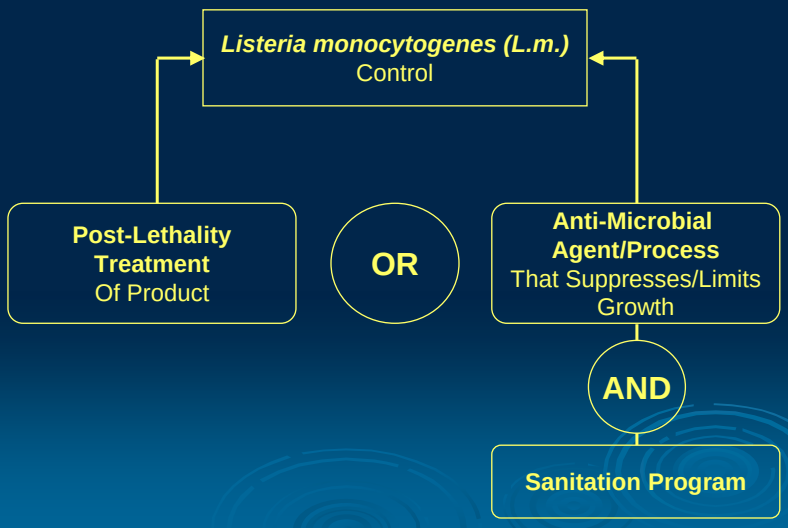
7

Alternative 1



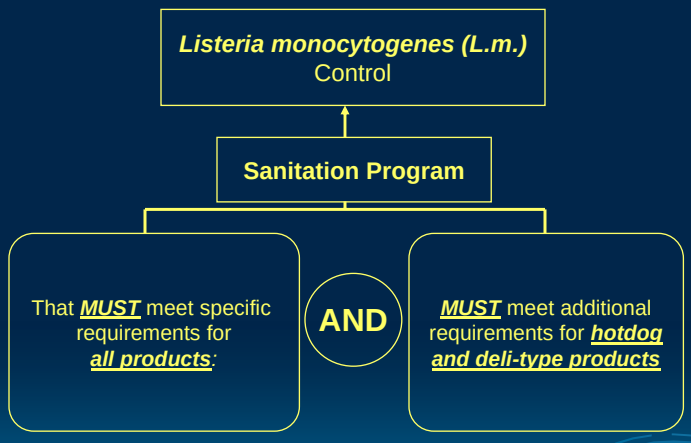
8

Alternative 2



9

Alternative 3



10

Risk to Product

11

For All Three Alternatives

1) Establishments may use verification testing, which would be in addition to FSIS verification testing, that includes tests for *Lm* or an indicator organism, such as *Listeria* species, to verify the effectiveness of their sanitation procedures in the post-lethality processing environment.

12

For All Three Alternatives (cont.)

2) Sanitation measures and procedures for antimicrobial agents or processes that control *Lm* may be incorporated either in the establishment's HACCP plan or in its SSOP or other prerequisite programs. If these control procedures are included in the SSOP or prerequisite program, and not as a CCP in the HACCP plan, the establishment must have documentation supporting the decision in its hazard analysis that *Lm* is not a hazard reasonably likely to occur.

13

For All Three Alternatives (cont.)

3) Establishments must maintain sanitation in the post-lethality environment in accordance with part 416.
4) If *Lm* control measures are included in the HACCP plan, the establishment must validate and verify the effectiveness of these *Lm* control measures in accordance with § 417.4.

14

For All Three Alternatives (cont.)

5) If *Lm* control measures are included in the SSOP, the effectiveness of these measures must be evaluated in accordance with § 416.14.
6) If the *Lm* control measures are included in a prerequisite program other than the SSOP, the program and the results produced by the program must be included in the documentation that establishment is required to maintain in accordance with § 417.5.

15

For All Three Alternatives (cont.)

7) The establishment must make the verification results that demonstrate the effectiveness of the *Lm* control measures it employs, whether under its HACCP plan or SSOP or other prerequisite program(s), available to FSIS inspection personnel upon request.

16

Supplying Information to FSIS

An establishment that produced post-lethality exposed RTE product shall provide FSIS, at least annually, or more often as determined by the Administrator, with estimates of annual production volume and related information for the types of meat and poultry products processed under each alternative specified in § 430.4(b).

17

Labeling

Establishments that control *Lm* by using a post-lethality treatment or an antimicrobial agent or process that eliminates or reduces, or suppresses or limits the growth of *Lm*, may declare this fact on the product label provided that the establishment has validated the claim.

18

Workshop
Breakout sessions

19