Alternatives 1 & 2 for Control for *Listeria monocytogenes*

Components of the Individual Alternatives

1

Alternative 2

- Establishments that choose Alternative 2 will likely be subject to less agency sampling than establishments that choose Alternative 3.
- Alternative 2 would likely be subject to less testing because the risk of contamination in the finished product by *Lm* decreases from Alternative 3 to 2, based on the control methods used by the establishment.

2

Alternative 2

- An establishment that chooses to utilize Alternative 2 in processing its product must apply either:
  - A post-lethality treatment; OR
  - An antimicrobial agent or process that controls the growth of *Lm*

3

Alternative 2

- When using a post-lethality treatment, the establishment must:
  - Include the treatment in the HACCP plan
  - Validate the effectiveness of the treatment per 417.4 of the regulations

4

Alternative 2

- When using an antimicrobial agent or process, the establishment must:
  - Include the treatment in either the HACCP plan or Sanitation SOP (SSOP), or other prerequisite program
  - Document in the HACCP plan, SSOP, or other prerequisite program that the antimicrobial agent or process is effective in suppressing or limiting the growth of *Lm*

5

Alternative 2

- Using only an antimicrobial agent or process, the establishment must:
  - Maintain sanitation in the post-lethality environment according to Part 416 (SSOP)
  - Include, in the sanitation program, testing for food contact surfaces in the post-lethality environment to ensure that the surfaces are sanitary and free of *Lm* or its indicator organism (*Listeria* species)
    - An effective sanitation program is important because antimicrobials are not effective at high levels of contamination

6

Alternative 2

Sanitation Program Workshop Discussion

7

Alternative 2

- What do the regulations require to be in the sanitation program to prevent *Lm* contamination on food contact surfaces when using the antimicrobial treatment or process?

8

Alternative 2

- The sanitation program must:
  - Test food contact surfaces in the post-lethality processing environment
  - Indicate the frequency of testing
  - Identify the size and location of the sites to be sampled
  - Include an explanation of why the testing frequency is sufficient to ensure the effective control of *Lm* or its indicator organisms
  - An establishment must implement a hold-and-test procedure for a positive test for *Lm* or its indicator organism

9

Alternative 1

- Establishments that choose Alternative 1 will likely be subject to less agency sampling than establishments that choose either Alternative 2 or 3.
- Alternative 1 would likely be subject to less testing because the risk of contamination in the finished product by *Lm* decreases from Alternative 2 to 1, based on the control methods used by the establishment.

10

Alternative 1

- An establishment that chooses to utilize Alternative 1 in processing its product must apply both:
  - A post-lethality treatment; AND
  - An antimicrobial agent or process that controls the growth of *Lm*

11

Alternative 1

- For the post-lethality treatment, the establishment must:
  - Include a CCP for the treatment in its HACCP plan that has been validated for effectiveness per 417.4 of the regulations
- For the antimicrobial agent or process, the establishment must:
  - Include the treatment in its HACCP plan, SSOP, or other prerequisite program

12

Alternatives 1 & 2

- Examples of post-lethality treatments
  - Steam/Hot water Pasteurization
  - Pre-Package/Post-Package Surface Pasteurization
  - High Hydrostatic Pressure Processing
  - Ozone
  - Pulse electrical field
  - Organic acids

13

Post-Lethality Treatment

Workshop Discussion

14

Post-Lethality Treatment

- Post-lethality treatment that may be used by small/very small plants.
  - Can anyone provide an example that may be used or that you are using in your establishment?

    (e.g., Hot water pasteurization)

15

Post-Lethality Treatment

- Example, when evaluating a post package product pasteurization process using hot water in a product heating vat
  - What are the important factors to control and monitor for this treatment?

    (e.g., product surface time/temperature profile)

16

Alternatives 1 & 2

- Validation of the post-lethality treatment
  - Specifying and confirming the reduction level achieved by the treatment should be a part of the validation.
  - Points to consider during validation:
    - The post-lethality treatment must be sufficient to eliminate the levels of *Lm* contamination that may occur.
    - Products, treatments, or other variables that are used in the establishments' process should be the same as those used in the published literature, or the treatment should be validated for the plant's specific conditions and product characteristics.

17

Alternatives 1 & 2

- Examples of Outreach Contacts and Resources:
  - University professors
  - University/USDA Extension Service
  - Meat and Poultry Associations
  - University/Public Libraries
  - Agricultural Research Service (ARS) Scientists
  - International HACCP Alliance
  - Equipment Manufacturers
  - Enforcement Regulatory & Analysis Officers (ERAO) (CSO's)
  - Company supplying antimicrobial agents/processes
  - Strategic Initiatives, Partnerships and Outreach (SIPO) Staff (FSIS)
  - FSIS Compliance Guidelines

18

Alternative 1 & 2

- The effectiveness of the post-lethality treatment should be verified by testing for *Lm*
  - Points to consider:
    - Plant data must verify the elimination or reduction of *Lm*
    - Establishment documentation must support the verification procedures selected and the frequency of those procedures

19

Alternatives 1 & 2

- Examples of antimicrobial agents and processes
  - Addition of lactates and diacetates to meat formulations
  - Growth inhibitor packaging
  - Lethality treatment and antimicrobial process that renders RTE product shelf stable (e.g., beef jerky)
  - Freezing during shelf life of RTE product

20

Antimicrobial Agents and Processes

Workshop Discussion

21

Antimicrobial Agent or Process

- Antimicrobial agents or processes that may be used by small/very small plants
  - Can anyone provide an example, other than sodium lactate or freezing, that may be used or that you are using in your establishment?

22

Antimicrobial Agent or Process

- For example, when evaluating a process that renders a RTE product shelf stable
  - The important factors to control and monitor this treatment.
    - Water activity
    - pH

23

Alternatives 1 & 2

- Validation of the antimicrobial agent or process
  - As a part of their validation, the plant should have documentation to demonstrate that the antimicrobial agent or process, as used, is effective in suppressing or limiting the growth of *Lm*
    - For example, the plant should be able to support the reduction levels of the pathogen that the antimicrobial agent or process can achieve, or to what growth suppression level, and length of time in days that the antimicrobial agent or process is effective
  - Points to consider during validation:
    - Documentation must support the use of the particular antimicrobial agent or process

24

Alternatives 1 & 2

- The effectiveness of the antimicrobial agent or process should be verified by testing for *Lm*
  - Points to consider:
    - Plant data must show that the growth of *Lm* is either suppressed or limited
    - Establishment documentation must support the verification procedures selected and the frequency of those procedures

25

CONCLUSION

A General Session For Questions and Answers Will Convene In 15 Minutes

26