IFSH Annual Meeting

*Listeria* Control - Regulatory Perspective

Mickey Parish
CFSAN Senior Science Advisor
Background

- *Listeria monocytogenes* (Lm) in foods can cause listericidal gastroenteritis and a severe, invasive illness (listeriosis) with a relatively high mortality rate.
- Persons at greatest risk: pregnant women and their fetuses, the elderly, and persons with weakened immune systems.
- Foods that have caused outbreaks are typically ready-to-eat (RTE) foods contaminated from the environment during manufacturing/processing.
- The greatest risk for listeriosis is from RTE foods that support growth of Lm.
Lm Time Points

- “Zero tolerance” established in 1986 by US agencies and explained in 1996 *Food Control* publication
- 2003 FDA/FSIS risk assessment – Food risk
- 2004 FAO/WHO risk assessment – Dose response
- 2008 FDA draft guidance documents:
  - *Listeria* in RTE foods Guidance for Industry (GFI)
  - *Listeria* Compliance Policy Guide (CPG)
- 2011 JIFSAN-IRAC workshop on dose-response
- Notable outbreaks (produce and dairy)
- Ice cream enumeration studies
Lm Time Points (cont.)

- 2015 FDA new dose-response study
- 2015 FDA Food Advisory Committee meeting
- 2017 FDA new draft guidance document
- Final Guidance for Industry under development
- New draft Compliance Policy Guide under review
- New draft RTE/NRTE Guidance for Industry under development
- Bottom line: FDA has three documents “in the works.”
  - *Listeria* GFI final guidance document
  - *Listeria* CPG draft document
  - RTE/NRTE draft guidance document
FSMA Definitions

- Environmental Pathogen
- Ready-To-Eat Food
Environmental Pathogen

*Environmental pathogen* means a pathogen capable of surviving and persisting within the manufacturing, processing, packing, or holding environment such that food may be contaminated and may result in foodborne illness if that food is consumed without treatment to significantly minimize the environmental pathogen. Examples of environmental pathogens for the purposes of this part include *Listeria monocytogenes* and *Salmonella* spp. but do not include the spores of pathogenic sporeforming bacteria.
Ready-To-Eat Food (RTE Food)

*Ready-to-eat food (RTE food)* means any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.
§ 117.165 Verification of implementation and effectiveness.

• (a) *Verification activities.* You must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing or preventing the hazards. To do so you must conduct activities that include the following, as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility’s food safety system:

• (3) Environmental monitoring, for an environmental pathogen or for an appropriate indicator organism, if contamination of a ready-to-eat food with an environmental pathogen is a hazard requiring a preventive control, by collecting and testing environmental samples;
Control of *Listeria monocytogenes* in Ready-to-Eat Foods: Draft Guidance

PUBLISHED
Federal Register / Vol. 82, No. 10 / Tuesday, January 17, 2017
Controlling Growth of Lm in Foods

• Formulation of RTE foods to prevent growth:
  – pH ≤ 4.4; or
  – $a_w ≤ 0.92$; or
  – One or more inhibitory substances that alone, or in combination, prevent growth of Lm.

• Hold foods under frozen conditions. (Lm grows at refrigeration temperatures.)
Listericidal Process Control

• Consider whether a listericidal process control during manufacturing is practical.
  – Consistently destroys viable cells of Lm
  – Leads to a food product that does not contain detectable Lm
Design of the EM Program

• Test for *Listeria* spp. rather than Lm in the environment

• Test both FCSs and non-FCSs at each sampling time.

• Collect environmental samples several hours into production and preferably just before cleanup.

• Finding *Listeria* spp. on occasion is expected.
Corrective Action Procedures

• Types of corrective actions are highly varied, depending on the situation but include:
  – conducting intensified cleaning and sanitizing,
  – conducting intensified sampling and testing,
  – conducting a root cause analysis, and
  – implementing "hold and test" procedures.
Escalating Actions Based on Risk

• If *Listeria* spp. is found during routine sampling:
  – Clean and sanitize the area with the positive
  – Retest during next production cycle(s)
  – Conduct comprehensive investigation for FCS+
  – Return to routine testing if follow up (retest) samples are negative
Escalating Actions Based on Risk

- If follow up testing shows a second positive:
  - Conduct intensified cleaning and sanitizing (with disassembly if positive is a FCS)
  - Conduct intensified sampling and testing
  - Begin “hold and test” for FCS positive and product supports growth
  - Consider “hold and test” for FCS positive and product does not support growth
  - Conduct comprehensive investigation
Corrective Actions for *Listeria* spp. on an FCS

• Corrective actions in guidance differ slightly based on FCS or non-FCS

• If firm sells food that does not support growth of *Lm* to establishments such as hospitals and nursing homes, the corrective actions should be applied as though the food supports growth.
Corrective Actions for *Listeria* spp. on an FCS (cont.)

• Guidance describes corrective action procedures that specify 3 consecutive days of negative tests before returning to routine sampling and testing.

• Guidance recommends that if follow up testing results in a 3rd FCS-positive for foods that support growth, production be stopped pending consultation with food safety experts.

<table>
<thead>
<tr>
<th>Retest</th>
<th>Results</th>
</tr>
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<tbody>
<tr>
<td>Day 1</td>
<td>Negative</td>
</tr>
<tr>
<td>Day 2</td>
<td>Negative</td>
</tr>
<tr>
<td>Day 3</td>
<td>Negative</td>
</tr>
</tbody>
</table>

*Return to routine* 😊
Summary of Recommended Corrective Actions for *Listeria* species positive environmental sample

- Table 6 in GFI
- Recommendation depends on:
  - If the food supports growth of Lm or not
  - FCS v. non-FCS
  - Number of positive follow-up samples
Trends in EM Indicating Lm is Not Being Controlled

• Increases in positive environmental samples in particular sites or areas;
• Finding *Listeria* in the same area on multiple but non-consecutive sampling occasions (e.g., positive one week and negative the next, appearing to be isolated positives); and
• An increase in the percentage of overall positive environmental samples in the plant.
Thank you

Questions?