

FDA

U.S. FOOD & DRUG  
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CENTER FOR FOOD SAFETY & APPLIED NUTRITION

# Control of *Listeria monocytogenes* in Ready-to-Eat Foods: Draft Guidance

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Jenny Scott  
Mickey Parish  
FDA CFSAN

Alliance for Listeriosis Prevention  
International Association for Food Protection

# Applicability

- Guidance intended for those subject to the CGMP & PC rule in 21 CFR part 117, and it identifies the relevant sections of the rule in various sections.
- Applies to production of RTE foods exposed to the environment prior to packaging where there is no Lm control measure that would significantly minimize Lm
- Replaces the previous draft guidance from 2008

# Disclaimer

- The revised draft guidance, when finalized, will represent the current thinking of FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

# 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.

# CGMPs/PCHF Requirements Can Minimize/Prevent Contamination

- Through
  - controls on raw materials or other ingredients,
  - listericidal control measures to consistently destroy viable cells of *L. monocytogenes*
  - listeristatic formulations to prevent viable cells of *L. monocytogenes* from growing
  - segregation of foods that have been cooked from those that have not
  - sanitation controls
  - sanitary equipment design

# Controls

- Controls on personnel
- Design, construction and operation of the plant
- Sanitation
- Controls on raw materials and other ingredients
- Listeristatic formulation controls
- Listericidal process controls
- Storage practices, time/temperature controls
- Transportation

# Environmental Monitoring to Verify Control

- Goals
- Design of environmental monitoring programs
- Corrective actions – food-contact surfaces, non-food-contact surfaces
- Analysis of data for trends

# Sampling and Testing of Foods

- Uses of sampling and testing
- Corrective actions
- Analysis of data for trends



# Formulation as a Control

- Consider whether formulation of RTE foods to prevent growth is practical.
  - $\text{pH} \leq 4.4$
  - $a_w \leq 0.92$
  - One or more inhibitory substances that alone, or in combination, prevent growth of Lm.

# 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
    - 5 log reduction if food is unlikely to be contaminated with more than 100 CFU/g
    - Other log reductions may be appropriate.

# Goal of an Environmental Monitoring (EM) Program

- Verify the effectiveness of control programs for Lm;
- Find Lm and harborage sites if present in a plant; and
- Ensure that corrective actions have eliminated Lm and harborage sites when found in a plant.

# Well-Designed EM Program

- Should include
  - Collecting environmental samples from food contact surfaces (FCSs) and non-FCSs in a plant;
  - Testing the collected environmental samples to identify potential sources of contamination; and
  - Taking appropriate corrective actions if test results indicate the presence of *Listeria* spp. or *L. monocytogenes* in an environmental sample.

# More on Design of the EM Program

- The guidance recommends testing for *Listeria* spp. to correct situations that could potentially lead to contamination with Lm.
- The guidance recommends testing both FCSs and non-FCSs at each sampling time.
- The guidance recommends collecting environmental samples at a time several hours into production and preferably just before cleanup.
- The guidance acknowledges that finding *Listeria* spp. is expected.

# Risk-Based Corrective Action Procedures

- Consider:
  - Whether the environmental contamination is on an FCS or a non-FCS;
  - Whether testing environmental samples results in an isolated positive result or multiple positive results; and
  - The proximity of a contaminated non-FCS to FCSs.

# 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.
- Examples are provided; it is not possible to provide a comprehensive set of corrective actions that apply in all situations.

# 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
  - Conduct comprehensive investigation if FCS
  - Return to routine testing if follow up (retest) samples are negative
- If follow up testing shows a second positive:
  - Conduct intensified cleaning and sanitizing (with disassembly if positive FCS)
  - Conduct intensified sampling and testing
  - Begin “hold and test” if FCS positive and product supports growth (consider for no-growth food)
  - Conduct comprehensive investigation



# Intensified Cleaning and Sanitizing

- Includes sanitation measures that are performed in addition to normal sanitation procedures and are escalated in response to continuing findings of positives. Can include
  - increasing the frequency of cleaning and sanitizing for certain pieces of equipment,
  - breaking down the equipment into its parts for further cleaning, and
  - steam treating equipment.

# Intensified Sampling and Testing

- Collecting and testing follow-up samples to a positive test site.
  - The follow-up samples should include the positive site and at least 3 surrounding sites, which could include both FCSs and non-FCSs in close proximity to the positive site.

# Corrective Actions for *Listeria* spp. on an FCS

- Guidance describes corrective action procedures that differ based on whether a food supports growth of Lm or not.
- Guidance recommends that for foods that do not support growth, but that are specifically intended for establishments such as hospitals and nursing homes, the corrective actions for foods that support growth be applied.

Continued

# 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 3<sup>rd</sup> FCS-positive for foods that support growth, production be stopped pending consultation with food safety experts

# Comprehensive Investigation for an FCS- Positive

- Examine equipment and area surrounding positive for potential harborage sites
- Review HACCP/Food Safety Plan and its implementation
- Conduct intensive sampling and testing, collecting samples several times during production and testing upstream from the positive site

Continued

# Comprehensive Investigation for FCS- Positive (cont.)

- Check maintenance records
- Interview and observe sanitation, maintenance, and production personnel
- Review production, maintenance, and sanitation procedures
- Review traffic patterns, equipment layout, and adherence to personnel hygiene procedures

# Sampling and Testing Foods

- Could be done to verify supplier control programs
- Could be done for “hold and test” during corrective actions
- Could be done to verify adequacy of Lm controls for an RTE food
- Could be done to satisfy customer request/requirement

Continued

## Sampling and Testing Foods (cont.)

- Guidance recommends that foods be tested for Lm rather than *Listeria* spp.
- Guidance recommends holding product represented by the food tested (e.g., food lots produced from cleanup to cleanup)



# Corrective Actions for Detection of *Lm* in RTE food

- Reprocess with a validated listericidal control measure,
- Divert to a use in which the food will not be consumed by humans or animals,
- Send for use in food to be consumed by animals where appropriate, or
- Destroy the lot(s) of RTE food in which *L. monocytogenes* has been detected

Continued

# Corrective Actions for Detection of Lm in RTE food (cont.)

- Determine whether other lot(s) of food are potentially contaminated with Lm and segregate and hold those lots of food.
- Review environmental monitoring results to determine if other lots could be contaminated and subject them to “hold and test”
- Conduct intensified sampling and testing of FCSs and non-FCSs followed by corrective actions until source of contamination is found and eliminated
- Determine whether any food in commerce would be subject to a recall.

# Analysis of Data for Trends

- Guidance recommends analyzing the data collected through environmental monitoring over time for trends that can help to continuously improve sanitation conditions in the plant by reducing the percentage of overall positive environmental samples in the plant.
- Guidance recommends analyzing product testing data for trends to improve performance and identify the need for corrective actions.

# 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.

# Training

- Guidance recommends providing training in health and hygienic practices specific to control of Lm for all personnel and contractors who enter production and storage areas (e.g., individuals who conduct production, maintenance, quality assurance, quality control, or warehousing operations).

# Training

- Guidance recommends training in the application of the principles of the practices recommended in the guidance to the control of *L. monocytogenes* in RTE food for personnel responsible for:
  - Establishing and implementing listericidal and listeristatic controls;
  - Collecting and testing environmental and food samples;
  - Determining and taking corrective actions; and
  - Establishing and implementing written sanitation procedures.

# Please Submit Comments

- *Federal eRulemaking Portal:*  
*<https://www.regulations.gov>*
- **Docket No. FDA–2008–D–0096** (Formerly Docket No. 2007D–0494)
- to ensure that we consider your comment on the draft guidance before we issue the final version, submit comments by **July 26, 2017**



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