

FDA's Revised Draft Guidance for Control of *Listeria monocytogenes* in Ready- To-Eat Foods

Presentation for the Wisconsin Association for Food Protection

June 13, 2017

Agenda

- Regulatory Background
- Key Takeaways
- Key Issues from the Guidance
 - Sanitation controls
 - Controls on raw materials and other ingredients
 - Environmental Monitoring
 - Recommendations for Corrective Actions
 - Product “Hold and Test” Sampling Plans
 - Employee Training
- Recap
- Next Steps
- Questions and Answers



Regulatory Background

- FDA issued draft guidance on control of *Lm* in RTE foods in 2008
 - Recommended facilities determine whether *Listeria* spp. detected on food contact surface (FCS) is *Lm* or treat as if it is *Lm*
- Since then, food safety regulations and knowledge of *Listeria* have changed significantly
- 2017 revised draft guidance intended to:
 - Reflect amended cGMP requirements and Preventive Controls for Human Food rule
 - Change recommended corrective actions in response to concerns that 2008 draft guidance may have deterred robust *Listeria* control programs



Regulatory Background continued...

- This draft guidance document is in draft form
 - FDA is accepting comments (generally due by July 26, 2017)
 - Represents FDA's current thinking
 - Guidance does not establish legally enforceable requirements
 - But expect to see FDA investigators using the draft guidance during inspections
- Expect to see draft guidance regarding how to distinguish between RTE and non-RTE foods
- Expect to see an updated draft Compliance Policy Guide that outlines the agency's *Lm* enforcement policy for FDA staff

Statutory and Regulatory Framework

- FFDCa Section 402(a)(1) – Food is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to health
- FFDCa Section 402(a)(4) – Food is adulterated if it has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or been rendered injurious to health
- Multiple provisions in the cGMPs are designed to protect food from contamination
- 21 CFR 117.130(c)(1)(ii)- Hazard analysis must include an evaluation of environmental pathogens whenever a RTE food is exposed to the environment prior to packaging
- 21 CFR 117.165(a)- Verification activities must include, as appropriate, product testing and environmental monitoring, if contamination of an RTE food with an environmental pathogen is a hazard requiring a preventive control
 - Testing program must be written
- 21 CFR 117.150(a)(1) – Must establish and implement corrective actions procedures to respond to testing results

Top 10 Key Takeaways

1. A “must read” for facilities producing RTE foods exposed to the environment prior to packaging
 - Contains detailed recommendations on *Listeria* control
2. The recommended measures for controlling *Listeria* are more goal-based and flexible
 - FDA notes that alternative approaches may be necessary or appropriate
3. Feedback from industry on the 2008 draft guidance was incorporated into the 2017 version
4. FDA wants to encourage a “seek and destroy” approach to *Listeria*
 - Positive environmental samples are to be expected
5. Facilities get a “mulligan” after one positive FCS test to continue production, with requirements for sanitation, retesting, and investigation
 - Helpful to facilities under dual jurisdiction

Key Takeaways Continued...

6. Guidance continues to distinguish between foods that do/don't support the growth of *Lm* with respect to corrective actions
 - No “tolerance” of 100 cfu/g of *Lm* in foods that don't support growth
7. Detailed recommendations for a comprehensive investigation to support goal of finding and eliminating source of contamination
8. Only applies to RTE food and does not change definition of RTE food
9. Emphasis on recordkeeping (e.g., written program for equipment maintenance)
10. Guidance also is instructive beyond *Listeria* for development of robust environmental monitoring, sanitation, and supplier verification programs

Key Topics in the Draft Guidance

- Controls on personnel
- Design, construction, and operation of plants
- Design, construction, and operation of equipment
- Sanitation controls
- Controls on raw materials and other ingredients
- Formulation controls
- Listericidal process controls
- Storage practices and time/temperature controls
- Transportation
- Environmental monitoring programs
- Corrective actions when *Listeria* spp. is detected on FCS or non-FCS
- Sampling and testing of RTE foods
- Analysis of environmental monitoring and product testing data for trends
- Training
- Procedures to collect, prepare, and test samples
- Records
- Potential sources of *Lm*
- Examples of scenarios that could lead to contamination of RTE foods with *Lm*
- Recommended cleaning schedules

Sanitation Controls

- Draft guidance outlines:
 - What SSOPs should include
 - Recommended steps for cleaning and sanitizing
 - How to clean drains; equipment when production running
 - Use of sanitizers
 - Sanitation monitoring
- Frequency should be based on:
 - Sanitary design of equipment and room
 - Microbiological profile during a production run
 - History of *Listeria* in the room and on the line
 - Degree of product exposure to the line and the environment
- Appendix 4 has recommended schedules for routine cleaning/sanitizing
 - FCS at least once every 24 hours, or validate alternative schedule
 - Non FCS vary daily to semi-annually



Controls on Raw Materials and Ingredients

- Recommended controls on suppliers include:
 - Periodic onsite audits
 - Verifying the supplier's environmental monitoring program and results
 - Obtaining materials under a Certificate of Conformance (COC) along with:
 - Statement of adherence to the draft guidance
 - **Periodic testing of the materials to verify the supplier's controls**
 - Obtaining the materials under a Certificate of Analysis (COA) along with:
 - The supplier's sampling plan for testing the material
 - **Initial and periodic testing of the material to verify the supplier's controls**
- Facility should have written procedures for sampling and testing materials



Environmental Monitoring

- Goal of the EMP:
 - Verify effectiveness of control programs for *Lm*
 - Find *Lm* in your plant
 - Ensure that corrective actions are effective and have eliminated *Lm*
- FCS and non-FCS have replaced “critical surface or area” and “critical food contact surface”
- Zone definitions and examples provided
- FDA recommends testing for *Listeria* spp. vs. *Lm* because the conditions for *Listeria* are suitable for survival and/or growth of *Lm*, but:
 - “A positive test results for the presence of *Listeria* spp. on a FCS or non-FCS does not establish the presence of *Lm* on a FCS or non-FCS”

Environmental Monitoring continued...

- Test both FCS and non FCS sites at each sampling time
- Number of sites based on size of plant, features, product flow, food characteristics, processing methods, previous sampling results
- Number of samples generally higher in Zones 1 and 2
- Examples of sites to sample in Appendix 1
- Recommended minimum of 5 FCS and 5 non-FCS on each line
- Collect samples several hours into production (3-4)
- Frequency should be based on risk (growth/no-growth)
- Compositing not recommended

Environmental Monitoring Continued...

- Key statements:
 - “You should expect to detect the presence of *Listeria* spp. or *Lm* on an occasional basis in environmental samples collected from your plant.”
 - “If you consistently see negative test results . . . We recommend that you revise your environmental monitoring procedures to add, substitute, or both add and substitute other surfaces in your plant for sample collection and testing.”
 - “We recommend that you periodically verify your written environmental monitoring procedures with increased and intensive environmental sampling of the plant to assess whether the sampling sites are appropriate.”
- Develop an aggressive program!

Corrective Actions- Summary

- 2008 draft guidance suggested a positive test for *Listeria* spp. on FCS be followed by test to determine whether positive was *Lm* or assume it was *Lm*
 - Either way, facilities would need to stop production, segregate and hold food, even if food did not support growth
- In 2017 draft guidance:
 - Corrective actions are the same if a test is positive for any species of *Listeria*
 - Firms allowed one “free pass” when *Listeria* spp. detected, but should perform root cause analysis, clean, and sanitize; no need to stop production or hold product
 - If there is a second positive test for *Listeria* spp. on a FCS and the food supports growth, FDA recommends hold and test and other corrective actions

First FCS Positive Test = Investigate!

- If *Listeria* spp. detected on FCS, firms should conduct comprehensive investigation (i.e., expanded root cause analysis):
 - ❑ Examine equipment that tested positive and surrounding area
 - ❑ Review/modify HACCP or Food Safety Plan
 - ❑ Intensify sampling and testing
 - ❑ Test upstream from positive testing location
 - ❑ Check maintenance records for major equipment
 - ❑ Interview and observe sanitation, maintenance, production personnel
 - ❑ Review/modify production, maintenance, sanitation procedures
 - ❑ Review potential scenarios in Appendix 2 to identify potential causes
 - ❑ Review traffic patterns, equipment layout, and adherence to personnel hygiene procedures

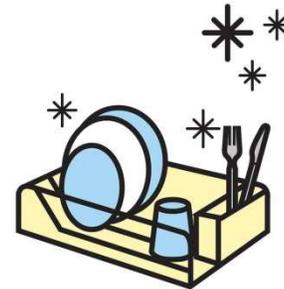


First FCS Positive Test, continued...

- If composite sampling from multiple sites resulted in positive test, firm should:
 - Conduct additional testing to identify specific positive FCS; or
 - Take action on each of tested sites
- Once FCS identified, firm should pay particular attention to cleaning and sanitizing
- Then retest FCS and surrounding area at least 3 hours into next production run
- If follow-up samples are negative, firm may assume contamination has been eliminated and resume routine environmental monitoring

Second FCS Positive Test

- If any follow-up sample is positive for *Listeria* spp., the firm should:
 - Conduct intensified cleaning and sanitizing, including disassembly of equipment, if practical;
 - Conduct intensified sampling and testing;
 - Follow “hold and test” procedures, as appropriate; and
 - Conduct a comprehensive investigation
- These corrective actions should continue for next two production days



2nd Positive: Recommended “Hold and Test” Procedures

Food Does Not Support *Lm* Growth

- Consider whether to hold the production lot for that production date
- Base decision on likelihood of product contamination and risk of contamination to consumer

Food Supports *Lm* Growth

- Hold production lot for production day and test product for *Lm* using statistically based sampling protocol.
- Hold food from second and third of 3 consecutive days

2nd Positive Corrective Actions continued...

- Firms then should test product lot for *Lm* and the FCS for *Listeria* spp. for at least 3 sequential production days
- If product tests negative for *Lm* and FCS is negative for *Listeria* spp. for 3 sequential production days:
 - May release product lot and any product on hold
 - May resume routine production and monitoring
- If product tests positive for *Lm*:
 - Firm should reprocess food, divert to non-food use, send for consumption by animals (if appropriate), or destroy product lots
 - Should also consider a recall

Third FCS Positive Test

- If a follow-up sample of FCS is positive for *Listeria* spp., firm should assume it has a harborage site

Food Does Not Support Growth

- Take same corrective actions taken for food that supports growth after second FCS positive
- If fourth test is positive for *Listeria* spp., consult food safety experts and escalate intensified cleaning, sanitizing, sampling and testing
- Then resume production and hold and test until 3 consecutive days of both the product and FCS testing negative

Food Supports Growth

- Stop production
- Consult food safety experts and escalate intensified cleaning, sanitizing, sampling, and testing
- Then resume production and hold and test product until 3 consecutive days of both the product and FCS testing negative

FCS Testing continued..

- If firm detects *Lm* on FCS, firm should:
 - Reprocess food, divert to non-food use, send for consumption by animals (if appropriate) or destroy the product lots
 - Firm also should consider a recall



Listeria spp. on Non-Food Contact Surfaces

- FDA recommendations focus on positives in Zone 2
- After first positive test, clean and sanitize the site at the end of production and retest the non-FCS and surrounding area at least 3 hours into the next production run
- If any follow-up samples are positive, firms should conduct intensified cleaning, sanitation, sampling, and testing
 - If food supports growth of *Lm*, cleaning and sanitation may include disassembly of equipment, as well as sampling of equipment prior to disassembly
 - If food does not support growth of *Lm*, firm may not need to disassemble equipment unless there is third positive

Listeria spp. on Non-Food Contact Surfaces, cont'd

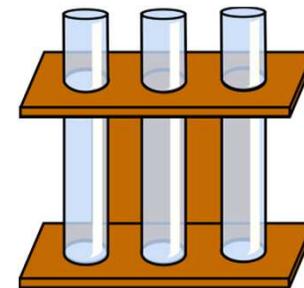
- If follow-up samples are negative, firm may assume contamination eliminated and resume routine environmental monitoring and production
- If third test is positive, firm should:
 - Conduct comprehensive investigation and root cause analysis
 - Escalate mitigation efforts
 - Consider consulting with food safety expert
- FDA says minimal value in determining if *Listeria* spp. is *Lm* because both should be eliminated

Responding to Trends

- Detecting *Listeria* spp. at several Zone 2 sampling locations during same sampling period could indicate:
 - Routine sanitation procedures are inadequate
 - Potential harborages
 - Increased risk of cross contamination from Zone 2 to Zone 1 or food
- FDA recommends review of sanitation procedures and escalation of corrective actions
- If firm detects *Listeria* spp. in same general area on multiple occasions
- FDA recommends firm conduct root cause analysis

Product “Hold and Test” Sampling Plans

- FDA recommendations based on FSIS’s guidelines for control of *Lm* in RTE meat and poultry products and ICMSF sampling plans
- Sampling plan should be based on (1) risk of *Lm* to population that will consume product and (2) whether conditions prior to consumption can influence growth of *Lm*
 - If risk unknown, FDA recommends sampling plan for severe hazard
- FDA recommends analyzing 25 g sample for *Lm* or *Listeria* spp.
 - Samples should be collected in one day
 - Firm should hold affected products during testing



Product “Hold and Test” Sampling Plans for RTE Foods

	Conditions Likely to Reduce Hazard (e.g., product will undergo kill step)	Conditions of Use Likely to Cause No Change in Hazard (e.g., no growth, no die off)	Conditions of Use Likely to Increase Hazard (e.g., high pH or water activity)
Serious Hazard	5 samples	10 samples	20 samples
	Mean Concentration 1 cfu/32 g	Mean Concentration 1 cfu/83 g	Mean Concentration 1 cfu/185 g
Severe Hazard	15 samples	30 samples	60 samples
	Mean Concentration 1 cfu/135 g	Mean Concentration 1 cfu/278 g	Mean Concentration 1 cfu/526 g

Product “Hold and Test” Sampling Plans for RTE Foods, cont’d

- FDA recommends firms test food for *Lm* because of risk to public health
 - If firm tests for *Listeria* spp., firm should either determine if *Lm* or assume as much
- If *Lm* is detected in food, the firm should:
 - Reprocess food with validated listericidal control measure, divert to non-food use, send for consumption by animals (if appropriate), or destroy product lots
 - Consider lots produced between two cleaning and sanitation cycles to be implicated by positive
 - Consider whether other lots are potentially contaminated and should be subjected to hold and test procedures
 - Take corrective actions, including intensified sampling and testing of FCS and non-FCS, followed by additional corrective actions
 - Consider whether food in commerce should be recalled

Employee Training

- Part 117 requires all individuals engaged in manufacturing, packing, holding to receive training in food hygiene and food safety, including personal health and hygiene
- FDA recommends
 - Training in health and hygiene specific to *Lm* control for all personnel and contractors who enter production and storage areas, along with annual refresher training
 - Training on the draft guidance for those responsible for or who supervise:
 - Establishing listericidal/listeristatic controls
 - Collecting and testing environmental and product samples
 - Determining and taking corrective actions
 - Establishing and using written sanitation procedures



Recap



- Detailed recommendations on how to design systems to control for *Listeria* in RTE foods, but with flexibility
- Facilities get a “mulligan” after one positive FCS test to continue production, with investigation, sanitation, and retesting
- Guidance continues to distinguish between foods that do/don’t support the growth of *Lm* with respect to corrective actions following environmental sampling; but no “tolerance” of 100 cfu/g of *Lm* in foods that don’t support growth
- Firms need to be sure to conduct comprehensive investigations to find and eliminate the source of contamination

Next Steps

- Thoroughly review the draft guidance
- Comments on this draft guidance due July 26, 2017
- Forthcoming FDA publications:
 - Draft guidance on determining foods that are RTE
 - Update to 2008 draft Compliance Policy Guide for FDA staff (CPG 555.320)

Questions?



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