

Listeria environmental monitoring initiatives in cheese and dairy manufacturing

Wisconsin Association for Food Protection Fall Food Safety Workshop

November 2, 2017

Julie Carver

Sargento Foods Inc.

Industry Groups

- ▶ Wisconsin Milk Marketing Board
- ▶ Innovation Center for US Dairy
- ▶ Center for Dairy Research - University of Wisconsin

Wisconsin Milk Marketing Board

- ▶ Work actively on education initiatives for dairy industry in Wisconsin
- ▶ Have delivered 10 sessions to train Preventive Control Qualified Individual and have trained more than 250 Wisconsin dairy professionals
- ▶ Created a Teaching Example of a Food Safety Plan for Pepper Jack Cheese Production which is in revision for approval by FDA
- ▶ Have held four sessions on Environmental Monitoring since the Lm Guidance Document was published

Innovation Center for US Dairy

- ▶ Dairy Food Safety Operating Committee started in 2011
- ▶ Strengthen manufacturing practices in all dairy process facilities and advance science-based tools to diminish food safety risks that could compromise the reputation of the U.S. dairy industry
- ▶ “Food Safety should not be used as a competitive advantage”

Innovation Center for US Dairy

- ▶ Dairy Plant Food Safety Workshop
 - ▶ Best practices, uniform approaches to in-plant pathogen control programs
 - ▶ 67 sessions since 2011; 2837 trained
 - ▶ 76 volunteer SMEs from 33 organizations
 - ▶ Courses for both wet operation and dry operation
 - ▶ 5 Courses in 2018, 3 wet and 2 dry

Innovation Center for US Dairy

- ▶ Supplier Food Safety Management Workshops
- ▶ Risk control tools and training to mitigate risk from materials / services
 - ▶ 12 sessions since 2011, 200 trained
 - ▶ Volunteer SMEs from major dairy producers across the country
 - ▶ Next course - March 2018 in Rosemont, IL

Innovation Center for US Dairy

- ▶ Artisan / Farmstead Cheese Food Safety
- ▶ Mitigate pathogen risks in small operations
 - ▶ 21 sessions since 2012, 750 Artisans and Regulators trained
 - ▶ Re-launched as an online class in June 2017
 - ▶ Artisan Advisory Team created
 - ▶ Hands on workshops
 - ▶ Food Safety Plan writing/coaching sessions

Innovation Center for US Dairy

- ▶ Pathogen Control Guidance Documents
 - ▶ Released Guidance for Control of *Listeria monocytogenes* in Dairy in 2015, revised 2017; Spanish version released in 2017
 - ▶ Broader “Pathogen Guide” under development
 - ▶ Available at www.usdairy.com/foodsafety

Innovation Center for US Dairy

- ▶ Listeria Research Platform
- ▶ IC collaboration for consortium funded Listeria research - 13 core companies; more are welcome
- ▶ Target areas of research
 - ▶ Listeria controls in products and plant environments
 - ▶ Listeria virulence research
 - ▶ Critical risk mitigation - surface ripened & fresh cheeses
- ▶ 4 projects started in 2016 and 4 more in 2017

Innovation Center for US Dairy

▶ Regulatory Roundtable

- ▶ Engagement strategy to enhance relationships and dialog with regulators
- ▶ Dialogs with FDA - CFSAN led to the Listeria guide, Hispanic cheese outreach, Artisan Cheese Platform

And now for something completely different...

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

Taken from Hogan Lovells, Elizabeth Fawell's Presentation to AFFI February 2017

Regulatory Background

- ▶ This guidance document is in draft form
 - Published by FDA January 2017
 - Replaces the previous draft guidance from 2008
 - FDA accepted comments through July 26, 2017
 - Represents FDA's current thinking
 - We don't know when final guidance will be issued

Top 10 Takeaways

1. A “must read” for facilities producing RTE foods exposed to the environment prior to packaging (especially ALL PCQIs)
 - 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 have “one free pass” after one positive FCS test to continue production, with requirements for sanitation, retesting, and investigation
 - Helpful to facilities under dual jurisdiction (FDA & USDA)

Top 10 Takeaways Continued...

6. Guidance continues to distinguish between foods that do/don't support the growth of *Lm* with respect to corrective actions
 - Removes language regarding allowance for 100 cfu/g of *Lm* in foods that don't support growth of the pathogen (2008)
7. Detailed recommendations for a comprehensive investigation to support goal of finding and eliminating source of contamination - Strong RCA and CAPA program
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

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 & Ingredients

Recommended controls on suppliers include:

- ▶ Periodic onsite audits
- ▶ Verifying Supplier's environmental monitoring program & results
- ▶ Obtaining materials under a COC along with:
 - ▶ Statement of adherence to the draft guidance
 - ▶ Periodic testing of materials to verify supplier's controls
- ▶ Obtaining materials under a COA along with:
 - ▶ Supplier's sampling plan for testing
 - ▶ Initial and periodic testing of materials to verify supplier's controls

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*
- ▶ FDA recommends testing for *Listeria* spp. versus *Lm* because the conditions for *Listeria* are suitable for survival and/or growth of *Lm*

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*
- ▶ FDA recommends testing for *Listeria* spp. versus *Lm* because the conditions for *Listeria* are suitable for survival and/or growth of *Lm*

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
 - ❑ 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 traffic patterns, equipment layout, and adherence to personnel hygiene procedures

First FCS Positive Test, continued...

- ▶ 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

- ▶ NOTE - Product not required to be on hold

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
 - ❑ Conduct a comprehensive investigation

These corrective actions should continue for the next two production days/runs

2nd Positive: Recommended “Hold and Test” Procedures

Food Does Not Support *Lm* Growth

- ▶ Consider whether to hold the production lot for that production date/run
- ▶ Base decision on likelihood of product contamination to consumer

Food Supports *Lm* Growth

- ▶ Hold production lot for production day/run and test product for *Lm* using statistically based sampling protocol (ICMFS)
- ▶ Hold food from second and third of 3 consecutive production days/runs

Second 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/cycles
- ▶ If product tests negative for *Lm* and FCS is negative for *Listeria* spp. for 3 sequential production days/runs:
 - ▶ 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 for 'first' product that was not produced under HOLD

Third FCS Positive Test

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

Food Does Not Support Growth

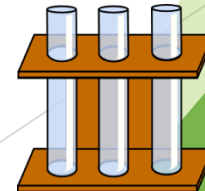
- ▶ Take same CAs taken for food that supports growth after second FCS positive
- ▶ If fourth test is positive for *Listeria* spp., consult food safety experts and escalate intensified cleaning, sanitizing, sampling and testing
- ▶ Then resume production and hold and test until 3 consecutive days/runs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

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 (serious or severe); 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, 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* detected in food, 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
 - ❑ Should consider whether other lots produced between two cleaning and sanitation cycles to be implicated by positive
 - ❑ Should consider whether other lots are potentially contaminated and should be subjected to hold and test procedures
 - ❑ Corrective actions should include intensified sampling and testing of FCS and non-FCS, followed by additional corrective actions
 - ❑ Should consider whether food in commerce should be recalled

IDFA Response to FDA Draft Guidance

- ▶ Support the Agency's encouragement of Seek and Destroy method to control *Listeria monocytogenes* in Ready to eat (RTE) Foods
- ▶ Supportive of recommendations for corrective actions following a positive test result for *Listeria monocytogenes* on a food contact surface (FCS)
- ▶ Support the Agency's position on providing incentives to facilities to conduct FCS testing in order to improve understanding the manufacturing environment and effectiveness of control measures

IDFA comments

- ▶ Remind Agency that the final Guidance document will be non-binding. It should not be used as a checklist of requirements that must be implemented in facilities producing RTE foods

IDFA Comments

- ▶ Maintain meaningful distinction between (monitoring) Zones
- ▶ The role of Zone 1 testing
- ▶ Risk-based approach to *Listeria* control
- ▶ Role of COAs and COCs - recognize other approaches to verification activities

IDFA Comments

- ▶ Recognize less than daily sanitation cycles
- ▶ Appreciate the time and resources necessary for adoption of recommended practices
- ▶ Recognize that many facilities in the Dairy industry are legacy buildings using legacy equipment
- ▶ Recommend that the Agency provide flexibility in managing transition points between raw and RTE areas in a facility

