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

Regulatory Perspective on Verification Activities and Corrective Actions to Ensure the Effectiveness of Controls at Preventing Foodborne Illness

3-A SSI Education Program

Hygienic by Design: Reducing Risk in Your Facility

May 10, 2023

3-A Standards and the PMO

ITEM 9r. UTENSILS AND EQUIPMENT – CONSTRUCTION
ITEM 11p. CONSTRUCTION AND REPAIR OF CONTAINERS AND EQUIPMENT

NOTE: 3-A Sanitary Standards and Accepted Practices for dairy equipment are developed by 3-A SSI. 3-A SSI is comprised of equipment fabricators, processors, and regulatory sanitarians, which include State milk regulatory officials, USDA Agricultural Marketing Service Dairy Programs, the USPHS/FDA CFSAN/MST, academic representatives and others.

Equipment manufactured in conformity with 3-A Sanitary Standards and Accepted Practices complies with the sanitary design and construction standards of this *Ordinance*. For equipment not displaying the 3-A Symbol, the 3-A Sanitary Standards and Accepted Practices may be used by Regulatory Agencies as guidance in determining compliance with this Section.

Topics we will discuss…

Verification

- Product Testing
- Environmental Monitoring
- Audits of a Supplier
- Validation

Corrective Actions

- Root Cause Investigation/Analysis
- Identifying Affected Product
- Whole Genome Sequencing

Updates / FDA Calls for Enhanced Safety Measures in Letter to Powdered Infant Formula Industry

FDA Calls for Enhanced Safety Measures in Letter to Powdered Infant Formula Industry

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Constituent Update

March 8, 2023

Today, the U.S. Food and Drug Administration sent a letter to manufacturers, packers, distributors, exporters, importers, and retailers involved in the manufacturing and distribution of powdered infant formula to share current safety information and call on the industry to take prompt action to improve processes and programs for the protection of our most vulnerable population.

Last year, safety concerns at one of the largest infant formula manufacturing facilities in the country led to a nationwide recall and temporary pause in production, which has had ripple effects across the infant formula supply chain. Since that time, the FDA has taken many steps to improve the resiliency of the infant formula supply, including by issuing

For this remainder of this presentation, statements in **black** are directly from this letter. Other statements will appear in **blue.**

Areas of Concern at Powdered Infant Formula Manufacturing Facilities

1. Controlling water in dry production areas
2. Verifying the effectiveness of controls through environmental monitoring
3. Implementing appropriate corrective actions following the isolation of a pathogen from an environmental sample or a product sample
4. Implementing effective supply-chain controls for biological hazards
5. Identifying all relevant biological hazards

Controlling Water in Dry Production Areas

- Reducing the presence of water in dry production environments for low moisture foods is essential to controlling environmental contamination
- During inspections at powdered infant formula manufacturing facilities, FDA observed water present during production in areas that were intended to remain dry (at least during production)
- Uncontrolled water in equipment and/or dry production areas has contributed to recent outbreaks in other low-moisture foods

Verification by Environmental Monitoring

- Environmental monitoring is an important verification measure to ensure that sanitation and hygiene controls are effectively preventing pathogens from entering or persisting in dry production areas.
- Environmental monitoring should be conducted for an environmental pathogen or for an appropriate indicator organism
- Some firms have EMPs that limit the collection of environmental samples for *Cronobacter* spp. while relying heavily on monitoring for Enterobacteriaceae (EB) within the production area.

Monitoring Indicators vs Pathogens

- However, FDA is not aware of sufficient data demonstrating a correlation between EB populations and the presence of *Cronobacter* spp. on environmental surfaces.
- Environmental samples collected by FDA investigators during these inspections recovered *Cronobacter* spp. from environmental surfaces where the firms were only conducting routine environmental testing for EB.

Role of Food Contact Surface Testing

- Regulatory policies that incentivize aggressive environmental monitoring and elimination of *L. monocytogenes* on food contact surfaces, offer an effective approach towards public health protection

from Farber *et al*., 2021. Alternative approaches to the risk management of *Listeria monocytogenes* in low risk foods. Food Control. 123 (2021) 107601

GUIDANCE DOCUMENT

Draft Guidance for Industry: Control of Listeria monocytogenes in Ready-To-Eat Foods

JANUARY 2017

Download the Draft Guidance Document | Read the Federal Register Notice

Draft

Not for implementation. Contains non-binding recommendations.

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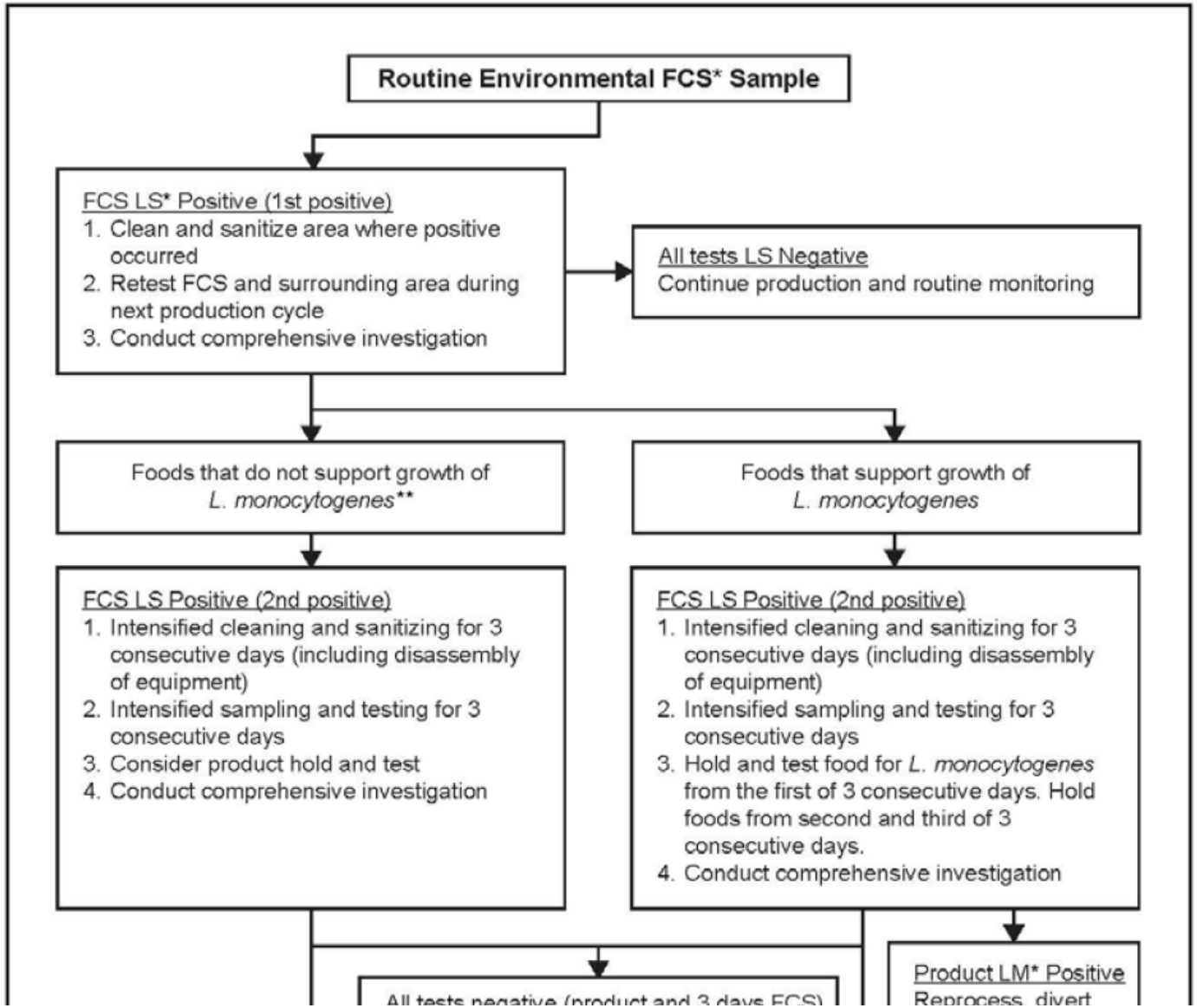
Docket Number: FDA-2008-D-0096

Issued by: Center for Food Safety and Applied Nutrition

This guidance is intended for those persons ("you") who are subject to our regulation, in 21 CFR part 117 (part 117), entitled "Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food" and who manufacture, process, pack, or hold ready-to-eat (RTE) foods. This guidance is intended for you regardless of whether you are only subject to the current good manufacturing practice requirements for human food of part 117 (CGMP requirements), the requirements for hazard analysis and risk-based preventive controls for human food in part 117 (PCHF), or both the CGMP

Listeria spp. on Food Contact Surfaces



- If you detect *Listeria* spp. on an FCS we recommend that you follow risk-based corrective action procedures to ensure that the cause of the contamination is identified and corrected, and to minimize the potential for release of RTE food that is contaminated with *L. monocytogenes*
- This approach allows the testing of FCS for *Listeria* spp. without immediate impact on product

Corrective Actions Following the Isolation of a Pathogen from the Product or Environment

- Effective corrective action plans often involve conducting a root cause investigation (RCI) to inform appropriate containment and corrective action activities

Root Cause Investigation (RCI): an investigation of firms/farms, products, and all aspects of the manufacturing process, including the environment, intended to determine factors that may have contributed to the introduction, proliferation, and transmission of pathogens or other hazards, including physical and chemical, that caused either death, illnesses, injury and/or food contamination

Root Cause Analysis (RCA): A retrospective analytical method used to attempt to determine the root cause(s) of a food-related trigger event and provide information for use in determining what actions can be taken to eliminate the root cause, if possible, and preventing a recurrence of the trigger event

Is Conducting an RCA Required?

- RCA is discussed in the preamble to the PCHF Rule in Comment/Response no. 472
  - "The rule does not use the term ''root cause'' but it does require the facility to take appropriate action, when necessary, to reduce the likelihood that the problem will recur (see § 117.150(a)(2)(ii)). Root cause analysis is simply part of a common approach to complying with this requirement. (Knowing the root cause is key to reducing the likelihood that a problem will happen again.)"
- The use of RCA is highly encouraged following the isolation of a pathogen from the product or food contact surface

Corrective Actions – Environmental Monitoring During Root Cause Investigation

- FDA investigators reviewed and/or observed corrective actions taken in response to detecting *Cronobacter* spp. in environmental and product samples
  - some facilities disassembled certain equipment, collected environmental samples from food contact surfaces, and tested those samples for indicator organism populations
  - some facilities immediately initiated sanitation activities on suspected environmental or equipment surfaces and then collected samples from these surfaces to verify sanitation effectiveness

Corrective Actions – Environmental Monitoring During Root Cause Investigation (cont)

- FDA encourages firms conducting an RCI to thoroughly investigate the potential sources of contamination by collecting environmental samples **before** performing sanitation activities, in addition to other RCI activities
- When conducting an RCI following detection of a pathogen, you may obtain more confidence by testing investigational samples for the pathogen instead (or in addition to) indicator organisms

Corrective Actions – Sanitation Breaks

- FDA has observed during inspections that many production lots may be processed on such equipment without an intervening sanitation break that would involve the application of a sanitizing treatment to all food contact surfaces (hereafter referred to as sanitation break)
- The best current available science demonstrates that the only adequate remediation for food contact surfaces contaminated by a bacterial pathogen is the application of a sanitizing treatment (e.g., a thermal treatment or a chemical treatment)
- To date, other remediation procedures, such as physical dry-cleaning techniques, have not proven effective against eliminating pathogens from equipment surfaces

Corrective Actions - WGS

- FDA strongly recommends the use of whole genome sequencing (WGS) to analyze and investigate any pathogen isolated from your production environment or product
- The data from this analysis can provide the most complete information available to identify and implement appropriate and effective corrective actions
- Recent outbreaks continue to demonstrate that if firms were routinely using WGS as part of corrective actions, illnesses and deaths could have been **prevented**

Supply-Chain Controls for Biological Hazards

- Some facilities involved in the manufacturing of powdered infant formula have processes or process steps that use raw materials or other ingredients in a manner that does not apply a treatment to these raw materials or other ingredients that would be lethal to bacterial pathogens, such as *Salmonella* or *Cronobacter* spp.

Supply-Chain Controls for Biological Hazards

- FDA observed that the supply-chain program at the powdered infant formula manufacturer did not always fully characterize the risk associated with bacterial pathogens, such as *Cronobacter* spp., at the supplier's facility.
- Suppliers of raw materials or other ingredients that will not receive a lethal treatment at the powdered infant formula manufacturing facility are an extension of the infant formula manufacturing process, particularly when it comes to sanitation controls for production and maintaining a production environment in conditions suitable for producing infant formula.

Annual Onsite Audits of a Supplier

- Required when a supply chain applied control is used to control a SAHCODH hazard
  - (unless a written determination that other verification activities or less frequent audits provide adequate assurance that the hazards are controlled)
- The purpose of the onsite audit is to verify that the supplier:
  - has identified the hazard as needing control
  - has identified appropriate controls for the hazard, and
  - has consistently implemented appropriate controls
- Third party audits that did not cover the hazard and/or the appropriate controls may not be sufficient for verifying supply-chain controls

PCHF Guidance Chapter 2 - https://www.fda.gov/media/99554/download

Identifying Relevant Hazards (and Risk)

- FDA reminds the industry that there are other known or reasonably foreseeable biological hazards (other than *Cronobacter* spp.) associated with powdered infant formula
- When estimating likely occurrence of a hazard in the absence of a preventive control, you should consider information from several sources, such as the following:
  - Data from outbreaks of foodborne illness,
  - Data from recalls,
  - Information in the scientific literature, and
  - Experience and historical information gathered by your facility

PCHF Guidance Chapter 2 - https://www.fda.gov/media/99554/download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