Listeria Control Resources for the Ice Cream and Frozen Ready-to-Eat Dairy-Based Dessert Industry

Disclaimer
The information provided in this document and in the related materials/links is for informational purposes only, and may not be used as a substitute for legal advice regarding food safety laws in any jurisdiction. The International Dairy Foods Association (“IDFA”) makes no representation or warranty with respect to the completeness, accuracy, reliability, or suitability of any information provided herein, including other website links or materials. We recommend that users of this site consult an attorney concerning the laws applicable to any particular situation. By using this document and the materials/links provided, the users agree to release IDFA from any and all liability that may result from use of the information provided.

The incidence of reported listeriosis—the disease syndrome caused by the pathogenic bacteria *Listeria monocytogenes* (Lm)—due to consumption of ready-to-eat (RTE) ice cream and dairy-based dessert/novelty products is very low. This is likely due to the fact that the final products are frozen, which prevents growth of Listeria and other pathogens that may get into the product during production. *Listeria monocytogenes*, however, is one of the most deadly foodborne disease-causing microorganisms, with a case fatality rate of about 20 percent, as compared to 0.5 percent for Salmonella infections, according to the U.S. Centers for Disease Control (CDC).\(^1\) If contaminated, these products may pose a risk to the elderly, infants, young children and others with weakened immune systems (“immuno-compromised”), as made evident by a recent outbreak linked to ice cream products.\(^2\)

To reduce this risk, it is vital that the presence of Lm in a RTE food facility is controlled using traditional “prerequisite,” preventive control programs—e.g., sanitation procedures (SSOPs) and good manufacturing practices (GMPs). These programs must be implemented fully, monitored and verified to ensure they are working effectively. Such programs are especially critical in production environments where RTE food is exposed to the environment after any kill steps are applied to ingredients (e.g., pasteurization), but prior to final consumer packaging. For many ice cream and dairy-based desserts/novelty products, this is a common scenario and not only for these plants, but ingredient suppliers, as well. For example, suppliers of ingredients added to ice cream mixes after pasteurization (e.g., inclusions) must also have robust preventive control programs in place, which should be verified by their customers and/or third-party food safety

---

\(^1\) CDC Vital Signs, [http://www.cdc.gov/vitalsigns/listeria/](http://www.cdc.gov/vitalsigns/listeria/)

\(^2\) FDA Investigates *Listeria monocytogenes* in Ice Cream Products from Blue Bell Creameries, [http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm438104.htm](http://www.fda.gov/Food/RecallsOutbreaksEmergencies/Outbreaks/ucm438104.htm)
experts. Ice cream manufacturers should consider requiring suppliers to test for pathogens and/or indicators of pathogens (e.g., *Listeria* genus, *Salmonella*, *Enterobacteriaceae*, etc.).

In addition, the sanitary design of processing equipment and other equipment used in production areas, along with the sanitary design of the facilities, employee hygiene and controlled movement of people, ingredients, packaging, pallets, etc., that can spread pathogens around facilities, all must be considered and continuously improved upon to help prevent product contamination. Careful scrutiny should also be devoted to the microbial integrity of all water used in the plant, including water that does not come in direct contact with products, ingredients or processing surfaces. These programs and practices are the foundation of any robust food safety program; without these in place and being implemented, RTE products are at a greater risk of being exposed to Lm.

To verify the effectiveness of the aforementioned facility environment controls, facilities should implement a Pathogen Environmental Monitoring (PEM) program, which employs the “Seek and Destroy” methodology referenced below. This PEM program should identify the specific testing steps and corresponding corrective actions in response to test results. Additionally the PEM should track and address Listeria trends, when a trend exists. The recently released document “Control of *Listeria monocytogenes*: Guidance for the U.S. Dairy Industry” (cited below) provides more in-depth guidance on what this sort of program should entail. Another example of this type of PEM is the Tyson Foods Sentinel Site Program®, which was designed for the poultry industry, but could be easily adapted for dairy products.

* * *

The following are resources available to the industry that provide valuable information regarding both requirements and expectations of federal regulators and good industry practice for controlling Lm in RTE environments.

**REGULATORY AGENCY REQUIREMENTS AND GUIDANCE**

- U.S. Food and Drug Administration Current Good Manufacturing Practices (cGMPs) (U.S. Code of Federal Regulations (CFR), Title 21, chapter 117, Subpart B.)

- Draft Guidance for Industry: Control of *Listeria monocytogenes* in Refrigerated or Frozen Ready-to-Eat Foods (FDA, 2008)


---

INDUSTRY-DEVELOPED GUIDANCE AND TRAINING OPPORTUNITIES

Comprehensive Guidance

- **Dairy Plant Food Safety Workshops.** Offered by the Innovation Center for U.S. Dairy, the workshop focuses on food-safety prerequisite programs to HACCP that will prevent the growth and establishment of pathogens in all dairy plant environments and on product contact surfaces. Specific attention is devoted to components of the Innovation Center for U.S. Dairy's pathogen-control program (PCP), which includes Good Manufacturing Practice, controlled floor conditions, separation of raw ingredients from ready-to-eat products, sanitation, sanitary design and environmental monitoring.

- **Dairy Pathogen Control Program Assessment**
  For evaluating a pathogen control program for the dairy industry.

- **Control of *Listeria monocytogenes*: Guidance for the U.S. Dairy Industry**
  (Innovation Center for U.S. Dairy, 2015)

- **Listeria monocytogenes Guidance on Environmental Monitoring and Corrective Actions in At-risk Foods**
  (Grocery Manufacturers Association, 2014)

- **Seek and Destroy Process: *Listeria monocytogenes* Process Controls in the Ready-to-Eat Meat and Poultry Industry**
  (Malley, T.J.V., Butts, J., Wiedmann, M. Journal of Food Protection; vol. 78: 436-445)

- **Control of *Listeria monocytogenes* in the food-processing environment**
  (Tompkin, R.B. Journal of Food Protection; vol. 65: 709-725.)

Topic-Specific Guidance

Sanitary Design:

- **Dairy Product “Outside the Pipe” Design Checklist**
  For evaluating dairy production equipment designs, especially for high-hygiene areas.

- **Equipment Design Checklist**
  Modified version of the above Dairy Product “Outside the Pipe” Design Checklist, for general use (not high-hygiene or dairy specific).

- **Dairy Facility Design Checklist**
  For evaluating dairy facility designs.

- **3-A Sanitary Standards**
  Sanitary design standards for equipment and accepted practices that help ensure cleanability, complete sanitation and compliance with regulatory requirements.

Sanitation:

- **Seven steps of effective wet sanitation**

- **Validation of Quaternary Ammonia and Hydrogen Peroxide Powder for Control of *Listeria monocytogenes* in Ready-to-eat Meat and Poultry Plants**
This study may be useful for validation of a dairy plant’s use of these dry sanitizers.

- **Sanitation SOP Development**
  - This form has been designed to provide a guide in assessing sanitation needs and procedures.

*Resources developed by Commercial Food Sanitation LLC™*

For additional information, specific advice and/or recommendations related to ensuring the safe production of ice cream and other frozen, dairy-based desserts, please contact John Allan, vice president of regulatory affairs & international standards at jallan@idfa.org or (202) 220-3519.