Control of Listeria in Ice Cream Manufacturing

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IDFA Ice Cream Technical Conference
St. Petersburg, FL
April 16, 2019

Thank you!

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Frozen Dessert Center Mission

Advance the Arts & Sciences associated with research & production of Frozen Desserts

We accomplish this mission through a coherent program that includes:

- **Services** focused on frozen desserts in the areas of manufacturing, sensory and microstructure analyses, product development, and quality control.
- **Outreach** to transplant our knowledge, skills and expertise to professionals in the frozen dessert industry and beyond
- **Educating** University of Wisconsin-Madison students to become the future high performers within the industry


23
8
21
7

- Couple CFD with ice crystallization kinetics
  - Population balance modeling approach
- Predict ice crystallization based on thermal profile within SSF

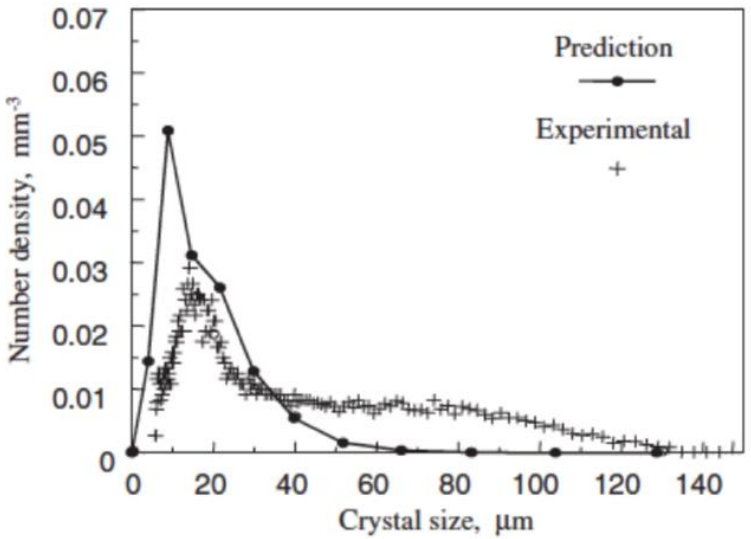
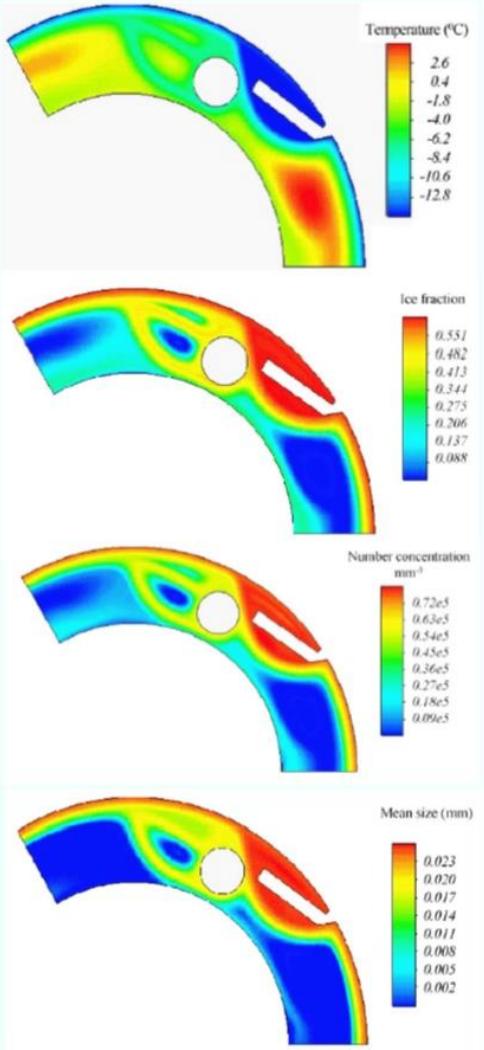


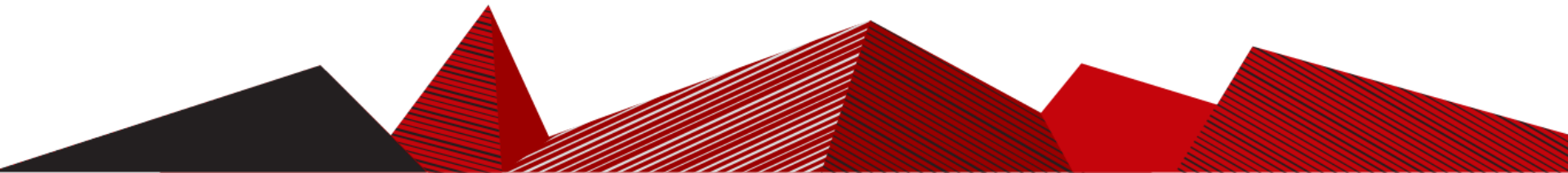
Fig. 7. Predicted population balance compared with experimental data.

Lian et al., 2006



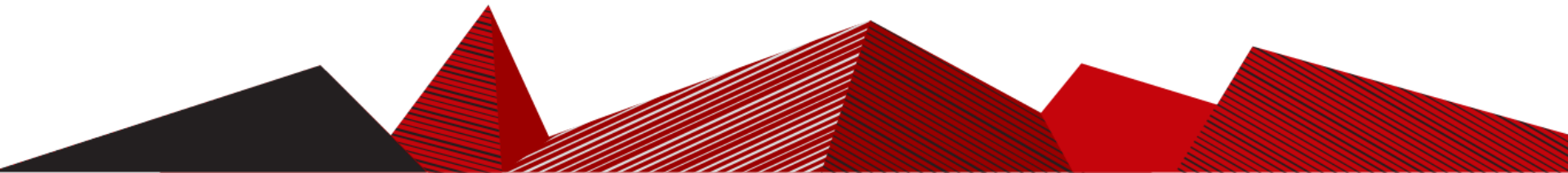
A few thoughts at the outset:

- The value of frozen desserts
- Illness from tainted frozen desserts
- Role of insurance companies
- Your name, discoverable documents
- Duty of care standards
- Validate, verify
- Learn from mistakes (other peoples')



Outline

- Background
- Hygienic design concerns
- Listeria and ice cream mix soil
- Recommendations



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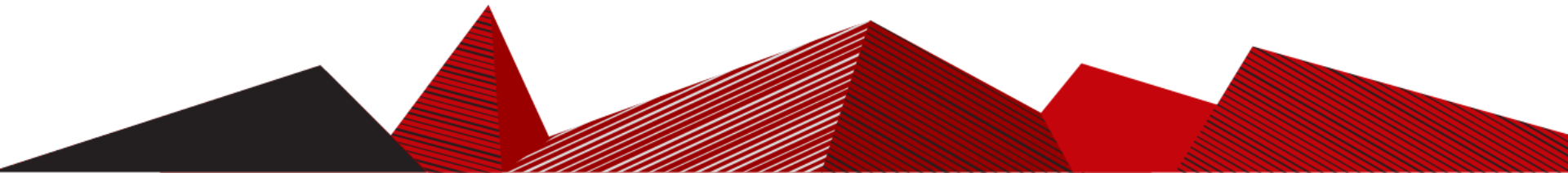
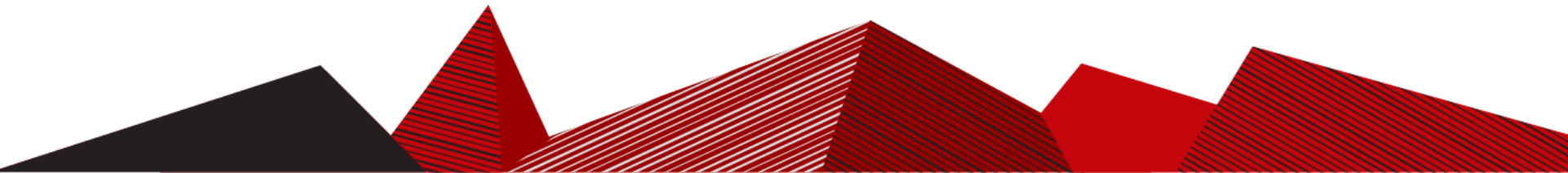


Background: Listeria and Ice Cream

- We still have outbreaks
- Outbreaks not inconsequential
- We know how to control, root cause(s)



Background: +/-

- On the positive side
  - High heat treatments
  - Cold temperatures
  - Heat-shock indications
  - Good track record
- Of concern
  - Complex product, equipment, facilities
  - Post heat-treatment additions
  - Cold temperatures (condensate)
  - Warm temperatures, tempering product
  - Change-overs
  - Entrepreneurial contingent
  - Listeria not uncommon

Background: Listeria homework

Journal of Food Protection, Vol. 77, No. 1, 2014, Pages 150–170
doi:10.4315/0362-028X.JFP-13-150

Review

Listeria monocytogenes Persistence in Food-Associated Environments: Epidemiology, Strain Characteristics, and Implications for Public Health

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[1]*Centro de Biotecnologia e Química Fina, Laboratório Associado, Escola Superior de Biotecnologia, Universidade Católica Portuguesa Porto, Rua Dr. António Bernardino Almeida, 4200-072 Porto, Portugal; and* [2]*Department of Food Science, Cornell University, Ithaca, New York 14853, USA*

MS 13-150: Received 10 April 2013/Accepted 11 September 2013

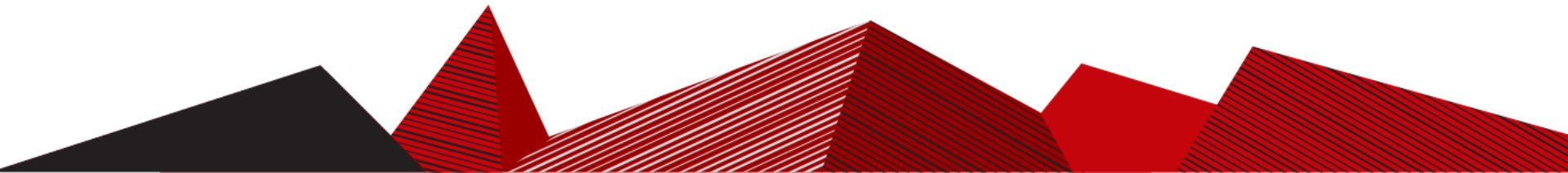
Background: Listeria homework

ABSTRACT

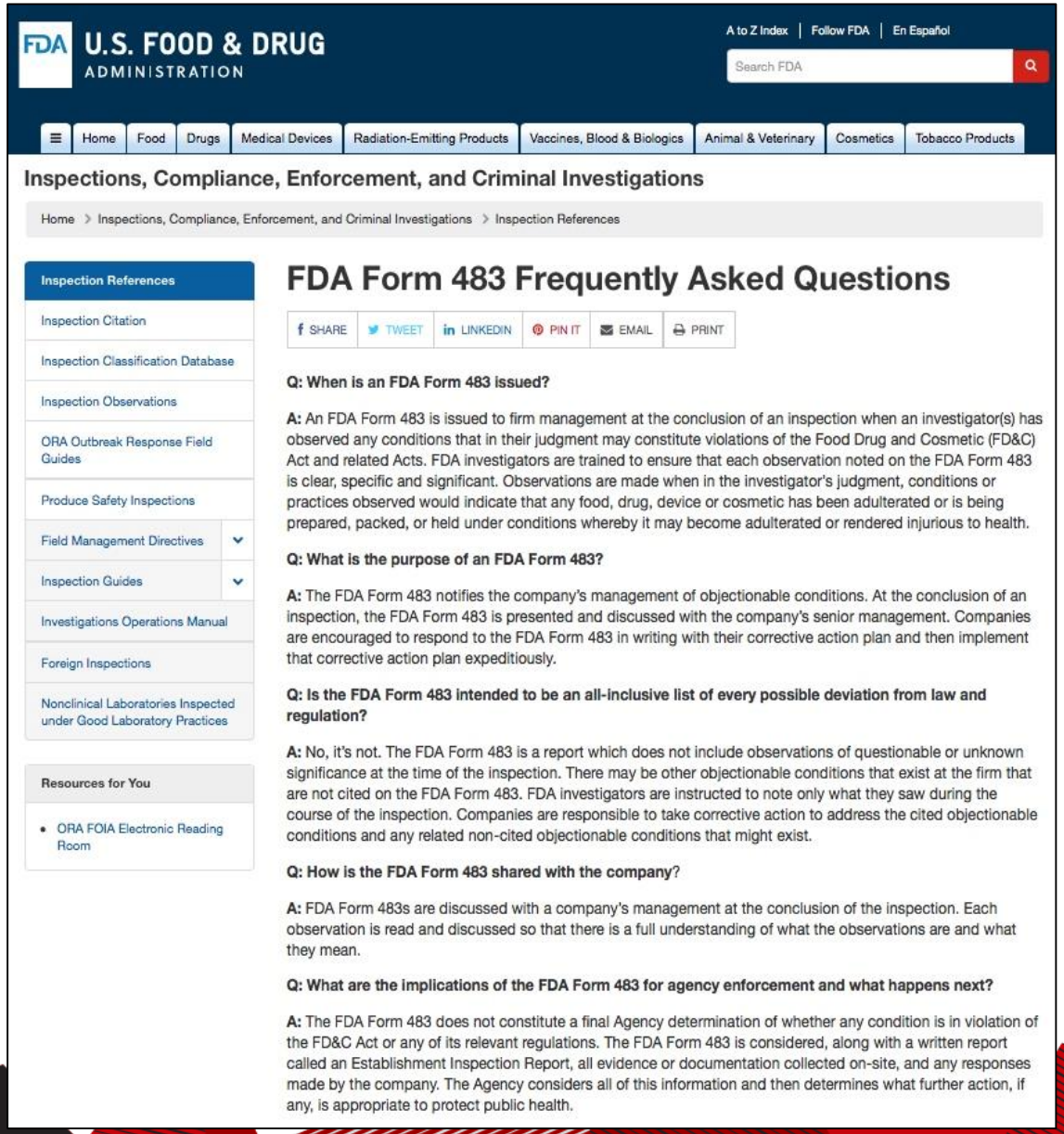
Over the last 10 to 15 years, increasing evidence suggests that persistence of *Listeria monocytogenes* in food processing plants for years or even decades is an important factor in the transmission of this foodborne pathogen and the root cause of a number of human listeriosis outbreaks. *L. monocytogenes* persistence in other food-associated environments (e.g., farms and retail establishments) may also contribute to food contamination and transmission of the pathogen to humans. Although *L. monocytogenes* persistence is typically identified through isolation of a specific molecular subtype from samples collected in a given environment over time, formal (statistical) criteria for identification of persistence are undefined. Environmental factors (e.g., facilities and equipment that are difficult to clean) have been identified as key contributors to persistence; however, the mechanisms are less well understood. Although some researchers have reported that persistent strains possess specific characteristics that may facilitate persistence (e.g., biofilm formation and better adaptation to stress conditions), other researchers have not found significant differences between persistent and nonpersistent strains in the phenotypic characteristics that might facilitate persistence. This review includes a discussion of our current knowledge concerning some key issues associated with the persistence of *L. monocytogenes*, with special focus on (i) persistence in food processing plants and other food-associated environments, (ii) persistence in the general environment, (iii) phenotypic and genetic characteristics of persistent strains, (iv) niches, and (v) public health and economic implications of persistence. Although the available data clearly indicate that *L. monocytogenes* persistence at various stages of the food chain contributes to contamination of finished products, continued efforts to quantitatively integrate data on *L. monocytogenes* persistence (e.g., meta-analysis or quantitative microbial risk assessment) will be needed to advance our understanding of persistence of this pathogen and its economic and public health impacts.

Background: Listeria homework

"Environmental factors (e.g., facilities and equipment that are difficult to clean) have been identified as key contributors to persistence…."



Background: FDA inspections



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Q: When is an FDA Form 483 issued?

A: An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. FDA investigators are trained to ensure that each observation noted on the FDA Form 483 is clear, specific and significant. Observations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health.

Q: What is the purpose of an FDA Form 483?

A: The FDA Form 483 notifies the company's management of objectionable conditions. At the conclusion of an inspection, the FDA Form 483 is presented and discussed with the company's senior management. Companies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and then implement that corrective action plan expeditiously.

Q: Is the FDA Form 483 intended to be an all-inclusive list of every possible deviation from law and regulation?

A: No, it's not. The FDA Form 483 is a report which does not include observations of questionable or unknown significance at the time of the inspection. There may be other objectionable conditions that exist at the firm that are not cited on the FDA Form 483. FDA investigators are instructed to note only what they saw during the course of the inspection. Companies are responsible to take corrective action to address the cited objectionable conditions and any related non-cited objectionable conditions that might exist.

Q: How is the FDA Form 483 shared with the company?

A: FDA Form 483s are discussed with a company's management at the conclusion of the inspection. Each observation is read and discussed so that there is a full understanding of what the observations are and what they mean.

Q: What are the implications of the FDA Form 483 for agency enforcement and what happens next?

A: The FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act or any of its relevant regulations. The FDA Form 483 is considered, along with a written report called an Establishment Inspection Report, all evidence or documentation collected on-site, and any responses made by the company. The Agency considers all of this information and then determines what further action, if any, is appropriate to protect public health.

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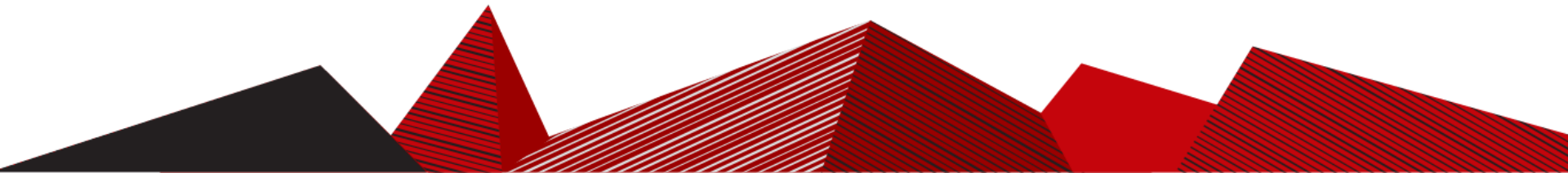
03/07/2019	3004593468	Coram Healthcare of Indiana, dba Coram CVS/Specialty Infusion Services	FMD-145 Letter	IN	Producer of Sterile Drug Products	04/01/2019
02/07/2019	3006031801	US Compounding Inc	483	AR	Outsourcing Facility	04/01/2019
03/05/2019	3014199548	BMD Skincare, Inc.	483	CA	Outsourcing Facility	04/01/2019
03/06/2019	3013452490	ARJ Infusion Services, Inc.	State Referral Letter	KS	Producer of Sterile Drug Products	04/01/2019

FDA Form 483 Report: Recent IC Plant

- Specifically, you failed to demonstrate your cleaning and sanitizing program is effective in controlling recurring microbiological contaminations.
- Failure to perform microbial testing where necessary to identify sanitation failures and possible food contamination.
- The procedure used for cleaning and sanitizing of equipment and utensils has not been shown to provide adequate cleaning and sanitizing treatment.
- The plant is not constructed in such a manner as to prevent drip and condensate from contaminating food, food-contact surfaces, and food-packaging materials.
- The design of equipment does not allow proper cleaning and maintenance.
- Failure to take apart equipment as necessary to ensure thorough cleaning.



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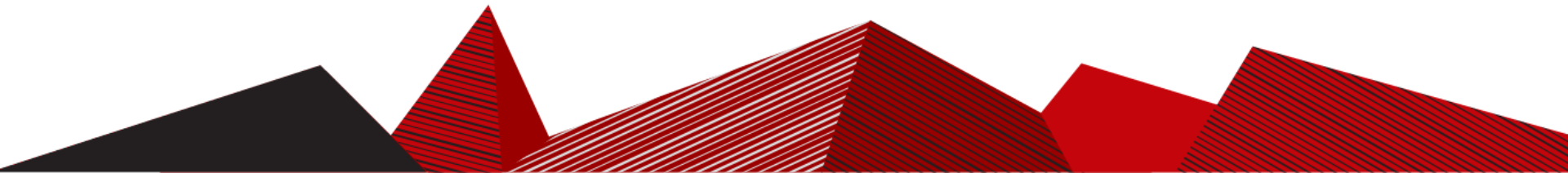


Background: Listeria homework

J Food Prot. 2017 Oct 19:1897-1902. doi: 10.4315/0362-028X.JFP-17-178. [Epub ahead of print]

Hygienic Shortcomings of Frozen Dessert Freezing Equipment and Fate of Listeria monocytogenes on Ice Cream-Soiled Stainless Steel.

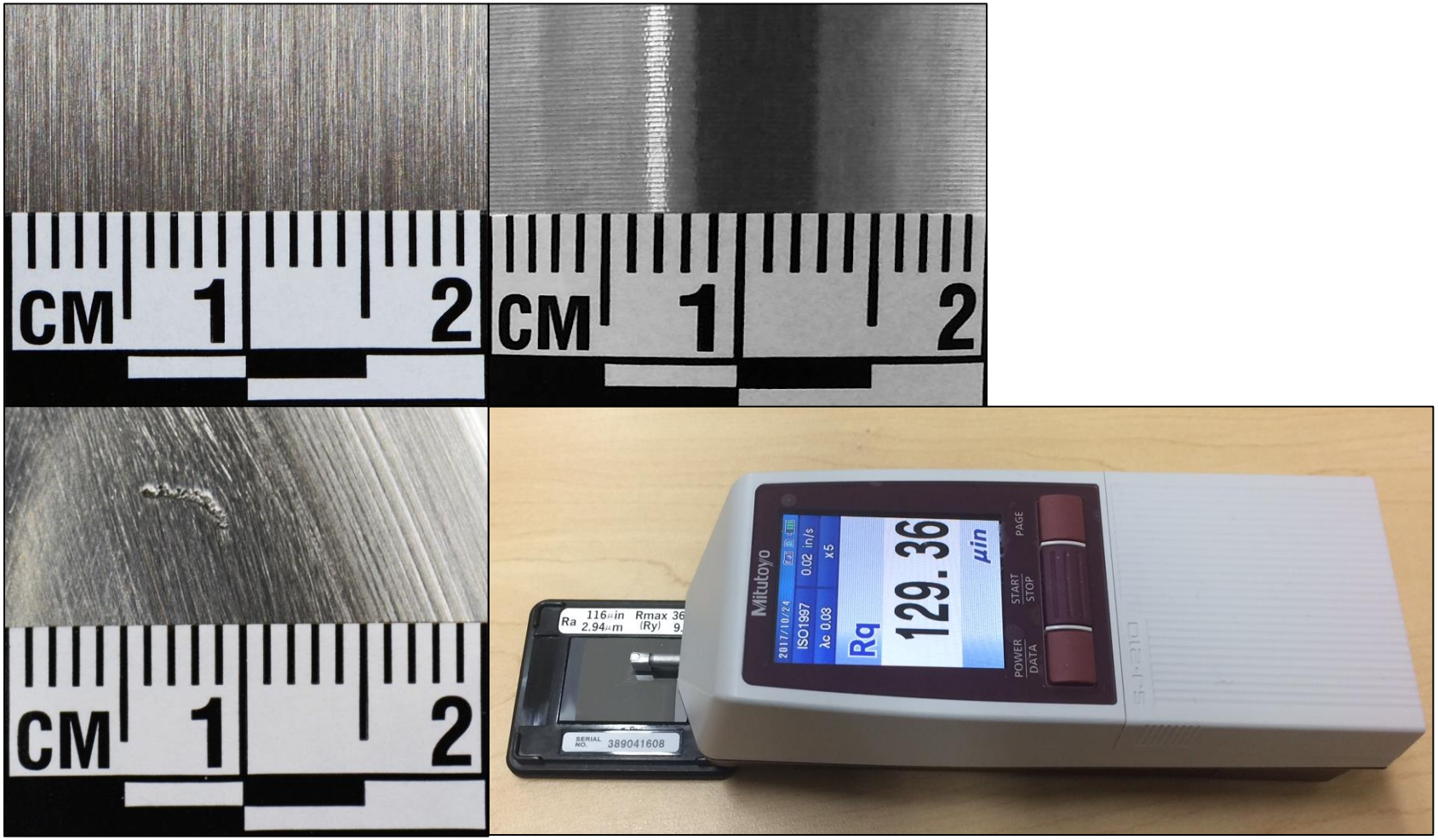
Inuwa A[1], Lunt A[2], Czuprynski C[1], Miller G[3], Rankin SA[2].

⊕ Author information

Abstract

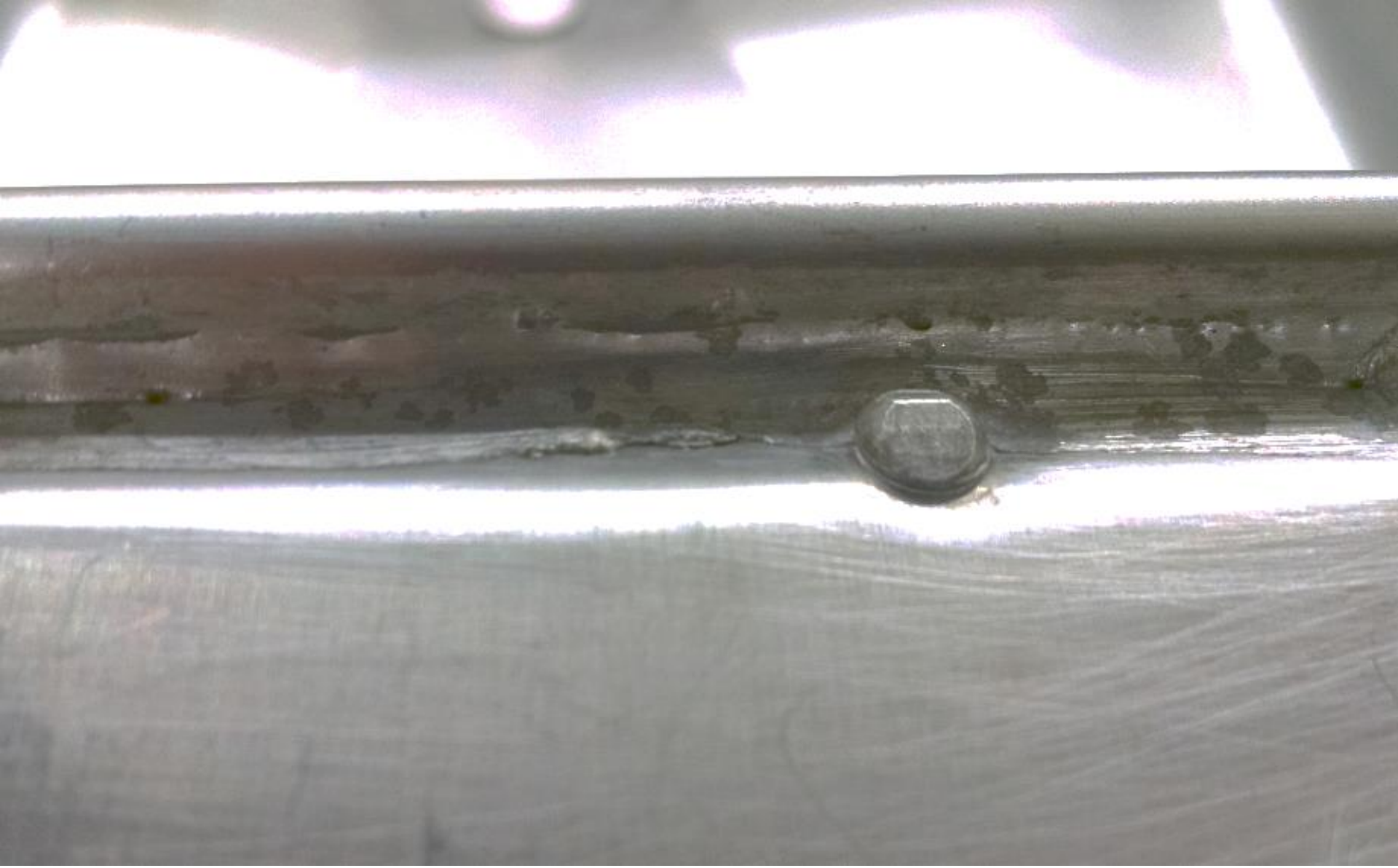
Although frozen dairy desserts have a strong record of safety, recent outbreaks of foodborne disease linked to ice creams have brought new attention to this industry. There is concern that small-scale frozen dessert equipment may not comply with or be reviewed against published comprehensive design and construction sanitation specifications (National Sanitation Foundation or 3-A sanitary standards). Equipment sanitary design issues may result in reduced efficacy of cleaning and sanitation, thus increasing the likelihood of postprocess contamination with pathogenic bacteria. In this context, and given that Listeria monocytogenes outbreaks are of great concern for the frozen dessert industry, a complementary study was conducted to evaluate the fate of L. monocytogenes in ice cream mix on a stainless steel surface. Our results showed that L. monocytogenes survived for up to 6 weeks at room temperature and 9 weeks at 4°C in contaminated ice cream on a stainless steel surface. Furthermore, chlorine- and acid-based surface sanitizers had no detrimental effect on the L. monocytogenes when used at a concentration and contact time (1 min) recommended by the manufacturer; significant reduction in CFU required 5 to 20 min of contact time.

Surface finish



Metal composition through X-ray fluorescence

- In general, food contact and splash surfaces were constructed of type 300 stainless materials.
- One food contact material was constructed of a nickel alloy with major elements 75% Ni, 8.61% Sn, 6.48% Zn, 6.26% Bi, and 1.97% Mn (see NSF/ANSI 6-2014, 4.1.1).
- The use of Ni alloys in food manufacturing equipment is limited in the NSF/ANSI specifications to foods with pH over 6.0 to limit metal dissolution.
- Lead-containing soldered seam showing a solder ‘‘bubble’’ and dark discoloration spots resulting from corrosion (see 3-A, 19-07, E1.1.1; NSF/ANSI 6-2014, 5.4). See NSF/ANSI 6-2014, 4.2 regarding the use of Pb in food equipment construction.



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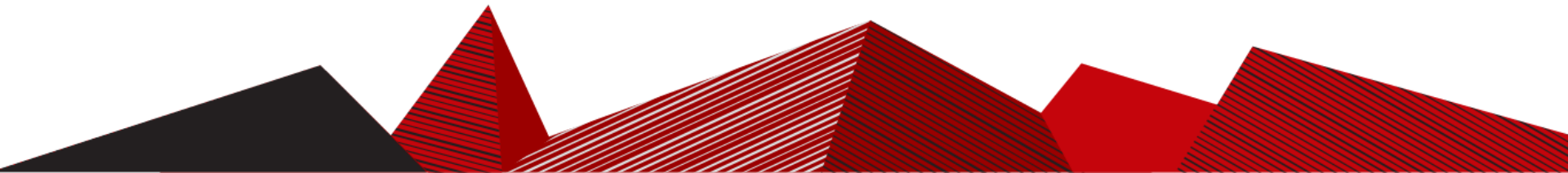
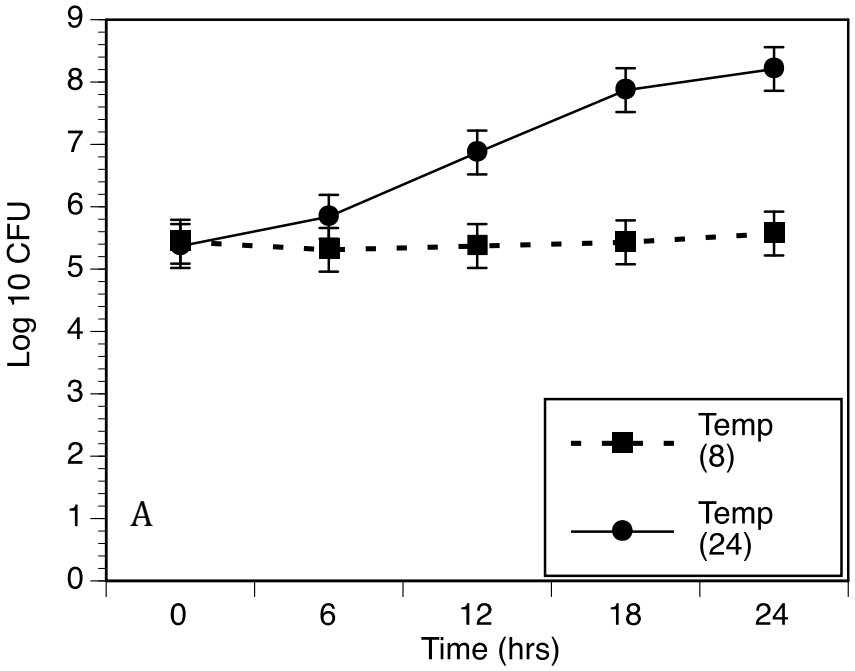
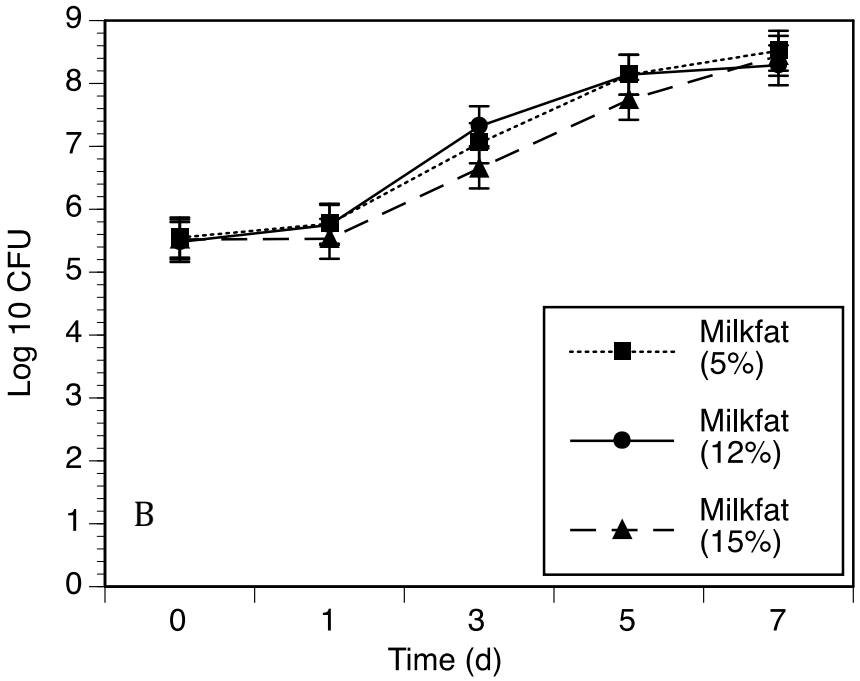
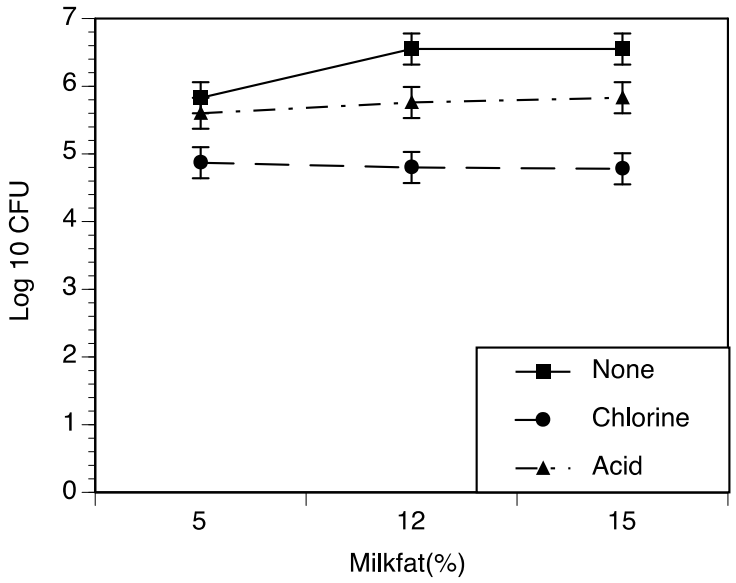


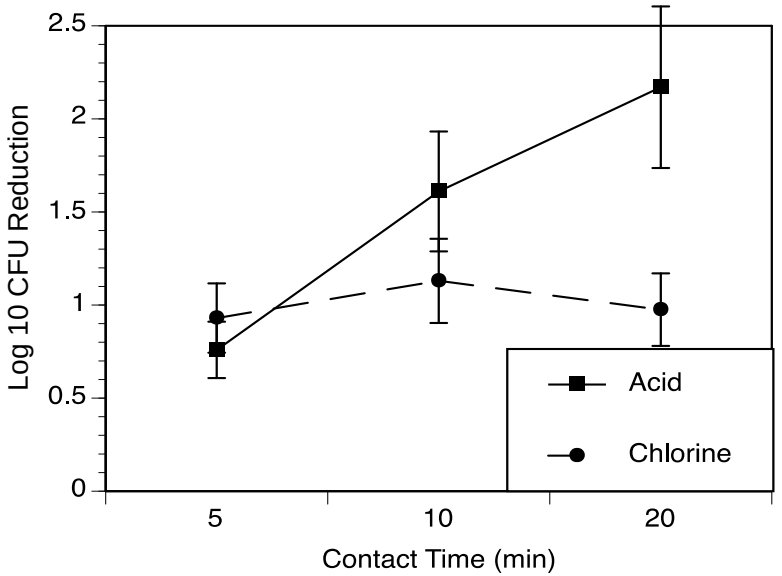
Listeria growth in ice cream mix



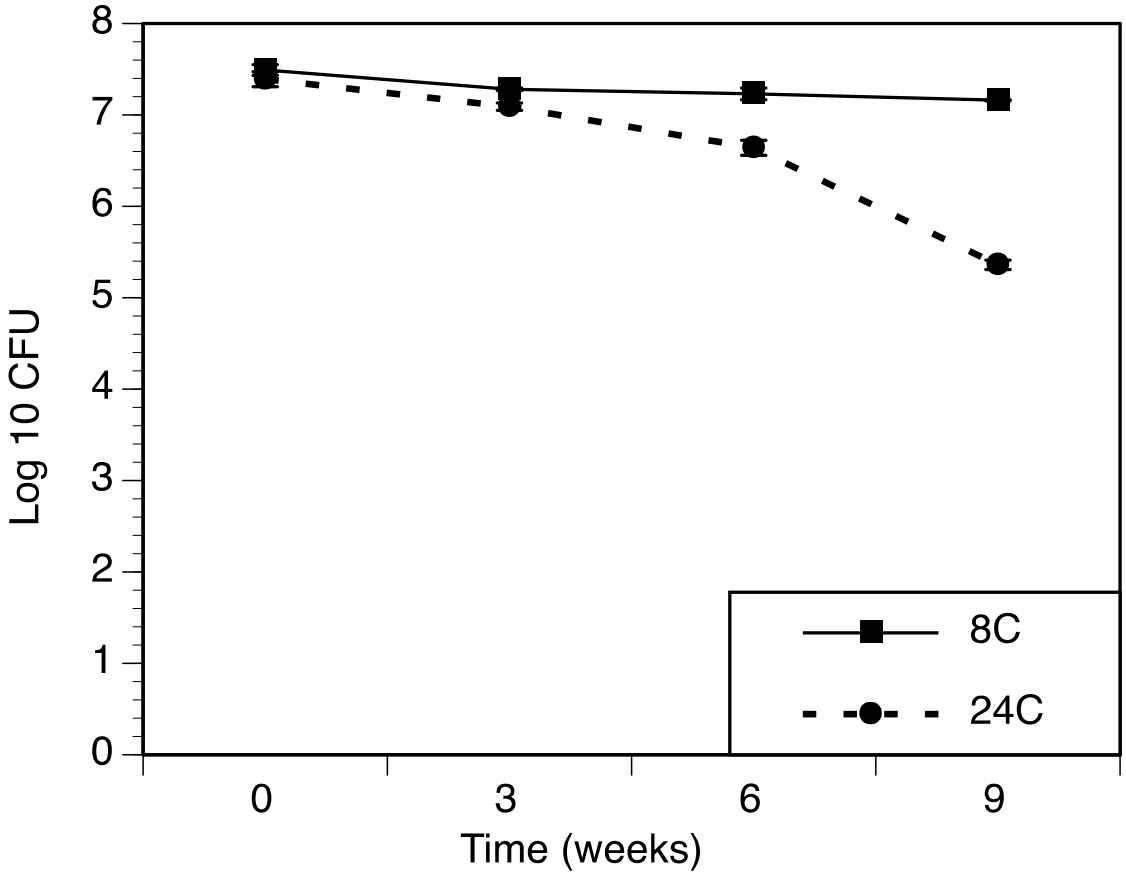


Listeria, ice cream mix, sanitizer





Listeria persistence in ice cream mix



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Recommendations

- Continual education
  - Read FDA reports
  - Literature
  - In-house data
- Invest in FSMA expertise – validate, verify
- Equipment (3A, NSF, EHEDG) and facility sanitary design

Recommendations

CONTROL OF *LISTERIA MONOCYTOGENES*

GUIDANCE FOR THE U.S. DAIRY INDUSTRY

INNOVATION CENTER FOR U.S. DAIRY

HEALTHY PEOPLE • HEALTHY PRODUCTS • HEALTHY PLANET

To keep in mind

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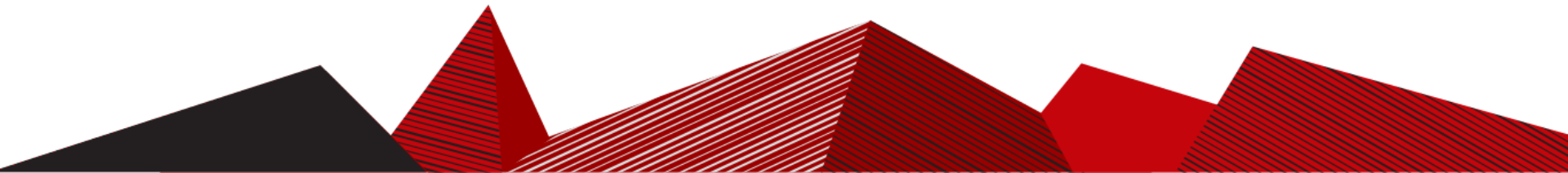

Questions?

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