REAGAN-UDALL FOUNDATION FOR THE FDA

APPLYING THE SCIENCE OF **INFANT FORMULA SAFETY:**

Insights from Recent Recall Activity and the Latest Research on *C. botulinum*

September 2026

ByHeart and International Dairy Foods Association provided funding for this project

About the Reagan-Udall Foundation for the FDA

The Reagan-Udall Foundation for the FDA is an independent non-profit created by Congress to advance regulatory science to help the U.S. Food and Drug Administration accomplish its mission. The Foundation manages a suite of programs that assist the FDA in engaging with external stakeholders and that facilitate evidence generation, improve public understanding of the FDA, and deliver more accessible health information to the public.

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Executive Summary

On July 13, 2026, the Reagan-Udall Foundation for the FDA (Foundation), in collaboration with ByHeart and the International Dairy Foods Association, convened an invitation-only roundtable discussion sharing insights from recent recall activity and the latest research on *Clostridium botulinum* (*C. botulinum*). Participants represented the infant formula industry, academia, consumer advocacy, and the Food and Drug Administration (FDA).

The roundtable collectively explored the lessons learned from manufacturer and regulatory investigations to build a shared understanding of the most recent learnings and research into *C. botulinum*. Participants discussed how to better identify and evaluate factors that may increase the risk of *C. botulinum*, strengthen preventive controls, and improve testing methods to help protect the infant formula supply and the families who rely on it.

Discussions focused on five key areas:

> ***C. botulinum* state of the science.** Participants acknowledged significant knowledge gaps regarding the prevalence of *C. botulinum* spores across farms, dairy ingredients, supply chains, and finished products. There was broad agreement on the need for baseline prevalence studies, standardized testing methods, and further research to better understand the relationship between spore concentrations and infant health risk.
>
> **Data sharing.** Participants identified data sharing as critical for future progress. Greater transparency and collaboration across manufacturers, suppliers, researchers, regulators, and laboratories can accelerate learning, improve risk assessments, and support the development of science-based standards. Establishing trusted mechanisms for collecting, analyzing, anonymizing, and sharing data was viewed as essential to building a stronger industry knowledge base.
>
> **A collaborative, multifactorial approach to maintain infant formula safety.** The discussion reinforced that testing alone cannot ensure product safety. Participants emphasized the importance of developing evidence-based mitigation strategies, validating preventive technologies, and balancing safety improvements with supply chain resilience and affordability for families.
>
> **FDA collaboration.** Participants highlighted opportunities for FDA and other government agencies to support fit-for-purpose testing guidance, standardized methods and thresholds, validation and accreditation efforts, and improved cross-agency collaboration.
>
> **Potential next steps.** These discussions informed a series of actionable recommendations to enhance infant formula safety (see Appendix A).

The roundtable concluded with a strong commitment to continued collaboration, scientific advancement, and information sharing. Participants agreed that addressing *C. botulinum* risks will require coordinated action across the infant formula ecosystem, increased research investment, and a foundation of transparent, data-driven decision-making. By working together, industry and regulatory stakeholders can strengthen infant formula safety while maintaining a reliable and affordable supply for the families who depend on it.

Meeting Purpose

Infant formula* manufacturers and the FDA share a common goal: ensuring a safe, nutritious, and reliable supply of infant formula. Prior to November 2025, *Clostridium botulinum*† had not been demonstrated to cause outbreaks of infant botulism due to its presence in infant formula, consistent with guidance from the International Commission on Microbiological Specifications for Foods. Recent outbreaks in the U.S. have now demonstrated this illness pathway and have raised questions about prevalence, current control measures and testing protocols across the infant formula supply chain. Over the last nine months, there has been a critical acceleration of knowledge and research on testing for *C. botulinum* in infant formula powder and safety practices throughout the supply chain.

The in-person roundtable collectively explored the lessons learned from investigations to build a shared understanding of the most recent insights and research into *C. botulinum*. Participants discussed how to better identify and evaluate factors that may increase the risk of *C. botulinum*, strengthen preventive controls, and improve testing methods to help protect the infant formula supply and the families who rely on it. This discussion focused on:

- The risk of *C. botulinum* spores in dairy-based ingredients that may be used in the production of powdered infant formula
- Learnings from the ByHeart *C. botulinum* recall, including findings from the root cause investigation, published data on the limitations of the sulfite-reducing clostridia (SRC) testing method, and current plans for prevention and *C. botulinum*-specific testing
- Opportunities to better understand the prevalence of spores on farms and in the supply chain, as well as reduce spore presence and improve detection, while maintaining practices that are scientifically credible, operationally feasible, and regulatorily sound

This report summarizes key insights and potential recommendations to support efforts to strengthen the safety and nutritional integrity of the infant formula supply. It also offers an illustration of opportunities for collaboration to make infant formula even safer.

* Throughout this document, the term “infant formula” refers to powdered infant formula.

† Throughout this document, *C. botulinum* also applies to spores.

Background

Infant formula safety requires a collaborative, industry-wide approach that prioritizes scientific advancement, transparency, and continuous improvement. Safety is not a competitive advantage, but a shared responsibility across manufacturers, ingredient suppliers, researchers, and regulators to strengthen practices and improve outcomes. Strong partnerships are critical to driving innovation while maintaining the highest standards of safety for infants.

Learning from outbreaks of foodborne illness is an important part of the safety system. A recall was announced in mid-June 2026 after federal and state public health partners investigated confirmed or suspected infant botulism illnesses associated with use of powdered infant formula. Recent FDA resources and communications provide a chronological foundation for understanding the infant formula recall.[1,2] Subsequent updates, including the FDA Consumer Constituent Update released on July 13, 2026,[3] placed the recall in a broader safety context by emphasizing the need for infant formula manufacturers, suppliers, and distribution partners to strengthen oversight of ingredients and supply-chain controls. Together, these resources help trace the progression from the initial outbreak investigation and voluntary recall to FDA's broader communication about preventing contaminants from entering the infant formula supply chain.

The roundtable discussion was informed by presentations covering ByHeart's investigation findings, an overview of the environmental sources of *C. botulinum* spores and possible mitigation strategies in the dairy system, and FDA's *C. botulinum* interim testing workflow. Consistent with participants' commitment to transparency and information sharing, full presentation slide decks are included in Appendices B, C, and D, respectively.

The roundtable was intentionally limited in size and scope; it was designed to serve as a starting point for broader engagement. Advancing safety and scientific understanding will require continued dialogue and collaboration among a wider range of stakeholders across the supply chain. By convening quickly and meeting in person, participants demonstrated a shared commitment to working collectively, recognizing progress made over the past nine months, and identifying areas where additional evidence is needed. The roundtable represents tangible progress toward potential collaboration and established an initial foundation for participants who wish to maintain momentum moving forward.

PRESENTATIONS INFORMING THE DISCUSSION

APPENDIX B

Shaping a safer tomorrow

APPENDIX C

Bacterial spore prevalence in the dairy system and mitigation strategies

APPENDIX D

Summary *C. botulinum* workflow (outbreak)

TOPIC 1

C. botulinum state of the science

DISCUSSION

The discussion focused on *C. botulinum* prevalence across the ecosystem, current testing practices, data and research funding gaps, and the need to identify meaningful benchmarks. ByHeart shared their comprehensive investigation findings, sample data and evolved protocols, to ensure all participants shared a common knowledge baseline (see Appendix B). Participants also considered what has changed over the past ten years and what changes may be emerging in the infant formula space. Continued progress depends on strengthening understanding of the current science, clarifying what is known, what remains uncertain, and where evidence is still developing. Such progress will also require strengthening collaboration across stakeholders to improve safety of the infant formula supply. Despite many unanswered questions, practical interim actions can be taken as the science evolves.

FDA representatives presented their interim outbreak workflow and testing methods (see Appendix D). Polymerase chain reaction (PCR) positive results were further tested with EndoPep[‡] mass spectrometry and, when applicable, whole genome sequencing. The industry has seen material advancement in testing methods, including novel PCR primers and enrichment methods for SRC, in the past nine months. The next step is to harness this new and critical innovation into standardization.

The infant formula industry cannot rely on testing alone to ensure quality or food safety, particularly for products intended for the most vulnerable populations. However, testing remains critical for understanding expected spore levels in dairy ingredients and for verifying that spore-reduction practices and preventive controls are functioning as intended.

[‡] Endopeptidase-Mass Spectrometry.

CURRENT CHALLENGES

Significant gaps currently exist in understanding *C. botulinum* prevalence, optimal testing methodologies, and how testing thresholds correlate with risk and clinical outcomes.

Prevalence data of *C. botulinum* on farms and in the supply chain is limited and identified as a key knowledge gap raised by participants looking to adopt preventative measures. There is a need to build on work conducted by Cornell University[4] and the University of Wisconsin-Madison[5] to find practical and scientifically sound methodologies for *C. botulinum* testing. Prevalence data will assist with determining where in the infant formula production continuum (farm to finished product) spores can be introduced or concentrated and thus where interventions should be focused.

Key unknowns include

- What impact regional, environmental, and climate factors have on the presence of *C. botulinum* and how these factors have changed over time and may continue to change
- Conditions that may allow low levels to grow to a higher level
- How changes in the powdered infant formula ecosystem (e.g., diversity of milk sources and ingredients in the infant formula supply that were not present prior to five or six years ago) may or may not contribute to contamination

Without prevalence data, the scale of the risk due to pathogen presence, and the factors that might contribute to a contamination, remain an open question. The lack of prevalence data across the supply chain, from farm to finished product, also limits the industry's ability to identify and prioritize the most effective control measures at the farm, dairy processing, and manufacturing levels.

Testing for *C. botulinum* presents significant challenges. There are currently no standardized methods for detecting the organism or its spores in the infant formula industry, and only a limited number of laboratories perform testing due to strict safety regulations. There is a lack of coordinated effort and funding focused on *C. botulinum*, particularly in areas such as accreditation and validation of commercial test kits and new testing methods, as well as research on farm practices, environmental prevalence, and manufacturing practices.

CURRENT CHALLENGES CONTINUED

Important questions remain regarding when testing should occur, which methods are most appropriate, and how results should be interpreted in relation to risk. Greater industry coordination and investment are needed to support accreditation and validation of commercial test kits and emerging methods. Establishing standardized testing approaches will require alignment among stakeholders across the entire supply chain, from farm to final product.

Based on data presented, contamination should be considered non-homogenous and to occur at very low levels. When contamination is non-uniform and at very low levels, the ability to detect a positive result becomes more challenging. Optimal testing methods and protocols have not been established, resulting in many types of tests and methodologies being used across the industry. These inconsistencies include when, where, and how much to test from farm to product and across product lots. The ByHeart investigation demonstrated limitations of the traditional direct-plating SRC method.[6] Learnings from the ByHeart and FDA investigations showed that trace amounts of *C. botulinum* spores can be present at levels too low for SRC detection by direct plating, but enough to make infants sick. Guidance is needed to drive opportunities and indications for using enrichment SRC, polymerase chain reaction (PCR), and/or whole genome sequencing (WGS).

Research is needed to better understand the relationship between the current contamination levels and the risk of adverse health outcomes. Specifically, the assessment should determine:

- The spore concentrations at which health risks become significant.
- The level of spore reduction required to meaningfully reduce or eliminate the risk of illness.
- The expected impact of spore reduction when contamination levels are already low.

This analysis should provide a clear, evidence-based understanding of how reductions in spore concentrations correlate with decreased exposure risk and improved health protection.

RECOMMENDATIONS

It is essential to move forward with a clear understanding of prevalence so that the appropriate preventive controls and risk mitigation strategies can be determined. Defining the right target outcome is critical to achieving the desired impact. Research should be conducted to answer key questions and generate insights that inform effective short-, intermediate-, and long-term solutions.

1. Conduct an initial assessment of *C. botulinum* prevalence on farms, along the supply chain, and in finished goods. Many downstream questions depend on the initial assessment of prevalence.
2. Develop screening methods that are efficient but also sufficiently specific and sensitive.
3. Investigate what other indicators may exist to help gauge *C. botulinum* spore presence in milk or powder.
4. Investigate how to monitor environmental, supply chain, and processing changes, with an aspiration to protect against the next incident. Determine whether current *C. botulinum* findings reflect increased prevalence, improved detection capabilities, climate impacts, processing innovations, changes in the milk supply or a combination of factors.
5. Increase research funding from multiple agencies and industry to generate the data needed for risk assessments, validating mitigation strategies, and other evidence broadly important for the industry.

TOPIC 2

Data sharing

DISCUSSION

The discussion focused on the opportunity for collective learning by sharing screening and testing data. Addressing current data gaps, managing data from multiple contributing sources, reporting both positive and negative findings, and maintaining source anonymity are each important steps for collaboration. Initially, all data has value in helping organizations understand what information currently exists and what companies are learning from collected data. Please see Appendices B, C, and D for data and publications shared by presenters.

CURRENT CHALLENGES

As the infant formula industry faces potentially new and evolving challenges, there is an important opportunity to strengthen collective efforts to protect infants through greater collaboration, consistent data sharing, and transparency.

Currently, there is limited visibility into existing screening and testing data, including how frequently *C. botulinum* has been identified throughout supply chains and manufacturing processes. Questions remain regarding what data is available, which data is most useful, and the purpose for collecting and sharing it. While all data should be considered potentially valuable, the intended use of the information should be clearly defined before it is shared. Participants also discussed the need for a centralized and accessible data repository; however, such a resource does not currently exist, largely because data sharing within the field remains limited.

Data from all sources (e.g., suppliers, manufacturers, products, academia, regulatory agencies) is important to develop a holistic view of the ecosystem. Findings that reduce uncertainty by demonstrating that a factor is not significant are as valuable as positive findings. Both types of information are critical for directing resources and focusing investigations on the most relevant risks. Sharing this research contributes to collective knowledge, helps prevent duplication of effort, and supports more informed decision-making across the industry.

CURRENT CHALLENGES CONTINUED

Participants highlighted the importance of providing context and transparency around investigations and the data collected. Clear documentation of why specific issues were selected for investigation, how decisions were made, and when testing occurred helps explain the rationale behind findings and enables others to better assess how results may apply across the broader industry.

RECOMMENDATIONS

Data sharing is essential for developing harmonized, future-ready standards. As production systems, supply chains, and risks continue to evolve, greater sharing of scientific knowledge and safety data can help the industry respond more effectively. In light of recent contamination events and product recalls, there is a growing need for increased transparency, collaboration, and data sharing to improve understanding of risks and support evidence-based infant formula safety decisions.

6 Explore engaging a trusted third party that will receive, house, and safeguard the data as well as create a data exchange and sharing infrastructure.

7 Establish transparent governance, data-use policies, and confidentiality protections to build trust and encourage participation.

8 Through collaboration, strengthen the data foundation and share testing information (e.g., who is doing what, lessons learned, context of data collection). Expand testing and data collection to quantify prevalence, assess risk across the supply chain, and establish acceptable risk thresholds.

9 Within the data collaboration, determine how the data will be used, compiled, aggregated, and anonymized before any analysis or sharing of the data occurs.

RECOMMENDATIONS CONTINUED

10 Define the critical data needed to understand emerging and future risks, while ensuring data collection supports the generation of robust, aggregated insights that lead to actionable takeaways to improve safety of infant formula products.

11 Align on data collection goals and build databases thoughtfully and intentionally. Include appropriate methods and context that can be pragmatically applied and adequately measure impact.

TOPIC 3

A collaborative, multifactorial approach to maintain infant formula safety

DISCUSSION

Safety in the infant formula industry requires collaboration across the full ecosystem, from farm level control measures and ingredient processing to infant formula manufacturing. Data sharing is one important component, but shared learnings and solutions need to incorporate dairy, nondairy, and clinical elements. Because there may be multiple effective ways to reduce or mitigate *C. botulinum* spores, collaboration and continuous improvement is essential to ensure that solutions are appropriate for the specific production, processing, and ingredient supply-chain conditions of each powdered infant formula.

Clear communication will help build partnerships and trust across the ecosystem. Ongoing collaboration will be especially important as technology advances, assays become more sensitive, and new risks emerge. At the same time, the industry must consider the resilience of key inputs while maintaining a strong focus on quality and safety.

CURRENT CHALLENGES

The complexity of the infant formula ecosystem makes it challenging to fully understand activities and risks across the production chain. This ecosystem spans raw material production, ingredient sourcing, manufacturing, distribution, and ultimately consumer use.

A key question facing the industry is what practical, coordinated control measures and mitigation strategies can be implemented today to further reduce the risk of infant botulism. While testing remains an important component of risk management, even the most advanced currently available methods cannot, on their own, ensure protection against contaminated powdered infant formula. A broader preventive approach that incorporates controls throughout the supply chain is essential.

CURRENT CHALLENGES CONTINUED

As new preventive measures are considered, it is also important to recognize the potential economic impacts. Increasingly complex and costly control requirements place additional burdens on suppliers, creating a risk that infant formula manufacturers could lose critical supply partners if compliance becomes too challenging or economically unfeasible. Balancing risk reduction with supply chain sustainability will be an important consideration for the industry moving forward.

RECOMMENDATIONS

Recommendations emphasize a coordinated, data-driven approach to strengthening the safety and resilience of the powdered infant formula supply chain. By combining industry collaboration, evidence-based mitigation strategies, practical supply chain controls, and affordability considerations, stakeholders can advance solutions that protect infants.

12 Nurture industry collaboration. Continue collaborative efforts across stakeholders to develop methodologies and solutions that are scientifically sound, operationally and economically feasible, and regulatorily compliant.

13 Build a clear, evidence-based mitigation strategy to ensure safety of infant formula. Use data to demonstrate both the scope of the issue and the effectiveness of proposed interventions, ensuring recommendations are supported by measurable outcomes.

14 Determine what supply chain control measures may eliminate or adequately reduce the risk of spores in product streams. Consider how these controls can benefit all involved parties, including raw material providers and manufacturers.

15 Establish and validate preventive controls and preventive practice technologies (e.g., bacteria removal separators, ultrafiltration, on-farm practices).

16 Maintain supply continuity and affordability of powdered infant formula for families.

TOPIC 4

FDA collaboration

DISCUSSION

The question of what might FDA do that would be helpful for the industry was posed to roundtable participants. Input was also provided by Agency participants based on their experience with recent and past recall events.

CHALLENGES

Improved transparency and data sharing among regulatory and other governmental agencies regarding *C. botulinum* would support a more consistent understanding of the broader picture, including prevalence, risk, and risk management. Testing remains challenging. One barrier of testing adoption is the accreditation and the validation of *C. botulinum* testing. Very few labs can conduct *C. botulinum* testing validation or regular testing given the level of biosecurity required because the neurotoxin produced by the bacterium poses severe bioterrorism and public health risks. There is also a need for suppliers, manufacturers, and government agencies to have a clear and shared understanding of the optimal tests, methods, and thresholds to use for screening and outbreak assessment.

RECOMMENDATIONS

Building on the need for coordinated industry action and evidence-based mitigation, participants focused on the potential role of federal regulators in creating greater consistency, transparency, and scientific alignment. Standardized testing expectations and stronger collaboration across agencies would help support more systematic decision-making while advancing research needed to better assess and manage risks associated with *C. botulinum*.

17 FDA should provide guidance on the most appropriate fit-for-purpose tests and associated thresholds, as well as establish standardized testing methods and requirements to ensure consistent, systematic processes across the industry.

18 Collaborate with other governmental agencies (e.g., CDC, USDA) to facilitate information sharing among agencies, researchers, and industry.

Potential Next Steps

DISCUSSION

The roundtable discussion focused primarily on one point in the supply chain: infant formula manufacturers. Participants identified additional conversations, considerations, and actions to advance the science while maintaining a safe and available infant formula supply.

ADDITIONAL QUESTIONS TO CONSIDER

- What interventions could be implemented at the infant formula manufacturing stage?
- Do changes in the milk supply over the past 10 years, such as changing milk composition or increased use of whole milk powder in formulas, affect the risk of exposure to *C. botulinum* spores?
- How should potential risks from other formula ingredients, such as minerals, non-dairy protein sources, and vitamins, be assessed?
- How might regional climate variations affect ingredients, finished products, and subsequent infant risk?

RECOMMENDATIONS FOR POTENTIAL NEXT STEPS

19 Engage with the dairy industry in a similar forum; combine objectives to maintain supply, ensure safety, and develop a more comprehensive understanding of the contamination.

20 Educate stakeholders on supply chain risk mitigation and elimination options and potential gaps in these options.

21 Work toward testing accreditation and validation with a fit-for-purpose test with established thresholds.

22 Assemble lessons learned outside of the U.S. and identify individuals or companies doing innovative or new things in the infant formula space.

Conclusion

Participants demonstrated openness and a strong commitment to addressing this issue and ensuring the continued safety of infant formula, both now and in the future. There was considerable enthusiasm to explore greater data collection and sharing and consider establishing a mechanism that enables the safe, practical, and timely exchange of information across the industry.

The discussion also reinforced the importance of maintaining access to safe, reliable, and affordable infant formula for consumers. Participants recognized that meaningful progress will require collaboration across the entire ecosystem, including suppliers, manufacturers, researchers, regulators, distributors, and ultimately, healthcare practitioners and consumers

Moving forward, industry-wide collaboration will be essential to developing solutions that are scientifically credible, operationally and economically feasible, regulatorily sound, and grounded in risk-based decision-making. Participants expressed a desire to continue engaging on this topic, strengthen information-sharing efforts, and proactively consider emerging challenges to ensure the industry remains prepared for future risks.

End Notes

1. U.S. Food & Drug Administration. (2025). Outbreak investigation of infant botulism: Infant formula. www.fda.gov. https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025

2. U.S. Food & Drug Administration. (2026, May 13). HFP advances collaborative vision for enhancing food safety. www.fda.gov. https://www.fda.gov/food/hfp-constituent-updates/hfp-advances-collaborative-vision-enhancing-food-safety

3. U.S. Food & Drug Administration. (2026, July 13). Post-outbreak response activities: *Clostridium botulinum* illnesses associated with consumption of powdered infant formula. www.fda.gov. https://www.fda.gov/food/outbreaks-foodborne-illness/post-outbreak-response-activities-clostridium-botulinum-illnesses-associated-consumption-powdered

4. See Appendix C

5. Scott, J., Pellett, S., Roman, M., Grove, S. Opportunities and Challenges: Developments in *Clostridium botulinum* Challenge Studies. Annual Meeting of the International Association for Food Protection, Phoenix, AZ [or virtual]. Journal of Food Protection Supplement A, 84. https://docs.google.com/document/d/1kyx-y8q1UHOHTuJS_EYzXwkX7fEljVyGa2RjEVZi1fQ/edit?usp=drivesdk

6. Nadala, C., Themeli, E., Forghani, F., Ha, Y., Han, S., Shapovalova, A., Roach, J., Kim, S. H., Thorson, J. L. M., Lee, J.-Y., Spear, M., Buhrman, B., Chiu, K., Mullane, N., & Samadpour, M. (2026). Detection and characterization of *Clostridium botulinum* isolated from powdered infant formula. *Frontiers in Microbiology*, *17*, 1800624. https://doi.org/10.3389/fmicb.2026.1800624

APPENDIX A

Recommendations

Twenty-two recommendations emerged from the Roundtable, organized here by the four themes that shaped the discussion.

THEME 1	*C. botulinum* state of the science	1–5
1	Conduct an initial assessment of *C. botulinum* prevalence on farms, along the supply chain, and in finished goods. Many downstream questions depend on the initial assessment of prevalence.	
2	Develop screening methods that are efficient but also sufficiently specific and sensitive.	
3	Investigate what other indicators may exist to help gauge *C. botulinum* spore presence in milk or powder.	
4	Investigate how to monitor environmental, supply chain, and processing changes, with an aspiration to protect against the next incident. Determine whether current *C. botulinum* findings reflect increased prevalence, improved detection capabilities, climate impacts, processing innovations, changes in the milk supply or a combination of factors.	
5	Increase research funding from multiple agencies and industry to generate the data needed for risk assessments, validating mitigation strategies, and other evidence broadly important for the industry.	

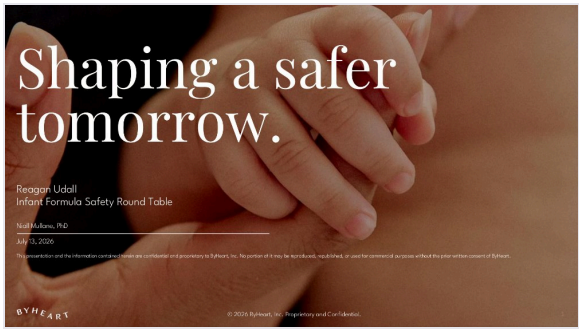
THEME 2	Data sharing	6–11
6	Explore engaging a trusted third party that will receive, house, and safeguard the data as well as create a data exchange and sharing infrastructure.	
7	Establish transparent governance, data-use policies, and confidentiality protections to build trust and encourage participation.	
8	Through collaboration, strengthen the data foundation and share testing information (e.g., who is doing what, lessons learned, context of data collection). Expand testing and data collection to quantify prevalence, assess risk across the supply chain, and establish acceptable risk thresholds.	
9	Within the data collaboration, determine how the data will be used, compiled, aggregated, and anonymized before any analysis or sharing of the data occurs.	
10	Define the critical data needed to understand emerging and future risks, while ensuring data collection supports the generation of robust, aggregated insights that lead to actionable takeaways to improve safety of infant formula products.	
11	Align on data collection goals and build databases thoughtfully and intentionally. Include appropriate methods and context that can be pragmatically applied and adequately measure impact.	

THEME 3	A collaborative, multifactorial approach to maintain infant formula safety	12–16
12	Nurture industry collaboration. Continue collaborative efforts across stakeholders to develop methodologies and solutions that are scientifically sound, operationally and economically feasible, and regulatorily compliant.	
13	Build a clear, evidence-based mitigation strategy to ensure safety of infant formula. Use data to demonstrate both the scope of the issue and the effectiveness of proposed interventions, ensuring recommendations are supported by measurable outcomes.	
14	Determine what supply chain control measures may eliminate or adequately reduce the risk of spores in product streams. Consider how these controls can benefit all involved parties, including raw material providers and manufacturers.	
15	Establish and validate preventive controls and preventive practice technologies (e.g., bacteria removal separators, ultrafiltration, on-farm practices).	
16	Maintain supply continuity and affordability of powdered infant formula for families.	

THEME 4	FDA collaboration and potential next steps	17–22
17	FDA should provide guidance on the most appropriate fit-for-purpose tests and associated thresholds, as well as establish standardized testing methods and requirements to ensure consistent, systematic processes across the industry.	
18	Collaborate with other governmental agencies (e.g., CDC, USDA) to facilitate information sharing among agencies, researchers, and industry.	
19	Engage with the dairy industry in a similar forum; combine objectives to maintain supply, ensure safety, and develop a more comprehensive understanding of the contamination.	
20	Educate stakeholders on supply chain risk mitigation and elimination options and potential gaps in these options.	
21	Work toward testing accreditation and validation with a fit-for-purpose test with established thresholds.	
22	Assemble lessons learned outside of the U.S. and identify individuals or companies doing innovative or new things in the infant formula space.	

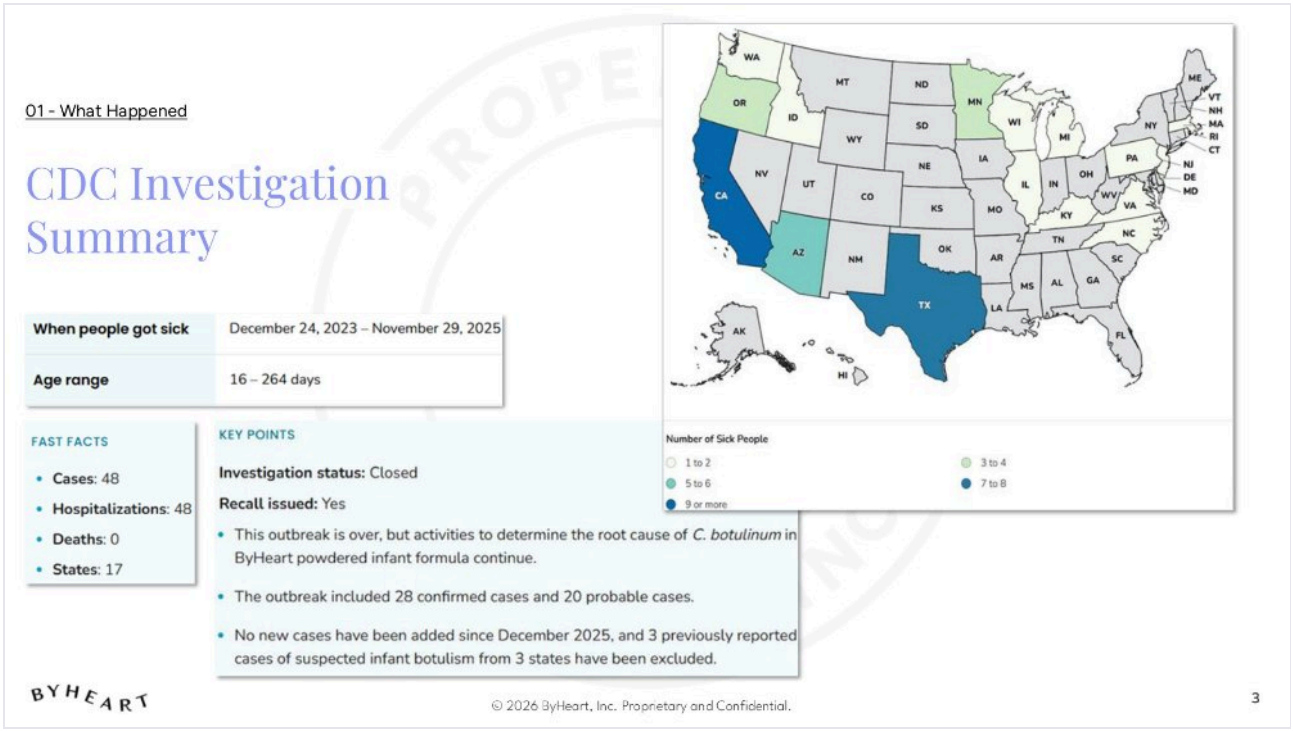
APPENDIX B — PRESENTATION

Shaping a safer tomorrow



APPENDIX B · SLIDE 1

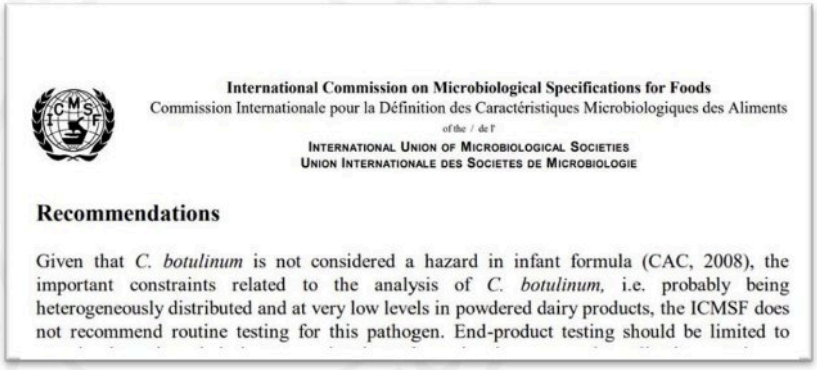
APPENDIX B · SLIDE 2



APPENDIX B · SLIDE 3

01 - What Happened

A pathogen previously not considered a likely hazard in infant formula made its way into our product.



International Commission on Microbiological Specifications for Foods
Commission Internationale pour la Définition des Caractéristiques Microbiologiques des Aliments
of the / de l'
International Union of Microbiological Societies
Union Internationale des Societes de Microbiologie

Recommendations

Given that *C. botulinum* is not considered a hazard in infant formula (CAC, 2008), the important constraints related to the analysis of *C. botulinum*, i.e. probably being heterogeneously distributed and at very low levels in powdered dairy products, the ICMSF does not recommend routine testing for this pathogen. End-product testing should be limited to

BYHEART

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APPENDIX B · SLIDE 4

APPENDIX B · SLIDE 5

02 - Our Investigation

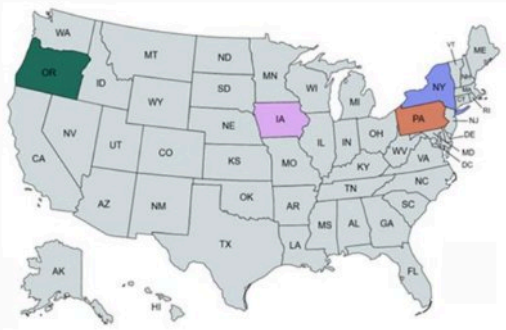
Our Supply Chain

New York, NY
Corporate Headquarters

Reading, PA
Bulk-Powder Manufacturing Facility

Allerton, IA
Bulk-Powder Manufacturing Facility

Portland, OR
Dry-Blending & Packaging Facility



BYHEART

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APPENDIX B · SLIDE 6

02 - Our Investigation

External Expert Support

IEH Laboratories & Consulting Group

An expert team was deployed to assess the process end-to-end, identifying potential root causes in the *C. botulinum* investigation. IEH laboratories supported all microbiological testing, including speciation and WGS analysis. IEH Consulting supported the root cause analysis and development of the forward plan.

Dr. Kathleen Glass

A retired UW–Madison Distinguished Scientist and leading *C. botulinum* expert, visited the Allerton and Portland site to assess potential process-related root causes during the investigation.

Dr. Eric Johnson

A University of Wisconsin–Madison microbiologist with over 40 years of experience, specializing in *C. botulinum*, neurotoxins, and food safety, advancing toxin detection in food systems. Supported the review of ByHeart investigation reports.

BYHEART

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APPENDIX B · SLIDE 7

02 - Our Investigation

Our Investigation Scope

C. botulinum risk was evaluated through two key pathways: spore ingress and growth.

Spore ingress risk is associated with external sources, including water, the environment, and materials—especially ingredients—through which contamination can enter the process

Growth risk is linked to process conditions that support anaerobic, wet, or stagnant environments that could create an anaerobic, biofilm-forming environment, such as equipment, piping, and areas prone to accumulation.

Included ~ 5,000 *C. botulinum* tests conducted by **IEH Laboratories**

Extensive cultural isolation efforts (over 1,000 isolates screened) and whole-genome sequence-based strain characterization.

BYHEART

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APPENDIX B · SLIDE 8

02 - Our Investigation

C. botulinum Testing Results

Environmental Testing at ByHeart Facilities

Zone	Allerton	Portland
1	244	26
2	100	26
3	49	12
4	3	2
HVAC Pre Filters	10	0

All tests negative for C. botulinum

Ingredients, ByHeart Base Powder & Finished Good Testing

Sample Type	Unique Lots Sent for Testing	Total Individual Testing [1]	# of Lots PCR Positive [2]	# of Lots with Culture Confirmation
GOS	5	5	0	N/A
Lactoferrin	37	30	0	N/A
Lactose	47	552	0	N/A
Whole Milk Powder	15	2348	1	1 Lot
Whey Protein Concentrate	23	257	0	N/A
Whey Protein Hydrolysate	22	458	1	0
Other Ingredients	65	108	0	N/A
ByHeart Bulk base	22	83	3	1 Lot
ByHeart Finished Product	241	387	8	6 Lots

[1] *For some samples, testing was conducted on multiple subsamples obtained from the same original sample*

[2] *Toxin type specific PCR detection and amplicon sequence identification*

One confirmed *C. botulinum* positive ingredient – Whole Milk Powder

ByHeart is Committed to data sharing

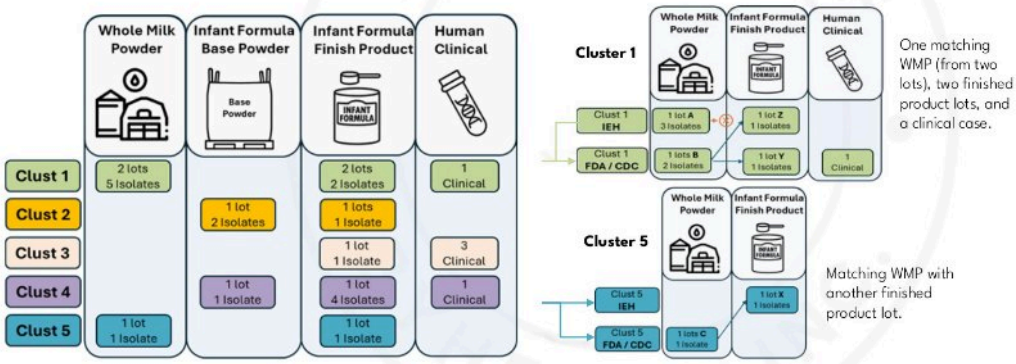
BYHEART

9

APPENDIX B · SLIDE 9

02 - Our Investigation

Whole Genome Sequencing Match



WGS Clustering across different laboratories supporting robust root cause determination

10

APPENDIX B · SLIDE 10

02 - Our Investigation

Sulfite-Reducing Clostridia (SRC)

Our investigation included testing finished product and ingredients for sulfite-reducing clostridia (SRC) as a possible indicator for *C. botulinum*. All samples that tested positive for *C. botulinum* were <10cfu/g for SRC by direct plating.

Results demonstrate limited reliability of SRC as an indicator.

Sulfite-Reducing Clostridia (SRC) Testing results vs *C. botulinum* PCR presumptive positives.

Category	*C. botulinum* PCR Presumptive Positives*	SRC cfu/g
Finished Product	17	All results <10
Base Powder	3	All results <10
Ingredients	13	All results <10

**A multiplex PCR-positive for BoNT and 16S gene targets*

Results demonstrate limited reliability of SRC by direct plating as an indicator

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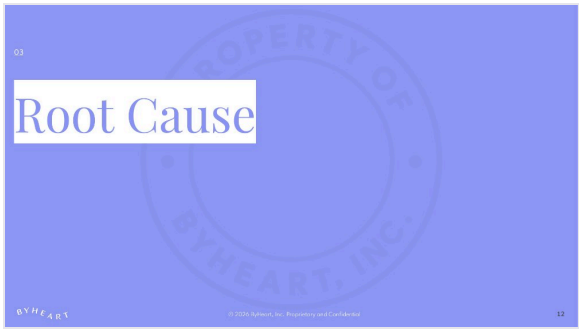
APPENDIX B · SLIDE 11



APPENDIX B · SLIDE 12

APPENDIX B · SLIDE 13

APPENDIX B · SLIDE 14

04 - Our Actions

A sweeping set of actions, from farm to factory.

Investigation

Understanding the root cause of the outbreak, in full cooperation with the FDA and leading external experts.

Supplier & Ingredient QA

Strengthening our entire supply chain through expanded audits, increased testing frequency, and new technological control measures.

Farm Level Control Manual

Bactofuge/Bacterial Removal Separator (BRS)

Manufacturing & Quality

Enhancing our facilities, sanitation protocols, and manufacturing processes to exceed the highest infant-grade standards.

Testing & Verification

Implementing an industry-first *C. botulinum* testing protocol with independent third-party verification on every batch.

BYHEART

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APPENDIX B · SLIDE 15

04 - Our Actions

FDORA Response to FDA

Sporicidal clean break + verification to eliminate *C. botulinum.*

Food Safety Plans updated with enhanced controls.

Expanded testing: routine sampling and validated methods for *C. botulinum* across all dairy ingredients, bulk powder, and finished products, with results required as a release criterion.

Supplier actions: WMP supplier delisted; alternate supplier qualification in progress with **strengthened spore control requirements**.

Independent audit (IEH) to validate readiness

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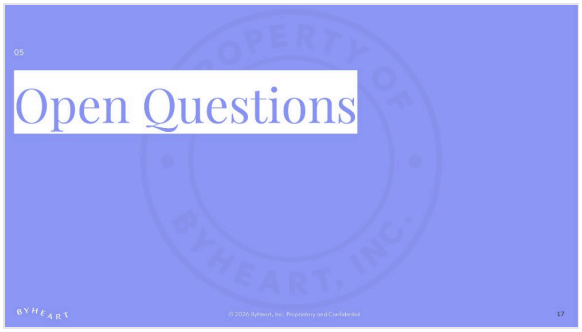
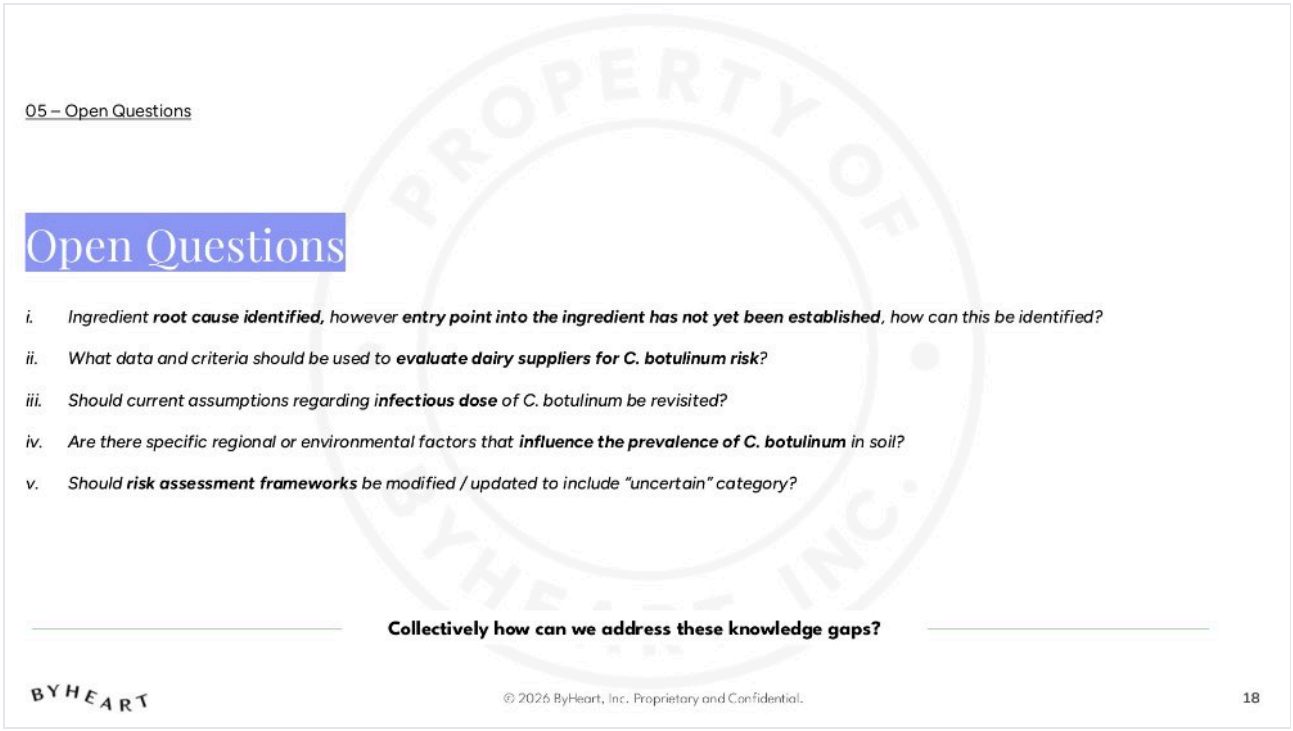
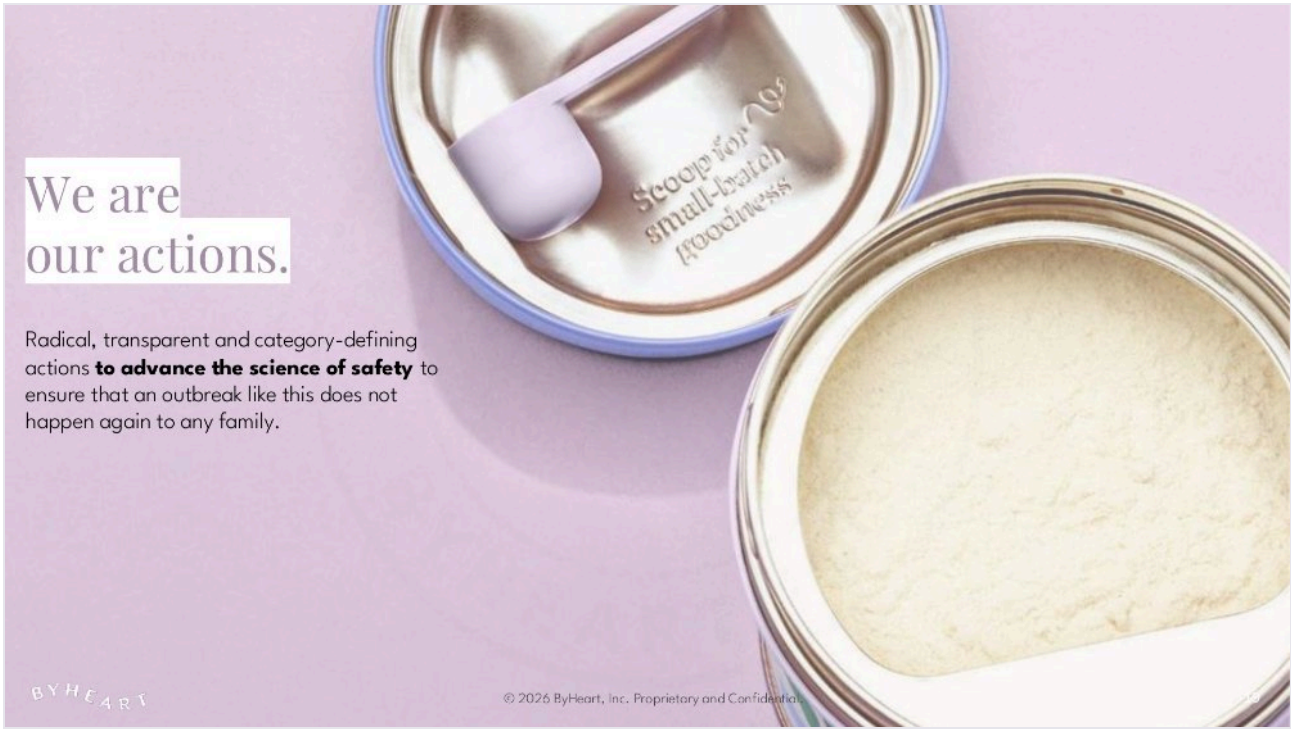
APPENDIX B · SLIDE 16



APPENDIX B · SLIDE 17



APPENDIX B · SLIDE 18



APPENDIX B · SLIDE 19

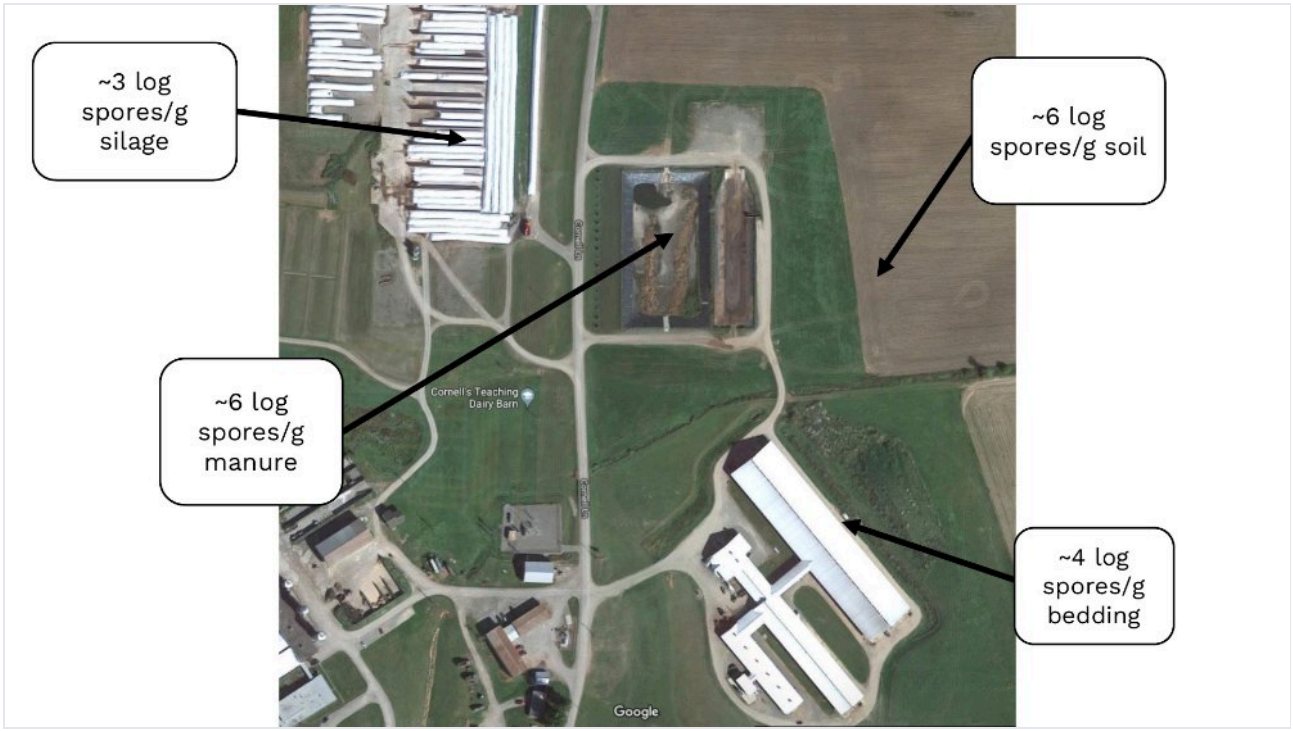
APPENDIX B · SLIDE 20

APPENDIX C — PRESENTATION

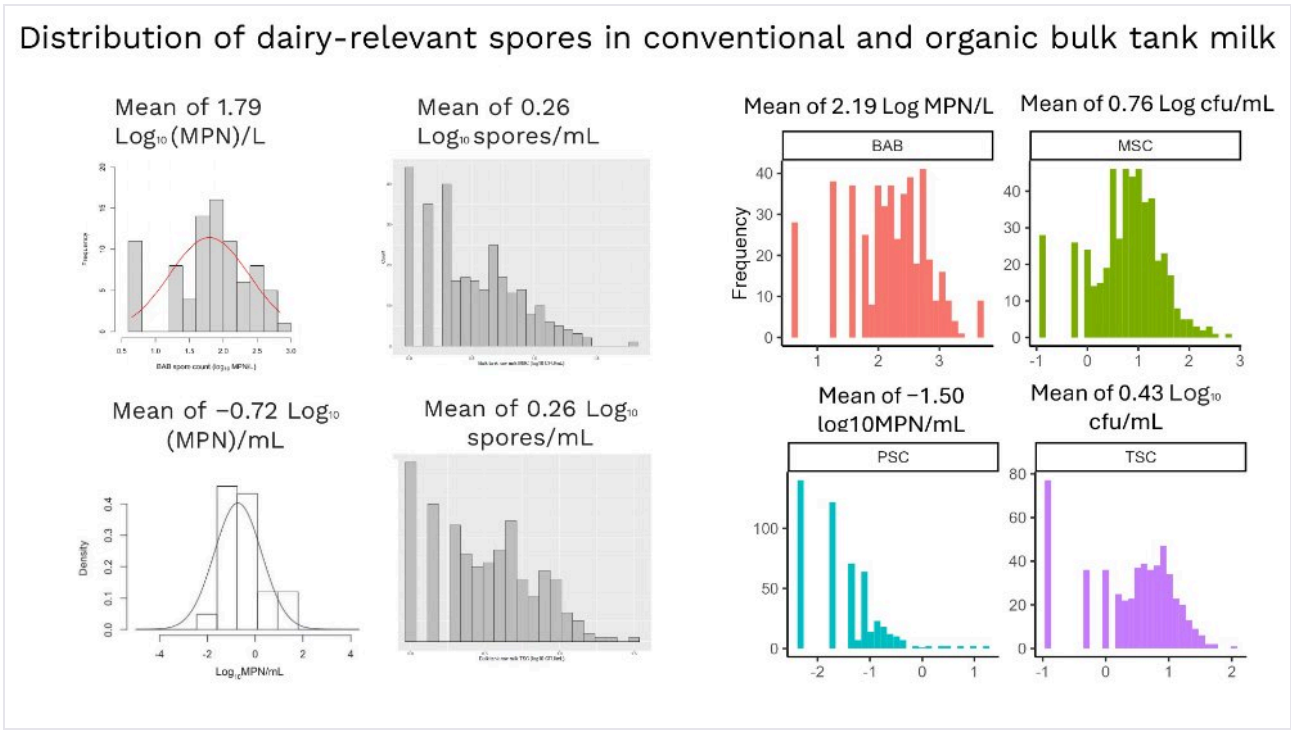
Bacterial spore prevalence in the dairy system and mitigation strategies

APPENDIX C · SLIDE 1

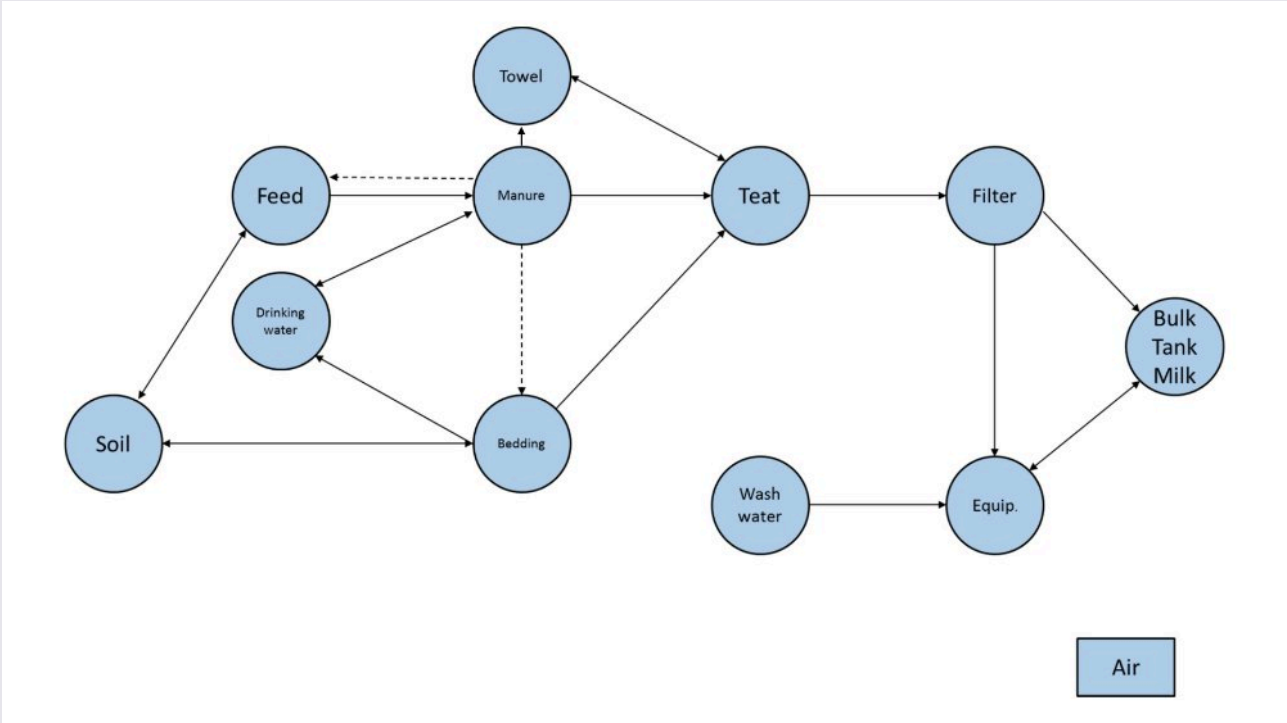
APPENDIX C · SLIDE 2



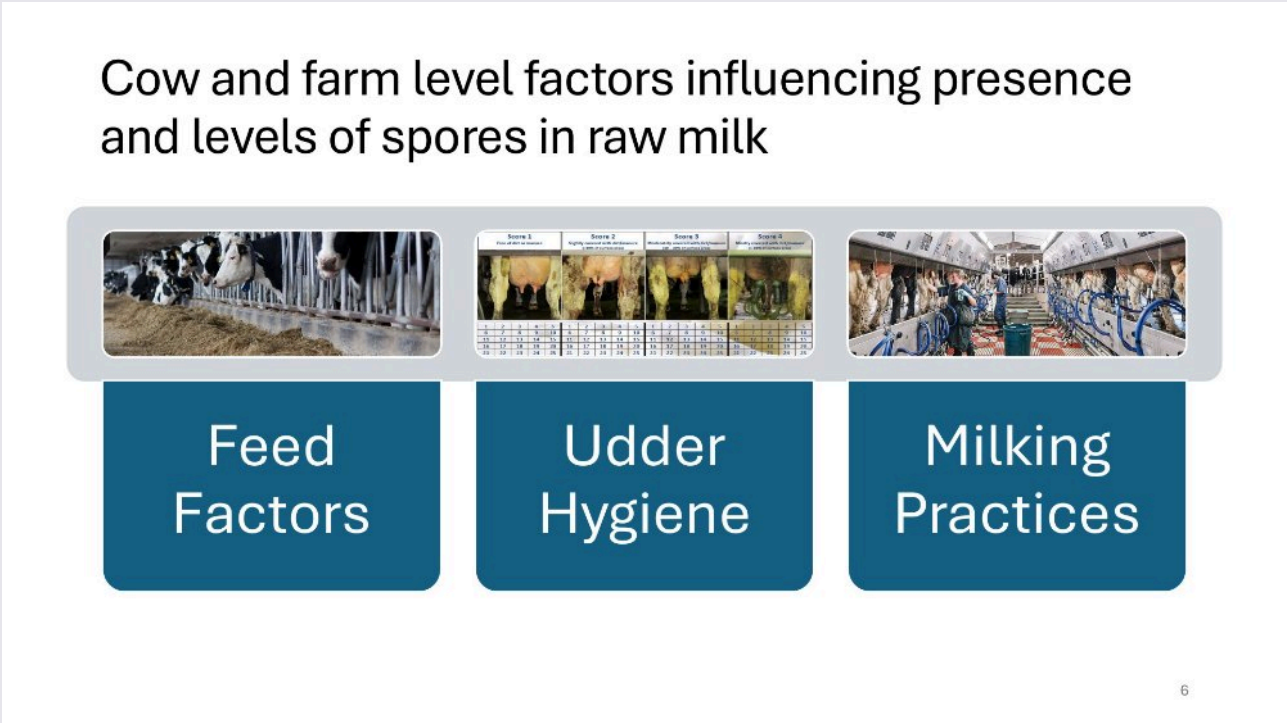
APPENDIX C · SLIDE 3



APPENDIX C · SLIDE 4

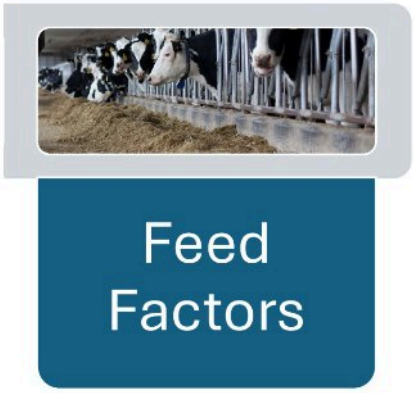


APPENDIX C · SLIDE 5



APPENDIX C · SLIDE 6

Cow and farm level factors influencing presence and levels of spores in raw milk

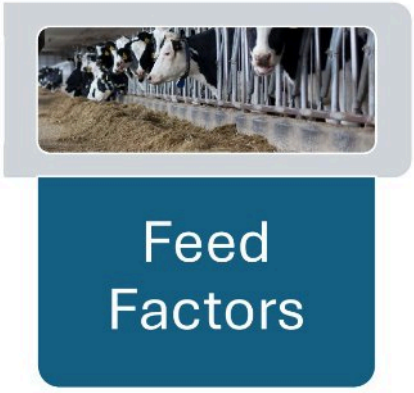


- Historical association with high levels of anaerobic spores in silage – raw milk used for certain cheeses in Switzerland cannot come from cows fed silage
- Anaerobic conditions may lead to proliferation and resporulation, especially under conditions where pH is increased due to yeast growth
  - Of particular importance for spoilage clostridia and *C. perfringens*

7

APPENDIX C · SLIDE 7

Cow and farm level factors influencing presence and levels of spores in raw milk

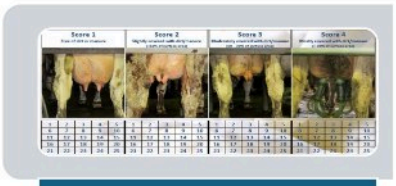


- Presence of animal carcasses in feed, including in silage, baleage/haylage, grains, etc. is of importance to *C. botulinum* transmission
  - Dairy cattle are susceptible to intoxication with *C. botulinum* toxin, most often resulting from types C and D, but cases of A and B have also been reported
  - Vaccination against type C and D toxins is available, but not routinely administered – prevents toxin mediated disease, but not transmission of spores

8

APPENDIX C · SLIDE 8

Cow and farm level factors influencing presence and levels of spores in raw milk



Udder Hygiene

- Overstocking
- Loose consistency of manure
- Frequency of renewal of bedding and grooming of stalls
- Cleanliness of cow walkways
- Frequent access to outside areas
- Rushing animals resulting in manure splatter

9

APPENDIX C · SLIDE 9

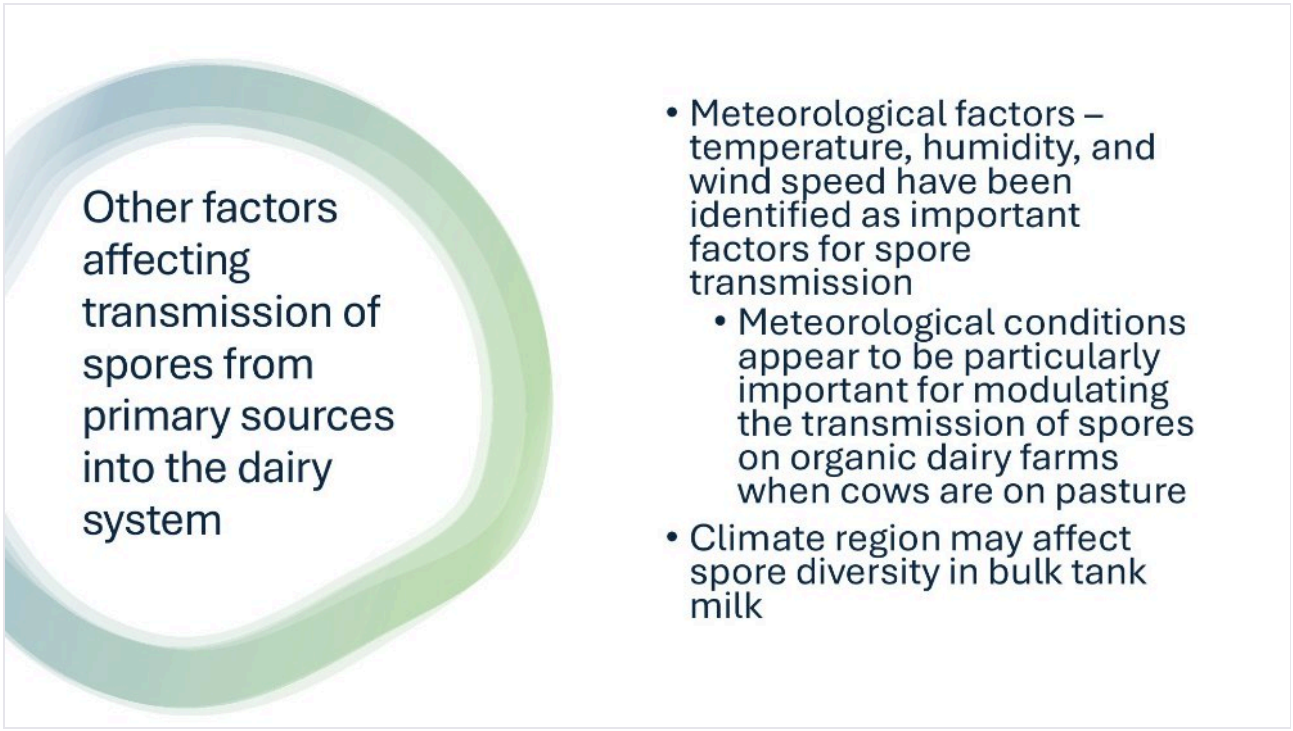
Cow and farm level factors influencing presence and levels of spores in raw milk

Milking Practices

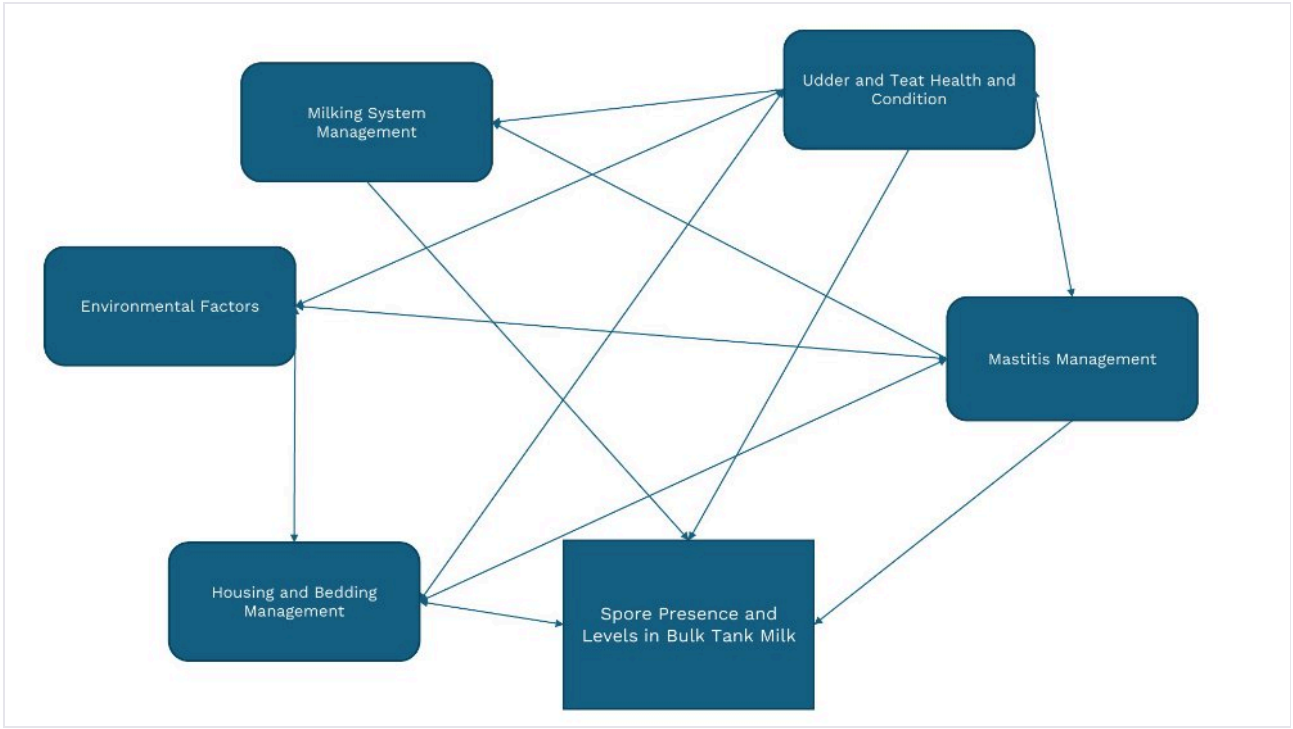
- Forestripping prior to unit attachment
  - Physical removal of spores
  - Adequate stimulation
- Teat end condition
- Reducing kick-offs
- Udder hair removal
- Training milking staff to consistently perform practices

10

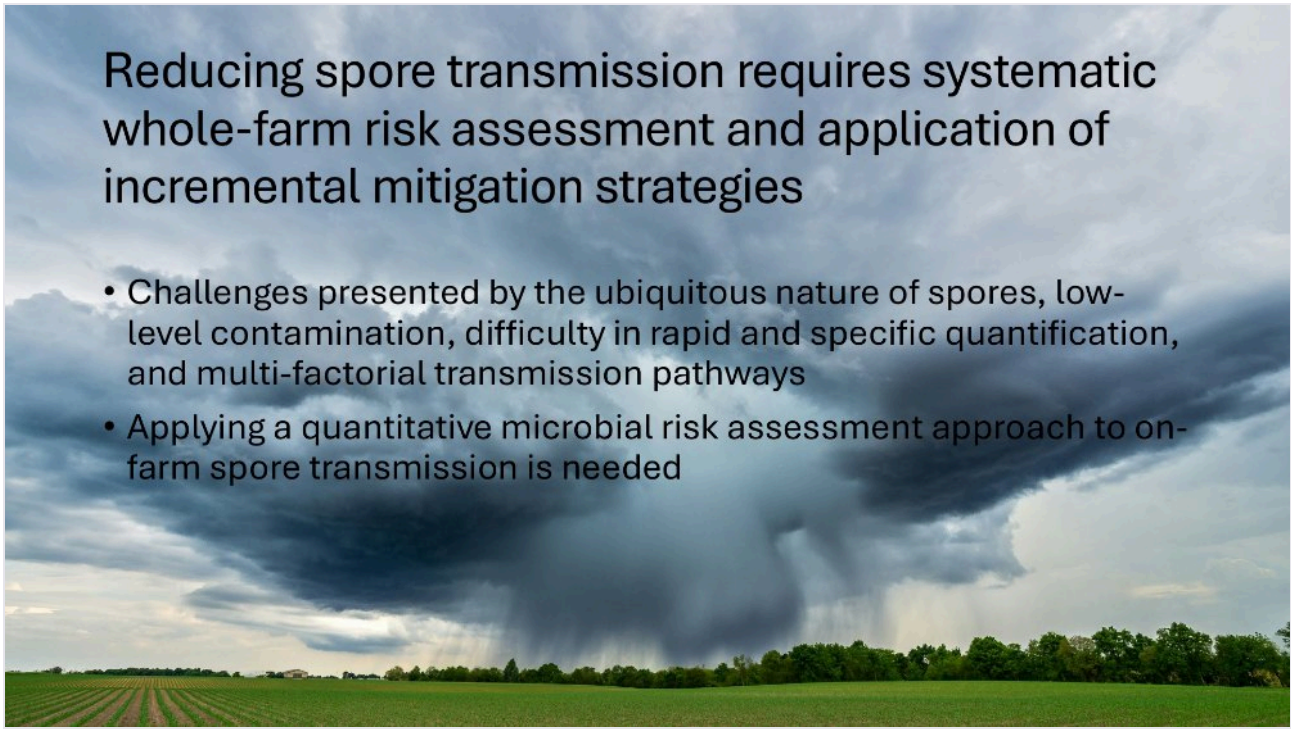
APPENDIX C · SLIDE 10



APPENDIX C · SLIDE 11



APPENDIX C · SLIDE 12



APPENDIX C · SLIDE 13

APPENDIX C · SLIDE 14

Bacterial clarification for spore reduction

- Centrifugation at high speeds for spore removal
- Density of spores facilitates their removal
- Protein loss of 2.5-3.5%

Table 15.2 Average bacteria removal by bactofugation and centrifugation

	Bactofugation		Centrifugation (classical cream separator)		References
	Efficiency (%)	Decimal reduction (-)	Efficiency (%)	Decimal reduction (-)	
Total count	86.0–92.0[a]	0.85–1.10			van den Berg *et al.* (1986)
Anaerobic spores	97.4–98.7[b]	1.58–1.88			van den Berg *et al.* (1986)
Aerobic spores	94.1–97.7[b]	1.23–1.64			van den Berg *et al.* (1986)
Somatic cells	95	1.30	30–50 /5	0.15–0.30 0.6	Wicking (2004) Saboya and Maubois (2000); Maubois (2002)

[a] Bactofugation temperature 55–65°C.
[b] Bactofugation temperature 48°C.

APPENDIX C · SLIDE 15

Bacterial clarification for spore reduction

Table 1. Mesophilic (MSC) and psychrotolerant (PSC) spore count in various product streams obtained with and without bactofugation[1]

	Temperature at collection (°C)		MSC (log cfu/mL)		PSC (log MPN/mL)	
Product stream	With bactofuge	Without bactofuge	With bactofuge	Without bactofuge	With bactofuge	Without bactofuge
Raw whole milk	2.2 ± 1.8	1.4 ± 1.5	0.92 ± 0.39^{a}	1.30 ± 0.35^{a}	-0.63 ± 0.47^{yx}	-0.88 ± 0.49^{yx}
Bactofuged raw whole milk	60.3 ± 2.6	N/A[2]	-0.16 ± 0.59^{bc}	N/A	-1.49 ± 0.35^{xy}	N/A
Raw skim milk	63.5 ± 1.1	64.0 ± 1.0	-0.47 ± 0.67^{c}	0.93 ± 0.40^{ab}	-2.12 ± 0.00^{yz}	-1.24 ± 0.81^{yxz}
Raw cream	63.5 ± 1.5	63.5 ± 1.4	0.26 ± 0.20^{abc}	0.53 ± 0.46^{abc}	-1.00 ± 0.70^{xw}	-1.27 ± 0.77^{yxz}
Pasteurized milk	2.1 ± 0.2	1.9 ± 0.1	-0.49 ± 0.65^{c}	0.99 ± 0.34^{ab}	-1.90 ± 0.35^{vwy}	-0.97 ± 0.42^{yxz}

[a–c]Means with different superscripts within MSC are significantly different from each other ($P < 0.05$).
[v–z]Means with different superscripts within PSC are significantly different from each other ($P < 0.05$).
[1]Counts below the detection limit were treated as 25% of the detection limit value (e.g., PSC under the detection limit of 0.03 cfu/mL were counted as 0.0075 cfu/mL, and MSC under 0.5 cfu/mL limit of detection were counted as 0.125 cfu/mL); MPN = most probable number.
[2]N/A = not applicable.

J. Dairy Sci. 105:9439–9449
https://doi.org/10.3168/jds.2022-22174

Monte Carlo simulation model predicts bactofugation can extend shelf-life of pasteurized fluid milk, even when raw milk with low spore counts is used as the incoming ingredient

E. R. Griep-Moyer, A. Trmčić,* C. Qian, and C. I. Moraru*
Department of Food Science, Cornell University, Ithaca, NY 14853

APPENDIX C · SLIDE 16

Microfiltration for spore reduction

- Used for the reduction of spores and vegetative bacteria in raw skim milk
- Pore sizes commonly used range from 0.8 to 1.4 µm

Table 1. Average reduction (±SD) of bacterial spores by microfiltration (MF) processing (n = 3)

Challenge study	Initial load (log cfu/mL)	After MF (log cfu/mL)	Total log reduction (log cfu/mL)
Bacillus licheniformis			
1.4-µm MF membrane	6.11 ± 0.53	3.94 ± 0.13	2.17 ± 0.64[a]
1.2-µm MF membrane	6.98 ± 0.08	2.41 ± 0.15	4.57 ± 0.09[b]
Geobacillus sp.			
1.4-µm MF membrane	6.56 ± 0.29	ND[1]	>6 log
1.2-µm MF membrane	6.38 ± 0.24	ND	>6 log

[a,b]Means within a column with different superscripts differ significantly ($P < 0.05$).
[1]Not detected (counts were below the detection limit of 25 cfu/plate).

J. Dairy Sci. 101:9703–9713
https://doi.org/10.3168/jds.2018-14888

Efficient removal of spores from skim milk using cold microfiltration: Spore size and surface property considerations

Emily R. Griep, Yifan Cheng, and Carmen I. Moraru[1]
Department of Food Science, Cornell University, Stocking Hall, Ithaca, NY 14853

APPENDIX C · SLIDE 17

Microfiltration for spore reduction

Table 1. Aerobic plate counts, mesophilic spore counts, and psychrotolerant spore counts of raw skim milk before and after microfiltration with 0.8- or 1.2-µm membranes

	Aerobic plate count (log_{10} cfu/mL)			Mesophilic spore count (log_{10} cfu/mL)			Psychrotolerant spore count (log_{10} cfu/mL)		
Trial | pore size	Raw skim	Microfiltered skim	Reduction[1]	Raw skim	Microfiltered skim	Reduction[1]	Raw skim	Microfiltered skim	Reduction[1]
1 | 1.2	5.02	<1.30	>3.72	1.45	<−1.00	>2.45	−0.57	<−1.00	>0.43
2 | 0.8	5.35	3.07	2.28	2.34	<−1.00	>3.34	<−1.00	<−1.00	NA[2]
2 | 1.2	5.36	<1.30	4.06	1.09	0.42	0.67	−0.54	<−1.00	>0.46
3 | 0.8	3.05	1.00	2.05	0.56	−0.51	1.07	−0.54	<−1.00	>0.46
3 | 1.2	3.08	<1.30	>1.78	0.56	<−1.00	>1.56	0.52	<−1.00	>1.52
4 | 0.8	3.09	1.95	1.14	0.20	1.10	−0.90[3]	−0.36	<−1.00	>0.64
4 | 1.2	3.00	<1.30	>1.70	0.40	<−1.00	>1.40	−0.30	<−1.00	>0.70

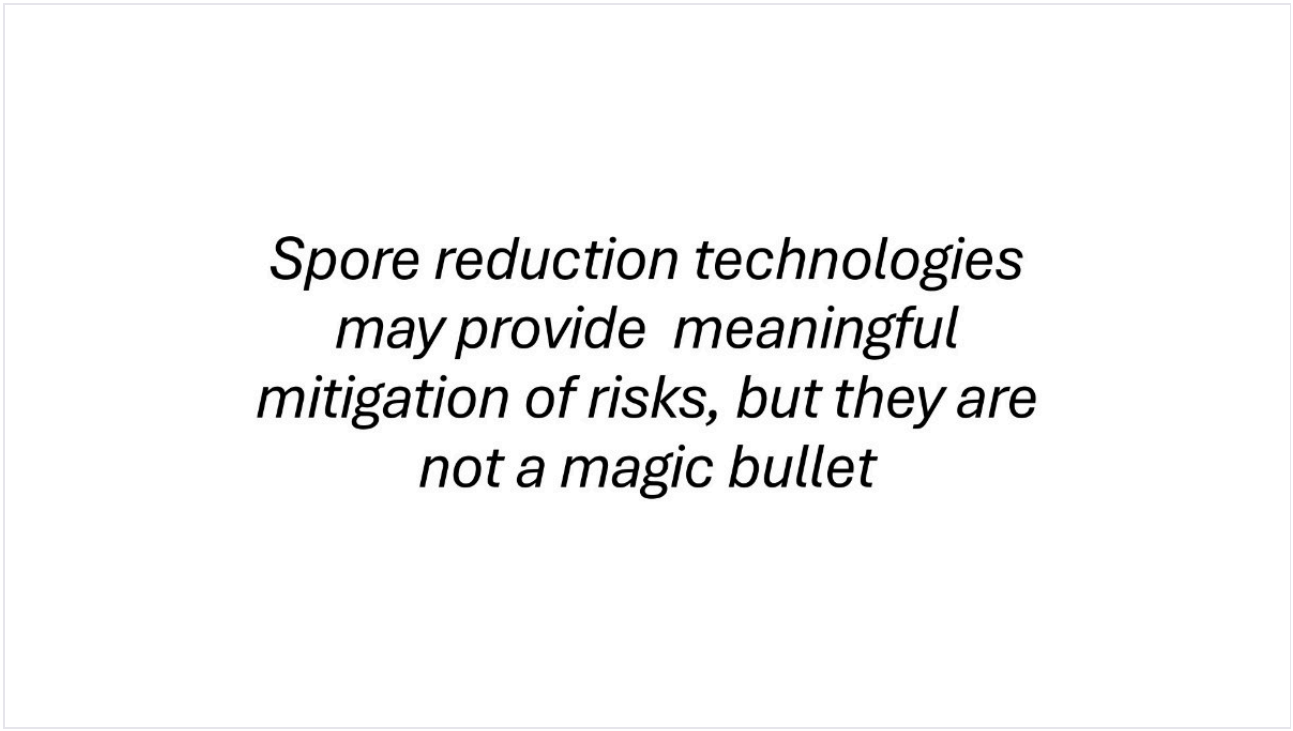
[1]Reduction is reported as the raw skim plate count minus the microfiltered skim count.
[2]Not available. Some reduction values could not be computed (i.e., if the raw skim milk count and the microfiltered skim test were below the detectable limit).
[3]The only case where the microfiltered skim bacterial count was greater than the corresponding raw skim bacterial count. Sample or media contamination cannot be ruled out as a cause of this data point.

J. Dairy Sci. 106:8434–8448
https://doi.org/10.3168/jds.2023-23734

***Microbacterium* represents an emerging microorganism of concern in microfiltered extended shelf-life milk products**

T. T. Lott, N. H. Martin,* J. Dumpler, M. Wiedmann, and C. I. Moraru*
Department of Food Science, Cornell University, Ithaca, NY 14853

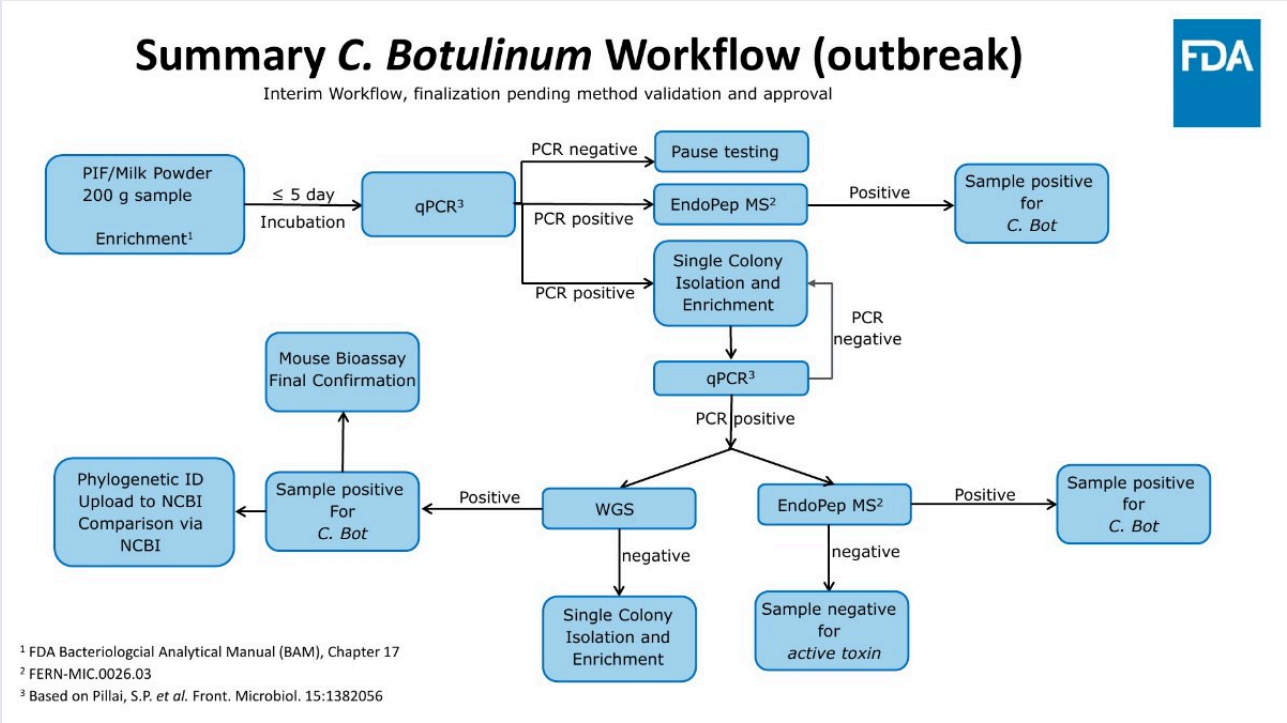
APPENDIX C · SLIDE 18



APPENDIX C · SLIDE 19

APPENDIX D — PRESENTATION

Summary *C. botulinum* workflow (outbreak)



APPENDIX D · SLIDE 1

ABBREVIATIONS

PIF	powdered infant formula
PCR	polymerase chain reaction
qPCR	quantitative PCR
EndoPeP MS	endopeptidase-mass spectrometry
NCBI	National Center for Biotechnology Information
WGS	whole genome sequencing

APPENDIX E

Applying the Science of Infant Formula Safety:

Insights From Recent Recall Activity and the Latest Research on *C. botulinum*

Roundtable

Monday, July 13, 2026, 12-3pm ET

Rooftop Conference Center
1333 New Hampshire Avenue, NW, Washington, DC 20036

MEETING PURPOSE: Infant formula manufacturers and the Food and Drug Administration share a common goal: ensuring a safe, nutritious, and reliable supply of infant formula. Recent outbreaks in the US caused by *Clostridium botulinum* have raised questions about preventive controls and testing protocols across the infant formula supply chain. Over the last 9 months, there has been a critical acceleration of knowledge and research into these emerging risks.

These risks and the lessons learned from investigations will be explored collectively during our in-person roundtable. The aim is to build a shared understanding of the most recent insights and research into *C. botulinum* and explore ways to strengthen preventive measures and testing methods that protect the infant formula supply and the families who rely on it. This discussion prioritizes shared learning among infant formula manufacturers, regulators, researchers, and consumer advocates and will focus on:

- The risk of *C. botulinum* spores in powdered infant formula and dairy-based ingredients
- Learnings from the ByHeart *C. botulinum* recall, including findings from the root cause investigation, published data on the sulfite-reducing clostridia (SRC) testing method, and current plans for prevention and *C. botulinum*-specific testing
- Opportunities to reduce spore presence and improve detection while maintaining practices that are scientifically credible, operationally feasible, and regulatorily sound

Following the discussion, the Foundation will publish a public report summarizing key insights and potential recommendations to help extend the reach of the conversation—particularly to other individuals and entities in the infant formula supply chain—and ultimately support efforts to strengthen the safety and nutritional integrity of the infant formula supply.

Agenda

12 pm

Welcome

Moderator: Susan C. Winckler, RPh, Esq.
Chief Executive Officer
Reagan-Udall Foundation for the FDA

12:03 pm

Participant Introductions/ Opening Thoughts

When called on, please share your name, organization affiliation, and answer the following question: **What is the most important lesson, or the most pressing unanswered question, raised by recent infant formula contamination events?** (Each participant will have one minute to introduce themselves.)

12:25 pm

Advancing The Science of Safety - Understanding the *C. botulinum* Risk

Brief Presentations:

- Presentation #1: Niall Mullane, PhD, Chief Quality Officer, ByHeart
- Presentation #2: Nicole Martin, PhD, Assistant Research Professor in Dairy Foods Microbiology, Cornell University
- Presentation #3: Greg Noonan, PhD, Director, Office of Chemistry and Toxicology, Human Foods Program, FDA

1 pm

Discussion – Implications and Recommendations

Key Discussion Questions:

What We Heard - The *C. botulinum* Contamination Risk (Ingredients, Processes, Finished Goods)

- From the presentations, is there anything that was unexpected? How did the investigation findings and research reflect your experience or concerns?

What is Missing and What Needs to Be Done - Preventive Measures & Testing Methods

- What other questions do these findings prompt? How might current research be scaled or accelerated for safety?

Opportunities

- What opportunities are there to improve preventive strategies and detection of *C. botulinum* risks while maintaining practices that are scientifically credible, operationally feasible, and regulatorily sound?
- What are the two or three highest-priority actions coming out of today's discussion?

2:45 pm

Wrap Up

- Rapid recap/reflection from each participant (60 seconds per person)
- Synthesis of Next Steps

3pm

Adjourn

ByHeart and International Dairy Foods Association provided funding for this meeting

APPENDIX F

Roundtable and Report Contributors

We appreciate the contributions of the following individuals to the roundtable and this report. While all had the opportunity to review the draft report, their inclusion does not represent their endorsement of or agreement with the content of this report, either individually or on behalf of their organization. The Reagan-Udall Foundation for the FDA retains sole responsibility for this report.

Sam Alcaine

Ron Belldegrun

Conrad Choiniere

Robert Cleveland

Vanessa Coffman

Luke Douglas

Keith Garrard

Brian Kineman

Devon Kuehn

Sam Levy

Ben Lewis

Nicole Martin

Niall Mullane

Gregory Noonan

Colin O'Neil

Richard Paine

Lee Perry

Jena Rostorfer

Shashi Sharma

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Benjamin Warren

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Reagan-Udall Foundation for the FDA, independent 501(c)(3) organization created by Congress to advance the mission of the Food and Drug Administration.

September 2026