Clostridium botulinum in Dairy: Risk, Control, and Prevention Strategies – A Live Expert Roundtable

May 4, 2026

WEBINAR MODERATOR: Sarah Murphy, FDA

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FEATURED SPEAKERS

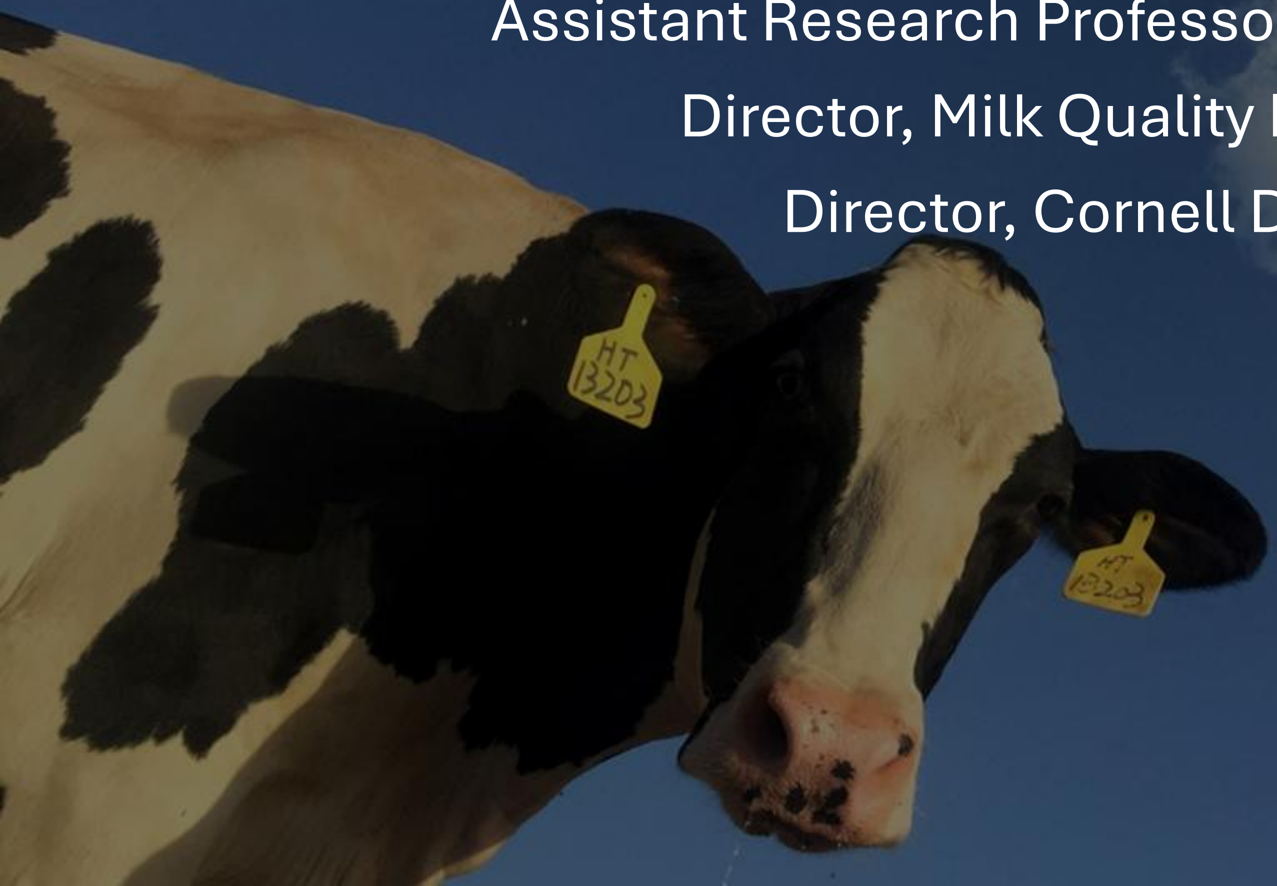
Dr. Nicole Martin is an Assistant Research Professor in Dairy Foods Microbiology in the Department of Food Science at Cornell University and the Director of the Milk Quality Improvement Program (MQIP). Nicole conducts farm-to-consumer dairy microbiology research and works closely with dairy industry stakeholders including producers and processors. Nicole's research interests take a holistic approach to dairy product quality and safety, with the mindset that providing consumers with high quality dairy products must start at the farm and be a priority throughout processing, distribution, and retail. In particular, Nicole is interested in the transmission of dairy associated microorganisms from environmental niches into raw and processed dairy products, strategies to reduce or eliminate this transmission, implications of microbial contamination on finished products, and methods of detection.

Dr. Kristin Schill is a Research Assistant Professor at the University of Wisconsin-Madison's Food Research Institute (FRI) and leads the Applied Food Safety Laboratory. In this capacity Kristin works directly with the food industry to design food challenge studies on a wide variety of food products and foodborne pathogens including Clostridium botulinum. Kristin served on the FAO Expert Meeting on Microbiological Risk Assessment of Clostridium spp. in Foods (2025) and was invited to participate in the Joint FAO/WHO Expert Meetings on microbiological risk assessment on powdered formula for infants and young children.

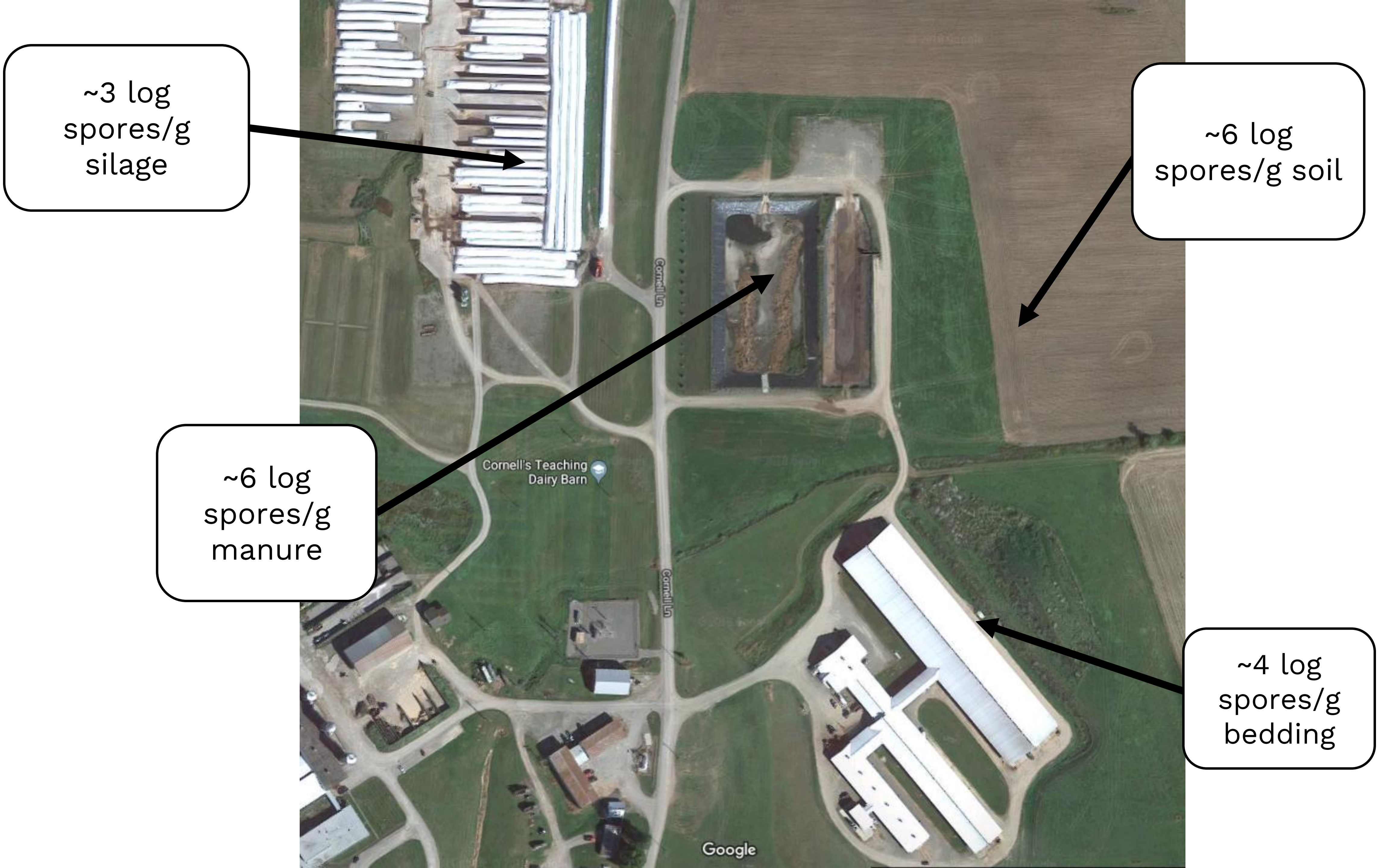
Miquela Hanselman is the Senior Director of regulatory affairs for the National Milk Producers Federation. Hanselman leads NMPF's nutrition strategy in addition to working on a range of topics including food safety, animal health and public health. In addition to her regulatory roles, she works as part of the National Dairy FARM team, overseeing the biosecurity program and updating the program's antibiotic stewardship components. Miquela received her Master of Public Health with a concentration in Food Systems and her Bachelor of Science from Cornell University. She is an upstate New York native and enjoys returning to help on her family's dairy farm.

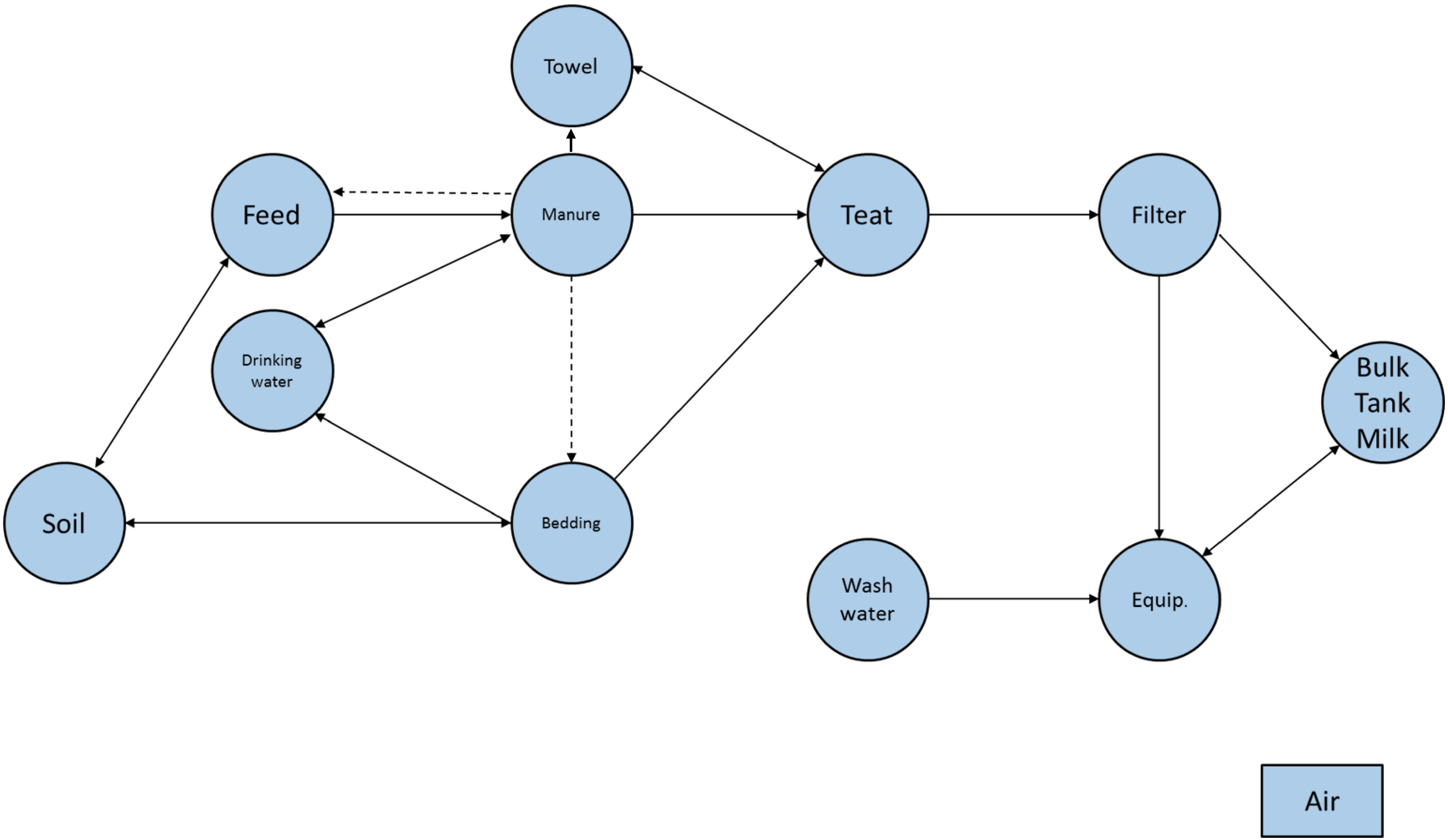
On-farm bacterial spore transmission risk factors

Nicole Martin, PhD
Assistant Research Professor in Dairy Foods Microbiology
Director, Milk Quality Improvement Program
Director, Cornell Dairy Foods Center




Spores are found ubiquitously in natural environments including soil, water and the plant rhizosphere


~3 log spores/g silage
~6 log spores/g soil
~6 log spores/g manure
~4 log spores/g bedding
Cornell's Teaching Dairy Barn
Cornell Ln
Cornell Ln
Google


Towel
Feed
Manure
Teat
Filter
Drinking water
Bulk Tank Milk
Soil
Bedding
Wash water
Equip.
Air

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

Feed Factors

Udder Hygiene

Milking Practices

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

Feed Factors

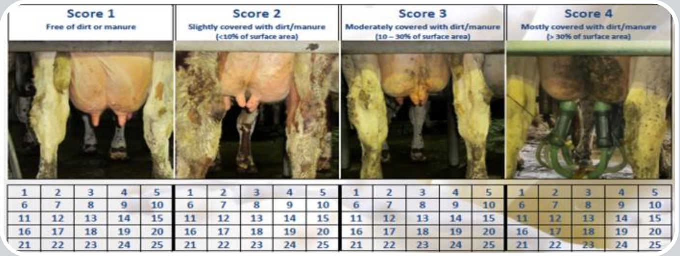
- Historical association with high levels of anaerobic spores in silage – raw milk used for certain cheeses in Switzerland cannot come from cows fed silage
- Anaerobic conditions may lead to proliferation and resporulation, especially under conditions where pH is increased due to yeast growth
    - Of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

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

Feed Factors

- 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

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

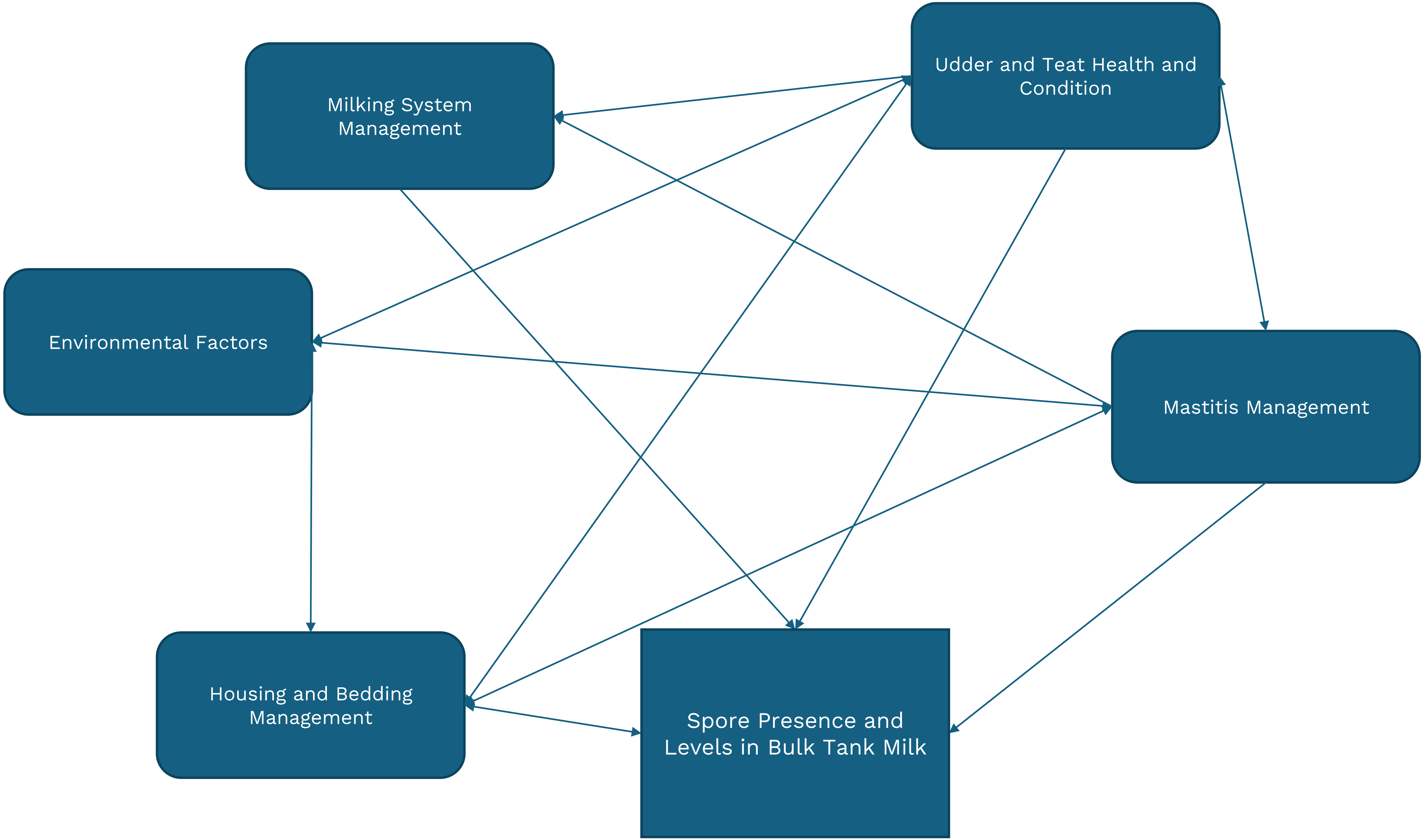
Cow and farm level factors influencing presence and levels of spores in raw milk

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

Other factors affecting transmission of spores from primary sources into the dairy system

- Meteorological factors – temperature, humidity, and wind speed have been identified as important factors for spore transmission
  - Meteorological conditions appear to be particularly important for modulating the transmission of spores on organic dairy farms when cows are on pasture
- Climate region may affect spore diversity in bulk tank milk


Milking System Management
Udder and Teat Health and Condition
Environmental Factors
Mastitis Management
Housing and Bedding Management
Spore Presence and Levels in Bulk Tank Milk

Reducing spore transmission requires systematic whole-farm risk assessment and application of incremental mitigation strategies

- Challenges presented by the ubiquitous nature of spores, low-level contamination, difficulty in rapid and specific quantification, and multi-factorial transmission pathways
- Applying a quantitative microbial risk assessment approach to on-farm spore transmission is needed

Coming soon: Best practices in reducing spore transmission risk on-farm, a workshop for field staff and farm inspectors

Contact me at nicole.martin@cornell.edu

Infant Formula Safety Update

Kristin Schill, Research Assistant Professor, Food Research Institute

University of Wisconsin-Madison

Contact: Kristin.Schill@wisc.edu; 608-264-1368

Infant Botulism

- **Ingestion of *C. botulinum* bacteria or spores, which germinate, grow and produce toxins in the intestine**
- **"infectious dose" = 10-100 spores** (Arnon, 1992)
- Usually affects babies who are between 2 weeks and 6 months old, but all babies are at risk <1 yr old
- Avoid honey for first year (5-80 spores/g associated with infant botulism)
  - Other sources of spores: Corn syrup, soil, dust are risk factors
- Fatality rate associated with infant botulism is about **2%**.
- Among hospitalized infants, recovery usually takes several weeks
- Antitoxin (Baby-BIG/ BIGIV) can significantly decrease hospitalization time

BOTULISM TYPES

Total Cases / yr U.S. (110 - 145)

Infant (65-75%) – ingestion of spores

Foodborne (15-25%) – ingestion of preformed toxin

Wound (3-20%)

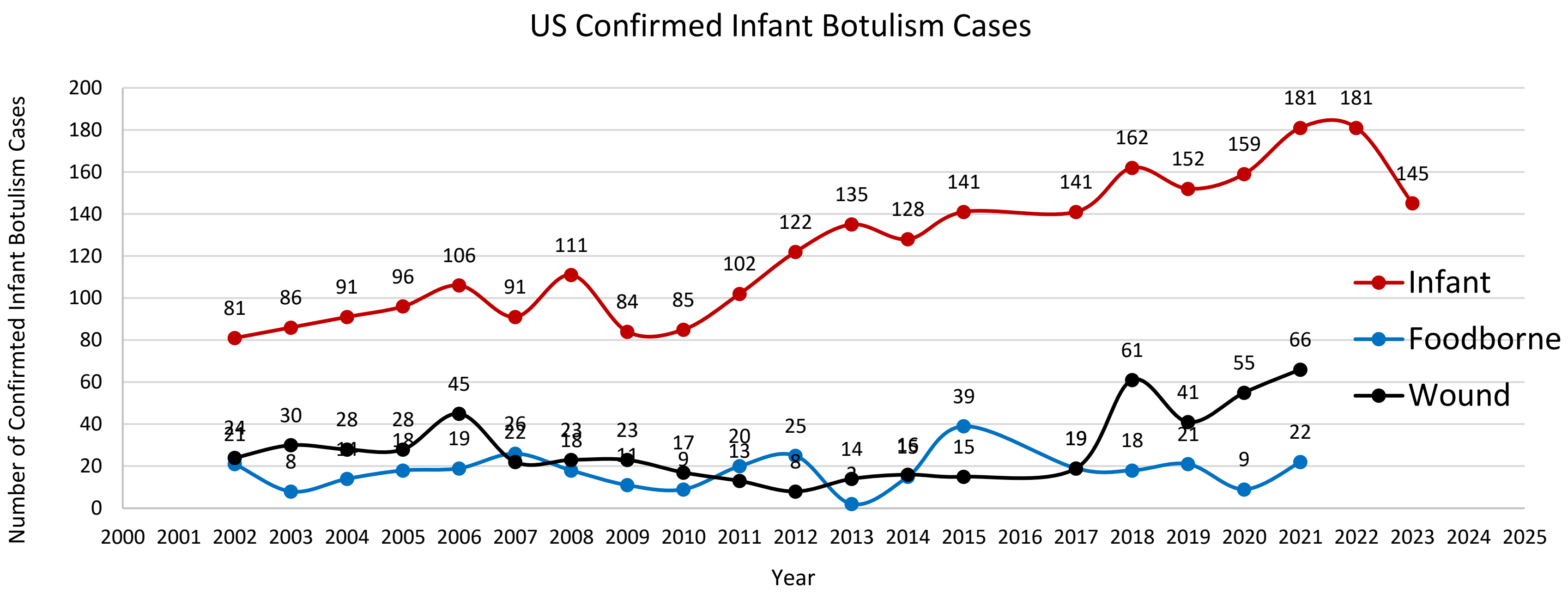
- % Increasing due to increased use of Black Tar Heroin injection worldwide
- Injection of spores

Adult Colonization (rare)

Aerosolization of the toxin (more rare)

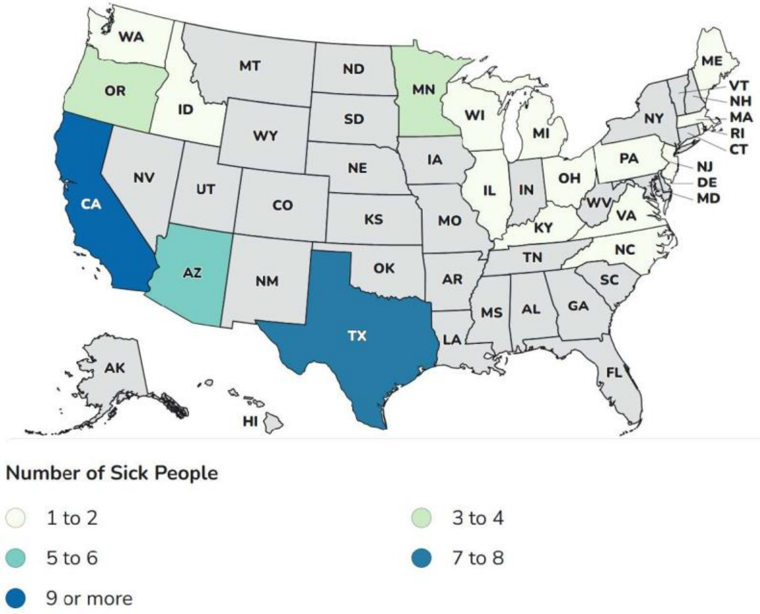
Iatrogenic injection of unlicensed preparation

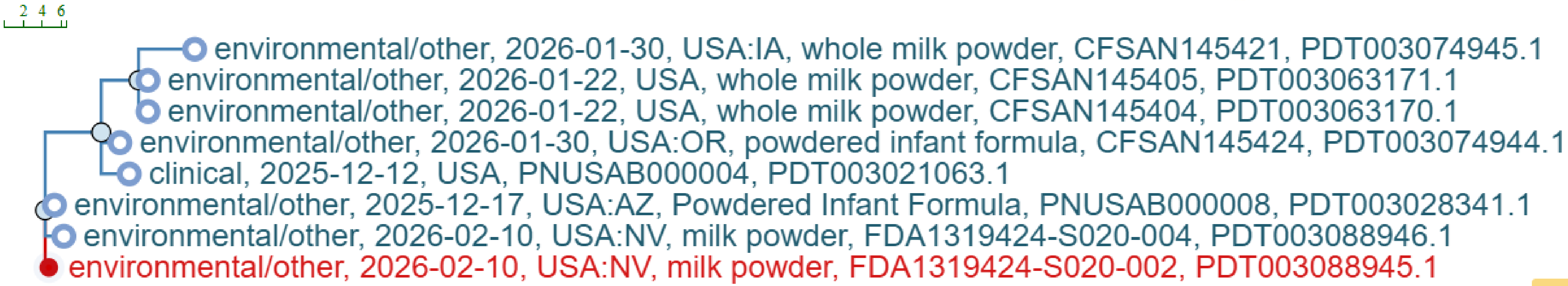
Unknown



ByHeart Infant Formula

- August - November 8, 2025 – California Dept. Public Health (CDPH), Infant Botulism Treatment and Prevention Program (IBTPP)
  - 84 infant botulism cases under treatment
    - **36 had consumed powdered infant formula**
      - 13 of those cases had consumed ByHeart-brand powdered infant formula
- February 26, 2026 – CDC declares outbreak over
  - 48 cases/hospitalizations; 17 states
  - FDA sampling of ingredients revealed isolates from PIF, whole milk powder (ingredient) and clinical isolates match





Pathogen Detection Database https://www.ncbi.nlm.nih.gov/pathogens/tree/#Clostridium_botulinum/PDG000000059.203/PDS000250219.4?accessions=PDT003074945.1

2001 UK Infant Botulism Case

- United Kingdom – 1978-1994
  - 5 reported infant botulism cases with out an identified source
- June 9, 2001 – formula-fed, 5-month-old infant with botulism
  - *C. botulinum* type B was detected in rectal washout and feces
    - 9 different pure isolates of *C. botulinum* type B recovered
  - Open container of PIF - 16 pure isolates
    - 0.38 spores/100g (95% CI, 0.09 – 1.51)
  - Unopened container of PIF - 5 separate *C. botulinum* type B isolates
    - 0.14 spores/100g (95% CI, 0.02 – 0.86)

Table 1. Results of microbiological analysis of food samples

Food and no. of samples tested	Total amount tested	No. of enrichment cultures per food sample	Results of enrichment culture for *C. botulinum* organisms
Opened food samples collected from patient's home			
Dried food			
Rice pudding with fruit* ($n = 1$)	58 g	17	Type A isolated from one enrichment culture
Oat porridge ($n = 1$)	58 g	17	Not isolated
Infant formula milk powder† ($n = 1$)	58 g	13	Type B isolated from two enrichment cultures
Sterilized shelf stable puréed food			
Mixed fruit dessert jar ($n = 1$)	3 g	2	Not isolated
Mixed fruit pudding jar ($n = 1$)	3 g	2	Not isolated
Mixed fruit purée jar ($n = 1$)	3 g	2	Not isolated
Honey ($n = 1$)	50 g	10	Not isolated
Unopened food samples collected from patient's home			
Dried food			
Infant formula milk powder ($n = 1$)	3 g	2	Not isolated
Sterilized shelf stable puréed food			
Concentrated mixed fruit juice ($n = 1$)	40 ml	2	Not isolated
Vegetables and chicken purée ($n = 1$)	3 g	2	Not isolated
Vegetable purée ($n = 1$)	3 g	2	Not isolated
Vegetable and chicken purée ($n = 1$)	3 g	2	Not isolated
Fruit purée ($n = 1$)	56 g	16	Not isolated
Rusks ($n = 1$)	56 g	16	Not isolated
Unopened food samples obtained from manufacturer or retailer			
Dried food			
Rice pudding with fruit* ($n = 10$)	50 g	16	Not isolated
Infant formula milk powder† ($n = 25$)	100 g	11	Type B isolated from one food sample

Survey of PIF

- Survey of 30 PIF revealed *C. sporogenes* spore counts to be 2.2-6.9 per 100 g (95% CI, 0.37-15)
  - Typical patient would ingest 2.2-7.0 (95% CI, 0.38-15.2) *C. sporogenes* spores every 24 hours
  - *C. sporogenes* is a close genetic relative to Group I *C. botulinum* that likely share the same environment
- 21 strains of *C. sporogenes* have been found to produce serotype B toxin
- Wide array of different clostridia identified in PIF

Table. *Clostridium* species isolated from U.S.-made PIF

Positive sample	Brand*	Sample origin	*Clostridium* species identified	MPN/100 g (95% CI)
1	I	P	*C. bifermentans*	1.1 (.05-5.9)
2	I	P	*Clostridium* species†	>23 (12- ∞)
3	II	P	*C. sporogenes*‡	5.1 (1.6-13)
4	II	P	*C. sporogenes*‡	1.1 (.05-5.9)
5	II	S	*C. beijerinckii*	1.1 (.05-5.9)
6	II	S	*C. butyricum*	1.1 (.05-5.9)
			C. sporogenes bv. *pennavorans*‡,§	3.6 (0.91-9.7)
7	II	S	*C. butyricum*	1.1 (.05-5.9)
			C. cochlearium‡	1.1 (.05-5.9)
			C. septicum‡	1.1 (.05-5.9)
			C. sporogenes‡	3.6 (0.91-9.7)
8	II	S	*C. butyricum*	2.2 (0.37-8.1)
			C. novyi/haemolyticum‡	2.2 (0.37-8.1)
			C. sporogenes‡	2.2 (0.37-8.1)
9	II	S	*C. lundense*‡	1.1 (.05-5.9)
			C. sporogenes bv. *pennavorans*‡,§	3.6 (0.91-9.7)
10	II	S	*C. butyricum*	1.1 (.05-5.9)
			C. innocuum	1.1 (.05-5.9)
			C. tyrobutyricum‡	1.1 (.05-5.9)
			C. subterminale‡	1.1 (.05-5.9)
11	III	S	*C. sporogenes*‡	2.2 (0.37-8.1)
			C. perfringens	1.1 (.05-5.9)
12	III	P	*C. sporogenes*‡	6.9 (2.5-15)
N/A	IV	P	No *Clostridium* species Isolated	—
N/A	V	P	No *Clostridium* species Isolated	—

P, Patient; *S*, surveillance.
*Brand I accounted for 20 case-associated samples, Brand II accounted for 5 case-associated samples, and Brands III, IV and V accounted for 5 case-associated samples. Eight surveillance samples for Brand II and 1 surveillance sample for Brand III were purchased (see Methods).
†Organism identifiable to genus level only.
‡Identification confirmed by 16S rDNA sequence analysis
§Listed in Genbank as *C. sporogenes* ssp. tusciae; current nomenclature for this species is *C. sporogenes* biovar *pennavorans*.[33]

Barash, et al., 2009, J. Pediatr

Risk Assessments

"Causality less plausible or not yet demonstrated" – Food and Agriculture Organization (FAO)/World Health Organization (WHO), 2004

Risk assessment for the presence of spores in infant food with a mean value of 0.3 spores/kg and a range of 0.001 spores/kg to 10 spores/kg

10 spores/pk of 121 g (<1 spore per serving of PIF) would be a low risk of disease (UK Food Standards Agency; ACMSF, 2006)

- Challenges exist for the sampling and enumeration of *C. botulinum*
- Testing for Sulfite-Reducing Clostridia as an indicator has been suggested previously
  - 25 – 100 cfu/g for import of dairy derivatives, including milk proteins (Russian Federation, 2008)
  - 10-25 cfu/g advisory maximum levels in the USA (US Dairy Export Council, 2013).

Sulfite-Reducing Clostridia and *C. botulinum*

- Whole milk vs. Non-Fat Dry Milk (NFDM)
- Organic vs. Conventional
- Non-Dairy
- Cow and Goat

- Direct Plating: 25 g PIF in 25 mL Butterfields phosphate
  - Tryptose Sulfite Cycloserine Agar
- SRC Enrichment: 10 g PIF in 90 mL RCM→37°C, 5 days
- MPN – 100g PIF in 200 mL BP →10 tube MPN, 37°C, 7 days

Dairy/Protein Solids	Organic/Conventional	Direct Plating Sulfite Reducing-Clostridia (SRC) (CFU/g)	SRC Enrichment (10 g/90 mL RCM)	Average MPN SRC/100g	Presumptive BoNT/A, B (DIG-ELISA)
Whole Milk, WPC, WPH	Organic[b]	< 1.0	In process	11.9±10.5	BoNT/A
Whole Milk, Skimmed milk, whey protein powder, demineralized milk	Organic[b]	< 1.0	2 (-)[a]	0.7±0.6	-
Whole Milk, skimmed milk, demineralized whey powder, WPC a-lactalbumin	Conventional [b]	< 1.0	1 (-)[a]	29±10.3	BoNT/A, B
		8.0			
NFDM, WPC	Organic	< 1.0	2 (-)[a]	0.7±0.6	-
NFDM, WPC	Organic	< 1.0	2 (-)[a]	1.1±0.6	-
NFDM, WPC	Conventional	< 1.0	1 (-)[a]	18.3±8.5	BoNT/A
NFDM, WPC	Conventional	< 1.0	(-)	1.4±1.5	-
Soy Protein Isolate	Conventional	<1.0	2 (-)	1.6±1.7	-
Goat Whole milk, WPC	Conventional	<1.0	1 (+), 1 (-)[a]	31.7±13.4	BoNT/A
Goat NFDM, WPC	Conventional	<1.0	2 (-)	2±0.9	-

WPC=Whey Protein Concentrate; WPH=Whey Protein Hydrolysate; NFDM=Non-Fat Dry Milk

[a] Presence of non-sulfite reducing clostridia

[b] Grass Fed indicated on product label

Screening of 29 Commercially Available Dairy-based PIF Brands (50 total lots) for the presence of Sulfite-Reducing Clostridia (SRC)

Duplicate Lots of N Brands Tested	Dairy Solids	Organic/Conventional	Direct Plating Sulfite-Reducing Clostridia (SRC) (CFU/g)	SRC Enrichment (10 g/90 mL RCM)
N=1 (2)	Whole Milk, WPC[c]	Organic	<1.0	1 (+); 1 (-)[a]
N=2 (3)	Whole Milk, NFDM[d], WPC	Organic	<1.0	1 (+); 2 (-)[a]
N=1 (2)	Whole Milk, Skimmed milk, WPC	Organic[b]	<1.0	2 (-)
N=1 (2)	Whole Milk, Skimmed milk, whey protein powder, demineralized milk	Organic[b]	<1.0	2 (-)[a]
N=1 (1)	Whole Milk, WPC, WPH[e]	Organic[b]	<1.0	NT In process
N=1 (2)	Whole Milk, WPC	Conventional	<1.0	2 (-)
N=1 (2)	Whole Milk, skimmed milk, demineralized whey powder, WPC α-lactalbumin	Conventional [b]	<1.0, 8.0	1 (-)[a]
N=4	NFDM, WPC	Organic	<1.0	8 (-)[a]
N=1	NFDM, WPC, WPC a-lactalbumin	Organic	<1.0	1 (+), 1 (-)
N=1	Partially hydrolyzed whey protein	Organic	<1.0	2 (-)[a]
N=2	Skimmed milk, whey product	Organic	<1.0	3 (-)
N=2	SMP, partially demineralized whey	Organic	<1.0	4 (-)[a]
N=5	NFDM, WPC	Conventional	<1.0 (8), 2.0 (1)	8 (-)[a]
N=1	NFDM, WPC, WPC a-lactalbumin	Conventional	<1.0	1 (+)
N=1	NFDM, Partially hydrolyzed whey protein	Conventional	1.0 (2)	NT
N=2	Milk Protein Isolate (MPI)	Conventional	1.0, <1.0 (2)	2(-)
N=1	Whey Protein Hydrolysate (WPH)	Conventional	<1.0	NT In process
N=1	Casein Hydrolysate	Conventional	<1.0	NT In process

[a] Non-SRC positive colonies

[b] Grass Fed, [c] Whey Protein Concentrate, [d] Non-Fat Dry Milk, [e] Whey Protein Hydrolysate, [f]NT (Not Tested)

Non-Dairy and Goat Milk Based PIF

Table 2. Screening of 1 Commercially Available Non-Dairy PIF for the presence of Sulfite Reducing Clostridia (SRC)				
Brands Tested	**Protein**	**Organic/ Conventional**	**Direct Plating Sulfite Reducing Clostridia (CFU/g)**	**SRC + Enrichment (10g/90 mL RCM)**
N=1	Soy Protein Isolate	Conventional	<1.0	2 (-)

Table 3. Screening of 5 Commercially Available Goat Milk-Based PIF for the presence of Sulfite Reducing Clostridia (SRC)				
Brands Tested	**Goat Milk**	**Organic/Conventional**	**Direct Plating Sulfite Reducing Clostridia (CFU/g)**	**SRC + Enrichment (10g/90 mL RCM)**
N=2	Whole milk	Organic	2.0, <1.0	3 (-)[a]
N=1	Whole milk	Conventional	<1.0	1 (-)[a]
N=2	Whole milk, WPC	Conventional	<1.0	1 (+), 2 (-)[a]
	NFDM, WPC	Conventional	<1.0	2 (-)

[a]Non-SRC positive colonies

Knowledge Gaps

- Increase in infant botulism cases over the last decade in the US –WHY?
  – Many cases are not associated with PIF…so what are the sources of those cases?
- Historically, there is a low prevalence of spores of botulinum neurotoxin-producing *Clostridium* in powdered infant formula
  – Do we test for *C. botulinum* directly?
  – Is there a correlation between the Sulfite-Reducing Clostridia (SRC) and the presence of *C. botulinum*?
- What methodology is best for testing for Sulfite-Reducing Clostridia
  – Direct plating vs. enrichment vs. MPN
  – Pass fail criteria? <10 CFU/g or <100 CFU/g

Miquela Hanselman

Senior Director of regulatory affairs for the National Milk Producers Federation

Q & A

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Upcoming Food Safety Webinars (April – June 2026)

Date	Time (Eastern Time)	Webinar Title
May 20	12:30 PM – 1:30 PM	Neurodivergent Thinking in Food Safety: Implications for Practice, Performance, and Inclusion
May 28	1:00 PM – 2:00 PM	Using Data Trends to Improve Microbial Risk Detection in Food Safety Systems
May 29	2:00 PM - 3:30 PM	How FSMA Qualified Exempt and Not Covered Produce Growers are Filling Learning Gaps Using Innovative Education Program Delivery Methods
June 10	1:00 PM – 2:00 PM	The State of Food Safety Professionals in a High-Risk World (IAFP and Partnership for Food Safety Education)

This webinar is being recorded and will be available for access by **IAFP members** at www.foodprotection.org within one week.

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