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FoodSafety magazine

Controlling Salmonella and Cronobacter in Dry Processing Environments by Managing System Breaches

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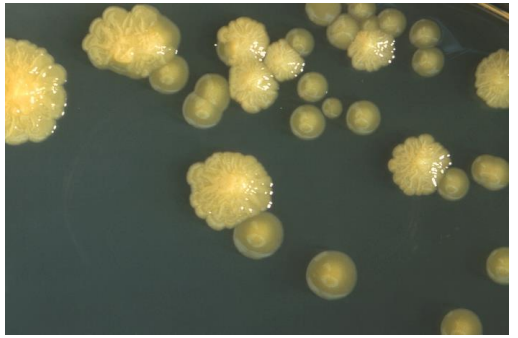
History of Cronobacter

- Infant infections of “yellow pigmented Enterobacter” documented in the 1950’s
- 1958 first case of documented infant (neonatal) meningitis; cases continued at very low levels
- Officially named Enterobacter sakazakii (E. sak) in the 1970s
- 1987/88 outbreaks in the Netherlands and US linked to powdered Infant Formula
- Early 2000s safety warning sent to health care professionals, FDA took interest
- FDA sampling in 2002 found 22.7% of US manufactured IF were contaminated with E. sak; further contamination can happen in the home
- Mid 2000s renamed “Cronobacter” with 8 different organisms, C. sakazakaii being the one most linked to illness
- 2014 FDA CGMP Final Rule for IF to require hygiene control and Cronobacter testing



2014 FDA Sampling Assignment
Dairy is the #1 supplier to IF, both dry and wet blend

Cronobacter Spp.

- Identified in the environment of 69% of the facilities (38/55)
- Prevalence from all sites sampled was 4.4% (total 5671 sites sampled)
- Out of the 38 facilities, average prevalence in the environment was 6.25%
  - Most prevalent in Zone 4 with decreasing levels down to product contact Zone 1
- Found in all types of dry dairy plants

Salmonella

- Identified in the environment of 5.5% of the facilities (3/55)
- Prevalence from all sites sampled was 2.5% (total 5714 sites sampled)
- Out of the 3 facilities, average prevalence in the environment was 2.5%
  - Most prevalent in Zone 4, then 3 with **no positives** in Zone 2 or 1
- Found only in whey plants

Why Breach Management is Important

- *Salmonella* and *Cronobacter* sakazakii are key pathogens of concern in dry dairy foods with long survival in dry conditions.

Salmonella

- 2nd most common intestinal foodborne illness in US
  - #1 requiring hospitalization
  - #1 for deaths
- Long lasting/permanent complications

Cronobacter sakazakii

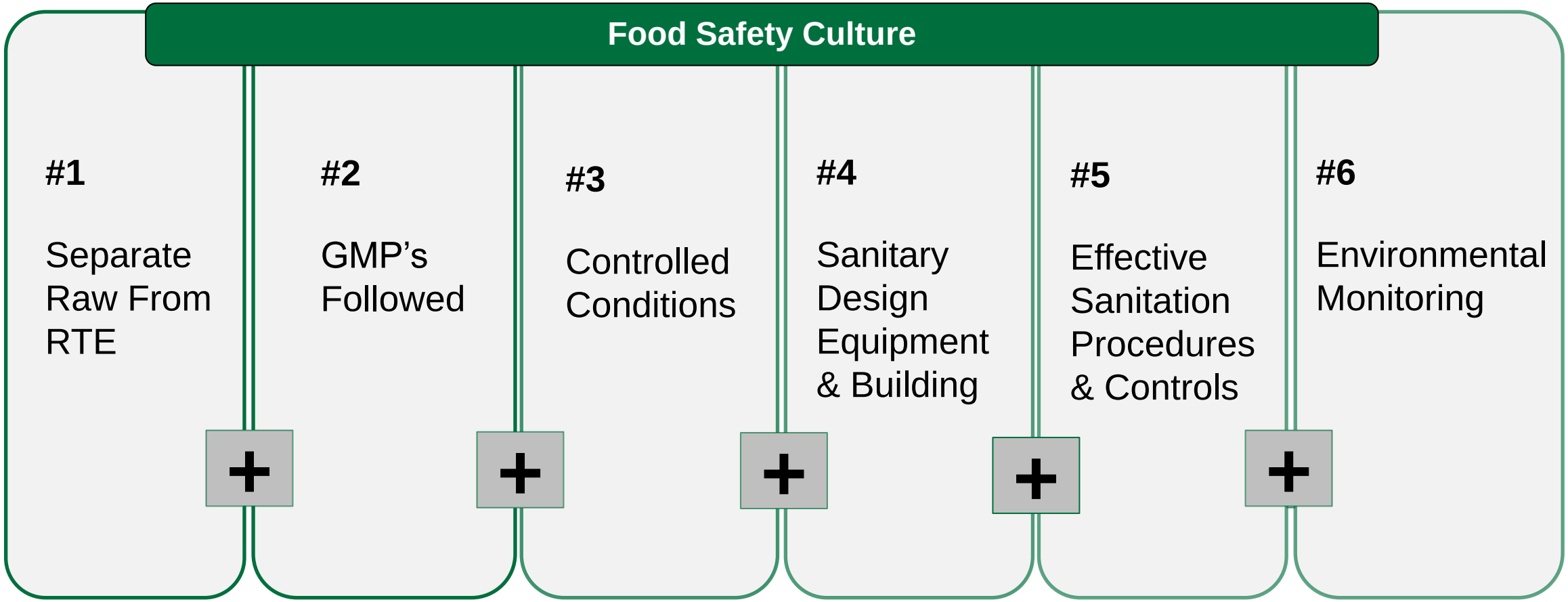
- Opportunistic Pathogen
  - Newborn babies
  - Elderly nursing home residents
  - Tube fed patients
- 40-80% Fatality Rate

Dry Dairy Powders is often used <u>without further heat processing.</u>
Both pathogens <u>share the same ecology</u> in dry dairy plants

The Pathogen Control "Equation"

A Food Safety/Quality Principles Approach

Pathogen Control Programs



PEM Monitors Equation for Pathogen Control

What is a Breach?

- **Breach** - Any exposure, planned or unplanned, of the dairy powder system or controlled hygiene area that poses a risk of contamination. Disruption to the normal operations of the manufacturing process should be put into consideration for breach control
- **Common types of a breach**
  - Routine/Planned
  - Unplanned
  - Controlled Hygiene Areas
- Whether planned or not, **breaches increase the risk** to the product zone.

Similarities and Differences in Management

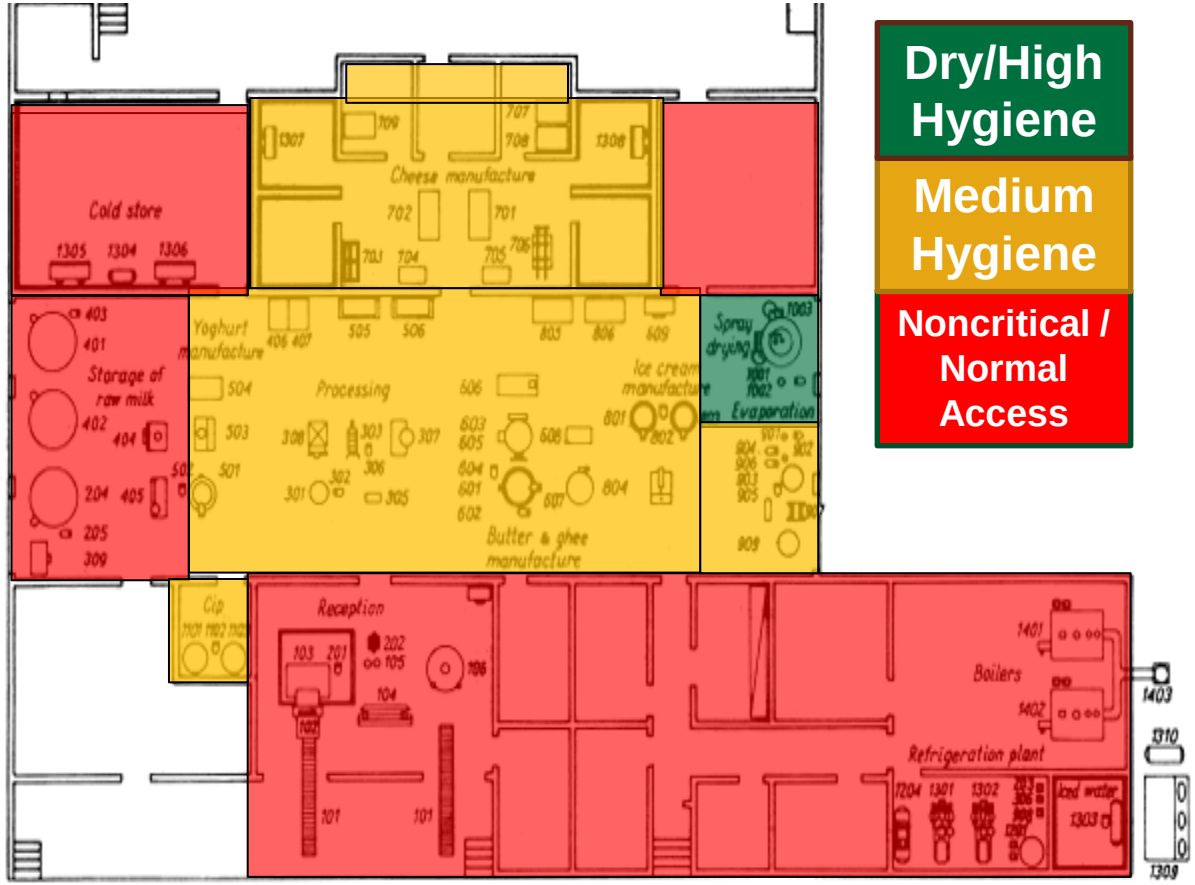
Salmonella

- Positives are often linked to a clear, significant event
- Hits in a controlled plant are rare
- Eliminate water
- Control breaches of the system
  - Focus zones 1 and 2
- Environmental monitoring of traffic and for cause
- Swabs can be routine to validate your program

Cronobacter

- C. sak control by controlling at spp. level
- Cronobacter positives are linked to many small, seemingly insignificant events
- Hits in a controlled plant can be common
- Never get it wet
- Eliminate breaches of hygiene zones
  - Structured control of all zones
- Environmental monitoring of behavior and process controls (pathogen equation)
- Swabs sites must be chosen for specific validation of controlled processes

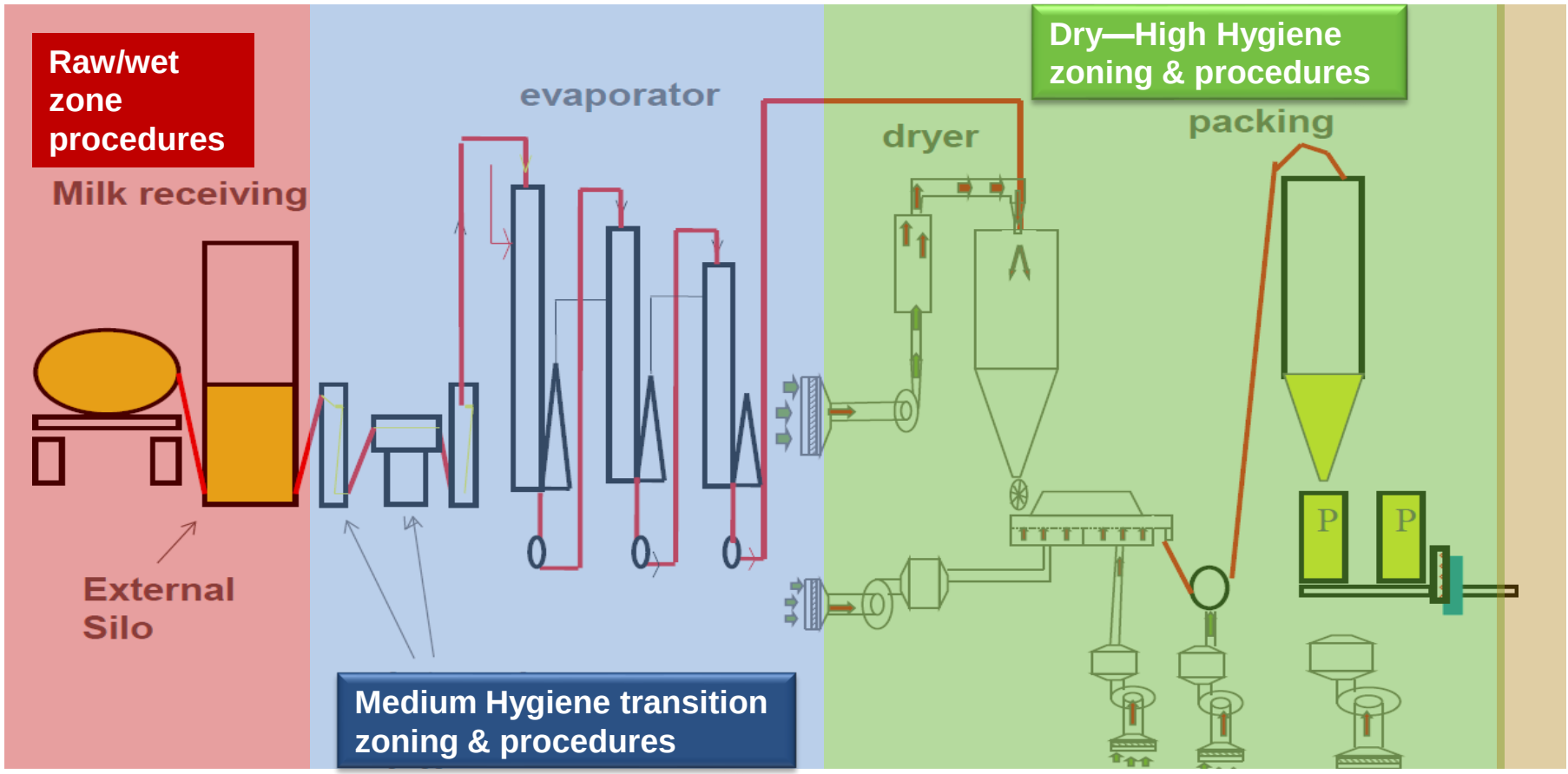
Separate Wet from Dry (Raw from RTE): Hygienic Zones



Protect the castle at all costs!

GMP and Personnel

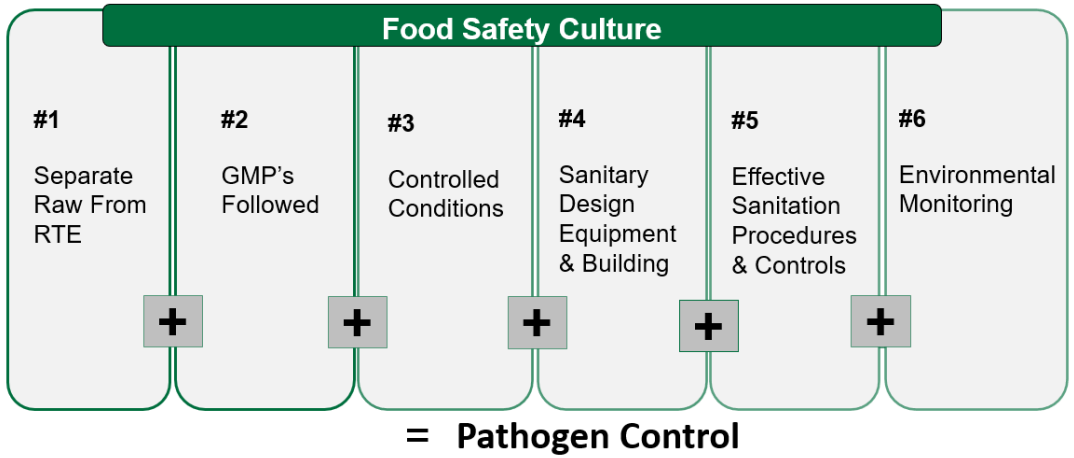
How are your GMP changing over zones?



Food Safety Culture

…the enduring culture of food safety places equal emphasis on both the food sciences and the behavioral sciences…

…. a strong food safety culture is a choice or value not a priority. Priorities can change; values should not….



Where Is Your Food Safety Culture?

DOUBT	REACT	KNOW	PREDICT	INTERNALIZE
Majority of food safety actions are taken due to external pressures.	Quality department takes most food safety actions, usually to close gaps or remove issues.	Food safety knowledge is prevalent across the organization and all act to improve food safety.	Food safety actions mostly taken on results based on predictive analysis.	Food safety actions driven by everyone and mostly based on managing risks.

Poll Question
How many breaches occur in a 1-month period at your facility?

Now…Ask Yourself Again…What is a Breach in My Plant?

- **Breach** - Any exposure, planned or unplanned, of the dairy powder system or controlled hygiene area that poses a risk of contamination.

So…You're saying I breach my system every day??

Planned

- Sampling
- Magnet Inspections
- Sifter Screen Inspections
- Air filter changes
- Maintenance Activities
- Sanitation
  - Dryer systems washes
  - Bin sweep outs between products

Unplanned, but not Unexpected

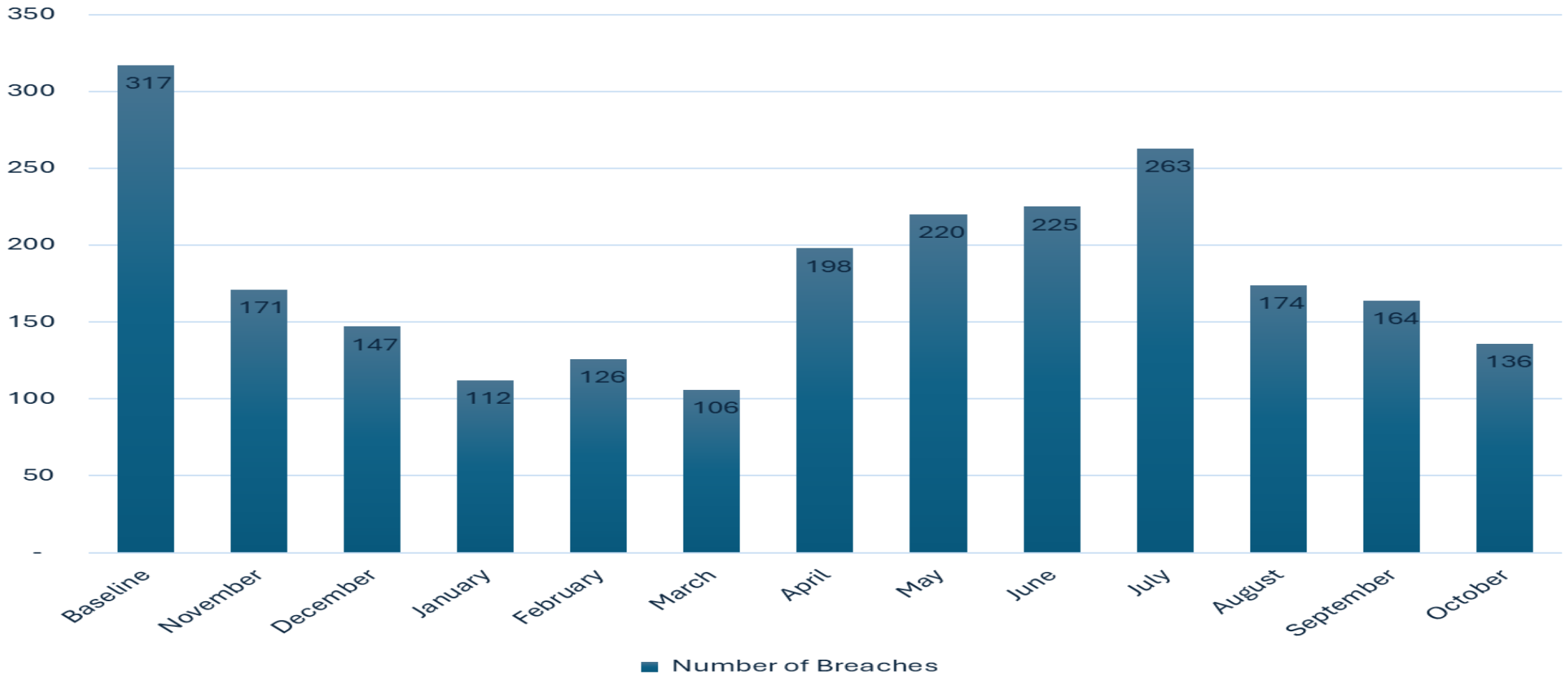
- Opening the enclosed system
- Sifter cleaning
- Flexible boot ruptures
- Damaged rotary airlock
- Wet chamber cleanout
- Plugging
- Deluge System triggered
- Fires

Tracking Dryer System Breaches – Case Study

A dairy powder manufacturer started to track dryer system breaches to:

- Understand how often the system is breached
- Understand why it is breached
- Understand if breach incidents could be reduced

Tracking Dryer System Breaches (Cont.)



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What was learned?

- Baghouse checks are the major contributor to breaching this dryer system
- The dryer system had more issues during summer months due to higher humidity
- Capital projects needed to improve the operation and reduce checks
- Leverage tools to reduce baghouse checks
  - Cameras, Sensors, etc.
  - Stricter humidity control

OK…but what about hygiene zone breaches?

- Employees entering into a high hygiene room without donning the appropriate PPE gear.
- Roof leaks/Outside environment ingress
- Drain back-ups
- Unplanned construction
- Identification of food pests

OK…but what about hygiene zone breaches?

- Loss in pressure differential within the dryer system
- Dryer system CIP
- Other events and situations that present product contamination risks.
  - Equipment plug ups.
  - Fire event

Considerations/Mitigations for Breaches

- What is the frequency required for **testing/inspections**?
  - What is the purpose of the sampling and is it value added?
  - Can the time between the sampling be extended to prevent frequent system openings?
  - Review historical data. Does the data support a reduction in the required testing frequency?
- What is the method for **sampling**?
  - Is opening an access port required to pull the sample?
  - Can an auto sampling device be installed to keep the system enclosed?

Considerations/Mitigations Cont.

- Evaluate the effectiveness of the **magnet checks** ability to determine equipment failure
  - Can the time between magnet checks be extended and still be a useful tool in equipment breakdown prediction?
- Is there a preventative maintenance plan set up for **sifter screens**? Can the inspections be coordinated with the PM work?
  - How effective are your sifter reviews? Can you observe the entire surface without physically removing?

Considerations/Mitigations Cont.

- Verify proper **dry-out time and temperatures** of the chamber, and transport systems post-CIP prior to going on product as a pre-operational check

Considerations/Mitigations Cont.

- Is the **maintenance team** trained on how to work in a sensitive dry environment?
  - Proper PPE that satisfies the safety risks but also prevents potential contamination
  - Sufficient tool sanitization before entering into a controlled area. Or can dedicated tools be used in the controlled area?
  - Use of defined work permits that remind and document specific mitigation / precautionary practices
- Operations and maintenance should work closely to plan and group all work required to limit multiple **system stoppages**
  - This reduces overall downtime of the dryer process
  - Downtime causes other quality or long-term issues

Potential Steps to Follow in a Controlled Hygiene Area Breach

- **How severe is this?**

- **Do you have an Escalation protocol in place?**

- Notify the QA manager and Production manager immediately and assemble a meeting to determine the following:
  - Identify potential affected product
  - Clean and sanitize the area affected and document the corrective action
  - Coordinate extra environmental monitoring swabs as needed

Considerations for product release

- Does the site have an effective way to notify the individuals responsible for product release that there has been a breach in the dryer system and product might be compromised?
- Identify standards for each dry product and review the records before every product release
  - Don’t rely on finished product testing alone (PEM results, indicator organisms in environment, etc.)
  - Review special circumstances or unplanned activities that disrupted production or the environment
- Document a protocol:
  - Develop a procedure for monitoring and alerting the key individuals when there is a system breach.
  - **Escalation protocol based on severity and risk to product.**

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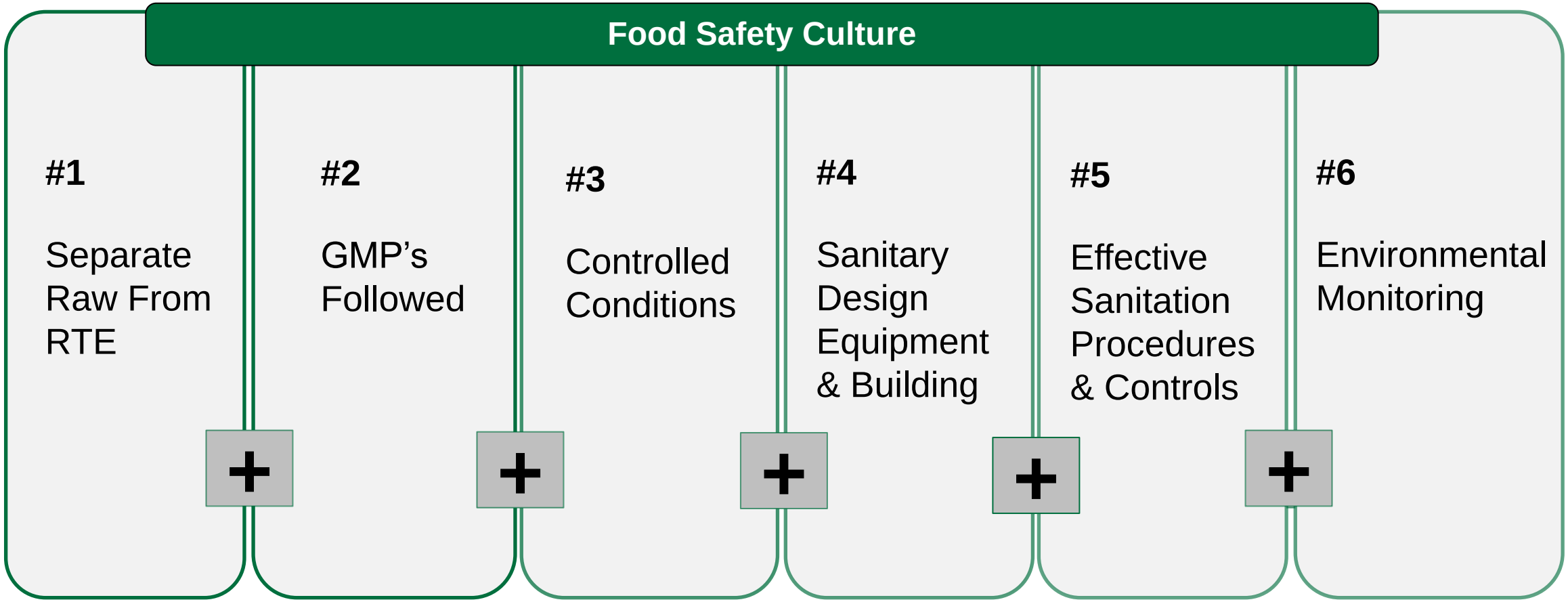

PEM Monitors Equation for Pathogen Control

What Can You Do Better – A few design examples

Planned

- Sampling Autosampler, Access
- Magnet Inspections
- Sifter Screen Inspections
- Air filter changes
- Maintenance Activities
- Sanitation
  - Dryer systems washes
  - Bin sweep outs between products

Unplanned, but not Unexpected

- Opening the enclosed system
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- Damaged rotary airlock Eq. Selection
- Wet chamber cleanout
- Plugging Humidity Control, Heat and Mass transfer mapping
- Deluge System triggered
- Fires

Examples of Good Practices

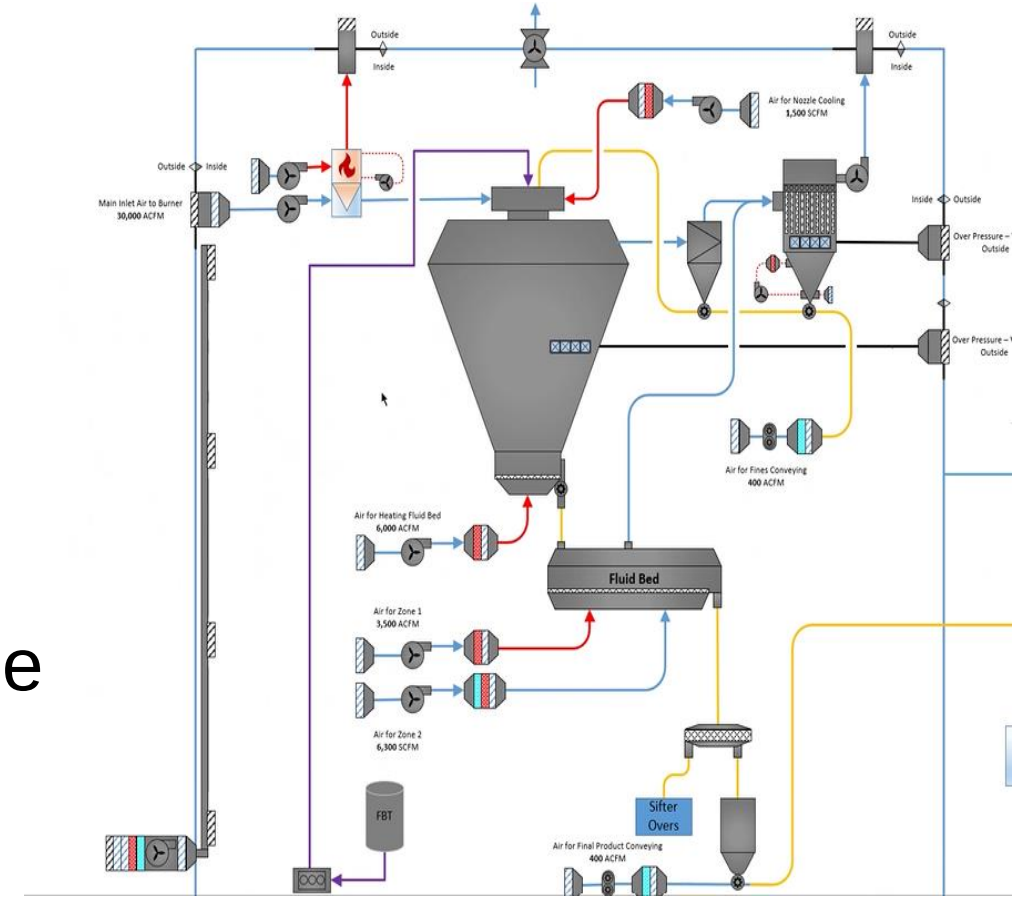
VS

Auto-samplers

Auto samplers have been installed to allow the dryer operators to take inline samples without needing to completely open the system

Design out Plugging – Good Design, Humidity &Temperature Mapping

- Know your design limits
- Temperature and Rh are highly correlated
- Hitting the dew point at the wrong time can cause clumping and plugging
- The building maters. Temperature inside or outside the process can cause issues. Is the room too cold?
- Map Temp, Rh through your process



Design - Boots

VS

BFM connections with complete **seal vs. clamped** connections that develop niche or powder ingress / egress These can also be used for CIP return connections and sampling

Design – Controlled inspection/swabbing ports

VS

Dehumidification Boxes

Inspection ports were added to the box doors to allow a visual inspection during dryer system versus removing and opening the box doors entirely for inspection.

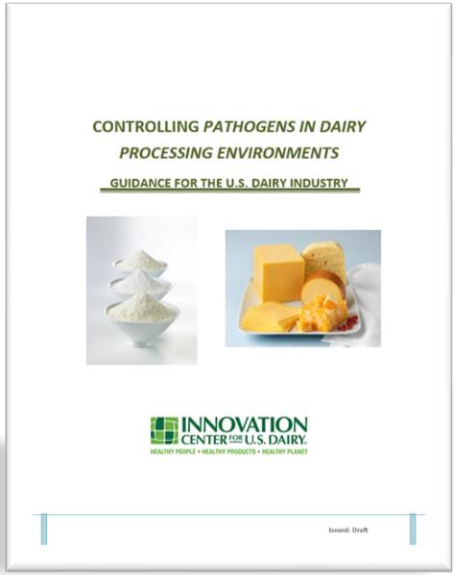
Design - Magnets

VS

- Magnet Inspections

Design - What Can You Do Better

Key Thoughts



- Don’t accept “It’s Always Been That Way”
  - You don’t need to accept leaking connections and powder
  - If you don’t need to open it, don’t
  - Plugging is not a given
- IC Guidance Document – USE IT !
- We’re not suggesting anything truly new, we’ve known all this for a while
- Leverage your OEM’s and other experts
- Capital now can save you later
- Leading and Lagging Indicators of Quality, Breaches are a "Near-Miss"

Resources: Food Safety Pathogen Controls Guidance

www.usdairy.com/foodsafety

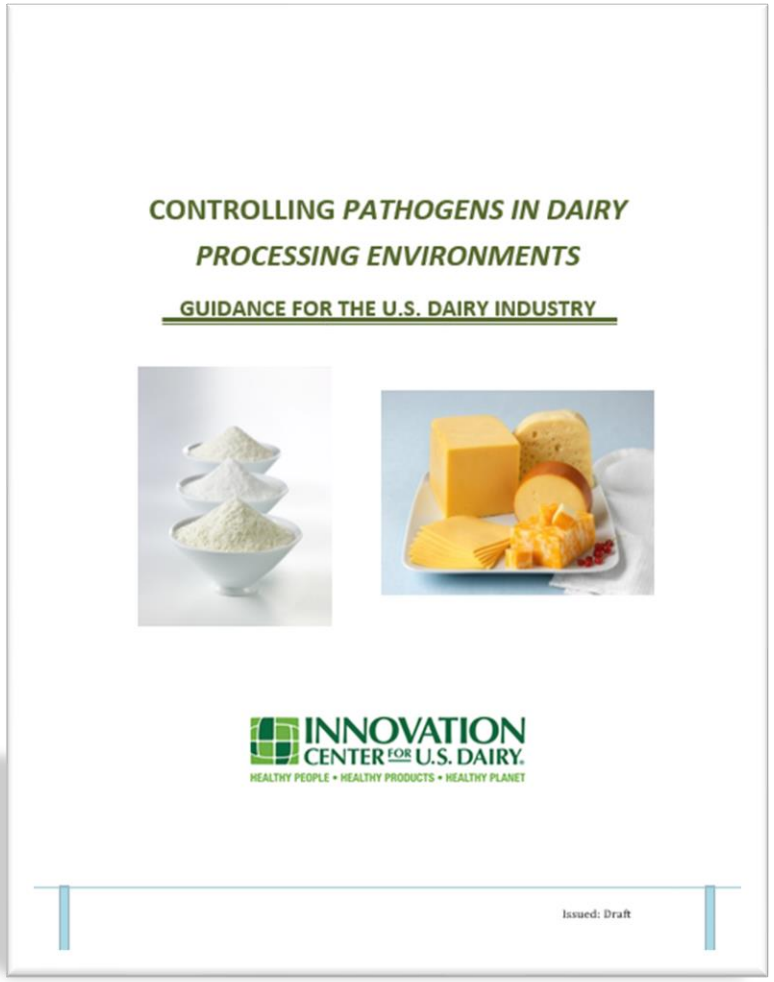
IC Food Safety Mission

Strengthen manufacturing practices to diminish food safety risks that could compromise the reputation of the U.S. dairy industry

Guide Objective

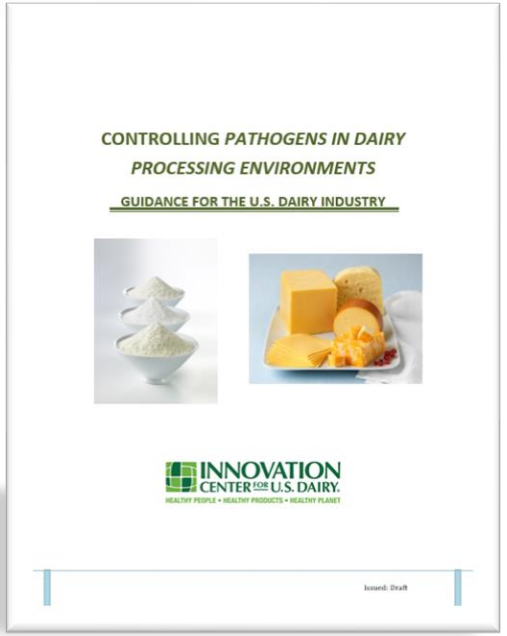
Expand Control of Listeria: Guidance for the US Dairy Industry into a full pathogen controls guidance document

- Additional pathogens and controls
  - *Salmonella* and *C. sakazakii*
- Add best practices for dry dairy facilities



Pathogen Control Guidance for the Dairy Industry

Organized by the 5 Principles of the Pathogen Equation and all tied together by Food Safety Culture



New Addition - Breach Management Content

Managing Equipment and Infrastructure Breaches

- Routine/Planned Breach Considerations and Opportunities to Reduce
- Unplanned Breach Considerations
- Controlled Hygiene Area – Breach Recovery Actions
- Product Dispositions after Dryer Breach – Considerations for Disposition

Case Study 5 – Reducing Routine System Breaches Through Tracking

A system breach exposes the dairy powder and the system to the risk of contamination. Balancing the need for quality and operations checks of the system with protecting the powder from contamination risk can be challenging in normal dryer operations. A dairy powder manufacture started to track their system breaches to better understand how often the system was breached and if it was possible to reduce the number of routine breaches to the system. Below is an outline of the company's approach, questions they asked and outcomes.

Data Collection:

THANK YOU !

Q&A